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Closing the gap between fork and farm for circular nutrient flows



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1 Executive summary

This document concerns the Deliverable (D) 3.7 of the P2GreeN project entitled "Scoping review" describing the status of the legislative framework, led by SustChem SA. In this report the broader legal and regulatory frameworks governing fork to farm and fork again are documented, reviewed and challenged. These frameworks are not simply local or national but exist on a multilevel basis.

An initial survey was sent to the pilot regions to identify key frameworks, points of interest and bottlenecks. Then, extensive research took place regarding the possible applicable legislative frameworks that concern the processes and the products of P2GreeN. This research is mainly focused on the EU legislative framework since this is determined as essential to address at this stage.

The scoping review will be the basis for Deliverable (D) 3.8, which is a final report describing the status of the legislative framework, future perspectives and recommendations, both in pilot and follower regions, that will include recommendations on implementing circular solutions. The mapping of the applicable EU legislative framework will enable us to compile additional surveys as well as perform interviews with the regions which will focus not only on the domestic legislative frameworks but also questions around the implementation of the EU and international legislative frameworks. The D 3.8 is due in M36.

2 Introduction

2.1 Project Overview

The continuing crises facing the world are a source of constant concern – from the COVID-19 pandemic to the war in Ukraine, which add to the on-going problems posed by Climate Change, biodiversity loss and the need to promote Sustainable Development. To address these crises, the EU has adopted a range of policies – for example on an environmental front, actions include the Green Deal, the Circular Economy Action Plan, the Zero Pollution Strategy, and the Biodiversity Strategy. In the wake of the war in Ukraine, among the many measures taken were those to increase the resilience of agriculture in the EU, including by reducing external EU dependency on imported fertilisers, on which the Commission concluded:¹

In the medium and long term, an important part of the solution to the challenges concerning the supply of fertiliser, as well as the environment and the climate, lies in supporting the transition to the sustainable use of fertilisers and the deployment of sustainable alternatives to mineral fertilisers.

P2GreeN will cause a paradigm shift in the way we think about Agriculture and assist in the transition from a linearly organised resource and nutrient system towards a circular material flow system between urban and rural areas following the 3R principles "Reduce, Reuse, Recover". P2GreeN aims to develop new circular governance solutions for the transition from fork to farm, focussing on circular nutrient flows of Nitrate (N) and Phosphorus (P). It seeks to halt and eliminate N and P pollution

¹ COM (2022) 590 Ensuring the availability and affordability of fertilisers, p. 20.

by connecting blue urban with green rural infrastructure, while also reducing the dependence on limited (and imported) mineral fertilisers and enabling tailored, sustainable use of alternatives. Viable fertilisation alternatives to reduce the current usage of mineral fertilisers, as well as minimize the pressure on the natural resources, will be explored to develop innovative green bio-based fertilisers. In this context, varied innovative N & P recovery solutions to utilize human sanitary waste from urban areas are implemented and demonstrated, with the aim to convert them into bio-based fertilisers for agricultural production in three pilot regions in Germany, Spain and Sweden. This approach will be extended to follower regions in Italy, France, Greece and Hungary.

2.2 Deliverable Overview

In determining which areas (and in some cases, laws) to focus on, we bore in mind: 1) the regions' preliminary identification of issues and laws within the project proposal; 2) responses from the first survey of the regions undertaken early in 2023 (along with supplementary information gathered in on-going meetings); 3) information regarding the regions' on-going activities; and 4) literature regarding related activities. In the case where regions identified local and/or national laws and policies, we then used these to identify relevant EU laws.

This Scoping Review addresses several issues relating to the use of human waste (urine and faeces) as fertiliser as part of a fork-to-farm approach, examining not only EU policies in relation to the environment and agriculture but also the contribution which this approach can make to a range of EU policies. In doing so, we largely keep our focus to the EU level for the time-being, with the subsequent full legislative review also addressing international, national and local levels. While the international, national and local levels are essential to operationalizing the P2GreeN activities, the EU laws provide the overarching frameworks applicable across all of the regions in quite significant detail. This will thereby provide the foundation for developing further examination of these issues at the different levels within the subsequent Legislative Report. We would also note that, where there is conflict between the national or local laws and EU laws, the EU laws must still be upheld.

The Review is structured as follows:

- A. From Fork to Farm This section will examine the current core EU legislation on waste, the Chemicals legislation that applies to fertilisers and the new Fertiliser Regulation.
- B. The Environmental Dimension This section will examine a range of EU policies including those on water, soil, nature conservation, and environmental impact assessments.
- C. Commercialization and Upscaling This section will examine a range of existing policies which may impact on the commercial realities of the P2GreeN products, notably the Free Movement of Goods, the Common Agricultural Policy and Food Law.
- D. The Policy Contribution This section will examine the contribution which this alternative source of fertilisers could make to core, evolving EU policies including the Green Deal and the Circular Economy, as well as flagging aspects where they may impact on P2GreeN activities. The Green Deal is multifaceted

and encompasses numerous elements such as biodiversity, agriculture and climate change.

3 Description of the pilot regions

The understanding of the raw materials used, the procedures followed, and the composition of the final product is needed to identify the applicable framework and potential bottlenecks.

3.1 Sweden

The formulation developed in the Swedish pilot region derives from dried urine and is intended for application in large-scale field trials on barley. In this pilot region, the contraptions used include female and male urinals (**Figure 1***Fehler! Verweisquelle konnte nicht gefunden werden.*).



Figure 1 Portable urinals used in the Swedish pilot region.

An insert for the chemical toilet is currently being developed and will work similarly to the urine-diverting toilet described later in the section related to the German pilot's processes.

A chemical stabilizer in powder form is added into the collection tanks to assist in retaining the nitrogen and controlling the odours. It is worth noting that the collection tanks only contain the chemical solid stabiliser and not water. Following this step, the portable urinals are transported to public locations such as festivals. All project activities (collection, transportation, processing, etc) take place on the island of Gotland in Sweden.

The quality of the barley grown with the application of this formulation will be evaluated during the field trial and the beer production stages that will be subsequently produced at a commercial scale to close the value chain.

The process of collecting and handling can be summarised in the following steps (*Figure 2*):

- 1. Mechanical collection of urine (yellow-water) from all contraptions to appropriate tanks
- 2. Transportation of the tanks to the treatment facility in Gotland (Sweden)
- 3. Concentration (x25) and drying
- 4. Mixing of the produced material with other materials (for example sawdust) to achieve the right consistency
- 5. Transportation of the mixed material to the pelletising facility

- 6. Pelletising and packaging
- 7. Transportation to farmers for use



Figure 2. Diagram depicting the manufacturing process of the urine-derived pellets in the Swedish pilot region.

The nutrient content of this product is determined as:

- 15% of Nitrogen (N),
- 1.7 2% of Phosphorus (P) and
- 4% of Potassium (K).

Since the concentration refers to the elemental nutrient form or to their respective oxides, the concentration of the nutrients can be recalculated using the conversion methods laid in the Regulation (EU) 2019/1009 (FPR) into:

- 15% of Nitrogen (N),
- 3.9-4.6% phosphorous pentoxide (P2O5) and
- 4.8% potassium oxide (K2O).

Due to the low concentration of phosphorous in urine, mineral phosphorous is added into the formulation to increase its concentration.

It is worth noting that the manufacturing process has not been fully standardised yet and is subject to changes and optimisations as the project evolves. For example, there are plans for a scheduled investment to make a urine-diverting insert to fit in blue chemical toilets. Also, one of the objectives of the pilot region is to expand the collection capacity of the yellow-water and manage to collect it from the mainland of Sweden and not just from Gotland. Furthermore, the concentration factor could reach higher values resulting in a higher nutrient content. Additionally, the pilot region is aiming to increase the phosphorous (P) concentration in the final product by adding P from other nutrient recovery processes, such as biological removal of P from wastewater or sludge, and not from mineral sources. Within the coming two years, the material will not be transported to the pelletising facility, since the process will be performed locally. Finally, there is ongoing research regarding the presence of pharmaceuticals to comply with forthcoming legislative frameworks, while heavy metals and pathogens have already been investigated in a regulatory perspective by

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the pilot. All these examples concern actions that could alter the applicable local or EU legislative framework and should be considered in the full legislative report.

Currently, the product is allowed to be produced, sold and used in Sweden.

3.2 Germany

The German pilot region will utilise both liquid and solid human waste to produce two different products.

3.2.1 Liquid product (Aurin®)

The yellow-water, including the toilet flush fraction and the urine, will be collected from the residential Urine Diverting Flush Toilet (UDFT) (separating flushing toilets) (*Figure 3Fehler! Verweisquelle konnte nicht gefunden werden.*) in a pilot building, drained via a dedicated network, processed and packaged on-site.



Figure 3. Images and schematic representation of the Urine Diverting Flush Toilet (UDFT) used to separate and collect yellow-water.

A multi-step processing of urine is employed to obtain the final product; hydrolysis, biological nitrification, filtration on activated carbon to remove micropollutants, and finally sanitization and concentration by distillation.

This product contains:

- 4.2% of Nitrogen (N),
- 0.4% of Phosphorous pentoxide (P2O5),
- 1.8% Potassium Oxide (K2O),
- 0.8% of Sulphur Trioxide (SO3)
- Micronutrients in low quantities

Aurin® is authorised as a fertiliser in Switzerland since 2018 and has been also approved in Liechtenstein since 2019 and in Austria since 2022.

3.2.2 Solid product (KIT)

For this formulation, initially both the liquid and the solid human waste are collected from public events via portable dry toilets (Urine-Diverting Dry Toilet - UDDT) (*Figure 4*). The toilets do not contain any chemical stabilisers. Then, the urine is

partially separated by pumping and the solid human waste is further processed. The moisture present from residual urine is useful for the composting process.



Figure 4. An example image of the Urine Diverting Dry Toilet (UDDT) used to collect faecal matter.

The material collected is transported to the composting plant to produce a solid soil-nurturing compost. The processing is a container-based thermophilic composting and includes the sanitization in aerobic conditions at over 65°C for over 7 days, the oxygen-controlled follow-up composting using additional bulk material and finally the screening of inadequate material. Additional bulk material consists of loamy soil, biochar and plant biomass and constitutes 80% of the total raw composting material with 20% being the collected faecal material.

Changes in the production process of both formulations can be expected, such as the utilization of faecal contaminated urine originating from the collection of solid faecal matter. Such actions could alter the applicable local or EU legislative framework in the future. Finally, parameters such as pharmaceuticals residues, hormones, heavy metals are determined based on the standards from DIN SPEC 91421.

3.3 Spain

In the Spanish pilot region, the municipal wastewater is converted into a nutrient-optimised irrigation water, tailored for agricultural application (*Figure 5*).



Figure 5. Schematic representation of the process followed in the Spanish pilot region.

Initially, municipal wastewater undergoes secondary treatment in a municipal Wastewater Treatment Plan in accordance with the legal requirements for reuse. Subsequently, the treated wastewater is transported to the Water Reclamation Plant and undergoes tertiary treatment, including disc filtration and ozone disinfection (*Figure 6*).



Figure 6 Discs filtration towers, control panel, pipeline, storage tanks and mixing unit.

The reclaimed water is a nutrient-rich effluent with agronomic value. It is then transported through a pipeline and stored in a deposit tank. A small amount of sodium hypochloride (NaClO) is added to prevent the growth of harmful organisms (algae, microbes) during storage in the deposit and the irrigation pond. Reclaimed water from the deposit tank will be used to fertigate the crops (avocado and mango) and, if needed, it will be automatically supplemented by mineral fertilisers or diluted with local water, under the control of the Smart Fertigation Tool (SFT) (*Figure 7*).



Figure 7 Tensiometers, lysimeters and iTelemeter components installed as part of the Smart Fertigation Tool.

According to preliminary nutrient content determination, the reclaimed water contains 30 mg/l Nitrogen (N), <10mg/l phosphorous (P) and approximately 35 mg/l Potassium (K), which correspond to 0,3% w/v, <0,1% w/v and 3,5% w/v. In the future parameters such as pharmaceuticals residues, hormones, heavy metals should be determined.

4 The EU legal and policy frameworks

Within the sections below, we outline some of the key points from the different EU legal and policy frameworks applicable to P2GreeN activities: (4.1) From Fork to Farm; (4.2) The Environmental Dimension; (4.3) Commercialization and Upscaling; and (4.4) The Policy Contribution. There are then expanded upon in considerably more detail within the attached Annexes. Some general comments and analysis are included, as well as flagging elements that merit further research over the forthcoming two years for the project's full legislative report (Deliverable 3.8) and highlighting some key issues and questions for the pilot and follower regions. This chapter provides the basis for undertaking a preliminary application of the frameworks to the pilot regions' activities, undertaken in the subsequent chapter (Chapter 5).

It bears highlighting: environmental and human health considerations (i.e. the sustainability and safety) of the processes and products will be essential features across a wide range of regimes, impacting upon their categorisation, management and marketability. Evidencing these elements will be of fundamental importance on a short, medium and long-term basis.

4.1 From Farm to Fork - Core Legal/Regulatory Concerns

A fundamental question for P2GreeN activities is simply, what is the substance? For instance, is it waste (or a specific type therein), fertiliser or water? The answers to these questions are likely to vary across the product lifecycles and across the different P2GreeN activities/regions. The answers will have significant implications regarding requirements for permits/licences, controls, labelling, use in food production, costs etc and may impact thereby on the development of P2GreeN activities and eventual products.

4.1.1 Waste

For the purposes of P2GreeN activities, the main initial question is whether the substance being processed for use in agriculture is waste or not. Without even

considering the legal specifics initially, urine and faecal matter are typically thought of as 'human waste' – a good case would need to be made that such substances are not waste. If it is waste, then waste law applies – at least initially. It then becomes necessary to delve deeper and see what are the consequences and, for instance, whether a specific branch of waste law applies. The main legislation considered is the 2008 Waste Framework Directive (WFD) (Directive 2008/98),² the Urban Wastewater Treatment Directive (Directive 91/271) (UWWT Directive),³ and the Animal By-Products Regulation (Regulation 1069/2009).⁴

A starting point is that the WFD defines waste as anything discarded, intended to be discarded or required to be discarded.⁵ This would apply normally to both human urine and faecal matter, whether separated, mixed together or with other substances. It also does not seem capable at the current time to label it as a by-product based on Article 5 of the WFD,⁶ thereby not being waste. Consequently, the main consideration is whether the substances remain within the scope of the WFD, both pre- and post-treatment, or fall within other legislation.

Separated faecal matter (prior to treatment/recovery) would appear to fall within the scope of the WFD. There is the potential to argue that it is excluded under Article 2(1)(f), but this is highly challenging as the faeces must be 'non-hazardous', 'agricultural... material' and 'used in farming... through processes or methods which do not harm the environment or endanger human health'. As discussed in Annex I, this merits further examination, but the implication is that the faeces should be animal faeces produced through or from agriculture. An argument likewise could be made that faeces and urine, whether separated or not, are 'animal by-products', but even if they fell within the definition, they are not within the scope of the Animal By-Products Regulation⁷ and therefore not excluded from the WFD by this pathway.⁸

Urine and faeces found within wastewater would appear likely to be waste initially, but excluded from the scope of the WFD to the extent that they are covered

² Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives [2008] OJ L 312/3.

³ Council Directive 91/271/EEC of 21 May 1991 concerning urban waste water treatment [1991] OJ L 135/40.

⁴ Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) [2009] L 300/1.

⁵ Article 3(1) of the WFD.

⁶ Criteria include that 'the substance or object is produced as an integral part of a production process' and 'can be directly without any further processing other than normal industrial practice'.

⁷ As noted in the appended Annex 1, Article 2(2) of the Animal By-Products Regulation expressly excludes some animal by-products from the scope of the Regulation, including: (k) excrement and urine other than manure and non-mineralised guano. Article 3(20) then states that "manure' means any excrement and/or urine of farmed animals other than farmed fish, with or without litter'. (emphasis added).

⁸ Article 2(2) of the Waste Framework Directive only excludes animal by-products to the extent that they are covered by other EU legislation – hence, part of the reason why the limited scope of the Animal By-Products Regulation is significant, as it cuts off a further avenue to avoid the application of the WFD.

by other EU law – in particular, the UWWT Directive and the Sewage Sludge Directive. 9

The WFD provides for Member States to develop waste management systems, including permits and prioritising the treatment and recovery of waste. The UWWT Directive similarly provides for a collecting and treatment system for UWW, based on prior authorisation. Products derived from waste (whether separated faeces or urine or faeces in wastewater) that have gone through a recovery process (such as composting) are likely to cease to be waste (subject to meeting relevant criteria) and therefore can be deemed to be something else, such as some form of water or fertiliser. Those criteria include meeting the standards and technical requirements of the new product and also that the new product 'will not lead to overall adverse environmental or human health impacts'.¹⁰

Fertilisers are addressed below, but it is worth highlighting that Regulation 2020/741 on water reuse/the use of reclaimed water¹¹ is specifically applicable in the context of water treated under the UWWT Directive. It has established uniform minimum requirements for water reuse applicable to all Member States, with a particular emphasis on agricultural irrigation. The responsibilities of reclamation facility operators are underlined to ensure the quality and safety of reclaimed water for human or animal health and for the environment.

Regulation 2020/741 is complemented by Regulation 852/2004 on hygiene in foodstuffs,¹² which requires, for instance, that potable or clean water be used in the production of plant products 'whenever necessary to prevent contamination'.¹³ Clean water entails water 'that does not contain micro-organisms, harmful substances or toxic marine plankton in quantities capable of directly or indirectly affecting the health quality of food'.¹⁴ Where reclaimed water does not meet the criteria to be deemed 'clean', it might be permissible to be used in irrigating some crops and not others – depending on elements such as what substances are present in it, how the crops are processed prior to distribution and consumption, and what rules exist for specific types of crops or agri-types.

Future research is needed regarding how the EU regime is interpreted (especially at the EU level) and the domestic implementation and development of these regimes, e.g. via the permitting/prior authorisation systems.

Questions/issues for the regions:

• What is the nature of the P2GreeN materials/ingredients, how are they initially collected and at what point are they separated from other substances?

⁹ Residual sludge from the UWWT Directive attracts the application of the Sewage Sludge Directive: Council Directive 86/278/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture [1986] OJ L 181/6.

¹⁰ Article 6(1) of the WFD.

¹¹ Regulation (EU) 2020/741 of the European Parliament and of the Council of 25 May 2020 on minimum requirements for water reuse, [2020] OJ L177/32.

¹² Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs [2004] OJ L139/1.

¹³ Annex 1, Part A (II) (5)(c).

¹⁴ Article 1(h) read in conjunction with Article 1(i).

- How are the materials/ingredients likely to be classified (and why)?
- What are the overall environmental and human health risks/impacts of both the original ingredients and the final P2GreeN products?

4.1.2 Fertilisers

Fertilising products are governed by Regulation (EU) 2019/1009¹⁵ known as the Fertilising Products Regulation (FPR), which entered into force on 16th of July 2022.

This new Regulation retains optional harmonization. If a product does not comply with the requirements of FPR, it still can potentially be authorised in one Member State and placed on the local market. Then, the mutual recognition principle can be used, described in the Regulation 2019/1009, to place the product on another EU Member State's market. The mutual recognition principle makes sure that EU countries generally accept products marketed in another EU country (see the discussion in 4.3 on mutual recognition). However, the mutual recognition procedure is different for each country, in terms of simplicity, cost and time. It could be highly resource intensive and complex, depending on the evaluation procedures, fees and timelines in an individual jurisdiction. Finally, authorisation may be rejected by certain Member States if the product does not comply with national requirements on the grounds of public safety, health or the environment, i.e. going through the local authorisation process successfully in one EU Member State does not guarantee access to the market in another Member State, despite the principle of mutual recognition.

On the other hand, any product that complies with the requirements of the Regulation can be characterized as an EU fertilising product (authorised across the EU) and bear the CE marking on its label. The CE marking is intertwined with highquality and safety for humans and the environment, thus providing added value to the product and the brand. It takes into account the product's ingredients and final characteristics in relation to the claimed function. For a product to be labelled as an EU fertilising product and bear the CE mark, it must:

- fulfil the requirements defined in Annex I of the Regulation for the corresponding Product Function Category (PFC);
- satisfy the requirements defined in Annex II for the corresponding Component Material Category(/ies) (CMC) contained in the product;
- be labelled according to the labelling requirements described in Annex III; and,
- has been successfully assessed according to the applicable Conformity Assessment Procedure.

Future research is needed regarding the CMCs and PFCs that are most relevant to P2GreeN products, including how they have been interpreted to-date. This

¹⁵ Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 [2019] OJ L 170/1.

will also depend significantly on information regarding the final role, nature and characteristics of P2GreeN products, as well as their ingredients and processing.

Questions/issues for the regions:

- Whether the P2GreeN materials and/or products fall within the scope of the FPR?
- How are the products likely to be classified (and why)?
- What specific challenges exist for the individual products/ingredients?

4.1.3 Chemicals: REACH and CLP Regulation

As fertilising products are also chemical products, they must also comply with Regulation 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)¹⁶ and Regulation 1272/2008 on Classification, Labelling and Packaging of substances and mixtures (CLP).¹⁷ Together these Regulations ensure a high level of environmental and human health standards for chemicals, as well as their free movement throughout the EU's internal market. Neither Regulation applies to waste, but they do apply to substances that cease to be waste and more specifically to fertilisers.

The REACH Regulation aims to ensure a high level of protection against harmful substances, assess the safety of the chemicals used and enhance innovation and competitiveness in the EU internal market, while limiting the use of animal testing for the assessment of the hazards of substances. Registration is a key requirement. The FPR also sets additional REACH requirements for substances in fertilisers to further enhance the safety assessment of fertilisers - requirements referred to in industry as REACH+ (REACH plus). For instance, although REACH provides a tonnage threshold for registration, the FPR provides that all substances contained in fertilising products are registered regardless of the tonnage. Thus, it may be that a product requires registration under one or the other Regulation, or possibly both. The CLP Regulation aims to identify the hazardous properties of substances or mixtures, classify them according to their physical, health and environmental hazards and communicate them to all economic operators via standardized formats through labels and Safety Data Sheets (SDSs). Central under both Regulations is the need for a range of physical, chemical, toxicological and ecotoxicological data.

¹⁶ Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC [2006] OJ L 396/1.

¹⁷ Council Regulation (EC) 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1997/2006 [2008] OJ L 353/1.

Products or ingredients that are not covered by EU harmonised legislation, such as the WFD, the REACH and CLP Regulations and the FPR, fall within the scope of the General Product Safety Regulation, Regulation 2023/988.¹⁸

Future research is needed regarding the specific requirements, standards, focus points etc under each Regulation that are most relevant to P2GreeN products, along with domestic implementation and complementary domestic regimes. Of key concern will be whether any elements are considered particularly hazardous.

Questions/issues for the regions:

- Which of the P2GreeN materials and/or products fall within the scope of the REACH and/or the CLP Regulations?
- What data is available/will be gathered and how?
- How are the products likely to be classified (and why)?

4.2 The Environmental Dimension

A secondary, but still immediate, question relates to environmental impacts: how do the products and processes involved impact on and engage with environmental regimes? These regimes interrelate, but nonetheless are separate and numerous. Consideration of environmental (and human health) impacts is essential within these individual regimes, to determine if assessments or authorisations are required, potential conditions etc. It is also essential as the environmental credentials may impact upon categorisation of the products (as noted above), their ability to avail of political and financial supports (e.g. under the Common Agricultural Policy), and their eventual marketability (e.g. ecolabels).

A significant aspect here for the P2GreeN operators is that of considering how they will evidence each aspect – even if currently undertaking activities in a jurisdiction that is permissive (especially for trials), building up a portfolio of evidence demonstrating safety, lack of environmental risks and preferably environmental benefits will be highly valuable in complying with requirements when it comes to upscaling or indeed as EU policy develops.

The appended Annex 4 examines several environmental regimes that are of relevance to P2GreeN activities: water, nature conservation, environmental impact assessments (EIAs), soil, air, pesticides and industrial emissions. Issues such as antimicrobial resistance are not currently subject to their own independent, binding regimes, but will be relevant to general assessments of environmental and human health impacts, as well as being capable of being regulated directly under the Water

¹⁸ Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and of the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC [2023] OJ L 135/1.

Framework Directive¹⁹ and related legislation.²⁰ Likewise, soil quality is an essential consideration and is gradually developing in its own right, but currently is largely indirectly protected under areas such as pesticides, waste law, water law or nature conservation. Here, we highlight some brief elements from a few of the more generally applicable regimes that are of more immediate concern, encompassing: water law; nature conservation; soil; and pesticides.

4.2.1 Water law

This section does not consider the Urban Waste Water Treatment (UWWT) Directive or elements such as the use of water in irrigation (e.g. under both the Water Reuse Regulation (Regulation 2020/741) and the Hygiene in Foodstuffs Regulation (Regulation 852/2004), as these are discussed in the earlier section on waste. Instead, the focus here is more generally on water quality and pollution in the broader environment.

Directive 2000/60 (the Water Framework Directive)²¹ establishes a framework for Community action in the field of water policy, complemented by a wide range of other EU legislation. A core goal therein is a significant reduction in the pollution of groundwater, with N & P being identified as pollutants that contribute to eutrophication. It also seeks to achieve 'good' status of all surface water and groundwater bodies by 2027. It does this through a range of mechanisms, including domestic river basin management plans, requirements for general controls on pollution and deterioration of waterbodies, EU-level standards for priority substances, and domestic standards for substances of national concern. Currently, the priority substances entail a list of 45 substances (21 of which are priority hazardous substances), including some heavy metals and chemicals, with a 'watch list' to monitor water and consider whether this list needs to be amended (or the approach thereto).

In October 2022 the Commission adopted a proposal to amend the Water Framework Directive, the Groundwater Directive²² and the Environmental Quality Standards Directive (EQSD)²³ with the aim of setting "new standards for a series of chemical substances of concern to address chemical pollution in water, to facilitate enforcement based on a simplified and more coherent legal framework, to ensure

¹⁹ Council Directive 2000/60/EC of 23 October 2000 establishing a framework for Community action in the field of water policy [2000] OJ L327/22. See, e.g., M. Ågerstrand et al, 'Opportunities to tackle antibiotic resistance development in the aquatic environment through the Water Framework Directive', (2023) 52:5 *Ambio* 941-951.

²⁰ See the discussions in the appended Annex 4 regarding, for instance, proposed amendments to the list of priority substances targeted under water legislation.

²¹ Council Directive 2000/60/EC of 23 October 2000 establishing a framework for Community action in the field of water policy [2000] OJ L327/1.

²² Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration [2006] OJ L 372/19.

²³ Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council, [2008] OJ L348/84.

dynamic and up-to-date information on water status."²⁴ The proposals include a candidate list of 23 new substances, including some antibiotics.

Future research will need to examine the priority substances and their relationship with P2GreeN activities, monitor development of the Commission's Proposal, investigate national and regional developments (e.g. river basin management plans, national standards and polluting regimes) and consider how proposals regarding, for instance, addressing antimicrobial resistance might further impact the regime.

Questions/issues for the regions to consider:

- What impact would the P2GreeN products have on water quality/pollution?
- Are there specific traits that merit particular consideration/monitoring, e.g. heavy metals, nutrients, pharmaceuticals, salination levels etc? (Bearing in mind the priority substances/candidate list, watch list and general pollution controls)
- What chemical substances should be added to the list of environmental quality standards to minimise the impact on the environment of the use of human waste?
- How could the water legislation (e.g. WFD, Groundwater Directive, EQSD) or its implementation be amended to facilitate P2GreeN activities that benefit water quality/the environment?

4.2.2 Nature Conservation

The two key EU nature conservation laws are the Wild Birds Directive (now Directive 2009/147)²⁵ and the Habitats Directive (Directive 92/43),²⁶ which form the basis for what is known as the Natura2000 network and which are part of the Statutory Management Requirements (SMRs) of the Common Agricultural Policy (CAP). These laws provide for the designation of protected sites and, subsequently, significant restrictions on any activities on or near those sites. These include requirements for environmental assessments and evidence to demonstrate that the activities would not adversely affect the integrity of the site. While this is of relevance to the treatment of the human waste and its subsequent application on the land, it is worth flagging that the construction of new plants, pipelines or similar to transport and process human waste could also fall within the nature conservation legislation – especially if P2GreeN activities were to be upscaled and, for instance, be able to address excess human waste production in specific regions.

²⁴ Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2000/60/EC establishing a framework for Community action in the field of water policy, Directive 2006/118/EC on the protection of groundwater against pollution and deterioration and Directive 2008/105/EC on environmental quality standards in the field of water policy, COM (2022)540 final.

²⁵ Directive 2009/147 of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds [2009] OJ L 20/7.

²⁶ Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora [1992] L 206/7.

Future research will need to consider national and regional approaches to protected sites and species, in particular where these are proximate to existing P2GreeN activities but also where they might be developed in the future. This includes local site management plans, site specific conservation objectives and 'systems of protection'. Consideration will need to be given to the nature of the P2GreeN products and the manner of their use, and how this could impact on protected sites/species. Consideration will also need to be given to potential exemptions at both trial and commercialisation stages.

Questions/issues for the regions to consider:

- Whether the activities could impact on the protected species directly or indirectly and/or on their habitats? (bear in mind that this could include migratory birds that feed on land treated with P2GreeN products)
- Is there a protected area in the vicinity or not?
- What evidence they could produce to demonstrate the lack of an impact (and especially no adverse impact) on a species or the integrity of a site.

4.2.3 Soil

Soil remains largely unregulated at the EU level, with various related regimes providing elements of protection, but no tailored, overarching legislation focussed on soil. In addition to the recent Soil Strategy²⁷ published by the Commission and the Water Framework Directive, the core legislation of relevance to P2GreeN is Directive 2009/128 establishing a framework for the sustainable use of pesticides (SUP)²⁸ and the related CAP Regulation outlining 'good agricultural and environmental conditions' (GAEC) for financial support.²⁹ Together, these include reductions in pesticide use, buffer strips along water courses and elements regarding crop rotation and soil coverage. Further, Regulation 396/2005³⁰ (discussed below briefly) sets out maximum residue levels of pesticides in or on food and feed of plant and animal origin. Alongside these, is the very recent EU Proposal for a Soil Monitoring Law in July 2023.³¹ It clearly is an area that bears monitoring and also where the national and local levels may take the lead for the time being – or indeed where P2GreeN might have an opportunity to shape the EU policy and legislation.

Future research will need to examine national and regional approaches, monitor EU developments, and examine the controls regarding pesticide use and residues more closely.

²⁷ 'EU Soil Strategy for 2030: Reaping the benefits of healthy soils for people, food, nature and climate', Communication from the Commission, COM/2021/699 final.

²⁸ Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides, [2009] OJ L 309/71.

²⁹ Regulation (EU) 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008, [2013] OJ L 347/549.

³⁰ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC, [2005] OJ L70/1.

³¹ Proposal for a Directive of the European Parliament and of the Council on Soil Monitoring and Resilience, COM(2023)416 final.

Questions/issues for the regions to consider

- How will the use of the product impact the quality of the soil on the land to which it is applied?
- How can P2GreeN activities contribute to Strategy targets of reducing nutrient losses by at least 50%, the overall use and risk of chemical pesticides by 50% and the use of more hazardous pesticides by 50% by 2030?
- Will the product include any content that may be classified as a pollutant (broadly understood)?
- How much of that content will remain on the food grown as a result of the use of the product?

4.2.4 Pesticides/plant protection products (PPPs)

The law here addresses the authorisation,³² use³³ and residues of these products.³⁴ It is likely, but not guaranteed, that P2GreeN products will be waste, fertilisers or reclaimed water (at various stages) rather than PPPs. The key points of interest are whether there are PPPs within the P2GreeN products and the significance of this, e.g. regarding general potential impacts on the environment and/or human health, and what residues might be present on food.

Based on the EU legislative regime, the only PPPs available for use in the EU should be safe for humans and have 'no unacceptable effects on the environment', based on their nature and conditions of use. Complementing this, Regulation 396/2005³⁵ sets maximum residue levels (MRLs) for pesticides in or on food and feed of plant and animal origin, which are linked to good agricultural practices and thereby also the original authorisations. Consequently, one might expect that there should be no concerns for P2GreeN, even if some residue PPP is in P2GreeN products. However, complications arise,³⁶

- Good plant protection practice and realistic conditions of use do not always occur, e.g., the PPPs might be over-utilised or changed in some form, or there might have been unexpected events that impacted the 'conditions of use';
- (ii) It is possible that treatments or steps undergone (by P2GreeN or earlier on in the cycle) might impact the PPPs either negatively or positively, as other

³² Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC [2009] OJ L 309/1.

³³ E.g. the SUP Directive noted above regarding soil; and Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the sustainable use of plant protection products and amending Regulation (EU) 2021/2115, COM/2022/305 final.

³⁴ E.g. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC, [2005] OJ L70/1.

³⁵ Ibid.

³⁶ Comparisons can be seen here with the use of sewage sludge. e.g. Tayane C. R. Mesquita, Rizia R. Santos, Ane P. Cacique, Ludimara J. De SÁ, Flaviano O. Silvério & Gevany P. Pinho (2018) Easy and fast extraction methods to determine organochlorine pesticides in sewage sludge, soil, and water samples based at low temperature, Journal of Environmental Science and Health, Part B, 53:3, 199-206, DOI: <u>10.1080/03601234.2017.1405626</u>.

substances and processes interact with the PPPs. E.g. what of the impact of dehydration/concentration?

- (iii) Conditions might apply to any approval of the PPPs, e.g., not to be used on or near a protected site, near the habitat of a specific species, or at certain times or locations;
- (iv) P2GreeN or those using P2GreeN products might also be using PPPs, thereby accumulating with any residues found within P2GreeN products.

Future research will need to examine the developments of current proposals regarding the sustainable use of PPPs, dive deeper into the existing regime and domestic implementation, evaluate the particular significance to P2GreeN activities etc.

Questions for the regions include:

- Are residues tested for and/or are measures taken to address these?
- Are PPPs used in conjunction with P2GreeN products?
- Could the P2GreeN product fall within the definition of a PPP? (e.g. see Article 2(1) of Regulation 1107/2009)
- Are the MRLs in Regulation 396/2005 likely to be complied with?

Overall, environmental and human health issues are fundamental to the viability of P2GreeN activities.

Future research for D3.8 will need to engage with how these EU frameworks are developed at a national and regional level, including the general regimes, permitting, exemptions (perhaps available for trials, but not commercialization) etc, as well as looking to domestic regimes/elements. Further, it will be essential to consider more directly elements that may pose particular challenges, drawing on insights from the P2GreeN regions and their activities, such as pharmaceuticals, salination, heavy metals, energy consumption, infrastructure requirements etc.

More general questions/issues for the regions to consider:

- Are there protected sites in/near relevant localities? Both for current activities and potential future activities?
- What environmental/health aspects are actively researched/monitored during the
- activities and what gaps exist?
- What type and degree of evidence do they have regarding environmental or humanhealth impacts? (Bear in mind that different evidence might be required for trials, commercialization, export etc exemptions might no longer apply)
- What positive contributions can the specific processes/products make to environmental/human health standards?
- What risks are posed? (E.g. via run-off, heavy metals, pharmaceuticals (hormones and anti-microbial resistance), energy usage)

4.3 Commercialization and Upscaling

Alongside the above issues come the longer-term commercial and upscaling considerations: how to ensure access to markets across the EU and potentially beyond? What constraints might be imposed and how can these be navigated? For

the main part, these can and should be considered in detail at a later stage. However, within the appended Annex 5, we have noted 4 aspects: free movement of goods (FMG) and mutual recognition; the Common Agricultural Policy (CAP); food safety; and organic production. Two elements in particular bear highlighting here: (i) FMG and mutual recognition; and (ii) the CAP.

Under the EU's rules on FMG, once a good is authorised and in free circulation in one Member State, the general idea is that it should be able to circulate freely across all Member States. This includes prohibitions on custom duties, quantitative restrictions and measures equivalent to these, e.g. a prohibition on the sale or use of X unless it meets Y criterion. This also encompasses the rules on mutual recognition as outlined in brief detail in Annex 5, i.e. a general obligation to recognise the equivalence of standards, procedures, certifications etc in another Member State. However, crucially Member States have some leeway to impose restrictions for a range of objective justifications, including for environmental, human health and consumer protection reasons. For instance, a Member State/region might prohibit the use of a P2GreeN product if they consider that local standards are not met by the region where a P2GreeN product has been developed and authorised.

Regarding CAP, changes introduced under Regulation 2021/2115³⁷ (Articles 5 and 6) set the objectives for the National Strategic Plans which will form the core means of implementing the CAP from 2023 until 2027. Elements of these will be of particular relevance to the P2GreeN project. By virtue of Articles 12 and 13 of the Regulation an element of conditionality must be included by Member States in their CAP Strategic Plans, so that those farmers (and other beneficiaries) receiving direct payments or annual payments under a rural development programme must comply with the Statutory Management Requirements (SMRs) relating to climate and the environment, public health and plant health and animal welfare alongside standards for keeping land in Good Agricultural and Environmental Condition (GAEC). Crucially, Annex 1 of the Regulation includes indicators feeding into different objectives, including indicators regarding soil erosion and quality, air and water quality, and reductions in nutrient leakage. As well as Annex 5 of the scoping review, which provides some further information on CAP, further detail specifically on the SMRs and GAECs is found in Annex VII below.

Further research is needed to examine these regimes in detail at both an EU and regional level, as well as elements such as international trade law, including the SPS and TBT Agreements. It may also consider elements to do with intellectual property. Focus points will largely depend on what aspects are most significant to the P2GreeN regions, including in light of feedback and how their activities evolve.

³⁷ Regulation (EU) 2021/2115 of the European Parliament and of the Council of 2 December 2021 establishing rules on support for strategic plans to be drawn up by Member States under the common agricultural policy (CAP Strategic Plans) and financed by the European Agricultural Guarantee Fund (EAGF) and by the European Agricultural Fund for Rural Development (EAFRD) and repealing Regulations (EU) No 1305/2013 and (EU) No 1307/2013 [2021] OJ L 435/1.

Another aspect to consider regarding commercial issues is the ability to label the product as suitable for use in organic production. Regulation 2018/848³⁸ outlines the the rules for organic production and labelling of organic products. Certain products and substances, such as fertilisers, soil conditioners and nutrients, can be used in organic production if they are listed in the Regulation 2021/1165³⁹ and fulfil the conditions mentioned therein. This Regulation is amended on a regular basis, updating the list of authorised substances and products. In the case where a fertilising product or other product used in agriculture can be used in organic production based on the Regulation, it must also be compliant with the applicable Union and national legislative framework regarding its placement on the market.

Questions/issues for the regions include:

- Which markets are particularly desirable in future?
- What hurdles might be present in these markets or more generally regarding their products/processes?
- Whether they have (sufficient) evidence to assuage concerns regarding environmental or human health impacts, or consumer protection?
- How will they demonstrate and persuade others of the absence of risk/presence of these benefits/compliance with the indicators under the new CAP Regulation?

4.4 Policy Contribution

Finally, the overarching policy developments cannot be ignored, especially those at the EU level. They are already shaping legislative changes, e.g. regarding pesticide use, criteria for agricultural support, nature conservation etc and will continue to do so. P2GreeN must keep track of, and adapt in light of, these developments, but also has a significant opportunity to feed into these developments in the medium and long-term.

Two key, interrelated elements identified and sketched out briefly in the appended Annex 6 are: (i) the European Green Deal (EGD);⁴⁰ and (ii) the Circular Economy Action Plan (CEAP).⁴¹ Some others, e.g. regarding soil, have been considered in other sections. As a multifaceted approach, the EGD encompasses the foundations for a range of other policies, including elements on biodiversity, farm to fork, circular economy etc. For instance, the EGD's Farm to Fork Strategy⁴² is linked

³⁸ Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 [2018] OJ L 150.

³⁹ Commission Implementing Regulation (EU) 2021/1165 of 15 July 2021 authorising certain products and substances for use in organic production and establishing their lists, [2021] OJ L253/13.

⁴⁰ 'The European Green Deal', Communication from the Commission, COM/2019/640 final, <u>https://eur-lex.europa.eu/legal-</u>content/EN/TXT/?gid=1588580774040&uri=CELEX%3A52019DC0640.

⁴¹ 'A new Circular Economy Action Plan For a cleaner and more competitive Europe', Communication from the Commission, COM/2020/98 final.

⁴² 'A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system', COM (2020)381.

to the UN's Sustainable Development Goals and seeks to create a sustainable food system, reducing environmental impacts, while increasing resilience and ensuring food security. Specific proposals within the Farm to Fork Strategy include revising:

- The Sustainable Use of Pesticides Directive⁴³ to reduce use and risk and dependency on pesticides and enhance Integrated Pest Management; this would be accompanied by a proposal to revise the Regulation on Pesticides Statistics to reduce gaps in data on pesticide use.
- The Regulations implementing the Plant Protection Products framework to allow placing on the market of plant protection products containing biological active substances.
- The legislation on Food Contact Materials to improve food safety and to reduce the environmental footprint of the sector.

Alongside these, together the EGD and the Circular Economy Action Plan (CEAP) have led to other highly relevant proposals, including:

- A Proposal for an Ecodesign for Sustainable Products Regulation (ESPR),⁴⁴ which builds on the earlier ecodesign directive and the CEAP's Sustainable Products Initiative⁴⁵ and sets requirements for various product groups to improve their environmental impact.
- A Proposal for a Packaging and Packaging Waste Regulation (PPWR)⁴⁶ to minimize packaging waste and promote the use of environmentally friendly alternatives.

Questions for the regions include for instance:

- How do their activities currently contribute to the EU's 2030 and subsequent targets/ambitions under the EGD, and can they evidence this?
- How might P2GreeN activities contribute to the Integrated Nutrient Management Action Plan, as currently proposed? (And later, as adopted)
- How would they like existing policy/law to be adjusted to facilitate P2GreeN activities, while ensuring the broad objectives of these policies?

5 Preliminary analysis of the EU legislative framework applicable to the pilot regions

Following the documentation of the applicable EU legislative framework, a preliminary pilot-specific analysis was performed to identify potential gaps and

⁴³ Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides [2009] OJ L 309/71.

⁴⁵ <u>https://commission.europa.eu/energy-climate-change-environment/standards-tools-and-labels/products-labelling-rules-and-requirements/sustainable-products/ecodesign-sustainable-products-regulation_en.</u>

⁴⁴ Proposal and Annexes for a Regulation establishing a framework for setting ecodesign requirements for sustainable products and repealing Directive 2009/125/EC, COM/2022/142 final.

⁴⁶ Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on packaging and packaging waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904, and repealing Directive 94/62/EC, COM(2022)677.

bottlenecks at EU level and guide a further investigation of domestic frameworks. All pilot regions utilize human waste, however they use different raw materials and their end goals are divided in two distinct categories: fertilisation (Sweden, Germany) and irrigation (Spain).

5.1 Raw materials

The primary investigation concerned the assignment of a regulatory framework to the raw materials used, human excreta. There are two Directives that relate to such materials; the Waste Framework Directive (WFD) and the Urban Wastewater Treatment Directive (UWWT Directive). Human faeces and urine found within wastewater would likely appear to be excluded from the scope of the WFD to the extent that they are covered by the UWWT Directive. Based on the processes of each pilot region, the following preliminary conclusions can be drawn:

- It seems that separated faecal matter would appear likely to be waste at collection point, without an adequate means of exclusion, and therefore within the scope of the WFD.
- Further clarifications will be needed to decide whether urine collected would likely appear to be waste in the context of WFD or governed by the UWWT Directive.
- Urine collected in the German pilot region is most likely subject to the UWWT Directive.
- Municipal wastewater utilized in the Spanish pilot region is governed by the UWWT Directive and tertiary treated water (reclaimed water) for irrigation use is subject to Reg. (EU) 2020/741.

However, the core EU legislative framework does not provide clear provisions for the human excreta as handled in this project; in-depth examination of EU-level guidance and cases will be required, along with further literature on the specific issue. Domestic legislation regarding the collection and handling of human excreta shall be examined in the Full Legislative Report.

The next part of the investigation included the determination of the applicable EU legislative framework for the end materials. To facilitate the document navigation the conclusions for each pilot are analysed in different chapters.

5.2 Swedish Pilot Region (Pellets)

A preliminary compliance check with the FPR requirements was performed based on the available information for the product. The preliminary examination of conformity included the assignment of a Product Function Category (PFC) based solely on nutrient content as well as the assignment of a Component Material Category (CMC) to collected urine, without considering possible additives. The product could be categorized as solid organic fertiliser under PFC1(A)(I) if the organic carbon content is equal or above 15%, otherwise it could be categorized as a compound solid inorganic macronutrient fertiliser under PFC1(C)(I)(a)(ii). Other requirements of the assigned PFC would have to be evaluated at a later stage. However, a suitable CMC was not found for the collected urine. In conclusion, it is not possible for the product to be placed on the market as an EU fertilising product currently. Unless and until a new suitable CMC is added to the list in the FPR, the pellets for this region would need to

seek authorisation in one or more EU Member States in compliance with their domestic legislation and then apply for equivalent authorisation through mutual recognition in other EU countries.

The final product is subject to the REACH Regulation and REACH registration is required. Also, fertilising products are chemical products, so they must comply with the CLP Regulation. Other substances or mixtures that take part in the blending process, are also required to meet the requirements of the REACH and CLP Regulations. Finally, the product cannot be used in organic production, as the raw material is not currently listed.

5.3 German Pilot Region (Aurin®)

The compliance of the product with FPR requirements was preliminarily examined on the basis of the raw material designation under FPR and the nutrient content. Regarding the raw material eligibility of use in an EU fertilising product, as noted above, urine seems to not be an allowed material of any CMC. In addition, the identification of a suitable PFC seems similarly daunting. The nutrient content of the product does not reach the minimum limits required by the Regulation for the product to be categorized as an organic or inorganic EU fertilising product. A potential alternative solution would be a different PFC, such as Soil Improvers, and this will merit further investigation in future. However, since human urine is not included in an existing CMC, Aurin® cannot be placed on the market as an EU fertilising product, even if it were to meet the criteria for an alternative PFC. Changes at the EU level might facilitate seeking EU-level authorisation in future, but this is not possible currently. Therefore, for the time being, Aurin® would need to be authorised in EU Member States according to national law. As the product is already authorised in an EU Member State, the mutual recognition principle could be applied to authorise in other EU Member States.

As with the Swedish product, other applicable EU Regulations include REACH, under which REACH Registration is required, and CLP. Other substances or mixtures that take part in the blending process, are also required to meet the requirements of the REACH & CLP Regulation. Finally, Aurin® is not eligible for use in organic production, as urine is not considered authorised under the respective Regulation.

5.4 German Pilot Region (KIT)

FPR compliance was investigated by examining the available information on the product on material origin and processing, as well as nutrient content. The material that makes up the product is compost, comprising faecal matter and bulk material. According to the description of CMC 3 corresponding to compost, faecal matter would fall within the vague description of one the allowed materials. Although, since this kind of material was likely not considered for fertiliser production and there is a clear reference to the proof of safety for the human and the environment, more investigation is necessary to conclude the eligibility of human faecal matter as a component material of an EU fertilising product. Concerning the PFC, this product cannot be categorized as PFC1 corresponding to fertilisers, and specifically to the solid organic fertilisers, since the nutrient content does not fulfil the minimum nutrient limits. So, an alternative solution could be to investigate other PFCs, such as PFC3 which corresponds to soil improvers. In conclusion, this product could be placed on the market as an EU fertilising product if CMC 3 is applicable and if additional requirements of the assigned CMC and PFC are met.

The final product is subject to the REACH Regulation. Compost is likely exempt from the REACH registration obligation under Entry 12 of Annex V stating that "*This exemption covers compost when it is potentially subject to registration, i,e, when it is no longer waste according to Directive 2008/98/EC, and is understood as being applicable to substances consisting of solid particulate material that has been sanitised and stabilized through the action of micro-organisms and that results from the composting treatment*." A preliminary interpretation of this exception suggests that compost, originating from any source, is subject to the exemption. However, further investigation is warranted to determine the eligibility of human manure for this *exception, as the origin of compost is not explicitly defined.* In addition, fertilising products are chemical products, so they must comply with the CLP Regulation. Although REACH registration may not required, the relevant toxicological and ecotoxicological data for hazard classification of the product under CLP must be still produced. Finally, the product cannot be used in organic production, as the raw material is not listed in the allowed material of the respective Regulation.

5.5 Spanish Pilot Region (Reclaimed water)

Reclaimed water produced at the Spanish pilot region is subject to the Regulation 2020/741. The treated wastewater received by the reclamation facility as input material must be further treated to meet specific standards and requirements as outlined in the aforementioned Regulation. These include the monitoring and quality requirements of the water, as well as the compilation of water reuse management plans.

The type of reclamation treatment depends on the desired class of reclaimed water, as it is defined in the Regulation. The appropriate class is determined by the intended irrigation methods and the selected crops. Specifically, the irrigation of food crops with reclaimed water can be performed only if the specifications of the reclaimed water correspond to the specifications of Class A regarding *Escherichia coli* content, BOD₅, TSS and turbidity. It is noteworthy that even though nutrient concentration monitoring is not compulsory by the legislation, it is indirectly mandated as end-users of irrigation water need to be properly informed about the nutrient content of the reclaimed water to avoid overfertilisation.

In summary, the requirements of a reclamation facility operator are the following:

- 1. Compliance with reclaimed water quality requirements specified in Annex I, Section 2 of Reg. 2020/741/EU with respect to the assigned Class based on applicable crops and irrigation methods.
- 2. Implementation of Risk Assessment and provision of Risk Management plan to identify and mitigate potential hazards throughout the whole water supply chain, from the point of entry to the Waste-water treatment plant to the point of use.
- 3. Submission for a permit to the competent authority of the Member State that the facility operates.
- 4. Continuous monitoring of the identified hazards/parameters

Further, under Regulation 852/2004 on hygiene in foodstuffs, clean water must be used wherever necessary to prevent contamination – impacting on both the standards and of use of reclaimed water. Reclaimed water meeting the general standards might be suitable for use on some crops, but not others.

The applicable Spanish national law for reclaimed water (Royal Decree 1620/2007)⁴⁷ also defined requirements for water treatment, quality standards and risk assessment that were tailored to Spain's specific agricultural requirements. In conclusion, further investigation and actions are required to ensure compliance of the Spanish pilot's processes with the applicable EU legislative framework.

Regarding the possibility of using reclaimed water for irrigation in organic production, Regulation (EU) 2018/848⁴⁸ outlining the rules for organic production and labelling of organic products does not contain a specific reference regarding reclaimed water. The Regulation primarily focuses on general principles and requirements for organic production rather than specific water sources.

Nevertheless, the Regulation underlines the significance of preserving soil fertility, prohibiting the utilization of specific synthetic substances, and ensuring that production methods align with organic principles. In the case reclaimed water is employed in organic production, adherence to the overarching principles of organic production, such as preventing contamination with prohibited substances, is imperative. So, the key consideration is whether the reclaimed water meets the organic production standards and some points to consider would be a) does it meet the water quality standards in terms of content in substances or contaminants that could compromise the "organic production' nature of the crops (risk assessment) and b) working closely with the Organic certification Bodies, which operate under the supervision of national authorities, playing a crucial role in the certification process to ensure this practice complies with organic standards. In conclusion, this possibility needs to be further examined by contacting competent authorities and certification control bodies.

5.6 Summarizing table

Following the analysis of the applicable EU framework, a summary table of the conclusions is provided below (*Table 1*).

⁴⁷ Royal Decree 1620 / 2007, Of December 7, Which Establishes The Legal Regime Of The Reuse Of The Wastewater (Original Language Title: Real Decreto 1620/2007, de 7 de diciembre, por el que se establece el régimen jurídico de la reutilización de las aguas depuradas.)

⁴⁸ Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 [2018] OJ L 150/1.

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Table 1. Applicable EU framework for the materials and products of the Swedish, German and Spanish pilot regions.

	SWEDEN		GERMANY (1)		GERMANY (2)		SPAIN	
EU Legislative frameworks	Raw material	Final Product (Pellets)	Raw material	Final Product (Aurin)	Raw material	Final Product (KIT)	Raw material	Final material
	Urine	Concentrated Urine	Yellow-Water	Treated Yellow-Water	Separated faeces	Faecal compost	Treated municipal wastewater	Reclaimed Water for Irrigation
Directive 2018/98 – Waste Framework Directive (WFD)	Needs further investigation	Not in scope	Likely not in scope	Not in scope	Likely applicable	Not in scope	Not in scope	Not in scope
Directive 91/271 – Urban Wastewater Treatment (UWTD)	Needs further investigation.	Not in scope	Likely applicable	Not in scope	Likely not in scope	Not in scope	Applicable	Not in scope
Reg (EC) 1907/2006 – Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)	Not in scope	Applicable. (REACH Registration Required)	Not in scope	Applicable. (REACH Registration Required)	Not in scope	Applicable. (REACH Registration likely not required)	Not in scope	Not in scope
Reg (EC) 1272/2008 – Classification, Labelling & Packaging (CLP)	Not in scope	Applicable	Not in scope	Applicable	Not in scope	Applicable	Not in scope	Not in scope
Reg (EU) 2019/1009 – Fertilising Products Regulation (FPR)	Not in scope, but affects final product	Not applicable	Not in scope, but affects final product	Not applicable	Not in scope, but affects final product	Not applicable	Not in scope	Not in scope
Reg (EU) 2021/1165 – Authorised products and substances for use in organic production	Not in scope, but affects final product	Not applicable	Not in scope, but affects final product	Not applicable	Not in scope, but affects final product	Not applicable	Not in scope	Not applicable
Reg (EU) 2018/848 – Organic production and labelling of organic products	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not in scope	Needs further investigation
Reg (EU) 2020/741 - Minimum requirements for water reuse	Not in scope	Not in scope	Not in scope	Not in scope	Not in scope	Not in scope	Not in scope	Applicable

6 Conclusions and Suggestions for future investigations

Following the analysis, an important point is that the EU legislative framework does not provide clear provisions for the human excreta as handled in this project. Domestic legislation regarding the collection and handling of human excreta shall be examined in the Full Legislative Report.

It is also worth noting that a suitable CMC for urine and faecal matter was not found in the FPR, whereas the possibility of faecal matter used in the form of compost in EU fertilising products needs further investigation. Maybe a proposal to amend the Regulation could be introduced so that either treated urine and faecal matter can be added to an existing CMC or a new CMC for human excreta could be created setting all necessary procedures to ensure safety for humans and the environment. Apart from the CMC eligibility issue of the basic raw materials (human excreta), further investigation should be performed for the additional components used in the manufacturing process (e.g. chemical stabilisers, sawdust, etc) regarding CMC requirements, as well as whether new or amended PFCs might likewise be adopted. Since the products are not within the scope of the FPR as it currently stands, the only option of placing them on the market is through the national legislative frameworks and mutual recognition procedures. These frameworks require investigation in great detail, since their application varies greatly per pilot and follower regions.

Following the inconclusive results of the examination of the raw materials as regards their relationship with the EU WFD and complementary waste legislation, further examination and possibly suggestions for policy and regulatory changes to relevant authorities should take place. The examination will also provide better insight into the permitting required for the manufacturing, storing and transporting of human excreta.

Finally, the domestic legislative frameworks concerning P2GreeN activities in Germany, Spain, Sweden, Italy, Greece and France will be documented and examined in detail in the full legislative report. In this regard, the survey distributed to the regions included a dedicated section to help identify relevant domestic frameworks, serving as the starting point of our investigation. This was complemented by subsequent discussions with the regions during the project. Studying these frameworks will serve as a valuable foundation for formulating policy recommendations at the EU level, as well as providing key insights into the practical challenges and opportunities within the individual regions and potential pathways for developments across the board. So far, a preliminary, non-exhaustive list of legislative acts has been catalogued (that will be expanded upon and analysed in the next deliverable). In some instances, these domestic frameworks have been updated or even repealed since and, consequently, the table below (*Table 2*) is simply the starting point for following the threads of legal and policy developments.

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Table 2. An indicative inventory of domestic legislative acts related to the process of P2GreeN project in the pilot and follower regions, based on the preliminary survey results and discussions.

REGIONS	RELEVANT FRAMEWORK	AREA
GERMANY	 Gesetz zur Neuordnung des Kreislaufwirtschafts- Abfallrechts (KomAbwVO) vom 24/06/1997 Hamburgisches Gesetz- und Verordnungsblatt Nr. 31 vom 07/07/1997 Seite 297 German wastewater ordinance (AbfKlärV) German bio-waste regulation (BioAbfV) 	Waste-related materials
	German fertiliser regulation (DüMV)	Fertilising products
SWEDEN	 Waste Ordinance (2011:927) Waste Ordinance (2020:614) SNFS 1994:7 SFS 1998:944 SNFS 1994:2 	Waste-related materials
	 SFS 2008:245 KIFS 2017:7 	Fertilising products
SPAIN	 Law 22/2011 Law 7/2022 Law 29/85 Royal Decree 1310/1990 	Waste-related materials
	Royal Decree 506/2013	Fertilising products
HUNGARY	 Act CLXXXV of 2012 Act No. LVII of 1995 Government Decree No. 455/2013 Government Decree No. 439 of 2012 (XII. 29.) Government Decree No. 50 of 2001 (IV. 3.) 	Waste-related materials
	• Decree No. 36 of 2006 (V. 18.) FVM	Fertilising products
ITALY	 Legislative Decree 152/2006 (Environmental Code) Legislative Decree no 258 GURI no 218 Legislative Decree (11 May 1999) 	Waste-related materials
	Legislative Decree 75/2010Ministerial Decree No 18534/2009	Fertilising products
	 Ministerial Decision 5673/400 Law 4042/2012 (A' 24) 	Waste-related materials
GREECE	 National Law 1565/85 (A'164) Ministerial Decision 291180/11034/02 (B' 1274) Ministerial Decision 217217/2004 (B' 35) 	Fertilising products
FRANCE	 Environment Code (1) General Code of the Territorial Authorities French Order of 21 July 2015 Public Health Code 	Waste-related materials
	French Order of 1 April 2020	Fertilising products

7 ANNEX I – DETAILED DESCRIPTION OF EU FRAMEWORKS FOR WASTE

7.1 General overview

P2GreeN's key focus is on the potential use of human excrement and urine in agricultural activities. In developed countries with established sanitation systems, these substances are typically mixed within waste water and flushed away before they undergo treatment within the sewage system. In the context of the EU, this raises the applicability of the UWWT Directive,⁴⁹ discussed below. However, P2GreeN is not simply seeking to take the outputs from existing sewage systems but is deploying new sanitation technologies to collect human excrement/faeces and urine. The potential for the separate collection of these substances, their desirability as an input for an end product in agricultural production and the approach to their processing all beg the question of whether something other than the UWWT applies to these substances.

For the purposes of P2GreeN activities, the main initial question is whether the substance being processed for use in agriculture is waste or not. Without even considering the legal specifics initially, urine and faecal matter is typically thought of as 'human waste' – a good case would need to be made that such substances are not waste when collected. If they are waste, then questions arise as to which specific field of waste law applies and when they might cease to be waste.

Waste law, as with much of environmental law, is dealt with at both EU and Member State level under shared competence. Further there is also relevant international law, e.g., the Basel Convention regarding the transport of waste. The primary focus here is on EU waste law and, specifically, the Waste Framework Directive (WFD).⁵⁰ This is complemented by some brief discussion of the UWWT, the Animal By-Products Regulation⁵¹ and the Sewage Sludge Directive.⁵²

7.2 The WFD

The main piece of EU waste law is the 2008 WFD, which simplified, clarified, and amended the previous framework directive. In doing so, this Directive incorporated and codified legislation such as Directive 91/689 on hazardous waste.⁵³

⁴⁹ Council Directive 91/271/EEC of 21 May 1991 concerning urban waste water treatment [1991] OJ L 135/40.

⁵⁰ Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives [2008] OJ L 312/3.

⁵¹ Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) [2009] OJ L 300/1.

⁵² Council Directive 86/278/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture [1986] OJ L 181/6.

⁵³ Council Directive 91/689/EEC of 12 December 1991 on hazardous waste, [1991] OJ L377/20.
As shall be seen, the WFD provides a general framework that is based on the idea of a waste hierarchy. It is centred on the idea of 'discarding' – this concept will help determine whether a substance falls within or outside the scope of waste law. Thus, for instance, if something is intended to be or must be discarded, it is waste. Further concepts such as 'by-products', 'animal residues' and when something ceases to be waste are also fundamental to this discussion. Other important elements include controls on, recovery and disposal operations. If it goes through a relevant recovery operation and meets relevant criteria, it may then cease to be waste. The management and recovery of waste must be undertaken in accordance with the EU and linked national law.

Besides being relevant to the WFD and other waste legislation, the definition of waste found herein is also relevant to other legislation, e.g., the Integrated Pollution Prevention Control/Industrial Emissions Directive⁵⁴ regime controls waste as defined by this legislation.

As already noted, the WFD provides a general framework, including outlining the objectives, key terms and indicating the division of roles between the EU and the Member States. The focus is on waste management – once identified as waste, its management should be appropriate until it ceases to be waste. As an area of shared competence, the national approaches will vary to a significant degree. However, crucially, the definitions themselves are EU concepts and therefore determined at the EU level on a harmonised basis. However, a final element to note before examining the Directive's content is that the Directive has been developed and elucidated on quite substantially by the Court of Justice of the EU (CJEU). Therefore, when it comes to the full legislative report, it will need to consider in some detail how the CJEU has interpreted and applied the provisions. This also will provide insights as to the future interpretation of the Directive, where it has yet to be determined.

7.2.1 Waste hierarchy

The waste hierarchy was introduced in 2006 by the then WFD. It reflects a move from just thinking of minimising environmental harm (with the focus being primarily on disposal) to recognising that waste can be a resource too (consider its production and more efficient use). The previous version simply included three stages:

- 1. Prevention: producer responsibility, eco-labelling, and the like.
- Recycling and Reuse (includes recovery)- including possibility of energy creation. E.g., End-of-Life Vehicles Directive 2000/53, WEEE Regulations, Landfill Directive 99/31 with requirements regarding recycling/recovery/take back etc. Also now even have funds dedicated to this purpose to be included in the price as in the case of WEEE.
- 3. Proper management and disposal focus on incineration.

⁵⁴ Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control), [2010] OJ L334/17.

This has now been expanded within Article 4(1) of the 2008 WFD, in order of priority: Waste Prevention; Preparing for Reuse; Recycling; Other forms of recovery such as energy recovery; and Disposal. The aim within the hierarchy is to first and foremost prevent waste creation, but then find ways to Reuse, Recycle or Recover value from the waste. Only as a last resort should waste be disposed of, which clearly links this to ideas of the Circular Economy. It therefore is a concept that would generally support the efforts of the P2GreeN project and similar activities. It remains to be considered what the definition is of waste and whether the substances in this project fall within it and thus within the scope of the legislation.

7.2.2 Goals, values, objectives, and principles?

The WFD includes a range of underpinning provisions within the Preamble (nonbinding) and substantive provisions (binding and vary as to nature) that denote the fundamental purposes of the Directive and the provisions therein. They are significant as they guided the original creation of the legislation, but also impact on the implementation, interpretation, and enforcement of the Directive's provisions. This is especially the case due to the CJEU's purposive or teleological approach to environmental law, including in the area of waste – this will be developed further in the subsequent full report.

For instance, the Preamble includes several recitals regarding being based on ex Article 175 TEC (within the Environmental Title of the TEC),⁵⁵ aiming for a high level of protection of the environment and human health,⁵⁶ minimising negative effects of waste on human health and the environment, reducing resource use and applying the waste hierarchy.⁵⁷ There are clear references also to ideas of sustainability and self-sufficiency, as well as the internal market (and therefore free movement of goods). There are also numerous implicit and express references to environmental principles (besides indirectly via the TEC), such as prevention,⁵⁸ precaution,⁵⁹ proximity⁶⁰ and polluter pays.⁶¹

Alongside these, the Directive also includes elements such as reliance upon best available techniques (BAT),⁶² minimum standards, updating guidelines etc and the aim of achieving the best overall environmental option⁶³ - indicating both high standards and a somewhat integrated, holistic approach, i.e., an approach is not acceptable if it does not pollute the water but devastates the air.

Finally, regarding the specific objectives of the Directive, Recital 6, and Articles 1 and 13 bear highlighting at this stage:

⁵⁵ Recital 9.

⁵⁶ Recitals 22 and 26.

⁵⁷ Recital 6.

⁵⁸ Recital 30.

⁵⁹ Recital 30 and Article 4(2).

⁶⁰ Article 16.

⁶¹ Recitals 25, 26 and 27.

⁶² E.g., Article 16(1).

 $^{^{63}}$ Recital 31 and Article 4(2).

Recital 6: The first objective of any waste policy should be to minimise the negative effects of the generation and management of waste on human health and the environment. Waste policy should also aim at reducing the use of resources and favour the practical application of waste hierarchy.

Article 1: This Directive lays down measures to protect the environment and human health by preventing or reducing the adverse impacts of the generation and management of waste and by reducing overall impacts of resource use and improving the efficiency of such use.

Article 13: Member States shall take the necessary measures to ensure that waste management is carried out without endangering human health, without harming the environment and, in particular: (a) without risk to water, air, soil, plants or animals; (b) without causing a nuisance through noise or odours; and (c) without adversely affecting the countryside or places of special interest.

Resource use is an important feature, but at the core of the Directive is the aim to protect the environment and human health – with a wide range of elements noted, indicating once more the holistic, integrated approach rather than, for instance, just considering the potential for water pollution.

7.2.3 Waste and related concepts – meaning and scope

While a range of concepts are important, including recovery and disposal (to be examined at a later point), the key ones to be considered here are waste, by-products and something that ceases to be waste. These definitions are technical, legal definitions as provided for initially in the legislation and interpreted by the CJEU.

Article 3(1) of the 2008 Directive provides: (1) 'Waste: any substance or object which the holder discards or intends or is required to discard.' Thus, the focus is on (i) the holder (not some potential future individual who desires the substance) and (ii) the concept of discarding. If a substance is desirable or has a putative value, this does not stop it being waste – it depends on the actions, intentions, or obligations of the holder. It is worth noting that the initial holder is the producer of the substance (in this context, the individual passing excrement or urine) and the evaluation of whether something or not is waste starts with them, rather than purely at a subsequent stage – something may become waste at any point in a chain. Nonetheless, despite what might seem like a reasonably simple and expansive definition, the concept has proven complex and contested⁶⁴ with the CJEU playing a key role in its evolution (along with legislative developments).⁶⁵

⁶⁴ E.g., I. Cheyne, 'The definition of waste in EC law,' [2002] Journal of Environmental Law, 61; and D. Pocklington, 'Opening Pandora's Box – the EU Review of the Definition of "Waste", [2003] 12 *European Environmental Law Review* 204.

⁶⁵ H. Nash, 'The revised directive on waste: resolving legislative tensions in waste management,' [2009] Journal of Environmental Law, 139. D. Pocklington, 'The Significance of the Proposed Changes to the Waste Framework Directive,' [2006] 15 European Environmental Law Review, 75-87.

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Of note, although it has been overtaken by legislative changes since, in a case involving the previous 2006 WFD, the CJEU considered that slurry in that specific case was not waste where it was used as a fertiliser as part of a lawful practice of spreading on clearly identified parcels and if its storage was limited to the needs of those spreading operations. This was because it was not 'discarded' and there was no intention or requirement to do so.⁶⁶ Clearly slurry from animals and human waste are not identical, but there are enough similarities to lay a basis for reflecting further on the reasoning in this case and related debates.

There is considerable case-law on the concept of discarding and how one might determine whether a substance is waste or not, including through considering whether the substance is subject to a recovery or disposal operation, or whether it is a core product or by-product of a process. Due to legislative developments since and the focus of this project, the key element to note here is that the CJEU takes a purposive approach in interpreting the legislation. For instance, stating that the term 'discard' must be interpreted in light of the aim of the Directive and the relevant Treaty provisions, with the result that "the concept of waste cannot be interpreted restrictively."⁶⁷ Thus, the question whether a given substance is waste must be interpreted in light of all of the circumstances, regard being had to the aim of the Directive and the need to ensure that its effectiveness is not undermined.⁶⁸ This links back thereby to the question of the objectives and principles of the Directive, as discussed above.

The 2008 WFD also introduced some key provisions, largely responding (positively and negatively) to CJEU case-law. These include Article 2 on exclusions, Article 5 on byproducts and Article 6 on where something ceases to be waste. While the approach to defining waste typically is expansive and is interpreted on a purposive approach, these are significant carve-outs. Nonetheless, they are limited and should not be considered as indicating that the EU will be open to further exclusions or limitations on a substance being waste.

Article 2 excludes some substances entirely from the scope of the WFD and some to the extent that other legislation covers them. Of specific relevance to human waste are four sub-clauses dealing with 'land (*in situ*)', 'natural non-hazardous agricultural' material, waste waters and animal by-products. Thus, Article 2(1) excludes '(b) land (*in situ*) including unexcavated contaminated soil...' and '(f) faecal matter... and other natural non-hazardous agricultural... material used in farming.... through processes or methods which do not harm the environment or endanger human health.' Further, Article 2(2) excludes the following from the scope of the WFD 'to the extent that they are covered by other Community legislation: (a) waste waters; (b) animal by-products including processed products covered by Regulation 1774/2002 [now Regulation 1069/2009], except those which are destined for incineration, landfilling or use in a biogas or composting plant....' Together these provide numerous avenues for P2GreeN to argue that the original substances and final products are waste but nonetheless fall outside the scope of the

⁶⁶ Case C-416/02 Commission v Spain [2005] ECR I-7487.

⁶⁷ Case C-9/00 Palin Granit [2000] ECR I-3533, Para 23

⁶⁸ Ibid, Para 24.

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WFD, but this will depend on numerous definitions found elsewhere within the legislation⁶⁹ and as interpreted by the CJEU. It also does not mean that they are unregulated – indeed Article 2(2) only excludes 'to the extent' that other EU law covers them (see the following section). This includes ensuring that the aims of the WFD are fulfilled, including safeguarding the environment and human health.⁷⁰

One issue of complexity in particular is worth highlighting here, which is the relationship between Article 2(1)(f), with its mention of faecal matter, and 2(2)(b) regarding animal by-products. Let us start with Article 2(1)(f) itself. 'Faecal matter' in a vacuum could clearly include human faeces. However, the remainder of the provision would provide a preliminary indication that this is not to include human faeces, as a natural legal interpretation is that the faecal matter must derive from agricultural or forestry activities,⁷¹ as well as normally being used in farming, forestry or energy production. Yet, Article 2(1)(f) expressly states that it encompasses 'faecal matter, if not covered by paragraph 2(b),' i.e. there must be some faecal matter that falls within 2(1)(f) that does not fall within 2(b). 2(b) in turn encompasses 'animal by-products including processed products covered by Regulation (EC) No 1774/2002, except those which are destined for incineration, landfilling or use in a biogas or composting plant'. Could this strengthen an argument that Article 2(1)(f) ought to encompass human faeces, to distinguish it from 2(b)?

As discussed below, animal by-products under the relevant EU law include manure, i.e. excrement and urine from farmed animals (other than farmed fish), but not any other forms of excrement or urine. To identify a distinction, this provides an initial basis to consider that perhaps 'faecal matter' under Article 2(1)(f) refers to that of wild animals, farmed fish or indeed humans. However, first, Article 2(2)(b) provides its own limitation (and thereby distinction), by stating that it excludes the animal by-products within the scope of that legislation, 'except those which are destined for incineration, landfilling or use in a biogas or composting plant....' For instance, if manure were destined for a biogas or composting plant, it would not fall within Article 2(2)(b) but could still potentially fall within Article 2(1)(f) provides for a more absolute exclusion. Consequently, it would not appear that the reference to Article 2(b) is sufficient to conclude that faecal matter in Article 2(1)(f) encompasses human faeces and facilitates an exclusion from the WFD via this pathway, but this is an issue that merits further investigation and teasing out.

⁶⁹ E.g., the understanding of 'hazardous' and thereby 'non-hazardous' is tied to Annex III of the WFD, including elements regarding chemicals and disease.

⁷⁰ G. Van Calster, *EU Waste Law*, (OUP, second edition, 2015), p.40.

⁷¹ The provision states: 'faecal matter, if not covered by paragraph 2(b), straw and other natural nonhazardous agricultural or forestry material used in farming, forestry or for the production of energy from such biomass through processes or methods which do not harm the environment or endanger human health.' The use of 'faecal matter... straw *and other* natural non-hazardous agricultural or forestry material...' would indicate that the faecal matter must be a material derived from agriculture or forestry, akin to straw.

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Articles 5 and 6 instead provide for something not to be deemed waste. They build upon previous CJEU case-law regarding what is or is not waste. Article 5(1) deals with by-products and essentially provides that if an object or substance is not the main product but is something created as integral to a production process and has a certain further lawful use which does not require further processing beyond the ordinary industrial practice, then it will not be waste. These are cumulative conditions. This, however, is a bare outline of the conditions. Articles 5(2) and (3) provide for creating implementing criteria by the European Commission or, failing that, potentially by the Member States. The Commission's criteria must 'ensure a high level of protection of the environment and human health and facilitate the prudent and rational utilisation of natural resources.' The issue of by-products is also relevant for consideration of 'animal by-products' and categories of fertiliser discussed below.

Article 6 addresses 'end-of-waste status', i.e., where a substance ceases to be waste for the purposes of the WFD. Member States are to 'take appropriate measures to ensure that waste which has undergone recycling or other recovery operation is considered to have ceased to be waste if it complies with the following conditions:

'(a) the substance or object is commonly used for specific purposes;

(b) a market or demand exists for such a substance or object;

(c) the substance or object fulfils the technical requirements for the specific purposes and meets the existing legislation and standards applicable to products; and

(d) the use of the substance or object will not lead to overall adverse environmental or human health impacts.'

The implication is therefore that the Member States may create their own criteria to implement this provision and the conditions therein. However, Article 6 also provides for the European Commission to create Union-wide criteria (with specific elements to be included) and for a case-by-case approach where criteria have not been set at either level. Irrespective of who sets the criteria or whether the actions are undertaken on a case-by-case basis, the criteria/considerations are to include 'limit values for pollutants where necessary' and 'take into account any possible adverse environmental and human health impacts.'

As with Article 2, these two provisions open up significant avenues to argue that the substances never were, or no longer are, waste. Here, it will be essential not merely to investigate the case-law of the CJEU, but also the criteria and practices of both the Member States and the EU.

7.2.4 Consequences of falling within the WFD?

It is worth briefly noting the core obligations on Member States, which include to transpose the WFD, create a permitting system (dealing with waste management), implement these provisions, and enforce them. In doing so, they must bear in mind the waste hierarchy, the principles and aims of the legislation, and requirements within the

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substantive provisions regarding human health, the environment, sustainability, and proximity. The consequence, therefore, is that anyone gathering, holding, transporting, treating etc human waste that falls within the WFD is likely to be bound by their local waste management regime. Exemptions and limitations always exist, e.g., ordinary individuals are treated differently regarding their household waste than businesses managing waste, but nonetheless obligations typically apply. The specific approaches will vary from Member State to Member State and frequently within a Member State, but within the general framework of the WFD and under the shadow of the CJEU. Consequently, in examining those local regimes that implement the WFD, it is essential to bear in mind the WFD's provisions and the CJEU's interpretation of these.

Further, some provisions are considered to have direct effect, e.g., Article 13.⁷² This is significant, as it would enable individuals affected to rely directly on the provision, irrespective of transposition. For instance, consideration will need to be given to the waste management regimes established within the relevant Member States; the criteria for products to be deemed by-products; criteria for waste to cease being waste; any lists regarding hazardous waste; and how the impacts on the environment and human health are evaluated. Consideration will also need to be given to any supplementary developments in the EU regarding definitions of concepts such as hazardous waste, or indeed how human waste is approached normally. Issues such as transmissible diseases and hormones may pose particular challenges and bear further investigation in this context. An aspect not examined here, but that will need investigation is that of the transport – including transboundary transport – of waste. This will be covered to an extent by waste management regimes and licensing but goes beyond this – including within EU and international law.

However, not all substances that appear to be waste (or even are considered legally to be waste) will necessarily fall within the scope of the WFD. The two issues of waste water and animal by-products have already been flagged above, with Article 2(2) excluding them from the scope of the WFD to extent that they are covered by other EU legislation. Urban waste water also raises the related issues of reuse of reclaimed water and of sewage sludge, especially residual sludge following treatment of the waste water. What follows is a very brief sketch of some of the key points, highlighting their significance and the need to investigate further.

7.3 Urban Waste Water

Waste water is primarily addressed under the UWWT Directive noted above and is of relevance to the inputs for P2GreeN products. Materials originating from humans, referred to as human excreta, can be categorized into two distinct streams: urine and faeces. Based on prevailing sanitation technologies in the EU, these streams of human

⁷² Article 13: Member States shall take the necessary measures to ensure that waste management is carried out without endangering human health, without harming the environment and, in particular: (a) without risk to water, air, soil, plants or animals; (b) without causing a nuisance through noise or odours; and (c) without adversely affecting the countryside or places of special interest. See Case C-236/92 *Comitato Di Coordinamento per a Difesa della Cava v Regione Lombardia*, [1994] ECR I-483.

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excreta become intermixed and are typically flushed away with water, resulting in what is commonly referred to as "*domestic effluents*", often characterized as 'blackwater' within literature. These domestic effluents, comprising urine and faeces, coalesce with other wastewater streams, primarily stemming from kitchen activities and cleaning processes (collectively described as 'greywater'). This collected untreated wastewater stream is known as *domestic wastewater* and its management is governed under the UWWT Directive.

Within the UWWT Directive, the only express EU legislative reference to waste treatment of human excreta is provided through the definition of domestic wastewater: 'wastewater from residential settlements and services which originates predominately from human metabolism and from household activities'. This legislation thereby indirectly addresses the management of human excreta (wastewater originating from human metabolism) as a component of this composite liquid wastewater stream, defined as domestic wastewater. Further investigation is needed regarding the applicability of the UWWT to the different P2GreeN inputs and the consequences of such applicability (or not).

The Directive focuses on aspects such as wastewater collection and treatment process and sets out quality standards for the discharge of treated wastewater to prevent pollution. Following treatment, two core substances exist: treated waste water and sludge, both of which can bring added benefits as well as pose environmental and human health concerns. The subsequent treatment and reuse of these two substances is barely addressed within the UWWT Directive, with Articles 12 and 14 recommending the reuse 'whenever appropriate' of the water and sludge respectively.⁷³ Crucially, this is where the Sewage Sludge Directive and the Water Reuse Regulation 2020/741 come into play – both of which are of great significance to agriculture.

As will be discussed subsequently, it is possible for P2GreeN inputs to fall originally within the scope of the UWWT and then, following treatment, to be used in agricultural irrigation subject to both Regulation 2020/741 and Regulation 852/2004 on hygiene in foodstuffs. Alternatively, it may be that P2GreeN products (or similar products in the future) might, for instance, avail of the residual sludge following treatment and thereby raise the application of the Sewage Sludge Directive.

7.4 Sewage Sludge

The Sewage Sludge Directive's stated aim is to regulate "the use of sewage sludge in agriculture in such a way as to prevent harmful effects on soil, vegetation, animals and man, while encouraging its correct use."⁷⁴ The Directive thus details how farmers may use sewage sludge as a fertiliser and outlines a series of measures to ensure the protection of humans, animals, plants and the environment, for example by setting limits

⁷³ For both, disposal routes are to 'minimize the adverse effects on the environment', with some further minimal but important content in the provisions.

⁷⁴ [1986] OJ L 181/6, Article 1.

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on the concentration of specific heavy metals in sewage sludge. The latest evaluation of the Directive reveals that its use in agriculture represents between 30% and 50% of the total sewage sludge in the EU and that there has been a decrease in the level of heavy metals in such sludge since the Directive came into force.⁷⁵ There is uncertainty about the latter finding as it was noted that many Member States have adopted more stringent requirements than those of the Directive and there have also been negative unintended effects from its implementation.⁷⁶ As for the future of the Directive, sludge management will be influenced by the outcomes of the revisions of the UWWT Directive and the proposal for a Soil Monitoring Directive⁷⁷ (discussed below). Greater use of sewage sludge can also be seen as consistent with the Green Deal and Climate Change policy, provided that it does not impact negatively on the environment, e.g., through the introduction of heavy metals or antibiotics.

It is of relevance to P2GreeN and similar activities on a number of fronts. It may be that certain activities or products avail of sewage sludge as a component (or might do so in the future), alternatively the final products might contain something highly similar to sewage sludge or be highly similar, and/or P2GreeN activities (for instance, in creating products from treated wastewater) might lead to the creation of sewage sludge that still needs to be considered and managed appropriately. Issues that arise include whether the substances cease to be waste (and how and when),⁷⁸ what is the relevance of hazardous waste legislation, whether the Directive merits amendment and whether similar products should be dealt with as sewage sludge or otherwise. This Directive will merit further investigation in the full legislative report.

7.5 Reclaimed Water for Irrigation Purposes

The EU, under the Water Reuse Regulation 2020/741,⁷⁹ has established uniform minimum requirements for water reuse applicable to all Member States, with a particular emphasis on agricultural irrigation. It demonstrates that the treated wastewater can cease being a form of waste and transform into 'reclaimed water' that may be suitable for reuse

⁷⁵ COMMISSION STAFF WORKING DOCUMENT EVALUATION regarding Council Directive 86/278/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture, SWD(2023)157, p 53.

⁷⁶ These included the presence of antimicrobial genes and microplastics in the soil, possible emissions of ammonia, methane, and nitrous oxide, as well as of other contaminants which it can contain, and which are not regulated by the Directive.

⁷⁷ Proposal for a Directive of the European Parliament and of the Council on Soil Monitoring and Resilience COM(2023) 416 final, https://environment.ec.europa.eu/system/files/2023-07/Proposal%20for%20a%20DIRECTIVE%20OF%20THE%20EUROPEAN%20PARLIAMENT%20AND% 20OF%20THE%20COUNCIL%20on%20Soil%20Monitoring%20and%20Resilience_COM_2023_416_fin al.pdf.

⁷⁸ E.g. EurEau, 'Enabling the circular potential of sewage sludge within the EU legislative framework - A critical analysis of the current urban waste water treatment sludge legislation with respect to the circular economy', Position Paper, July 2021, <u>https://www.eureau.org/documents/drinking-water/position-papers/5835-position-paper-enabling-the-circular-potential-of-sewage-sludge/file</u>.

⁷⁹ Regulation (EU) 2020/741 of the European Parliament and of the Council of 25 May 2020 on minimum requirements for water reuse [2020] OJ L 177.

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for different purposes. However, while water reuse is foreseen, this is not without conditions - in particular, those relevant to the environment and human health. The safety of agricultural irrigation is guaranteed in EU Regulation 2020/741 by two types of requirements for irrigation with reclaimed water, namely: i) monitoring and quality requirements, and ii) water reuse risk management plans. Before considering these aspects, it is worth noting that the Water Reuse Regulation is complemented by Regulation 852/2004 on hygiene in foodstuffs.⁸⁰ While this is technically relevant to food production (and thereby relevant to other discussions below), it has implications for the use of reclaimed water. The Hygiene in Foodstuffs Regulation requires, for instance, that potable or clean water be used in the production of plant products 'whenever necessary to prevent contamination'.⁸¹ Clean water is defined as water 'that does not contain microorganisms, harmful substances or toxic marine plankton in quantities capable of directly or indirectly affecting the health quality of food'.⁸² Therefore, any reclaimed water would need to meet these criteria to be used in plant production 'whenever necessary to prevent contamination'.

7.5.1 Water Quality and Monitoring

The input stream for reclamation facilities consists of treated wastewater derived from Urban Wastewater Treatment Plants (UWWTPs). This treated wastewater undergoes both primary and secondary treatment processes, adhering to the stipulated requirements outlined in table 1 of Annex I of the UWWT Directive. The criteria in this table pertain to parameters such as Biological Oxygen Demand (BOD), Chemical Oxygen Demand (COD), and Total Suspended Solids (TSS) (*Table 3*).

Table 3. Environmental permits for treated wastewater under the Urban Wastewater Treatment Directive (Directive 97/271/EEC).

Parameter	Concentration limit
BOD ₅ at 20oC without nitrification	25 mg/l O ₂
COD	125 mg/l O ₂
TSS	35 mg/l

The specific requirements for tertiary treatment regarding the removal of nitrogen and phosphorus, as outlined in the context of the UWWT Directive, are not compulsory for the input of reclamation facilities. This deviation is deliberate, reflecting the additional purpose of Regulation 2020/741, which extends beyond traditional wastewater treatment objectives. In the context of the circular economy, the Regulation also recognizes the importance of reclaiming useful nutrients, specifically nitrogen and phosphorus, from treated wastewater.

⁸⁰ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs [2004] OJ L139/1.

⁸¹ Annex 1, Part A (II) (5)(c).

⁸² Article 1(h) read in conjunction with Article 1(i).

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Regulation 2020/741 places emphasis on the dual goals of ensuring water quality for irrigation purposes and contributing to the circular economy by eliminating the use of fresh water and reclaiming valuable nutrients. This nuanced approach aligns with the broader goals of sustainable resource management and circular economy principles, acknowledging the potential for beneficial reuse of nutrient-rich water in agricultural practices. It is noteworthy that even though nutrient concentration monitoring is not compulsory by the legislation, it is indirectly mandated as end-users of irrigation water need to be properly informed about the nutrient content of the reclaimed water to avoid overfertilisation.

Regarding obligatory requirements, reclamation facilities are mandated to undertake further treatment of secondary treated wastewater, to meet the specific requirements delineated in Regulation 2020/741/EU, Annex I, Section 2. The extent of treatment is determined by the desired class of reclaimed water, which is categorized based on the intended irrigation methods and applicable crops (*Figure 8*).



Figure 8. A brief presentation of the requirements set out in Regulation (EU) 741/2020.

In essence, the reclamation process involves improving the quality of the treated wastewater received from UWWTPs to align with the requirements set by Regulation 2020/741 intended for irrigation. The classification of the reclaimed water into different classes facilitates the tailoring of treatment processes to meet the distinct needs associated with various irrigation methods and specific crops. This approach ensures that the reclaimed water meets the specified quality criteria for its intended use in agriculture, safeguarding both environmental and human health concerns.

Further requirements for reclamation facilities operators are to establish regular monitoring and quality control for reclaimed water at the point of compliance, meaning the point where a reclamation facility operator delivers reclaimed water to the next actor in the reclaimed water supply chain.

7.5.2 Risk Assessment and Risk Management plan

Article 5 of Regulation 2020/741 stipulates the mandatory inclusion of a risk management plan for the operation of a reclaimed water supply network. The responsibility for conducting the risk analysis and formulating the water reuse risk management plan (RMP) is entrusted to the operator of the reclamation facility. This process is to be conducted in collaboration with other relevant stakeholders, including responsible parties and, where appropriate, end-users.

The RMP is then to be submitted to the Competent Authority of the Member State in which the reclamation facility is situated. The findings of this management plan serve to augment the stipulated requirements for reclamation facility operators, as outlined in Annex I, Section 2 of the Regulation. Annex II of the Regulation incorporates general provisions outlining the preparation of water reuse risk management plans (RMP). In essence, a RMP shall 1) set out any necessary requirements for the reclamation facility operator, in addition to those specified in Annex I, to further mitigate any risks before the point of compliance; 2) identify hazards, risks and appropriate preventive and/or possible corrective measures; 3) identify additional barriers in the water reuse system and set out any additional requirements after the point of compliance to ensure that the water reuse system is safe, including conditions related to distribution, storage and use where relevant, and 4) identify the parties responsible for meeting those requirements.

In 2023, the Joint Research Centre (JRC) published technical guidance aimed at facilitating the implementation of the Risk Management Plan (RMP) mandated by Article 5 of the Water Reuse Regulation (Regulation 2020/741).⁸³ The JRC report serves as a comprehensive guide, offering detailed instructions on how to effectively address the key elements of risk management (KRMs) as established by Annex II of the Water Reuse Regulation. KRMs are structured into four modules, each representing specific aspects of the Risk Management Plan (*Figure 9*).

⁸³ European Commission, Joint Research Centre, Maffettone, R., Gawlik, B., Technical guidance water reuse risk management for agricultural irrigation schemes in Europe, Publications Office of the European Union, 2022,
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Figure 9. Key elements of Risk Assessment as outlined in the Regulation (EU) 2020/741.

The JRC report provide in-depth insights in each key element and is supplemented with detailed explanations. To provide an example, an identified hazard in the context of reclaimed water use is the potential for over-fertilisation, which poses risks to soil quality, nitrogen and phosphorus biochemical cycles, and crop growth. To proactively address this risk, preventive measures are essential. One key strategy involves the continuous monitoring of nutrient concentrations in the reclaimed water at designated compliance points. This ongoing surveillance enables swift detection of any deviations from acceptable nutrient levels, facilitating immediate corrective actions to prevent overfertilisation.

Complementing monitoring efforts, it is crucial to provide comprehensive training to farmers. This educational initiative should focus on ensuring the safe and accurate utilization of reclaimed water to mitigate the risk of over-fertilisation. Farmer training programs can cover topics such as proper irrigation practices, understanding nutrient composition in reclaimed water, and the adoption of sustainable agricultural methods to optimize crop growth while safeguarding environmental health. By integrating continuous monitoring with targeted education, the risk of over-fertilisation can be effectively managed. This approach emphasizes a holistic and collaborative strategy to promote responsible and sustainable practices in the use of reclaimed water in agricultural settings.

Apart from the provided examples, to enhance understanding, the JRC report incorporates previously published case studies. These real-world examples serve as practical demonstrations, offering valuable insights into the application of risk management principles within the context of water reuse. By combining theoretical explanations with concrete case studies, the JRC report aims to facilitate a more robust

comprehension of the key elements of risk management outlined in the Water Reuse Regulation.

7.6 Animal By-products

The key piece of legislation here is Regulation 1069/2009, which merits further exploration once more in the full legislative report. The key questions for the moment are 1) what is the meaning of an animal by-product (or derived product); 2) could human waste in principle fall within the scope of the Regulation, if within the meaning of an animal by-product or derived product; and 3) if yes, then what are the broad implications?

Having already considered the general idea of a by-product above, here the focus is on whether a human is included within the meaning of 'animal' for the purposes of the Regulation. Regulation 1069/2009 merely defines animals as 'any vertebrate or invertebrate animal (including fish, reptiles, and amphibians). It neither includes nor excludes humans expressly, yet it seems clear that the Regulation was not intended to encompass human by-products, even if simply because we do not use bags or soap made from humans. On the other hand, legislation such as Directive 2010/63 on the protection of animals used for scientific purposes⁸⁴ expressly states that it applies to 'live non-human vertebrate animals'. This aspect is not clearcut, most likely because it was not contemplated or deemed necessary at the time of the legislation's creation, thereby needing further investigation.

However, even if human waste is within the *meaning* of animal by-products, there then is the question of the *scope* of the Regulation. Article 2(2) therein expressly excludes some animal by-products from the scope of the Regulation, including: (k) excrement and urine other than manure and non-mineralised guano. Article 3(20) then states that "manure' means any excrement and/or urine of farmed animals other than farmed fish, with or without litter'. Consequently, since humans are not 'farmed animals', their waste (excrement and urine) cannot be manure and is excluded from the scope of the Regulation as it currently stands.

However, even if human waste fell within the scope of Regulation 1069/2009, then it would be necessary to identify which Category of by-product and derived product applied and comply with the conditions therein. Of note, Article 22 therein prohibits 'the application to pastureland of organic fertilisers and soil improvers, other than manure' (i.e. excrement or urine of farmed animals) that derive from animal by-products – whether processed or not. Thus, if a P2GreeN product were considered to be an organic (as meant within the context of this Regulation) fertiliser or soil improver, then it would not be permitted to be applied to pastureland. This calls for investigation to see if alternative categories might be viable or if the legislation might merit amendment.

⁸⁴ Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes, [2010] OJ L276/33.

This is only a very brief outline of some of the main considerations from this legislation and, again, it merits further review in future.

7.7 Detailed preliminary analysis of the applicability of waste-related EU Regulations to the pilot regions

The question is not simply whether human faeces or urine is waste, but whether subsequent products are also, when/how any of these might cease to be waste and/or whether they can fall outside the scope of WFD despite being waste. The picture is much for the same for all human waste, but some variations may and do arise between faeces that is not found within wastewater/faeces that is separated from wastewater and other human waste that typically is found within wastewater.

The initial consideration is that of 'discarding' and typically human faeces, urine and related material would be discarded, intended to be discarded and/or required to be discarded, thereby falling easily within the definition of waste. Even though the outputs may be valuable, the individual who creates them still intends to discard them. However, there is the potential to make four alternative arguments:

- Never waste as not discarding: If the human waste is commissioned in advance, it could be claimed that there was never any intention to 'discard' it *per se* but instead that it was created for a set purpose of becoming a fertiliser. However, this is a very tenuous argument, especially as the human waste would still be created even if not to be used as a fertiliser.
- 2. Never waste as a 'by-product': similarly, if a contract is in place that guarantees that the human waste will be used in a lawful manner that does not require further processing beyond the ordinary industrial practice, then it could be argued that the human waste is a by-product and not waste. However, again this is tenuous and would need to be explored in further detail. Is human waste an integral aspect of a 'production process'? Is the treatment it undergoes 'ordinary industrial practice'? If either is a 'no,' which seems likely for the moment at least, then it cannot be deemed a by-product. However, criteria at EU level and national/local level will need to be examined also.
- 3. Once, but no longer waste, as reached 'end-of-waste' status: it may be that the human waste is initially waste for the purposes of the WFD (and related legislation), triggering application of waste management law at an EU level and within the Member State, but then ceases to be waste at some point during the process. In particular, where the human waste has gone through recycling or recovery, e.g., via composting, and is now in the form of a substance used for irrigation and/or fertilising, then it could be argued that it is no longer waste. Of note, the substance will also need to comply with the standards, technical requirements, and legislative requirements of whatever category of law applies to the resulting substance, e.g., requirements for water/irrigation of food products and/or fertilisers. It is not that the substance would simply be in breach of those rules, but: without this, the substance would still be deemed waste. However, the main challenge here will be to demonstrate that the resulting substance 'will not lead to overall adverse environmental or human health impacts' this will depend

on the process and the nature of the final product. If this is achieved, there is a strong argument to make that the product is no longer waste and therefore that the WFD (or alternative legislation such as the UWWT) does not apply – opening the possibility for it to be deemed a fertiliser (discussed below) or water. To evaluate this further for each P2GreeN product, it will be necessary to investigate the implementation of the WFD, the UWWT and the Water Reuse Regulation in greater detail, including any EU or Member State criteria, along with the other related legislation that might apply to the final product.

- Waste, but outside the scope of the WFD entirely or to an extent (other laws will apply clearly):
 - a. An argument could be made that human faeces falls within the concept of 'faecal matter' and thereby is excluded by Article 2(1)(f). However, three challenges arise here: to demonstrate that human faeces are (i) 'nonhazardous', (ii) 'agricultural... material' and (iii) 'used in farming... through processes or methods which do not harm the environment or endanger human health'. The non-hazardous aspect applies not to the end produce, but to the original waste. It needs to be investigated whether human faeces are typically considered hazardous or not and what is required for them to be considered 'non-hazardous', e.g., to convert hazardous faeces to non-hazardous faeces. The environmental and human health consideration applies again to the final application, i.e., injecting or spreading the fertiliser. It must consider natural consequences, e.g., if there is significant rainfall. But the greatest hurdle, simply because it would not be the norm, is whether human faeces is considered 'agricultural material' or not. As noted above, the implication in the text is that it is animal faeces, produced through or from agriculture. However, it is not explicit, and an argument could be made that, since agricultural production leads to food for human consumption, this inevitably leads to human faeces which is therefore an agricultural material. Further, there is the relationship with Article 2(b) and a (somewhat tenuous) argument to be made that if 2(1)(f) included human faeces, this would provide for a clearer demarcation between the two provisions. Cases, criteria, and other legislation will need to be examined to test how strong an avenue this is, but currently it seems inadequate as a legal basis. It also does not deal with urine/urine-based products. Linked to that, there is an argument to be made that this provision is not intended to cover human faeces as Article 2(2) addresses wastewater and typically human faeces would be found within wastewater.
 - b. A historical concern for those familiar with waste law would be that, if land is contaminated including through leachate draining into it from nearby waste then it could also be deemed to be waste and managed accordingly.⁸⁵ However, Article 2(1) does at least provide for a clear exclusion, so that any land fertilised or irrigated with the final products even if these were deemed to be waste will itself not be waste, if left unexcavated.⁸⁶

⁸⁵ Case C-1/03 criminal proceedings v Paul Van de Walle et al [2004] ECR I-7613.

⁸⁶ Van Calster, op cit. n, p.40. However, this is of not much reassurance if the farmer would like to till his land, dig up drops or otherwise engage in some limited excavation.

- c. Wastewaters, including sewage,⁸⁷ are excluded from the WFD to the extent that they are covered by EU law. Since there is specific legislation in this field (in particular, the UWWT Directive, as noted), there will be a considerable carve-out. However, the WFD remains as a backstop for wastewater and does not become irrelevant unless the wastewater manages to be simply considered not waste as outlined above. Therefore, for instance, at a minimum, its management must not endanger the environment or human health. Further, the UWWT Directive and other relevant legislation must then be applied.
- d. That human waste is an 'animal' by-product, since humans are animals, and thereby excluded from the WFD to the extent that they are covered by EU law. This is a highly challenging argument to make, as reflected through the consideration above of the Animal By-Products Regulation's focus on farmed animals. Further, inclusion within the scope of the Regulation may actually prove counterproductive in light of the approach therein to categorisation of by-products. Again, both the Regulation and the original provision on by-products in the WFD merit further investigation, but currently it would appear unhelpful to seek this exclusion from the WFD unless Regulation 1069/2009 is amended.

The point about the overall adverse environmental or human health impacts raises the question of what is used currently and how this varies. Without engaging in-depth at this point, it is worth noting a few points that will merit further investigation:

- This includes consideration of all environmental media and all types of human health. A process or product will not tick the box if it does not harm the soil, but heavily pollutes the air; or if it is innocuous for the environment but is lethal to humans. However, it might pose minimal harms to some elements and still be positive overall.
- The impacts must consider the processing of the human waste, the application on the farm of the product, its presence in the environment and the final food produce. Both positive and negative impacts should be considered.
- It is useful to consider also what the alternative would be, e.g., what fertilisers it might replace, what happens with those fertilisers instead and what would happen to the human waste if not transformed as under the P2GreeN project.⁸⁸ This may be relevant depending on the issue being examined but is likely to be ancillary.
- While comparison with the product that is being replaced might be a useful and valid consideration, it is insufficient by itself – even if simply because it is possible to grow food without added nutrients and therefore technically fertilisers are not required on an individual farm. However, that is also an over simplistic argument, as fertilisers are used and probably required to meet the food needs of the EU's and the world's

⁸⁷ Thus, wastewater encompasses faeces found suspended in wastewater, as they are part of wastewater. This would be the norm. However, if the faeces are separated/found separately from wastewater, then they are not encompassed within this exclusion. Presumably, this is simply because there is no Community/EU legislation that deals precisely with human faeces that are not found within wastewater.

⁸⁸ E.g., if the treatments improve the safety of the urine and faeces, beyond what normally occurs, then an argument could be made that the overall impact is positive. However, the specific argument depends on which aspect of the WFD is being considered, e.g., something is not considered as not waste simply because it is less harmful than X or if it has been treated so it slightly less harmful than it was.

population. However, fertilisers vary in the benefits they provide, and one is not a perfect substitute for another (the new one may be more or less useful) and some fertilisers such as manure can be in overabundance and would need to be dealt with in some other fashion if not spread on the land as a fertiliser.

Overall:

- Separated faecal matter would appear likely to be waste initially, without an adequate means of exclusion, and therefore within the scope of the WFD – although with Article 2(1)(f) meriting further examination;
- Urine and faeces found within wastewater would appear likely to be waste initially, but excluded from the scope of the WFD to the extent that they are covered by other EU law, i.e. originally the UWWT and then, for instance, potentially the Sewage Sludge Directive or the Water Reuse Regulation.
- Separated urine or mixes of faeces and urine, not found within wastewater, are more complicated – arguably they could still fall within the UWWT, as they might be perceived as a form of waste water yet urine is a pure, uncontaminated waste flow. If not within the UWWT, then they would still fall within the scope of the WFD; and
- Products derived from waste (whether separated faeces or urine or found in wastewater) that have gone through a recovery process (such as composting) are likely to cease to be waste (subject to meeting relevant criteria) and therefore can be deemed to be something else, such as some form of water or fertiliser (again, subject to meeting criteria).

Finally, it is worth flagging that there will be procedural requirements in each region, and these will need to be examined to ensure compliance. This might be the case even if it seems apparent that the substance is not covered by the WFD, e.g., to obtain a certificate that X is not considered to be waste as it is a by-product. It is a complex area that has been the subject of considerable litigation and is worth having resolved at an early stage.

8 ANNEX II – DETAILED DESCRIPTION OF EU FRAMEWORK FOR FERTILISING PRODUCTS

8.1 General Overview

Plants require nutrients for their growth. Nutrient intake can be accomplished through the root system or the leaves. The application of fertilisers to supply nutrients to the plants leads to an increase in biomass production and therefore crop yields. Fertilising products have been applied to crops throughout history, with the first fertilisers originating from natural or biological sources, for example animal manure, minerals and by-products from the processing of fish or animal slaughtering. Around the 19th century, industrially produced fertilisers started to be used enabling larger-scale agriculture with higher yields. Fertiliser use is necessary to ensure a steady crop production with minimum losses for the accomplishment of feeding the growing world population, but (i) it can be accomplished using different fertilisers and methods of application and (ii) besides being costly, it can have significant negative side effects on the environment and human health, if not regulated effectively.

8.2 The Fertilising Products Regulation (FPR)

The current legislation here is the Fertilising Products Regulation 2019/1009⁸⁹ (FPR) which, for example, harmonized the conditions concerning the placement of certain types of inorganic fertilisers on the market that could be labelled as EU fertilisers. Annex I listed the types of fertilisers and the requirements for each type regarding nutrient composition, labelling etc. This Regulation harmonises the conditions for the EU marketing of all products used in agriculture that are not already covered by other EU legislative acts, including a variety of products that provide nutrients or improve the nutrition efficiency of plants or mushrooms. However, the FPR does not prevent the application of sixteen legal acts on the protection of human, animal, and plant health, of safety and of the environment including the Sewage Sludge Directive, the Nitrates Directive (Directive 91/676)⁹⁰ and the Water Framework Directive (Directive 2000/60).⁹¹

The FPR is the first item to be delivered under the European Commission's Circular Economy Action Plan and has been amended to advance the goals of the second Circular Economy Action Plan (a component of the Green Deal discussed below). Further amendments are expected to this Regulation in the future and will need to be monitored. Facilitating the access to fertilising products that contain recycled or organic materials promotes their use, reinforcing circular economy models. Any product that complies with

⁸⁹ Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 [2019] L 170/1.

⁹⁰ Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources [1991] OJ L 375/1.

⁹¹ Council Directive 2000/60/EC of 23 October 2000 establishing a framework for Community action in the field of water policy, [2000] OJ L 327/1.

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the requirements set in the FPR can be characterized as an EU fertilising product and bear the CE mark on its label. The CE marking is intertwined with high-quality and safety for humans and the environment, thus providing added value to the product and the brand. EU fertilising products can move freely within the EU (and EEA) and are not restricted by different product-related national regulations. More specifically, Article 3(1) of the Regulation states that "Member States shall not impede, for reasons relating to composition, labelling or other aspects covered by this Regulation, the making available on the market of EU fertilising products which comply with this Regulation." This thereby reflects the EU concept of free movement of goods and the value of being approved under the EU procedure. Products not bearing the CE mark may still be placed on the market appropriately justified.⁹²

Compliance with the Regulation is ensured through specific procedures of conformity assessment, by examining (i) the ingredients of the product and (ii) the characteristics of the final product in relation to the claimed function. Article 42 of the Regulation empowers the Commission to adopt delegated acts amending the Annexes to reflect technical progress, facilitating internal market access and free movement for EU fertilising products. In other words, if the FPR proves currently too restrictive for P2GreeN activities and products, it might be possible to persuade the Commission to update the Annexes accordingly – in which case, turning to the core purposes, objectives and standards of the FPR will be essential.

8.2.1 Economic operators

The FPR introduces the concept of an economic operator, which is defined in Article 2 as including manufacturers, authorised representatives, importers, and distributors. For example, a manufacturer is defined as "a person who manufactures an EU fertilising product or has an EU fertilising product designed or manufactured and marketed that EU fertilising product under his or her name or trademark."⁹³ Importers and distributors will only be considered manufacturers if they market something as a fertilising product under their own name or trademark. The responsibilities and obligations of the various economic operators are set out in detail in Articles 6-12 of the Regulation, with a new obligation being a requirement that all economic operators must ensure the traceability of the EU fertilisers they market.

8.2.2 CE marking requirements

As stated in Article 2: "CE marking' means a marking by which the manufacturer indicates that the EU fertilising product is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing." For a product to be

⁹² This will raise issues regarding the free movement of goods, mutual recognition etc. This is discussed briefly in the final section of the scoping review and corresponding Annex, before further detail in the full legislative report.

⁹³ Article 2(11).

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labelled as an EU fertilising product and bear the CE mark, it must also fulfil the requirements defined in Annex I for the corresponding Product Function Category (PFC); satisfy the requirements defined in Annex II for the corresponding Component Material Category(ies) (CMCs) contained in the product; be labelled according to the labelling requirements described in Annex III; and, have been successfully assessed according to the applicable Conformity Assessment Procedure. Additional requirements and guidance regarding the CE mark on products placed in the EU market are given in the 'Blue Guide' on the implementation of EU product rules (2022).⁹⁴

8.2.3 Product Function Categories (PFC)

As already stated, the Regulation harmonises the conditions for the EU marketing of all fertilising products and includes potentially all products that provide nutrients or improve the nutrition efficiency of plants or mushrooms. Based on the claimed mode of action, the Regulation establishes a 7-fold designation of EU fertiliser products into the following Product Function Categories (PFC): 1. Fertiliser: 2. Liming material; 3. Soil improver; 4. Growing medium; 5. Inhibitor; 6. Plant biostimulant; and 7. Fertilising product blend. Each main PFC is divided into subcategories which are further divided. For example, according to Part II of Annex I "[a] fertiliser shall be an EU fertilising product the function of which is to provide nutrients to plants or mushrooms". Fertilisers are designated as PFC1, which is further divided in the following subcategories:

- A. Organic fertiliser
 - I. Solid organic fertiliser
 - II. Liquid organic fertiliser
- B. Organo-mineral fertiliser
 - I. Solid organo-mineral fertiliser
 - II. Liquid organo-mineral fertiliser
- C. Inorganic fertiliser
 - I. Inorganic macronutrient fertiliser
 - a. Solid inorganic macronutrient fertiliser
 - (i) Straight solid inorganic macronutrient fertiliser
 - (a) Straight solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content
 - (ii) Compound solid inorganic macronutrient fertiliser
 - (a) Compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content
 - b. Liquid inorganic macronutrient fertiliser
 - (i) Straight liquid inorganic macronutrient fertiliser
 - (ii) Compound liquid inorganic macronutrient fertiliser
 - II. Inorganic micronutrient fertiliser
 - a. Straight inorganic micronutrient fertiliser
 - b. Compound inorganic micronutrient fertiliser

⁹⁴ 'The 'Blue Guide' on the implementation of EU product rules', Commission notice, [2022] OJ C 247/01.

Each subcategory may have different requirements that add up to describe the final product. An EU fertilising product will comply with all requirements set for each subcategory.

To provide an example, assuming that a product is categorized as PFC 1 (C) (1)(b)(ii), i.e., a 'Compound liquid inorganic macronutrient fertiliser', then the following standards, among others, must apply:

- All EU fertilising products must not contain intentionally added phosphonates and the unintentional presence should not exceed 0.5%.
- PFC1(C) which concerns inorganic fertilisers sets concentration limits of pathogenic microorganisms if organic carbon exceeds 1%, with some exceptions.
- PFC 1(C)(I) which concerns inorganic macronutrient fertilisers sets upper limits for heavy metal concentration.
- PFC 1(C)(I)(b) concerning a liquid inorganic macronutrient fertiliser specifies that a product categorized as such must be in liquid form.
- PFC 1(C)(I)(b)(ii) which concerns a compound liquid inorganic macronutrient fertiliser provides the minimum concentration of nutrients that the product should contain to comply to this subcategory.

Annex I that describes the PFCs is divided in two parts, which must be read together: Part I lists all categories and subcategories, whereas Part II provides the requirements/standards set for each one. The claim that an EU fertilising product complies with the function of the assigned PFC shall be supported by the product's mode of action, the content of its various components, and any other relevant parameter set.

8.2.4 Component Material Categories (CMCs)

Beyond requirements set for the final product, the Regulation also sets certain obligations regarding characteristics of the raw materials composing the product. It allows numerous types of raw materials to be used in the production of fertilising products, divided across Component Material Categories (CMCs) and described in Annex II. As with the PFCs, the Annex is divided in two different parts that must be read together: Part I lists all the CMCs, whereas Part II describes the specific requirements. So far, 15 CMCs are included, which are expected to be more accurately defined in the future by the Commission. The first publication of the Regulation included 11 CMCs. However, in accordance with Article 42 for the amendment of Annexes due to technical progress, 4 more CMCs have been added and more additions could be expected in the future.

Annex II indicates that "[a]n EU fertilising product shall consist solely of component materials complying with the requirements for one or more of the CMCs listed" in Part I of the Annex which are:

- CMC 1: Virgin material substances and mixtures
- CMC 2: Plants, plant parts or plant extracts
- CMC 3: Compost

- CMC 4: Fresh crop digestate Digestate other than fresh crop digestate CMC 5: CMC 6: Food industry by-products CMC 7: Micro-organisms CMC 8: Nutrient polymers CMC 9: Polymers other than nutrient polymers CMC 10: Derived products within the meaning of Regulation1069/2009 CMC 11: By-products within the meaning of Directive 2008/98 CMC 12: Precipitated phosphate salts and derivates CMC 13: Thermal oxidation materials and derivates
- CMC 14: Pyrolysis and gasification materials
- CMC 15: Recovered high purity materials

While these might seem quite expansive and thereby easily encompassing P2GreeN ingredients, it is essential to examine the details of what is entailed.

8.2.5 Conformity Assessment

Before placing the product on the market as an EU fertilising product, its compliance to the Regulation must be ensured. For this purpose, the Regulation imposes the performance of a conformity assessment, i.e., a procedure proving that the specifications set by the Regulation are fulfilled. The Regulation designates four different conformity assessment procedures described in Annex IV. The category of the Conformity Assessment applied to each product depends on the PFC claimed as well as the CMC(s) contained in it. Annex IV is divided in two Parts; Part I is used to assign the CMC and PFC to the corresponding Conformity Assessment types, whereas Part II describes the documentation required and procedure applied for each type. The CE marking may only be used if the conformity assessment procedure within the meaning of Article 15 and Annex IV has been successfully completed.

In all procedures the manufacturer compiles the technical documentation, which must contain all the necessary information for the product in relation to the requirements of the Regulation and be available to the authorities upon request. In Conformity Assessment Modules A1, B+C and D1, a Notified Body must be involved to perform tests or accredit some of the technical documentation aspects, such as the technical design of the product or the quality system for production, final product inspection and testing of the product. All notified bodies are listed in the NANDO database.⁹⁵ For products that can be assessed under Module A the manufacturer is responsible for performing the conformity assessment. Once compliance is ensured, the manufacturer draws up the declaration of conformity according to Annex V. The CE marking may only be affixed if the conformity assessment procedure has been successfully carried out.

⁹⁵<u>https://webgate.ec.europa.eu/single-market-compliance-space/#/notified-bodies/notified-body-list?filter=bodyTypeld:3,legislationId:159361</u>.

8.3 Detailed preliminary analysis of FPR applicability to the pilot regions8.3.1 General overview

A preliminary evaluation of the potential applicability of the FPR to P2GreeN type activities is essential, specifically whether EU fertilising products falling within the FPR could originate from human waste. As stated in the Introduction, this project deals with 3 types of raw materials that undergo different procedures to produce four materials for different intended uses. Since the treated wastewater from the Spanish pilot region is used for irrigation purposes, it is excluded from further analysis under the FPR Regulation in the Scoping review.

The first point is whether the materials used to produce this fertiliser are allowed according to the Regulation, which needs to be further evaluated. The second point is whether the specifications of the fertiliser satisfy the requirements of the Regulation regarding nutrient content and other parameters, such as heavy metals and other contaminants. The primary focus of the examination was the nutrient content requirements, since it is the most important one. If nutrient content reaches the concentration needed, then other parameters can be examined in the future to ensure compliance.⁹⁶

8.3.2 Assignment of raw materials to a Component Material Category

According to the FPR, all ingredients of the final fertiliser must comply with the requirements for one or more of the CMCs listed in Annex I. Examining the existing CMC, the materials used in this project cannot be categorized as Component Material Categories 2, 4, 5, 6, 7, 8, 9, 12, 14 or 15, since these categories refer to plant materials or materials derived from other non-relevant sources and processes. The other existing CMCs require some further examination.

Firstly, CMC 11 which refers to "By-products within the meaning of Directive 2008/98" (i.e., the WFD) should be explored. The concept of a by-product within the WFD was outlined briefly in the previous Annex. As noted there, an object or substance may be deemed a by-product and not waste, if it is not the main product but is something created as integral to a production process and has a certain further lawful use which does not require further processing beyond the ordinary industrial practice. This seems highly unlikely in the context of human faeces or urine, e.g., what production process was involved?

However, if human faeces or urine is deemed a by-product, it is important to note that CMC 11 excludes animal by-products or derived products within the meaning of

⁹⁶ It is worth flagging now, that irrespective of whether a P2GreeN product (and its ingredients) could potentially seem to fall within existing relevant PFCs and CMCs (perhaps subject to ticking further boxes) or whether an argument would need to be made for introducing new categories, consideration should be given by operators on an urgent basis as to the general criteria regarding heavy metals and other contaminants and how evidence could be provided regarding these, as this all takes considerable time and established processes.

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Regulation 1069/2009, polymers (subject to certain exclusions), compost, and digestate. The exclusion list continues with the following products recovered from waste or that are by-products as defined by the WFD, namely:⁹⁷

(e) precipitated phosphate salts or derivates;

(f) thermal oxidation materials or derivates;

(g) pyrolysis and gasification materials; or

(h) ammonium salts, sulphate salts, phosphate salts, elemental sulphur, calcium carbonate or calcium oxide which are recovered from waste.

The two key elements of relevance here are the references to animal by-products and compost. As discussed in the section on waste, while it would appear clear that human waste is excluded from the scope of Regulation 1069/2009, it is arguable that human excrement and urine are within the meaning of animal by-products – if they are deemed by-products in the first instance. Further, the reference to compost would seemingly encompass faecal compost. Consequently, it would appear likely that CMC 11 cannot be applied successfully to P2GreeN products.

It is worth noting that, if the component materials used were subject to the WFD, the final EU fertilising product would not be – once compliance with the Regulation is proven and the EU declaration of conformity is signed. More, specifically, Article 19 of Regulation 2019/1009 states:

This Regulation lays down criteria in accordance with which material that constitutes waste, as defined in Directive 2008/98/EC, can cease to be waste, if it is contained in a compliant EU fertilising product. In such cases, the recovery operation under this Regulation shall be performed before the material ceases to be waste, and the material shall be considered to comply with the conditions laid down in Article 6 of that Directive.

According to the additional explanation given in the FAQ document, "Waste rules may apply to component materials using waste as input... The EU end-of-waste status is reached the moment the manufacturer signs the EU declaration of conformity of the EU fertilising product containing such a material." From the moment of the component material's production until the signature of the EU declaration of conformity, the component material has not necessarily reached end-of-waste status. So, the waste rules may be applicable at the stages of transport, storage, packaging, etc., unless specific national rules apply to a Member State deeming the material as not waste. Once the EU declaration of conformity is signed and the CE marking affixed on the package, the component material achieves the status as end-of-waste and the product moves freely in the internal market. So, organic fertiliser bearing the CE mark will no longer constitute waste within the definition of waste under the WFD, but the component materials (biodegradable waste) used in its manufacture continue to constitute waste (if deemed so

⁹⁷ All substances in the fertiliser must be registered under Regulation 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency, [2006] OJ L 396/1. This Regulation has been amended on numerous occasions most recently by Regulation 2023/923, [2023] OJ L 123/1.

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in the first instance).⁹⁸ This should promote a greater number of EU fertilisers, particularly more environmentally friendly fertilisers.

Another CMC to explore for the materials used in P2GreeN would be CMC 1 which includes virgin material substances and mixtures. CMC 1 excludes compost, so the faecal compost produced in the German pilot region would not fall into this category. Also, CMC 1 excludes (a) waste within the meaning of Directive 2008/98/EC; (b) substances or mixtures which have ceased to be waste in one or more Member States by virtue of the national measures transposing Article 6 of Directive 2008/98/EC; (c) substances formed from precursors which have ceased to be waste in one or more Member States by virtue of the national measures transposing Article 6 of Directive 2008/98/EC; (c) substances formed from precursors which have ceased to be waste in one or more Member States by virtue of the national measures transposing Article 6 of Directive 2008/98/EC, or mixtures containing such substances and (d) by-products within the meaning of Directive 2008/98/EC.⁹⁹ Note here that the focus is on 'meaning' rather than scope. Irrespective, of whether these substances are excluded or not (wholly or in part) from the scope of the WFD, it remains highly likely that human faeces and urine both fall within the meaning of waste as outlined within that Directive and therefore they (and, for instance, any ingredients following a relevant recovery process) would not be categorised as CMC 1.

A further aspect needs to be considered regarding urine in the light of CMC 1. According to the FAQ document¹⁰⁰ that is available for the FPR:

"CMC 1 applies to substances and mixtures within the meaning of REACH Regulation (point 1 of Article 3 and point 2 of Article 3 of Regulation (EC) No 1907/2006 respectively). For the purpose of chemical complexity vs. homogeneity, REACH categorises substances into well-defined substances and substances of unknown or variable composition (UVCB). UVCB substances may cover biological materials or chemical and mineral substances with poorly defined, complex or variable composition (such as essential oils, natural pigments, or peat)."

The text continues by giving examples regarding materials covered and not covered by CMC 1. Materials which may be covered by CMC 1 include chemical extracts or hydrolysates from plant and microbial materials and materials of biological origin which are fossilized or embedded in geological formations. Materials not covered by CMC 1 include whole living or unprocessed dead organisms or parts thereof (e.g. body parts, blood, branches). So, it is unlikely that urine would be covered by CMC 1 for this reason also.

Another possibility specifically for the faecal compost produced by the German pilot region would be to categorise it as a CMC 3 "Compost". As mentioned in the

⁹⁸ Under Article 42(3) "The Commission may only adopt delegated acts pursuant to paragraph 1 amending Annex II to this Regulation to include in the component material categories materials that cease to be waste following a recovery operation if recovery rules in that Annex, adopted no later than the inclusion, ensure that the materials comply with the conditions laid down in Article 6 of Directive 2008/98/EC."
⁹⁹ CMC 1, Annex 1(a) to (c).

¹⁰⁰ FAQs related to Regulation (EU) 2019/1009 on fertilising products (the 'Fertilising Products Regulation') (<u>https://ec.europa.eu/docsroom/documents/54694</u>)

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Regulation text, this CMC includes compost obtained through aerobic composting of exclusively one or more of the listed input materials. One of these allowed input materials is bio-waste within the meaning of the WFD resulting from separate bio-waste collection at source (point a). Also, a previously composted or digested material that is considered bio-waste is allowed as input material for EU fertilising products if it contains no more than 6 mg/kg dry matter of PAH₁₆. This initially looks viable for P2GreeN products; however, faeces are not considered biowaste within the meaning of the WFD.¹⁰¹

CMC 3 also includes "living or dead organisms or parts thereof, which are unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which are extracted from air by any means". This subcategory excludes the following: "(i) materials originating from mixed municipal waste,'; (ii) sewage sludge, industrial sludge or dredging sludge, and (iii) animal byproducts or derived products within the scope of Regulation 1069/2009." Human faeces could be considered as part of living organisms, thus falling into CMC 3, so further investigation of the exclusions listed should be performed. According to Article 3 of Directive 2008/98 (the WFD):

2b. 'municipal waste' means:

(a) mixed waste and separately collected waste from households, including paper and cardboard, glass, metals, plastics, biowaste, wood, textiles, packaging, waste electrical and electronic equipment, waste batteries and accumulators, and bulky waste, including mattresses and furniture;

(b) mixed waste and separately collected waste from other sources, where such waste is similar in nature and composition to waste from households;

Municipal waste does not include waste from production, agriculture, forestry, fishing, septic tanks and sewage network and treatment, including sewage sludge, end-of-life vehicles or construction and demolition waste.

Since mixed municipal waste does not include waste from sewage network and treatment, then this exclusion is not applicable for the P2GreeN products and CMC 3 could be a possible match for faeces. Also, human faeces in the various P2GreeN projects are separately collected and could not be considered as mixed municipal waste. Similarly, P2GreeN products, as currently intended, are unlikely to be in the form of or derived from sewage sludge, as this encompasses the sludge left following treatment of urban waste water (or similar waters) (whether the sludge itself has been treated or not).¹⁰² This may of course change in future.

Also, although animal by-products or derived products within the scope of Regulation 1069/2009 are excluded as an input material in CMC 3, this may not pose an issue for P2GreeN products. As noted above, while an argument can be made that human

¹⁰¹ According to Article 3(4) therein, "bio-waste' means biodegradable garden and park waste, food and kitchen waste from households, offices, restaurants, wholesale, canteens, caterers and retail premises and comparable waste from food processing plants'.

¹⁰² As reflected in Article 2 of the Sewage Sludge Directive. See the discussion above in the Annex on Waste law.

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waste falls within the definition of an animal by-product as provided for by Regulation 1069/2009 (and thereby also that derived products would be relevant), it would not appear to fall within the *scope* of the Regulation. Article 2(2)(k) of Regulation 1069/2009 provides that the Regulation does not apply to 'excrement and urine other than manure and non-mineralised guano', where Article 3(20) defines manure as 'any excrement and/or urine of *farmed* animals other than farmed fish, with or without litter' (emphasis added).

The Regulation also sets standards regarding the manufacturing plant as well as the composting process. For example, paragraph 3 of CMC 3 in Part II of Annex II the following is stated:

- 1. The aerobic composting shall consist of controlled decomposition of biodegradable materials, which is predominantly aerobic and which allows the development of temperatures suitable for thermophilic bacteria as a result of biologically produced heat. All parts of each batch shall be either regularly and thoroughly moved and turned or subject to forced ventilation in order to ensure the correct sanitation and homogeneity of the material. During the composting process, all parts of each batch shall have one of the following temperature-time profiles:
 - 70 °C or more for at least 3 days,
 - 65 °C or more for at least 5 days,
 - 60 °C or more for at least 7 days, or
 - 55 °C or more for at least 14 days.

According to the composting process taking place in the German pilot region, it seems that it is compliant with the standards determined in this CMC in terms of temperature and duration of composting. Also, the Regulation sets criteria regarding the maximum content of PAH₁₆ and macroscopic impurities as well as specific stability criteria, which will need to be investigated at a later point.

An important point to investigate is whether faecal matter could be considered as an allowed input material. FPR emphasizes the significance of safety of the materials used in fertilising products. For example, point 2 of Article 4 concerning product requirements states that: "For any aspects not covered by Annex I or II, EU fertilising products shall not present a risk to human, animal or plant health, to safety or to the environment". Relevant references are mentioned in other sections such as in Article 42 regarding the amendments of the Annexes. So, even if faecal matter is considered as part of living organisms, therefore fulfilling the definition of CMC 3, evidence of safety would need to be provided. Such input materials were likely not provisioned during the compilation of FPR.

Finally, composting additives which are necessary to improve the process performance or the environmental performance of the composting process are allowed as input materials as long as they fulfil the REACH Registration obligation and the total concentration of all additives does not exceed 5% of the total input material weight. REACH Regulation is analysed in more detail in Chapter 9.2.

One could argue that the final possibility regarding the assignment of a CMC to the P2GreeN materials is the CMC 10, which includes derived products within the meaning of Regulation 1069/2009. This Regulation lays down health rules as regards animal by-products and derived products not intended for human consumption and provides for their possible use as organic fertilisers or soil improvers.¹⁰³ Of note here, CMC 10 focusses on the meaning, rather than the scope of Regulation 1069/2009. According to the definitions laid down in the Reg. (EC) 1069/2009:

- "animal by-products" means entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, including oocytes, embryos and semen
- 'derived products' means products obtained from one or more treatments, transformations or steps of processing of animal byproducts;
- 'animal' means any invertebrate or vertebrate animal;

Based on these definitions and since humans are vertebrate animals,¹⁰⁴ it may be possible to argue that human excrement and/or urine is an animal by-product and that the subsequently treated, transformed or processed by-product has become a relevant 'derived product'. However, by reading throughout the text of the Regulation 1069/2009, it seems clear that humans are distinguished from animals and that the Regulation's scope is rather anthropocentric.

This becomes more significant when looking at the further requirement under CMC 10, that the derived products have 'reached the end point in the manufacturing chain as determined in accordance with [Regulation 1069/2009], and which are listed in the following table and as specified therein'. This effectively requires that the relevant by-product (and thereby derived product) fall within the scope of Regulation 1069/2009, which does not appear to be the case in the context of human waste (as noted above). This issue is also highlighted by the categorisation undertaken within Regulation 1069/2009. Animal by-products and derived products are separated into three categories, which under Article 7 reflect the level of risk to public and animal health arising from such products. Manure falls within Category 2 according to Article 9 of the Regulation, but as noted above regarding CMC 3 it is defined in Article 2 as "any excrement and/or urine of *farmed animals* other than farmed fish, with or without litter" (emphasis added). The definition of "farmed animal" clearly excludes humans. Article 9 also categorises "animal by-products collected during the treatment of wastewater" in Category 2 subject to certain

 $^{^{103}}$ [2009] OJ L 300/1. This Regulation has been amended by Directive 2010/63, [2010] OJ L 276/33; Regulation 1385/2013, [2013] OJ L 354/86; Regulation 2017/625, [2017] OJ L 95/1; and Regulation 2019/1009, [2019] OJ L 170/1.

¹⁰⁴ Schoch CL, et al. NCBI Taxonomy: a comprehensive update on curation, resources and tools. Database (Oxford). 2020: baaa062. PubMed: 32761142 PMC: PMC7408187

conditions.¹⁰⁵ Consequently, it appears that CMC 10 is not a viable option for P2GreeN activities/products.

In conclusion, a suitable CMC was not found for urine, whereas CMC 3 is maybe a possible category for the faecal compost. Further investigation should be performed for these raw materials and for the additional components used in the manufacturing process (e.g. chemical stabilisers, biological waste, etc). Apart from the possible categorisation of human waste to an existing CMC or the amendment of an existing CMC to include human waste, a new CMC could also be introduced in the Regulation. This new CMC could be specifically designed for human waste including a list of processes allowed and possible novel requirements set to ensure safety for human and the environment. An EU survey on possible future development of the FPR was launched in 2022, related to the expansion or requirements' modification of a current CMC and the introduction of a new CMC. We participated in this survey proposing the inclusion of human excreta. Based on this survey, a call for a tender was initiated on June 2023 regarding technical studies for the inclusion of new materials under FPR among others. So, further developments are anticipated in this direction.

8.3.3 Assignment of final product to a Product Function Category

Supposing that the materials used to produce the fertilising products can be used as input materials in EU fertilising products according to the FPR, the compliance of the final products in terms of the PFCs must also be examined. The categorisation of a product to one of the 7 different PFCs depends on the claimed function of the product. Each PFC is divided into subcategories and the product must be compliant to the standards set in each subcategory.

In the case that the function of a product lies in the provision of nutrients to the plants or mushrooms, then it shall be categorized as a fertiliser (PFC1). Depending on the nature of the fertiliser (inorganic, organic, organomineral) and its form (liquid, solid), it can further be subcategorized. The requirements regarding fertilisers include the content in nutrients and contaminants among others. So, in the context of P2GreeN products whose intended use is fertilisation, the first requirement that should be investigated is whether their nutrient content is enough to be considered as fertilisers under the FPR.

Depending on the chemical nature and origin of substances contained in each product, these products could be categorized as organic or inorganic fertilisers. Human urine is composed primarily of water (95%). The rest is urea (2%), creatinine (0.1%), uric acid (0.03%), chloride, sodium, potassium, sulphate, ammonium, phosphate and other ions and molecules in lesser amounts. Faeces are primarily composed of water, protein,

¹⁰⁵ Article 27(c) provides that implementing measures will be laid down for "conditions and technical requirements for the handling, treatment, transformation, processing and storage of animal by-products or derived products and conditions for treatment of wastewater" and Article 9 also provides that the by-products come from "(i) from establishments or plants processing Category 2 material; or (ii) from slaughterhouses other than those covered by Article 8(e)."

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undigested fats, polysaccharides, bacterial biomass, ash, and undigested food residues. The major elements in faeces as a percentage of wet weight are oxygen 74%, hydrogen 10%, carbon 5%, and nitrogen 0.7%, including the hydrogen and oxygen present in the water fraction of the faeces.

According to FPR "[a]n organic fertiliser shall contain organic carbon (Corg) and nutrients of solely biological origin.". So, both urine-derived and faeces-derived products could be considered as organic fertilisers. An inorganic fertiliser would be "a fertiliser containing or releasing nutrients in a mineral form, other than an organic or organomineral fertiliser", according to the FPR. Inorganic fertilisers may also contain organic carbon according to FPR. In this sense and taking into consideration the products' use, urine-derived fertilisers could be categorized as inorganic fertilisers. The next step would be to explore PFC subcategories according to the products' declared nutrient content.

The urine-derived product manufactured in the Swedish pilot region (Pellets) is a concentrated solid product that contains 15% of Nitrogen, 1.7-2% of Phosphorus and 4% of Potassium. It remains ambiguous whether the concentration refers to the elemental nutrient form or to their respective oxides. If the former is true, then the concentration of the nutrients is recalculated using the conversion methods laid in the Regulation (EU) 2019/1009 (FPR) into 15% of Nitrogen, 3.9-4.6% Phosphorous pentoxide (P_2O_5) and 4.8% potassium oxide (K_2O).

The first possibility to explore would be the PFC 1(A)(I) corresponding to the Solid organic fertiliser. Individual declared nutrient content as well as the sum of declared nutrients satisfy the specifications of this PFC. Another specification concerns organic carbon content that must be determined at least 15% by mass, however this value has not been determined. The possible assignment to PFC 1(C)(I)(a)(ii), i.e. Compound solid inorganic macronutrient fertiliser, should also be examined. The nutrient minimum limits are satisfied, both individually and as a sum. So, pellets could be a Compound solid inorganic macronutrient fertiliser under FPR.

The liquid product Aurin® manufactured in the German pilot region contains 4.2% of Nitrogen, 0.4% of Phosphorous pentoxide (P_2O_5), 1.8% Potassium Oxide (K_2O), 0.8% of Sulphur Trioxide (SO₃) as well as some micronutrients. Aurin® could not be characterized as a PFC 1(A)(II), i.e. liquid organic fertiliser, declaring all three macronutrients, since the percentage of Phosphorous pentoxide is below the minimum limit set by the Regulation. However, it could be categorized in this PFC declaring only nitrogen as well as potassium oxide, since the individual percentages as well as their sum satisfies the FPR minimum limits. The last requirement nutrient-wise is that the organic carbon content must equal or exceed 5% by mass. However, Aurin® contains only 0.1% of total organic carbon, so this PFC is not an option.

This product could fit into the inorganic fertiliser category and the first possibility to examine would be the categorisation as a Compound liquid inorganic macronutrient fertiliser in PFC 1(C)(I)(b)(ii). According to the point 2 of this subcategory in Part II of Annex I:

2. A compound liquid inorganic macronutrient fertiliser shall contain more than one of the following declared nutrients in at least the following contents: (a) 1,5 % by mass of total nitrogen (N), (b) 1,5 % by mass of total phosphorus pentoxide (P2O5), (c) 1,5 % by mass of total potassium oxide (K2O), (d) 0,75 % by mass of total magnesium oxide (MgO), (e) 0,75 % by mass of total calcium oxide (CaO), (f) 0,75 % by mass of total sulphur trioxide (SO3), or (g) 0,5 % by mass of total sodium oxide (Na2O). However, the total sodium oxide (Na2O) content shall not exceed 20 % by mass. The sum of all declared nutrient contents shall be at least 7 % by mass.

According to the product's nutrient content, the concentration of Nitrogen, Potassium oxide and Sulphur trioxide are above the limits set in the Regulation. Phosphorous pentoxide would not be a declared nutrient because its concentration in the product is below the limit set in the Regulation. However, the sum of all declared nutrients reaches 6,8%, which is just below the 7% threshold, so this product cannot be categorized as a Compound liquid inorganic macronutrient fertiliser in PFC 1(C)(I)(b)(ii).

The category of the Straight liquid inorganic macronutrient fertiliser in PFC 1(C)(I)(b)(ii) should be considered instead. This product could not be categorized as a straight liquid inorganic macronutrient fertiliser that contains only one declared macronutrient, because the nutrient content is below the limits set by the Regulation. Another option is to be categorized as a straight liquid inorganic macronutrient fertiliser that contains only one declared primary macronutrient, and one or more declared secondary macronutrients with the declared nutrients being nitrogen or potassium oxide and sulphur trioxide. Although concentration limits are fulfilled, the requirement of 7% of declared nutrient sum is not fulfilled. Conclusively, this product cannot be categorized as an inorganic macronutrient fertiliser.

In conclusion, Aurin® does not fulfil the requirements of either organic fertilisers or inorganic fertilisers under the FPR, with the issue being the content of nutrients. A corrective action would be to achieve higher concentrations of the relevant nutrients within the product. An alternative solution to place the product on the market as an EU fertilising product is to consider another Product Function Category, such as Soil improvers.

The faecal compost (KIT) of the German pilot region contains 1,3% Nitrogen (N), 1,1% phosphorous pentoxide (P_2O_5) and 0,9% potassium oxide (K_2O). This nutrient content does not fulfil the requirements of PFC1(A)(I) (solid organic fertiliser). The category of inorganic fertilisers was not examined due to the nature of the product. For this material, another PFC to consider is PFC3 which corresponds to Soil improvers. A soil improver shall be an EU fertilising product the function of which is to maintain, improve or protect the physical or chemical properties, the structure or the biological activity of the soil to which it is added.

It is safe to assume that this product would fall under the subcategory of organic soil improvers and not inorganic ones. So, PFC3(A) corresponding to Organic soil

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improver is explored. An organic soil improver contains material of which the 95% is solely biological origin, at least 20% of dry matter and at least 7,5% organic carbon. Also, certain maximum limits are set relating to the concentration of specific contaminants (heavy metals), metals/micronutrients as well as pathogenic microorganisms. In conclusion, there are some parameters that must be determined in the future to reach a conclusion on FPR compliance. It is also clear that more detailed investigations regarding alternative PFCs, such as the soil improvers, will be of assistance more generally for P2GreeN products.

9 ANNEX III – DETAILED DESCRIPTION OF EU REGULATORY FRAMEWORKS FOR CHEMICAL PRODUCTS

9.1 General overview

Fertilising products are also chemical products, so they must also comply with Regulation 1907/2006 (REACH)¹⁰⁶ and Regulation 1272/2008 (CLP).¹⁰⁷ Regulation 1272/2008 on Classification, Labelling and Packaging of substances and mixtures (CLP) along with the REACH Regulation (Regulation 1907/2006) are the two main regulatory frameworks that ensure a high level of protection of human health and the environment, as well as the free movement of chemicals in the EU's internal market.

9.2 REACH Regulation

Regulation 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) is designed to protect the human health and the environment from the risks that can be posed by the use of chemicals. It aims to ensure a high level of protection against harmful substances, assess the safety of the chemicals used and enhance innovation and competitiveness in the EU internal market, while limiting the use of animal testing for the assessment of the hazards of substances. The Regulation places the responsibility on the manufacturers, importers and downstream users of the substances to ensure that the substances they manufacture, place on the market and use do not harm the human health or the environment – the "no data – no market" principle. The Regulation is also founded on the precautionary principle: if the use of a substance poses a potential risk to the human health or the environment and there is no scientific consensus on that risk, the authorities can impose measures to prevent or avoid serious or irreversible harm.

Substances as such, in mixtures and in articles that are manufactured, placed on the market or used in the EEA fall under the scope of REACH Regulation. The following definitions are provided within Article 3 to further clarify the scope of the Regulation:

• Substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to

¹⁰⁶ Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, [2006] OJ L 396/1.

¹⁰⁷ Council Regulation (EC) 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1997/2006, [2008] OJ L 353/1.

preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition

- Manufacturing: the production or extraction of substances in the natural state
- Placing on the market: means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market.
- use: means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation.

According to the REACH Regulation, substances cannot be manufactured or placed in the EEA market unless they have been registered. The manufacturers and importers of substances (as such or substances in mixtures or articles) in quantities of one tonne or more per year are required to submit registrations to the European Chemicals Agency (ECHA). The registration covers all the life stages of the substance: manufacture, formulation and uses by professional workers and consumers and ensures that all the identified uses are safe for the human health and the environment: this will require data on the physicochemical, toxicological and ecotoxicological properties of the substances. The required information is submitted to ECHA in the form of a technical dossier. Along with the technical dossier, the registrants shall perform a chemical safety assessment and document it in a chemical safety report, if they register in quantities of 10 tonnes or more per year per registration dossier and once the registration is completeness check in the submitted registration dossier and once the registration is completed, assigns a REACH Registration number. The registration number is an 18-digit number and unique for each registrant.

The generation of the required information should be preferably done – whenever possible – by means other than vertebrate animal tests (such as in vitro methods or qualitative or quantitative structure-activity relationship models or grouping and readacross from existing information on structurally related substances). In most cases, however, the information can only be obtained through testing that might be of significant cost and time, especially in the case of (eco-)toxicological information. Animal tests may be required to cover endpoints on:

- Aquatic/sediment/ terrestrial toxicity
- Acute toxicity by oral, inhalation, dermal or other routes
- Irritation/corrosion and sensitization potential
- Repeated dose toxicity
- Genetic toxicity
- Carcinogenicity
- Toxicity to reproduction

Along with the technical dossier, the registrants shall perform a chemical safety assessment and document it in a chemical safety report, if they register in quantities of 10 tonnes or more per year per registrant. The chemical safety assessment should include:

- Human health hazard assessment
- Physicochemical hazard assessment
- Environmental hazard assessment;
- Persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment

In case certain classification criteria are met for the substance, the chemical safety assessment should additionally include exposure assessment with exposure scenarios and exposure estimations and Risk characterization that address all the identified uses of the registrant.

As the Regulation requires data sharing and avoidance of unnecessary animal testing, the data used by multiple registrants need to be submitted jointly. When a substance is manufactured or imported by more than one manufacturer or importers, the data for the hazard assessment of the substance that are generated by animal testing are first submitted by one registrant, acting in agreement of the other assenting registrants. The registrant who submits this information is the Lead Registrant and all the registrants of the same substance participate in the Substance Information Exchange Forum (SIEF). The SIEFs are formed by the registrants of the same substances to facilitate the exchange of information for the purposes of registration and agree on the classification and labelling of the substance.

Waste, as covered by Directive 2006/12 originally (now under the Directive 2008/98 (WFD)), is not considered a substance under REACH Regulation and therefore REACH requirements for substances do not apply to waste. REACH requirements, however, do apply as soon as the material ceases to be waste (provided that the material would otherwise fall within the scope of REACH).

The FPR discussed above sets additional REACH requirements for substances in fertilisers to further enhance the safety assessment of fertilisers, requirement referred in industry as REACH+ (REACH plus). For instance, although the tonnage threshold for registration according to REACH is 1 tonnes/year, the FPR requires that all substances contained in fertilising products are registered regardless of the tonnage. Specifically, the FPR's Annex II describing the requirements for CMCs in EU fertilising products states that all substances incorporated into the EU fertilising product, must be registered according to REACH Regulation, with a dossier containing (a) the information provided for by Annexes VI, VII and VIII and (b) a chemical safety report covering the use as a fertilising product. These information requirements applying to tonnage 10-100 ton/year under REACH represent the minimum registration requirements in FPR. This means that for tonnage under 1 tonne/year, stricter REACH registration requirements apply for EU fertilising products. Consequently, P2GreeN actors would need to consider REACH registration requirements from a very early stage, if the proposed final product might fall within the scope of the FPR (as it currently stands, or if the Annexes therein were to be amended).
Further to the obligations that relate to substance registration, the REACH Regulation also sets out requirements and criteria on the passing of information of a product's safe use through a Safety Data Sheet (SDS). The Safety Data Sheet (SDS), also known as Material Safety Data Sheet (MSDS), is the document that contains information on the safe use of a specific product. It consists of 16 standardized parts that include essential information, such as:

- on a product's hazard and labelling

- first aid, firefighting measures
- storage, handling and transportation requirements
- physical, chemical, toxicological and ecotoxicological information, transport
- instructions on how to dispose of the product

In addition, if the supplier is required to perform a chemical safety report, the relevant exposure scenarios should be placed in an annex of the SDS.

It is the duty of the suppliers to provide a Safety Data Sheet, when required, free of charge, on paper or electronically. The SDS must be supplied in the official language of the Member State in which the product is being placed on. SDSs do not need to be provided to the general public (consumers).

Finally, Annex XVII of the Regulation sets a list of restrictions that apply to all chemical products and sometimes may even apply beyond the scope of the Regulation, such as in cosmetics or wastes. These restrictions refer to products that are grouped according to their use (paints, cleaners, fertilisers) and share specific ingredients or hazard types, classes, and categories. Companies are required to monitor Annex XVII and apply it according to the timeline set by the Regulation.

9.3 The CLP Regulation

The CLP Regulation aims to identify the hazardous properties of substances or mixtures, classify them according to their physical, health and environmental hazards and communicate them to all economic operators via a standardized format through labels and Safety Data Sheets (SDSs).

The CLP Regulation has a broad scope and field of application as it governs the safe use of most chemical substances, mixtures and some articles throughout the EU. It is important to note that, as with the REACH Regulation, although wastes are outside the scope of the CLP Regulation, once something ceases to be waste then it can be fall within the scope of the CLP Regulation. Fertilising products fall within the scope of the CLP Regulation.

Manufacturers, importers and downstream users are required to classify the hazard of their chemical products according to the criteria set by the CLP's Building Blocks Approach. Hazard is the potential for a substance or a mixture to cause harm, based on its intrinsic properties. The principle of the Building Blocks Approach is that all hazards described by the CLP Regulation are divided into 4 types: physical, health,

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environmental and additional hazard. These types are further divided into Hazard Classes, which state the nature of the hazard, and Hazard Categories and Subcategories, which represent the severity of the hazard. The CLP Regulation has a total of 34 Hazard Classes. The CLP Regulation takes into consideration only the intrinsic properties of any given substance or mixture and assesses the potential hazard of the product. The Regulation does not account for the potential exposure of the user to a product and its classification should not be confused with a risk assessment that relates to the actual exposure of humans or the environment. This also means that any classification here will not suffice for the purposes of any environmental or human health assessment (or similar) under other legislation.

For substances that are widely used, or that are very hazardous, the decision on the classification and labelling of some particular hazards is taken at the European level by the Commission according to opinions provided by the ECHA and the Member States. The use of a harmonised classification and labelling is mandatory by all economic operators. Once the hazard of a product is identified, its manufacturer, importer, downstream user and distributor is required to communicate the hazards to the rest of the supply chain, including the consumers. The usual forms of communication to make aware the user of potential hazards is the labelling of the product and the Safety Data Sheet (only for industrial and professional users).

For the classification of a chemical product, according to the CLP Regulation, various physical, chemical, toxicological and ecotoxicological data is required. For substances that fall within the scope of REACH Regulation, then the required data will be produced as part of the REACH Registration process. But, in case a substance does not fall within the scope of REACH or does not require REACH Registration (such as the composts), then it is uncertain whether there is enough data to properly classify the product.

Products or ingredients that are not covered by EU harmonised legislation, such the Waste Framework Directive, the REACH and CLP Regulations and the Fertilising Products Regulation, fall within the scope of the General Product Safety Regulation, Regulation 2023/988.¹⁰⁸ This is not examined here, but may merit further examination in the full legislative report if of relevance.

At the moment the CLP Regulation has undergone 32 amendments and another 3 are expected to be published in 2023. According to their public consultations, the upcoming amendments will have a great impact on the chemical products, including fertilisers, by introducing new hazard classes, new classification criteria and relevant labelling requirements.

¹⁰⁸ Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and of the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC [2023] L 135/1.

10 ANNEX IV – DETAILED DESCRIPTION OF THE EU LEGISLATIVE FRAMEWORK RELATED TO THE ENVIRONMENT

A wide range of environmental issues arise that are of relevance to P2GreeN activities and products, across the different stage. Likewise, there are numerous frameworks that exist across these areas that must be considered. Some of the main areas are outlined here, but with considerable scope for them to be developed further in the full legislative report.

10.1 Water

Water law encompasses a wide range of focus points and pieces of legislation. Some of these have been considered above and are consequently not addressed in any significant detail here, e.g. the Urban Waste Water Treatment (UWWT) Directive and elements such as the use of water in irrigation (e.g., under both the Water Reuse Regulation (Regulation 2020/741) and the Hygiene in Foodstuffs Regulation (Regulation 852/2004) or sewage sludge (under the Sewage Sludge Directive) are discussed in the earlier section on waste. Instead, the focus here is more generally on water quality and pollution in the broader environment.

Article 1 of Directive 2000/60 establishing a framework for Community action in the field of water policy sets out its purposes (the Water Framework Directive):¹⁰⁹

The purpose of this Directive is to establish a framework for the protection of inland surface waters, transitional waters, coastal waters, and groundwater which:

- (a) prevents further deterioration and protects and enhances the status of aquatic ecosystems and, with regard to their water needs, terrestrial ecosystems and wetlands directly depending on the aquatic ecosystems;
- (b) promotes sustainable water use based on a long-term protection of available water resources;
- (c) aims at enhanced protection and improvement of the aquatic environment, inter alia, through specific measures for the progressive reduction of discharges, emissions and losses of priority substances and the cessation or phasing-out of discharges, emissions, and losses of the priority hazardous substances;
- (d) ensures the progressive reduction of pollution of groundwater and prevents its further pollution, and
- (e) contributes to mitigating the effects of floods and droughts

These purposes are all relevant to the P2GreeN project. Indeed, the indicative list of the main pollutants of water in Annex VIII of the Directive identifies N and P as substances which contribute to eutrophication. A core goal pursued by the Directive is a

¹⁰⁹ [2000] OJ L 327/1.

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significant reduction in the pollution of groundwater,¹¹⁰ but also water bodies more generally. This is confirmed in Recital 27 of the Preamble to the Directive which indicates that the ultimate aim is "to achieve the elimination of priority hazardous substances and contribute to achieving concentrations in the marine environment near background values for naturally occurring substances." It does this through a range of mechanisms, including domestic river basin management plans, requirements for general controls on pollution and deterioration of waterbodies, EU-level standards for priority substances, and domestic standards for substances of national concern.

Thus, the Directive requires Member States to put in place a River Basin Management Plan, for which the environmental objectives are listed in Article 4, which shall according to Article 5 involve an analysis of the characteristics of the river basin district and require a review of the environmental impact of human activity and an economic analysis of water use. Within each river basin district, the Member States are required to establish a programme of measures to realise the objectives set in Article 4 taking into account the results of the information gleaned from the implementation of Article 5. A list of basic measures is contained in Article 11, and it is here in Article 11(3)(e) and (h) that the first Statutory Management Requirement (SMR) of the Common Agricultural Policy (CAP) is found.¹¹¹ Annex VI:A of the Directives gives further details on the measures to be included within the Plan by referencing eleven other Directives. These include the Wild Birds Directive, the Environmental Impact Assessment Directive, the Plant Protection Products Directive, the Nitrates Directive, the Habitats Directive, and the Integrated Pollution Prevention Control Directive.

The Water Framework Directive requires all surface water and groundwater bodies to achieve "good" status by 2027. A key method to achieve this is through controlling pollutants within the water bodies, with Annex X listing those pollutants that pose the greatest risk to the environment and which are to be monitored by the Member States. – priority substances and priority hazardous substances. For priority hazardous substances, Member States are required to reduce their emissions/discharges and phase them out within twenty years of their designation. Currently, the priority substances entail a list of 45 substances (21 of which are priority hazardous substances), including some heavy metals and chemicals,¹¹² with a 'watch list' to monitor water and consider whether this list needs to be amended (or the approach thereto).¹¹³ Further details are provided in

¹¹⁰ Groundwater is defined in Article 2(2) as "...all water which is below the surface of the ground in the saturation zone and in direct contact with the ground or subsoil." This definition can also be found in the Nitrates Directive.

¹¹¹ Reproduced in Annex VII (Chapter 13).

 ¹¹² See the current version of Annex X of the Water Framework Directive, available via the consolidated version here: <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02000L0060-20141120</u>.
 ¹¹³ E.g. T. Backhaus, 'Commentary on the EU Commission's proposal for amending the Water Framework Directive, the Groundwater Directive, and the Directive on Environmental Quality Standards', (2023) 35:22 *Environmental Sciences Europe*.

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Directive 2008/105¹¹⁴ which lists environmental quality standards for those substances listed in Annex X in the form of annual average concentrations (to protect water against long-term pollution) and maximum allowable concentrations (to protect water against short-term pollution). Satisfaction of the environmental quality standards will ensure that the water is deemed of good status.

Annex I of Directive 2006/118 on the protection of groundwater against pollution and deterioration (GWD) lists nitrates (and active substances in pesticides) as pollutants of EU-wide concern and sets out their quality standards with Annex II listing a number of other pollutants (and pollution indicators) for which Member States have to consider setting national threshold values (standards).¹¹⁵ Good quality water is achieved whenever the concentrations of these substances do not exceed the standards set. The quality standards and the list of priority substances are regularly subject to review based on a risk assessment of the dangers posed by a substance to humans and the environment.¹¹⁶ There is also a voluntary watch list mechanism for pollutants in groundwater which was introduced as part of the common implementation strategy of the Water Framework Directive.¹¹⁷ It is worth noting here that under the Good Agricultural and Environmental Conditions (GAEC) that are an element of the cross-compliance in the CAP, GAEC 4 provides for the protection of river courses against pollution and run-off by requiring the establishment of buffer strips along water courses; such strips should be a minimum width of three metres within which the use of fertilisers and pesticides should be avoided. The use of GAECs and SMRs within the context of the CAP provides an important complementary mechanism to help improve compliance and thereby support environmental objectives.

A 2021 analysis by the European Environment Agency, *Freshwater Pollution and Ecosystems* indicates that there has been a decline in nutrient concentrations in European rivers between 1990 and 2010 but they have levelled off since then and "rivers that drain land used for intensive agriculture activities tend to have high nitrate concentrations."¹¹⁸ In October 2022 the Commission adopted a Proposal to amend the Water Framework Directive, the Groundwater Directive and the Directive on environmental quality standards in the field of water policy with the aim of setting "new standards for a series of chemical substances of concern to address chemical pollution in water, to facilitate enforcement based on a simplified and more coherent legal

¹¹⁴ Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council, [2008] OJ L348/84. ¹¹⁵ [2006] OJ L 372/19.

¹¹⁶ See for example, Directive 2013/39 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy [2013] OJ L 226/1 and more recently, Commission Implementing Decision 2022/1307 establishing a watch list of substances for Union-wide monitoring in the field of water policy pursuant to Directive 2008/105, [2022] OJ L 197/117.

¹¹⁷ For details, see <u>Watch-List_Concept_Final.pdf (europa.eu)</u>

¹¹⁸ Available at <u>Freshwater pollution and ecosystems — European Environment Agency (europa.eu)</u>. See also *Nutrients in freshwater in Europe (8th EAP)* available at <u>Nutrients in freshwater in Europe (8th EAP)</u> (europa.eu).

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framework, to ensure dynamic and up-to-date information on water status."¹¹⁹ The proposal would add twenty-three individual substances to the lists of priority substances within the DEQS and set corresponding individual environmental quality standards. It would also revise upwards environmental quality standards for fourteen existing priority substances, whilst revising downwards those of two substances. The ECHA would provide scientific support in the review, carried out every six years of the surface water and groundwater pollutant lists.

Other EU measures supporting good quality water include Directive 91/676, the Nitrates Directive¹²⁰ and Directive 91/271, the Urban Wastewater Treatment Directive.¹²¹ The UWWT was examined above in the discussions on waste, from the perspective of examining waste water itself, but it is worth noting its significance to water law here. It targets pollution by organic matter and nutrients such as N and P which contribute to eutrophication and under the Directive Member States are required to take measures to reduce loads of these substances for sensitive areas subject to eutrophication according to the criteria in Annex II.¹²² The obligations of Member States under the Directive include ensuring that wastewater treatment plants are properly designed, constructed, operated and maintained, to ensure sufficient performance under all normal weather conditions and they have to monitor not only the performance of treatment plants to ensure they comply with the requirements for discharged wastewater but also the waters receiving the discharges. A 2019 study indicated that the objectives of the Directive "are mostly achieved when looking at the EU scale, although there are still regions and countries lagging behind and in need of stepping up the implementation."¹²³ The evaluation of the Directive by the Commission identified a number of challenges including insufficient and uneven levels of governance.¹²⁴ The Commission has recently proposed that the UWWT Directive be recast to address the presence of more pollutants and stricter standards would be introduced for N and P removal.¹²⁵ Similarly, the Sewage Sludge Directive was examined briefly in Annex I and it raises further issues for water quality that will merit further investigation later in this project.

¹¹⁹ Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2000/60/EC establishing a framework for Community action in the field of water policy, Directive 2006/118/EC on the protection of groundwater against pollution and deterioration and Directive 2008/105/EC on environmental quality standards in the field of water policy, COM (2022) 540.

¹²⁰ [1991] OJ L 375/1.

¹²¹ [1991] OJ L 135/40.

¹²² Thresholds for nutrient reduction are set in Annex I B, table 2. See also Commission Directive 98/15 amending Council Directive 91/271/EEC with respect to certain requirements established in Annex I thereof, [1998] OJ L 67/29.

¹²³ Pistocchi, A., Dorati, C., Grizzetti, B., Udias, A., Vigiak, O., and Zanni, *Water quality in Europe: effects of the Urban Wastewater Treatment Directive A retrospective and scenario analysis of Dir.* 91/271/EEC (JRC Science for Policy Report, Luxembourg, 2019) p.83

¹²⁴ Commission staff working document SWD (2019) 700, Evaluation of the Council Directive 91/271/EEC of 21 May 1991, concerning urban waste-water treatment. See also a Court of Auditors Report *Special Report 12/2021: The Polluter Pays Principle: Inconsistent application across EU environmental policies and actions.*

¹²⁵ COM (2022) 541.

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Less directly concerning water quality, in particular addressing chemicals in water, are a further range of EU measures including the REACH Regulation,¹²⁶ the Plant Protection Product Regulation,¹²⁷ the Biocidal Regulation¹²⁸ and two Directives on Industrial Emissions¹²⁹ and the Sustainable Use of Pesticides.¹³⁰ Several of these are discussed in various sections above and below.

In the context of the P2GreeN project, a number of questions arise about the nature of the product emerging from the treatment of human waste which need to be explored further and these questions may be addressed in the context of the revision of the various pieces of the Water legislation. These include:

- Do any of the P2GreeN products contain existing or proposed priority substances?
- Do they contain substances with similar traits that might be deemed to impact on the quality of water? (Potentially being added to lists in the future)
- How would they impact more broadly on water quality? (E.g. if used as an alternative product)
- What chemical or other substances should be added to the list of environmental quality standards to minimize the impact on the environment of the use human waste?
- Will there be a significant difference between the products to be developed and sewage sludge? If there is, what regime should apply to the former? If there is not, how would this apply and how should the Sewage Sludge Directive be amended? What knock-on effects might this have?
- What changes should be made to the Groundwater Directive (and other legislative measures) to facilitate a desired decline in nutrient concentrations in EU waters?

10.2 Habitats/nature conservation

There is a biodiversity crisis globally and across the EU – something of independent significance, but also in how it engages with and is impacted by climate change, war, food security etc. Nature conservation is a fundamental issue for the environment generally and for the human population. It generally encompasses three main aspects:

- 1. protecting all species from microbes to whales;
- 2. protecting a broad variety of habitats that support these species; and

¹²⁶ Regulation 1907/2006, [2006] OJ L 396/1.

¹²⁷ Regulation 1107/2009, [2009] OJ L 309/1.

¹²⁸ Regulation 528/2012, [2012] OJ L 167/1.

¹²⁹ Directive 2010/75, [2010] OJ L 334/17.

¹³⁰ Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides [2009] OJ L 309/71.

3. supporting variety in the genetic make-up of species (both between and within individual species).

However, in doing so, distinctions are drawn. For instance, specific types of species or habitats may be provided with enhanced protections due to their significance or level of endangerment. On the other hand, exceptions or limitations on the protections may be provided, e.g., where national security, public human health or perhaps national economic interests justify such limitations.

For the purposes of P2GreeN and similar projects or activities, it will be necessary to consider the detail further in the full legislative report, but for the moment it is worth highlighting the key EU nature conservation laws and their main components.¹³¹ At the EU level, while nature conservation is furthered by a wide range of EU environmental law including the TFEU environmental provisions (Articles 191-193 TFEU), water laws, Aarhus laws, waste law etc, the two key pieces of legislation relevant to us here are: Directive 2009/147 on the Conservation of Wild Birds¹³² and Directive 92/43 on the Conservation of Natural Habitats and of Wild Fauna and Flora.¹³³ These are the basis for what is known as the Natura2000 network nowadays and are part of the SMRs (reproduced in Annex VII). There are also laws regarding invasive species, trade in endangered species etc, but these are of less relevance to this project. The proposed EU Nature Restoration Law could be of considerable significance for P2GreeN activities and, after a brief overview at the end of this sub-section, a further discussion of this law will be undertaken in the final legislative report. The remainder of this sub-section will outline some of the main features and considerations from the two existing nature conservation directives.

10.2.1 Wild Birds Directive (WBD)

The focus of this Directive is on 'all species of naturally occurring birds in the wild state' in the EU, including their habitats and eggs. It is not just about conservation, but also acknowledges that they may require control and also may be exploited.¹³⁴ The protection as outlined in the Directive is not absolute – with some provision for the recognition of other interests. Further, its provisions distinguish between wild birds generally (receiving baseline protections, e.g., regarding population baselines)¹³⁵ and those that merit/require greater protections.¹³⁶

Alongside Articles 1-3, Articles 5-8 provide some general protections, e.g., Article 5 includes an obligation on Member States to 'establish a general system of protection

¹³¹ For general discussion of EU nature law, see e.g., S. Kingston et al, *European Environmental Law*, chapter 12 on 'Nature and Biodiversity Protection', (CUP, 2017); and A. Jackson (ed), *Nature Law and Policy in Europe* (2023, Routledge, Earthscan).

¹³² [2009] OJ L 20/7. This replaced the original Directive 79/409, [1979] OJ L 103/1.

¹³³ [1992] OJ L 206/7.

¹³⁴ Article 1.

¹³⁵ E.g., Articles 2 and 3, in conjunction with Article 1.

¹³⁶ E.g., Article 4 in conjunction with Annex 1.

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for all species of birds' within the scope of the Directive, including prohibitions on deliberate killing or capture, destruction of/damage to their nests and eggs, deliberate disturbance of these birds during breeding and rearing periods etc. This, for instance, is one basis for controls on cutting of hedgerows from spring to autumn. Article 9 provides for Member States to derogate from Articles 5-8, 'where there is no other satisfactory solution' and where the justification falls within an exhaustive list of reasons, including 'for the purposes of research...'. However, this would be expected to be controlled strictly by the CJEU and would also only provide some very limited flexibility (if necessary) during the research/field trial stages.

For those species considered to require further protection: Articles 4(1) and 4(2) require Member States to act to protect the habitats of the particular species of wild birds that are listed in Annex I of the Directive (particularly vulnerable and rare species) and also of all regularly occurring species of migratory birds not listed in this Annex. Member States are required to introduce 'special conservation measures' for these birds' habitats, to ensure their survival and reproduction. Member States are required to designate their "most suitable territories in number and size as special protection areas for the conservation of these species, taking into account their protection requirements in the geographical sea and land area where this Directive applies."¹³⁷ In doing so, these decisions are to be based purely on ornithological criteria, rather than elements such as economic or recreational factors (referred to in Article 2).¹³⁸

The original obligation that applied in Special Protection Areas (SPAs) under Article 4(4)¹³⁹ has been largely¹⁴⁰ replaced by that under Articles 6(2), 6(3) and 6(4) of the Habitats Directive (discussed below), due to Article 7 therein.¹⁴¹ The two Directives are now closely intertwined and the Birds Directive's obligations for SPAs are now found in the Habitats Directive instead. We turn now to the Habitats Directive, examining it for its own sake and for its relevance to the Birds Directive.

¹³⁷ Article 4(1).

¹³⁸ E.g., Case C-355/90 *European Commission v Spain* (Santoña Marshes Case) [1993 ECR I 4221; and Case C-3/96 *European Commission v the Netherlands* [1998] ECR I 3031.

¹³⁹ Regarding SPAs, "... Member States shall take appropriate steps to avoid pollution or deterioration of habitats or any disturbances affecting the birds, in so far as these would be significant having regard to the objectives of this Article. Outside these protection areas, Member States shall also strive to avoid pollution or deterioration of habitats." This was interpreted purposively by the CJEU in a manner that strengthened the protections provided by the Directive, for instance, excluding economic and recreational interests in the question of whether SPAs could be restricted or limited: Case C57/89 *European Commission v Germany* (the Leybucht Dykes Case) [1991] ECR I 883.

¹⁴⁰ E.g., see Case C-374/98 *Commission v France* [2000] I 10799, where the European Court of Justice ruled that Article 4(4) of the Wild Birds Directive applied to sites that had not been classified as SPA, but which ought to have been.

¹⁴¹ "Obligations arising under Articles 6(2), 6(3) and 6(4) shall replace any obligations arising under the first sentence of Article 4(4) of Directive 79/409 in respect of areas classified... [as SPA]... from the date of implementation of this Directive or the date of classification or recognition by a Member State..., where the latter date is later."

10.2.2 Habitats Directive (HD)

The core objectives of this Directive are set out in Article 2:

- 1. The aim of this Directive shall be to contribute towards achieving biodiversity through the conservation of natural habitats and of wild flora and fauna in the European territory of the Member States to which the Treaty applies.
- 2. Measures taken pursuant to this Directive shall be designed to maintain or restore, at a favourable conservation status, natural habitats and species of wild fauna and flora of Community interest.
- 3. Measures taken pursuant to this Directive shall take account of economic, social, and cultural requirements and regional and local characteristics.

The main focus and initiative of the Habitats Directive is Article 3's creation of an EUwide network (on land and sea) of specially protected sites to be known as 'Natura 2000' sites and forming the Natura 2000 network. These sites encompass:

- i) Those 'hosting the natural habitat types listed in Annex I' of the Directive;
- ii) Those 'hosting... habitats of the species listed in Annex II' of the Directive; and
- iii) Those designated as Special Protection Areas by Member States under the Wild Birds Directive.

Thus, as with the WBD, the HD is focussed on creating relevant protected sites. These include habitats for a wide range of flora and fauna (not being restricted to a specific type of organism), but clearly they are not all-encompassing in contrast with the WBD's approach to wild birds.

Annexes I and II have been updated over the decades since the HD was created, including at the time of new accessions to the EU to reflect the new territories' habitats and species and the need for conservation protection. Currently over 200 habitat types and over a thousand species are protected.¹⁴² This includes the identification of 'priority habitat types' (marked by an asterisk in Annex I) and 'priority species' (marked by an asterisk in Annex I), which are considered to be particularly vulnerable and essentially require especial attention/conservation measures.

Article 4 of the Directive sets out a long and complex procedure for the selection and designation of Special Areas of Conservation (SACs) (similar to SPAs).¹⁴³ Although the deadlines are long past, some Member States have yet to fully designate SAC, e.g., with Ireland very recently condemned by the CJEU.¹⁴⁴ While this undermines the effectiveness of the Directive's protections, e.g., the sites will lack tailored management plans, this does not remove the general obligations that apply and 'candidate' SACs

¹⁴² <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A01992L0043-20130701</u>.

¹⁴³ This is also complemented by Article 5, where the Commission considers that the national list proposed by Member States omits priority species or habitats.

¹⁴⁴ Case C-444/21 Commission v Ireland ECLI:EU:C:2023:524.

should be treated the same as fully designated SACs when considering legal implications.¹⁴⁵

Article 6 of the HD sets out the core legal protection measures that are provided for sites that come within the Natura 2000 network (SPAs and SACs). Article 6(1) is the equivalent to Article 4(1) and 4(2) of the WBD and provides that: "For special areas of conservation, Member States shall establish the necessary conservation measures involving, if need be, appropriate management plans specifically designed for the sites or integrated into other development plans and appropriate statutory, administrative or contractual measures which correspond to the ecological requirements of natural habitat types in Annex I and the species in Annex II present on the site." The CJEU has emphasised the importance of having tailored plans for individual sites and species,¹⁴⁶ as general obligations are important but of limited value. Consequently, there may be a wide range of site management plans that detail and/or create numerous obligations that may apply to SACs, with relevance to activities undertaken on or even near these sites. These may change and evolve over time or even be newly introduced (without the same publicity or transparency as with statute).

The remainder of Article 6 applies to both SPAs and SACs, courtesy of Article 7 of the Habitats Directive.¹⁴⁷ Article 6(2) sets out the following general duty: "Member States shall take appropriate steps to avoid, in the special areas of conservation, the deterioration of natural habitats and the habitats of species as well as disturbance of the species for which the area has been designated, in so far as such disturbance would be significant in relation to the objectives of the Directive."

Articles 6(3) and 6(4) set out a procedure which controls Member States' powers to authorise plans or projects that are likely to have a negative impact upon SACs or SPAs. Article 6(3) introduces the idea of appropriate assessments and prior authorisation – it is the fundamental provision in protecting the Natura2000 sites and has been interpreted purposively by the CJEU.¹⁴⁸ Article 6(3) states that: 'Any plan or project not directly connected with or necessary to the management of the site but likely to have a significant effect thereon, either individually or in combination with other plans or projects, shall be subject to appropriate assessment of its implications for the site in view of the implications for the site and subject to the provisions of paragraph 4, the competent

¹⁴⁵ E.g. see Article 4(5) applying Articles 6(2), (3) and (4) to sites selected as sites of Community importance, prior to national designation as an SAC.

¹⁴⁶ E.g. Case C-661/20 *Commission v Slovak Republic* ECLI:EU:C:2022:496, regarding Article 4(1) of the WBD.

¹⁴⁷ Article 7 states: 'Obligations arising under Article 6 (2), (3) and (4) of this Directive shall replace any obligations arising under the first sentence of Article 4 (4) of Directive 79/409/EEC in respect of areas classified pursuant to Article 4 (1) or similarly recognized under Article 4 (2) thereof, as from the date of implementation of this Directive or the date of classification or recognition by a Member State under Directive 79/409/EEC, where the latter date is later.'

¹⁴⁸ E.g., C-127/02 Landelijke Vereniging tot Behound van de Waddenzee, Nederlandse Vereniging tot Bescerming van Vogels v Statsecretaris van Landbouw, Natuurbeheer en Vizzerij [2004] ECR I-7405; and Case C-226/08 Stadt Papenburg v Germany [2010] Env LR 19.

national authorities shall agree to the plan or project only after having ascertained that it will not adversely affect the integrity of the site concerned and, if appropriate, after having obtained the opinion of the general public.' This has been interpreted purposively with the effect that:

- An appropriate assessment must be undertaken unless it can be ruled out (beyond reasonable doubt) that the proposed activities (plan or project) will not have a significant effect the site (whether positive or negative)¹⁴⁹ – this imposes the burden of proof on the activity operator and essentially creates a requirement to undertake a preliminary screening assessment. Any evidence provided by other parties must also be adequately addressed.
- Any appropriate assessment must conclusively establish that the proposed activities will not directly or indirectly, individually, or cumulatively, adversely affect the integrity of the site – in light of the site's general and specific conservation objectives.¹⁵⁰

Consequently, in general to be authorised, a relevant proposed activity must be shown either (i) to have no significant effect on the site (through a screening assessment) or (ii) to not adversely affect the integrity of the site (through an appropriate assessment, which is a much more detailed assessment).

The major limitation to Article 6(3) from an ecological perspective is that of Article 6(4) which provides that: 'If, in spite of a negative assessment of the implications for the site and in the absence of alternative solutions, a plan or project must nevertheless be carried out for imperative reasons of overriding public interest, including those of a social or economic nature, the Member State shall take all compensatory measures necessary to ensure that the overall coherence of Natura 2000 is protected. It shall inform the Commission of the compensatory measures adopted. Where the site contains either a priority natural habitat type and/or a priority species, the only considerations which may be raised are those relating to human health or public safety, to beneficial consequences of primary importance for the environment or, further to an opinion from the Commission to other imperative reasons of overriding public interest.' This provision has not yet been addressed adequately before the CJEU, with the Commission instead having granted several Opinions to Member States that were favourable to them - even where the criteria under Article 6(4) do not appear to have been fulfilled. The approach to this provision by both the Member States and the Commission has been heavily criticised by Ludwig Krämer, who highlighted issues over transparency and accountability, as well as questioning whether the CJEU would have approved any of the exemptions granted.¹⁵¹ This is particularly the case in light of the CJEU's general purposive approach to interpreting both the WBD and the HD.

¹⁴⁹ E.g. Case C-411/17, Inter-Environnement Wallonie and Bond Beter Leefmilieu Vlaanderen, EU:C:2019:622, paragraph 134.

¹⁵⁰ Ibid, para 120.

¹⁵¹ L. Kramer, 'The European Commission's Opinions Under Article 6(4) of the Habitats Directive', (2009) 21:1 *Journal of Environmental Law* 59-85.

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However, Article 6(4) tends to be used for major infrastructure projects, e.g., the development of highways, and would be less likely to be of relevance to activities under P2GreeN. However, it is worth flagging that the construction of new plants, pipelines or similar to transport and process human waste could fall within this provision – especially if P2GreeN activities were to be upscaled and, for instance, be able to address excess human waste production in specific regions. Nonetheless, Article 6(3) remains the provision of most immediate relevance, including the obligation to undertake a screening assessment and potentially an appropriate assessment depending on the context and evidence available.

The HD's other provisions include some important obligations on Member States, e.g., Article 12(1) requires the creation of 'a system of protection for species listed in Annex IV (a) in their natural range, prohibiting... [the] deliberate disturbance of these species... [and the] deterioration or destruction of breeding sites or resting places.' Article 13(1) includes similar obligations regarding 'plant species listed in Annex IV (b)', but each of the prohibitions on various forms of damage is limited by the qualifier 'deliberate'. This is supplemented, for instance by provisions on surveillance¹⁵² and further measures re those species listed in Annex V.¹⁵³ Article 16(1) does provide for potential derogations (read restrictively) to Articles 12-15, including for research, for public health and public safety, 'or for other imperative reasons of overriding public interest, including those of a social or economic nature and beneficial consequences of primary importance for the environment.'

10.2.3 P2Green Considerations

From P2GreeN's perspective, it will be especially important to consider (i) whether the activities could impact on the protected species directly or indirectly and/or on their habitats; (ii) whether the general or enhanced protections apply, including whether there is a protected area in the vicinity¹⁵⁴ or not; (iii) what the detailed implications of the EU provisions are for activity operators; and (iv) how the EU provisions have been developed at the national/regional level, e.g. through local site management plans or 'systems of protection'. For instance, if the products being applied to the land could impact the development of eggs or the food supply of protected species, this would be a valid consideration that would need to be evaluated. Some elements of the Directives and/or local site management plans might include relevant KPIs or standards (e.g., limits for pollutants, or controls on the use of fertilisers) that will need to be examined by those seeking to engage in P2GreeN or similar activities.

¹⁵² Article 11.

¹⁵³ Articles 14 and 15.

¹⁵⁴ It is important to note that site protections affect activities that are in the vicinity of the site and not solely those on the site, as environmental impacts can easily spread.

10.2.4 A Nature Restoration Law?

The current proposal for an EU Nature Restoration Regulation¹⁵⁵ has been passed by the European Parliament, but in an amended form and with a slim majority.¹⁵⁶ This is not the end of the story however, with the potential for further amendments and indeed for it to be rejected still – especially in light of the contention surrounding it and concerns over impacts on farming, fishing and security. The Proposal largely is supporting the existing obligations under the Wild Birds and Habitats Directives, as well as implementing commitments under the EU's Green Deal. The key difference is its focus on *restoration* and improvement, rather than conservation and maintenance. It includes objectives of restoration measures for 20% of degraded land and sea across the EU by 2030 and 100% thereof by 2050 (referring to 'ecosystems in need of restoration').¹⁵⁷ This is to be achieved by staggered goals for the Member States of the land and marine areas within their individual territories - within individual habitat types listed in Annex I and also through measures outside of those habitat types.¹⁵⁸ These will be part of a national restoration plan as outlined in the proposed Article 12. A few points to note at this stage include:

- the current draft has been watered down from the initial proposal, with some significant limitations introduced regarding agriculture, e.g., regarding rewetting peatland;¹⁵⁹
- Article 6 addresses urban ecosystems these are not ignored, but they do receive some differential treatment;
- the timeline varies depending on the elements in question;
- necessary considerations for the preparation of national restoration plans include CAP strategic plans under Regulation 2021/2115,¹⁶⁰ 'measures for achieving good quantitative, ecological, and chemical status of water bodies' in programmes of measures, river basin management plans and flood risk management plans under relevant EU Directives, marine strategies under Directive 2008/56 etc;¹⁶¹

¹⁵⁵ Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on nature restoration, COM/2022/304 final.

¹⁵⁶ <u>https://www.europarl.europa.eu/news/en/press-room/20230707IPR02433/nature-restoration-law-meps-adopt-position-for-negotiations-with-council.</u>

¹⁵⁷ Proposed Article 1.

¹⁵⁸ Proposed Article 4.

¹⁵⁹ E.g., see the Parliament's amendments to the proposed Article 9: https://www.consilium.europa.eu/media/65128/st10867-en23.pdf.

¹⁶⁰ Regulation (EU) 2021/2115 of the European Parliament and of the Council of 2 December 2021 establishing rules on support for strategic plans to be drawn up by Member States under the common agricultural policy (CAP Strategic Plans) and financed by the European Agricultural Guarantee Fund (EAGF) and by the European Agricultural Fund for Rural Development (EAFRD) and repealing Regulations (EU) No 1305/2013 and (EU) No 1307/2013 [2021] L 435/1.

¹⁶¹ Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive), [2008] OJ L164/19. This change would be undertaken under the proposed Article 11(7) in the proposed Nature Restoration Law. These provisions highlight the importance of being aware of and feeding into the development of such provisions, plans, measures, strategies etc.

- permitted considerations include the variations across and within Member States, as well as 'where appropriate.... the associated costs for protecting and restoring their ecosystems;^{'162} and
- while there are timelines and objectives within the proposed Regulation, the specifics and intermediary milestones with timelines are to be created by the Member States – providing considerable flexibility, with both positive and negative consequences.

This is only a very light touch overview of the proposed Regulation and its development at an EU and eventually national/local level will need to be monitored closely.

10.3 Environmental Impact Assessments¹⁶³

Environmental impact assessments (EIA) are found internationally within a range of documents that are of relevance to the EU, in particular the Espoo Convention on Environmental Impact Assessment in a Transboundary Context 1991,¹⁶⁴ but also, for instance, the Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters 1998, the Convention on Wetlands of International Importance especially as Waterfowl Habitat 1971, the United Nations Framework Convention on Climate Change 1992, and the United Nations Convention on Biological Diversity 1992. In the context of transboundary matters, an EIA is also considered to be a principle of customary international law (linked to the idea of no transboundary harm).¹⁶⁵ The precise nature of an EIA varies, but there is a general acceptance of their importance.

EIAs within the EU are primarily¹⁶⁶ regulated under two directives: the Strategic Environmental Assessment (SEA) Directive¹⁶⁷ and the Environmental Impact Assessment (EIA) Directive.¹⁶⁸ In both cases, they arise where a relevant plan or project is likely to

¹⁶² Proposed Article 11(9)(a).

¹⁶³ See generally Chapter 11 of S. Kingston et al, op cit. n131.

¹⁶⁴ This Convention and the related Kyiv Protocol may merit some further examination in the full legislative report, e.g., there are similarities with the EU Directives, but the obligations do differ, it has its own compliance mechanisms, and its territorial scope extends beyond the EU.

¹⁶⁵ E.g. *Pulp Mills in the River Uruguay (Argentina v Uruguay)*, Judgment of the International Court of Justice, ICJ Reports 2010, 14.

¹⁶⁶ There are requirements for environmental assessments in other areas also, but they are more narrow/siloed, whereas the EIA and SEA Directives apply more generally.

¹⁶⁷ Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment, [2001] OJ L197/30.

¹⁶⁸ Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment, [2011] OJ L26/1, (as amended). This codifies and updates the original EIA Directive, including to amend in light of developments such as under the Aarhus Convention and the Espoo Convention. The key amendments were undertaken by Directive 2014/52/EU of the European Parliament and of the Council of 16 April 2014 amending Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the

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have a significant effect on the environment (as interpreted by the CJEU). The SEA Directive relates to strategic or framework type projects and plans – think large-scale national or regional strategies/activities that are more focussed on policy formation and have the potential to have wide-sweeping, long-term and knock-on effects on other activities and on the environment. It still is relevant to P2GreeN activities indirectly, as SEAs will be undertaken within Member States for a range of plans that are of significance, for instance, for agriculture, the use of fertilisers, the treatment and management of waste, and water management. Consequently, there is a need to be aware of implementation within Member States of that Directive and also the potential to feed into the development, evaluation, and review of framework level plans/projects. It will merit some further examination during the fuller legislative review, but the focus of this section is on the EIA Directive, as that applies directly to operators and is of more imminent significance. It is also worth flagging at this stage that both Directives are closely linked to the EU's implementation of the Aarhus Convention and, for instance, public participation within the assessments is a core component.

The core objective of the EIA Directive is outlined in Article 2(1):

Member States shall adopt all measures necessary to ensure that, before development consent is given, projects likely to have significant effects on the environment by virtue, *inter alia*, of their nature, size or location are made subject to a requirement for development consent and an assessment with regard to their effects on the environment. These projects are defined in Article 4.

As with the Directives regarding nature conservation, provisions of the EIA have been interpreted purposively by the CJEU,¹⁶⁹ with reference to Article 2(1) – ensuring broad applicability and a precautionary approach where possible.

Annex I includes a list of projects where an EIA is mandatory, unless granted an exemption on a case-by-case basis (which will be read restrictively by the CJEU). Depending on the scale and nature of individual P2GreeN activities, or if they are part of a larger project, it might be appropriate to examine the full list of Annex I projects – e.g., it includes some wastewater treatment plants and some groundwater recharge schemes. It might be possible that some or all stages of a P2GreeN activity might fall within an Annex I project, thereby automatically requiring an EIA. However, if not deemed an Annex I project (as will quite likely be the case), there is a significant chance that a P2GreeN activity might fall within the scope of Annex II. Annex II includes a long of further projects, including ones regarding agriculture, silviculture, and aquaculture. For Annex II projects, a screening process applies in order to determine whether an EIA is required – either on a case-by-case basis or in accordance with thresholds and criteria that have been set by the relevant Member State. It is worth noting that if a project has been previously

effects of certain public and private projects on the environment, [2014] OJ L124/1. Alongside the 2011 Directive (as amended), there are various reports, reviews, soft law guidance documents etc that may merit further investigation.

¹⁶⁹ E.g., Case C-72/95 *Kraaijeveld* ECLI:EU:C:1996:404.

authorised, changes or extensions to the project may merit a further screening and/or EIA.

Annex II projects require development consent. The question is whether they also require an EIA or not, which is based on the question of whether the project is 'likely to have significant effects on the environment' or not. In determining this, the cumulative effects are considered in context (e.g., in conjunction with other activities)¹⁷⁰ and it is not permitted to split/divide activities for the purposes of screening (or the EIA)¹⁷¹ – otherwise it would be possible to have death by a thousand cuts. The objectives of the Directive are crucial here and the CJEU has developed significant judgments, e.g., that whole classes of projects cannot be exempted in advance from the EIA obligation, or thresholds imposed that focus purely on size or location, or the automatic exclusion of small-scale projects. Any national/regional criteria should be examined carefully, along with previous decisions to exempt or mandate screening, and any challenges to these nationally or at the EU level. Where screening is required, the developer is responsible under Article 4(4) for providing the relevant information (detailed in Annex IIA). Crucially, the developer and the eventual competent authority in the Member State must take into account any relevant environmental assessments undertaken pursuant to other EU legislation, although this does not exclude the provision and taking into account of further data that might help determine whether significant effects on the environment are likely or not.

As outlined by Kingston et al,¹⁷² the screening decision and the reasons for it must be made available to the public; where a decision is made that no EIA is required, further details must be included, e.g., the features and/or measures that will help 'avoid potential significant adverse effects on the environment.' Article 4(6) likewise provides for a timeline (max of 90 days post-submission of information by the developer, but as soon as possible) for the decision. As well as being publicly available, the decision is also subject to the access to justice provisions under Article 11 of the EIA Directive,¹⁷³ i.e., the public concerned may be able to challenge the decision before a court. Developers (including potentially P2GreeN actors) might wish to consider this potential for litigation and how to involve those in the vicinity and stakeholder in early discussions to assuage potential concerns. While there is technically the possibility for exemptions of projects on a caseby-case basis,¹⁷⁴ this is for very limited reasons, and will be read restrictively by the CJEU in light of the purposes of the Directive.

It is worth noting first that Article 2(2) provides for the potential for an EIA to be integrated into existing development consent procedures. Thus, if an appropriate assessment is required under the nature conservation directives (see above), then the Member State must provide for 'coordinated and/or joint procedures' 'where appropriate'. This is included as an option, rather than an obligation, where assessments are required

¹⁷⁰ E.g., Case C-531/13 *Marktgemeinde Strasswalchen* ECLI:EU:C:2015:79, para 43.

¹⁷¹ E.g., Case C-392/96 *Commission v Ireland* ECLI:EU:C:1999:431, para 76 and 82.

¹⁷² Ibid, p.392-393.

¹⁷³ Case C-570/13 Karoline Gruber v Unabhängiger Verwaltungssenat für Kärnten and Others ECLI:EU:C:2015:231.

¹⁷⁴ E.g., Article 1(3) and 2(4).

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under other legislation, e.g., water, waste, or industrial emissions directives. Further, when a Member State's competent authority is undertaking an EIA, it is to take into account any supplementary information provided.¹⁷⁵ Once an EIA is being undertaken, there are a number of key steps/elements. These include, in brief, a developer's EIA report,¹⁷⁶ potentially supplementary information from the developer (requested by the Member State's competent authority), communication to the public of relevant information and enabling of (meaningful) early consultation by the public concerned,¹⁷⁷ engagement with any Member States whose environment is likely to be significantly affected by the projects,¹⁷⁸ and a decision by the competent authority.¹⁷⁹ The eventual decision to grant or reduce development consent must 'duly' take into account the information and opinions gathered via the steps outlined in Articles 5-7 and the reasons must be provided within the decision. Conditions may be attached to a consent, along with monitoring measures.

Whether for the screening stage or the EIA, the information from the developer and the engagement with the public concerned will prove the two most important elements. The granular detail of what is or should be provided by developers is beyond the remit of this scoping report (and arguably beyond the scope of the full review), but each operator will need to ensure that these are completed accurately and comprehensively by experts. The same is true for any other assessments undertaken under other legislation, e.g., waste, water or otherwise. Of note, in contrast with the provisions under the nature conservation directives, there is no requirement that the project cannot be undertaken if there will be significant effects – this is a directive with procedural requirements rather than one requiring specific standards to be met in order for authorisation to be approved.

It will be important to examine:

- The details within the Annexes and their applicability to P2GreeN and similar activities;
- The screening criteria and approaches by the relevant Member States;
- The governance structures, key actors, and implementation measures by the relevant Member States;
- Information regarding relevant completed screening assessments, EIAs and decisions in Member States, if available;
- Whether further regimes exist within the relevant Member States either through building upon the EU law or independently; and
- What specific rules apply regarding transboundary impacts (beyond the Directive provisions).

¹⁷⁹ Article 8.

¹⁷⁵ Article 8 provides for any 'results of consultations and the information gathered pursuant to Articles 5, 6 and 7' to 'be taken into consideration in the development consent procedure.'

¹⁷⁶ Details outlined in Article 5(1), to include both technical and non-technical information, along with the results of any other relevant assessments undertaken under EU or national/regional legislation.

¹⁷⁷ See Article 6, implementing the Aarhus Convention's provisions on public participation. This includes environmental NGOs, with some limitations possible under national law but interpreted tightly by the CJEU. ¹⁷⁸ Article 7.

More from a general governance perspective, information regarding engagements with the public would likely be useful to see what has been useful for building positive relationships and how this has informed projects, developer information etc.

10.4 Soil

Healthy soils are essential as a 'key enabling resource,'¹⁸⁰ including for food production and general ecosystem services for humans and nature. However, any changes to the soils can impact on the existing balance (positively or negatively). This can be through a wide range of measures, e.g., introduction of minerals; changes to the nutrient balance (additional nutrients or leaching); impacts on soil structures; microbiomes etc. Soil contamination is therefore not, for instance, just through heavy metals. For example, 'organic or inorganic chemical substances of a hazardous nature and pathogenic microorganisms' pose risks to the environment and human health.¹⁸¹ This includes impacts on food safety and water quality, e.g., substances in the contaminated soil may enter the food chain and result in contaminated/unsafe food. The sources and presence of soil contamination vary considerably and are not just present in agricultural or industrial land, but, for instance, also in urban areas.¹⁸² Ramon and Lull note legal options to address this include: 'environmental liability' systems (for consumer protection), 'measures to prevent contaminants entering [the] soil', management of contaminated soil 'and a food traceability system'.¹⁸³ However, a significant issue currently is the very limited and piecemeal nature of soil legislation at the EU level - with a need to examine a broad range of sources to identify the parameters of the applicable legal frameworks.

In 2021, the Commission published a Communication on *EU Soil Strategy for 2030: Reaping the benefits of healthy soils for people, food, nature, and climate* setting medium-term objectives to be realised by 2030 and long-term objectives to be achieved by 2050.¹⁸⁴ Included in the former are the following objectives:¹⁸⁵

- a. Reach good ecological and chemical status in surface waters and good chemical and quantitative status in groundwater by 2027;
- b. Reduce nutrient losses by at least 50%, the overall use and risk of chemical pesticides by 50% and the use of more hazardous pesticides by 50% by 2030.

Soil protection is addressed across various pieces of EU legislation including, for example, the Directives on the Waste Framework, Sewage Sludge, Industrial

¹⁸⁰ 'FAO World Charter on Soils' https://www.fao.org/3/i4965e/l4965E.pdf> accessed 2 May 2023.

 ¹⁸¹ Francisca Ramón and Cristina Lull, 'Legal Measures to Prevent and Manage Soil Contamination and to Increase Food Safety for Consumer Health: The Case of Spain' (2019) 250 Environmental Pollution 883.
 ¹⁸² Ramon and Lull, ibid.

¹⁸³ Ramon and Lull, ibid, p.884.

¹⁸⁴ COM (2021) 699.

¹⁸⁵ Ibid, p. 3.

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Emissions¹⁸⁶ (briefly discussed below) and Environmental Liability¹⁸⁷ and the Regulation on land use, land use change and forestry (LULUCF).¹⁸⁸ As to whether this legislative framework has been sufficient to address soil degradation is an open question, but it is suggested that a more coherent legislative framework would assist in this process, hence the Commission's call for such a framework.¹⁸⁹

The existing patchwork of legislation includes Directive 2009/128 establishing a framework for Community action to achieve the sustainable use of pesticides which by virtue of Article 4 requires the establishment of National Action Plans that would:¹⁹⁰

"... set up their quantitative objectives, targets, measures, and timetables to reduce risks and impacts of pesticide use on human health and the environment and to encourage the development and introduction of integrated pest management and of alternative approaches or techniques in order to reduce dependency on the use of pesticides. These targets may cover different areas of concern, for example worker protection, protection of the environment, residues, use of specific techniques or use in specific crops."

The Directive goes on to address a number of issues including training (Article 5), equipment inspection and use (Article 8), reduction of pesticide use or risks in specific areas (Article 12) and the handling and storage of pesticides (Article 13). These articles are part of SMR 8 in the CAP¹⁹¹ and the GAEC standards also apply to pesticides. GAEC 4 provides for the protection of river courses against pollution and run-off by requiring the establishment of buffer strips along water courses; such strips should be a minimum width of three metres within which the use of fertilisers and pesticides should be avoided. GAEC 5-7 address soil protection and quality; so, to reduce the risk of soil degradation and

¹⁸⁶ Directive 2010/75/EU on industrial emissions, [2010] OJ L334/17.

¹⁸⁷ Directive 2004/35/CE of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage, [2004] OJ L143/56.

¹⁸⁸ Regulation (EU) 2018/841 of the European Parliament and of the Council of 30 May 2018 on the inclusion of greenhouse gas emissions and removals from land use, land use change and forestry in the 2030 climate and energy framework, and amending Regulation (EU) No 525/2013 and Decision No 529/2013/EU, [2018] OJ L 156/1. See also, Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2018/841 as regards the scope, simplifying the compliance rules, setting out the targets of the Member States for 2030 and committing to the collective achievement of climate neutrality by 2035 in the land use, forestry and agriculture sector, and (EU) 2018/1999 as regards improvement in monitoring, reporting, tracking of progress and review, COM/2021/554 final.

¹⁸⁹ E.g. *EU Soil Strategy for 2030: Reaping the benefits of healthy soils for people, food, nature, and climate* COM (2021) 699, pp.4-5. See also COM (2006) 231 *Thematic Strategy for Soil Protection* (pp 7-9) which proposed a Framework Directive on Soil Protection which was not adopted, as well as the discussion of the proposed Soil Monitoring Law below.

¹⁹⁰ [2009] OJ L 309/71 as amended by Regulation 652/2014, [2014] OJ L 189/1, Directive 2019/782, [2019] OJ L 127/4 and Regulation 2019/1243, [2019] OJ L 198/241. See also Regulation 1107/2009 ([2009] OJ L 309/1) concerning placing plant protection products on the market; Article 55 of this Regulation constitutes SMR7 and is reproduced in Annex VII to this scoping review. Regulation 1107/2009 has been amended nine times with the latest amendment being made by Regulation 2022/1438, [2022] OJ L 227/2.
¹⁹¹ Reproduced in Annex VIII below.

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erosion land/tillage management would reflect site specific conditions (GAEC 5); to protect soils in periods that are most sensitive, there would be minimum soil cover to avoid bare soil (GAEC 6); and, to preserve soil potential there would be crop rotation in arable land (GAEC 7).¹⁹²

In 2022, the Commission concluded on the basis of audits it conducted and various implementation reports that there were "weaknesses in the implementation, application and enforcement" of the Directive leading it to propose its replacement by a Regulation.¹⁹³ The new Regulation would pursue a series of objectives, in the context of a number of EU strategies including farm-to-fork, biodiversity, zero pollution and soil strategy. The first objective was identified as being to:¹⁹⁴

- (i) reduce the use and risk of chemical pesticides, in particular those containing more hazardous active substances;
- (ii) increase the application and enforcement of integrated pest management (IPM); and
- (iii) increase the use of less hazardous and non-chemical alternatives to chemical pesticides for pest control.

The proposal would ensure consistency with respect to pollutants and regulatory standards in areas such as Directive 2013/39, the Environmental Quality Standards Directive and Directive 2000/60, the Water Framework Directive. If the targets set in the Regulation were to realise the national targets to be set by each Member State, it would result in a 50% reduction across the EU in the use of both chemical and more hazardous plant protection products by 2030.

As to the applicability of this discussion to P2GreeN, as in the discussion of fertilisers and water, one question that arises is the content of the product(s) emerging from the various processes to be developed to transform human waste and their impact on soil quality. So, for example:

- How will the use of the product impact the quality of the soil on the land to which it is applied?
- How can P2GreeN activities contribute to Strategy targets of reducing nutrient losses by at least 50%, the overall use and risk of chemical pesticides by 50% and the use of more hazardous pesticides by 50% by 2030?
- Will the product include any content that may be classified as a pollutant?

¹⁹² Details on the nature of crop rotation are set out in Appendix III to Regulation 2021/2115, [2021] OJ L435/1. The details note that farmers certified in accordance with Regulation 2018/848, the Organic Farming Regulation ([2018] OJ L 150/1) are deemed to comply with GAEC 7.

¹⁹³ COM (2022) 305, p.1. See COM (2020) 204 On the experience gained by Member States on the implementation of national targets established in their National Action Plans and on progress in the implementation of Directive 2009/128/EC on the sustainable use of pesticides. See also European Court of Auditors Sustainable use of plant protection products: limited progress in measuring and reducing risks Special Report 5/2020 and Council conclusions of 2 July 2020 on this report available at pdf (europa.eu). ¹⁹⁴ Ibid, p. 3.

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 How much of that content will remain on the food grown as a result of the use of the product? In response to this question, it should be noted that Regulation 396/2005 sets out maximum residue levels of pesticides in or on food and feed of plant and animal origin.¹⁹⁵

A final point must be noted here, which is the very recent EU Proposal for a Soil Monitoring Law in July 2023.¹⁹⁶ However, this remains at very early stages and its precise nature and content, if adopted, is subject to change. Nonetheless, it is worth highlighting that the proposed Directive focusses primarily on monitoring and assessment of soil,¹⁹⁷ with some content also on land take and contaminated land. Despite the earlier Soil Strategy speaking of a soil health law¹⁹⁸ and the stated goal of ensuring all soils being in a healthy condition by 2050,¹⁹⁹ the proposal does not entail clear or binding standards for soil, although there are provisions regarding criteria and considerations for healthy soil and sustainable land management.²⁰⁰ This proposal needs to be investigated and monitored in detail, as will be of considerable significance for P2GreeN and related future activities.

Other potential significant changes could arise in this field also and will similarly need to be monitored, e.g. developments regarding the Land Use, Land Use Change and Forestry Regulation.

10.5 Air

P2GreeN activities raises a number of potential issues relating to air, including regarding air pollution and quality generally, ozone depletion,²⁰¹ greenhouse gas emissions (and climate change) (which will be dealt with separately in the scoping review and also in the final legislative report), and noxious smells/impacts on enjoyment of the use of land (largely will be an issue for the final legislative report and is more likely to be dealt with primarily at a national or regional level). This section will briefly outline some of the main elements regarding air pollution and quality in EU law, especially focussing on the Air Quality Framework Directive (AQFD)²⁰² and the National Emissions Reductions

¹⁹⁵ [2005] OJ L 70/1. This Regulation has been amended over 200 times with the latest amendment being Regulation 2023/163 [2023] OJ L 23/1.

¹⁹⁶ Proposal for a Directive of the European Parliament and of the Council on Soil Monitoring and Resilience COM(2023) 416 final, https://environment.ec.europa.eu/system/files/2023-07/Proposal%20for%20a%20DIRECTIVE%20OF%20THE%20EUROPEAN%20PARLIAMENT%20AND% 20OF%20THE%20COUNCIL%20on%20Soil%20Monitoring%20and%20Resilience_COM_2023_416_fin al.pdf.

¹⁹⁷ Similarities can be drawn here with the idea of noise maps found within EU law on noise pollution and the lack of binding obligations regarding reductions.

¹⁹⁸ COM (2021) 699, pp.4-5.

¹⁹⁹ https://ec.europa.eu/commission/presscorner/detail/en/qanda_23_3637.

²⁰⁰ <u>https://www.theguardian.com/environment/2023/jul/06/eu-sets-out-first-ever-soil-law-to-protect-food-security-and-slow-global-heating.</u>

²⁰¹ This is not covered in the scoping review and is unlikely to be covered in the full legislative report. ²⁰² Discritize 2020/50/50 on ambient size multiple and also are size for Europe (2000) 0.11450/4

²⁰² Directive 2008/50/EC on ambient air quality and cleaner air for Europe, [2008] OJ L152/1.

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Commitments Directive (NECD),²⁰³ both of which set maximum emissions levels amongst other elements. Other laws such as the Industrial Emissions Directive (IED)²⁰⁴ are relevant to air pollution/quality but are not dealt with here. There will be a brief section later on the IED. Unsurprisingly, international, EU, regional and even local laws, practices, structures etc are crucial to regulating air pollution and quality. The NECD is focussed on developing annual overall maximum emission quotas/levels for specific substances, as well as now in reducing those emissions. The AQFD is focussed more on the quality of air, examining it from the medium's perspective rather than the emissions that impact on its quality. The two directives thereby complement each other, through combining standards and approaches. A similar approach can be seen in areas such as water, e.g., seeking good ecological status for water, while also restricting emissions on substances such as nitrates.

As per Kingston et al's book, the NECD is primarily focussed on a range of pollutants 'responsible for acidification, eutrophication and ground-level ozone pollution'.²⁰⁵ The original Directive²⁰⁶ set overall emission limits for the Member States for 2010. The 2016 replacement Directive sets more ambitious, lower limits for 2020 and for 2030 for the 'five main air pollutants',²⁰⁷ i.e., nitrogen oxides, non-methane volatile organic compounds, sulphur dioxide, ammonia and fine particulate matter (PM2.5). The 2020 limits transpose those agreed under the 2012 revised Gothenburg Protocol under the Convention on Long-range Transboundary Air Pollution, with the 2030 limits being lower again. The 2016 Directive obliges Member States to have a national air pollution control programme (NAPCP) by April 2019, including a range of policies and measures that will help ensure they meet their reductions commitments. This complements the obligations under the AQFD discussed below, but there are considerable gaps at the EU level with corresponding scope for gaps nationally and regionally. It is also worth noting that there is a significant level of non-compliance by Member States regarding the reduction limits already. It will be worthwhile evaluating the NAPCPs in each of the relevant territories, as well as potentially any other implementing measures and complementary national or regional measures.

The purposes of the AQFD, outlined in Article 1, is to 'lay down measures to define and establish ambient air quality objectives' for a range of pollutants – specifically, sulphur dioxide, nitrogen oxide, oxides of nitrogen, particulate matter (PM10 and PM25), benzene and carbon monoxide. As with noise and water pollution, a key element of the EU legislation is the establishment of monitoring systems, common approaches to

²⁰³ Directive (EU) 2016/2284 of the European Parliament and of the Council of 14 December 2016 on the reduction of national emissions of certain atmospheric pollutants, amending Directive 2003/35/EC and repealing Directive 2001/81/EC, [2016] OJ L344/1.

²⁰⁴ Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control), [2010] OJ L334/17.

²⁰⁵ P.312. This was regarding the original 2001 Directive, but still applies to the replacement Directive.

²⁰⁶ Directive 2001/81/EC on national emission ceilings for certain atmospheric pollutants, [2001] OJ L309/22.

²⁰⁷ https://www.eea.europa.eu/themes/air/air-pollution-sources-1/national-emission-ceilings#:~:text=The%20National%20Emission%20reduction%20Commitments,5).

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measurements – enabling the creation, sharing and evaluation of data in a usable and comparable manner. Information and understanding that information is seen as the key initial step in managing air pollution. For instance, Article 4 requires Member States to identify and establish individual zones and agglomerations for assessing air quality, enabling the development of tailored assessments and plans and realistic comparisons. The measurement approaches are outlined within the Directive and depend in part on the level of pollution present. This obligation on Member States will have some impact on P2GreeN activities, e.g., through influencing the existence of national and regional obligations for monitoring emissions from individual activities/installations or in areas where P2GreeN operators (and future actors seeking to upscale these activities) might potentially be a significant contributor.

The second facet of the AQFD is the requirement to create air pollution reduction strategies and thereby to also reduce air pollution. This relates to the different limits and target values, as the obligation kicks in where these (and any margin of leeway granted) is exceeded. Only at that stage is there an obligation to create an air quality plan²⁰⁸ – identifying why and how levels have been exceeded and introducing measures to address the issue. It is largely, therefore, reactionary rather than anticipatory. Consequently, due to a combination of the localised approach (individual zones and agglomerations) and the reactive approach (where limits are exceeded), this leads to a somewhat piecemeal development of air quality plans.²⁰⁹ From P2GreeN's perspective, the challenge is therefore to identify and evaluate existing plans, but also to be aware that new or draft plans may be created and implemented at short notice, with knock-on effects for both current and future activities.

As a framework directive, it tends to leave considerable flexibility to the Member States and regions therein – especially regarding complying with thresholds, the nature of reduction measures, the content of temporary air quality plans (responding to alert thresholds) etc. Nonetheless, discretion is not unlimited and 2022 saw the CJEU condemn several EU Member States for failure to comply with their obligations under the AQFD.²¹⁰ However, whilst it does contain key obligations, from P2Green's perspective, it is how the AQFD is developed, implemented and enforced that is central to the impacts on individual activities and operators. Consequently, there is a need to investigate the implementation of the AQFD, e.g., review the air quality/pollution maps created within the relevant territories, identify where thresholds are currently or might in the near future be exceeded (leading to air quality plans and further measures), identify and evaluate current air quality plans, and identify and evaluate core CJEU judgments and responses thereto – it might be expected that policy/approaches in both those Member States and more broadly across the EU might adapt in light of the judgments and fines applied. Alongside

²⁰⁸ See Articles 22-24.

²⁰⁹ From an environmental and human health perspective, while this was understandable as an initial approach to allow for prioritisation of the most polluted and harmful areas, this is not particularly advantageous in the long-term. From a governance perspective, it also makes for a challenging and potentially incoherent system to engage with.

²¹⁰ E.g. Case C-286/21 *Commission v France* ECLI:EU:C:2022:319.

this, it is also necessary to investigate international, national and regional complementary measures that fall outside the AQFD.

10.6 Pesticides

Pesticides in EU law are broader in scope than they might first appear. They include plant protection products (PPPs) and biocides. They are designed to protect against pests (e.g., insects and diseases) and diseases. EU law regulates the authorisation,²¹¹ use²¹² and the maximum residue levels (MRLs) for pesticide residues in or on food and feed,²¹³ with a current proposal to enhance protections for the use of pesticides. This section very briefly outlines the main components at the EU level – it will merit some further investigation later in the project.

The approval of pesticides is regulated by Regulation 1107/2009 concerning the placing of plant protection products on the market.²¹⁴ The scope of that Regulation is, as per the name, on PPPs and Article 2 outlines this as:

1. This Regulation shall apply to products, in the form in which they are supplied to the user, consisting of, or containing active substances, safeners or synergists, and intended for one of the following uses:

- (a) protecting plants or plant products against all harmful organisms or preventing the action of such organisms, unless the main purpose of these products is considered to be for reasons of hygiene rather than for the protection of plants or plant products;
- (b) influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient or a plant biostimulant;
- (c) preserving plant products, in so far as such substances or products are not subject to special Community provisions on preservatives;
- (d) destroying undesired plants or parts of plants, except algae unless the products are applied on soil or water to protect plants;
- (e) checking or preventing undesired growth of plants, except algae unless the products are applied on soil or water to protect plants.

These products are referred to as 'plant protection products'. The concepts of active substances, safeners and synergists are further outlined later in Article 1.

²¹¹ Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC [2009] OJ L 309/1.

²¹² E.g., the SUP Directive noted above regarding soil; and proposal for a Regulation on the sustainable use of plant protection products and amending Regulation 2021/2115, COM/2022/305 final.

²¹³ E.g., Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC, [2005] OJ L70/1.

²¹⁴ [2009] OJ L 309/1.

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It would appear likely that P2GreeN products will be waste, fertilisers or reclaimed water (at various stages), rather than PPPs – especially in light of Article 2(1)(b) stating 'influencing the life processes of plants, such as substances influencing their growth other than as a nutrient or a plant biostimulant'. However, it will be important to examine the precise products and see whether they might fall within one of the categories of PPP somehow. This merits some further examination in the full legislative review. Further, even if a P2GreeN product is not itself a PPP, this does not prevent the existence of PPPs within sewage sludge, wastewater, or faeces or thereby within the final product. Consequently, the key information at this stage for P2GreeN actors is to be aware of the PPP regime, the need for prior approval and the general criteria that apply for EU approval of PPPs – this is also important in feeding into other environmental and human health assessments, as where the human waste is sourced in the EU, there should be very limited potential for there to be PPPs present in the waste other than those approved by the EU.

Chapter II of Regulation 1107/2009 outlines the approval process and criteria for the various types of PPPs: active substances, safeners, synergists and co-formulants. Annex II provides further complementary detail on the criteria and steps to undertake the evaluation of the PPP. At this stage, the general gist regarding environmental and human health criteria can be noted. For instance, Article 4(3) provides that the PPP shall be 'sufficiently effective', 'have no immediate or delayed harmful effect on human health... or human health' directly or indirectly and including cumulatively,²¹⁵ 'not have any unacceptable effects on plants or plant products', 'not cause unnecessary suffering and pain to vertebrates to be controlled' and 'have no unacceptable effects on the environment, having particular regard' to a range of considerations including contamination of water, air and soil, and 'the impact on biodiversity and the ecosystem'.²¹⁶ Consequently, PPPs must not impact negatively on human health at all, whereas the controls regarding the environment are based on the acceptability or not of the effects, i.e., a balancing exercise will be undertaken. However, note the links between the human health and environmental elements, e.g., Article 4(3)(b) addresses health impacts caused indirectly through drinking water, air etc, while Article 4(3)(e)(i) also notes this for impacts on the environment. While residues are also addressed under separate legislation, it is worth noting that Article 4(2) also notes that residues should similarly not have 'any harmful effects on human health... or animal health' or 'any unacceptable effect on the environment'. Finally, it is worth noting that these criteria are based on an assessment in

²¹⁵ Article 4(3)(b) fully states that 'it shall have no immediate or delayed harmful effect on human health, including that of vulnerable groups, or animal health, directly or through drinking water (taking into account substances resulting from water treatment), food, feed or air, or consequences in the workplace or through other indirect effects, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available; or on groundwater;'

²¹⁶ Article 4(3 (e) states: 'it shall have no unacceptable effects on the environment, having particular regard to the following considerations where the scientific methods accepted by the Authority to assess such effects are available: (i) its fate and distribution in the environment, particularly contamination of surface waters, including estuarine and coastal waters, groundwater, air and soil taking into account locations distant from its use following long-range environmental transportation; (ii) its impact on non-target species, including on the ongoing behaviour of those species; (iii) its impact on biodiversity and the ecosystem.

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light of 'application consistent with good plant protection practice and having regard to realistic conditions of use.'²¹⁷

Consequently, in principle, any potential PPPs found in human waste and potentially still left in P2GreeN products following processing (this depends on each activity by P2GreeN actors), should not have any harmful effects on human health or animal health or any unacceptable effect on the environment, based on their nature and conditions of use – presuming that they are authorised by the EU in the first instance. Complementing this, Regulation 396/2005 sets maximum residue levels (MRLs) for pesticides in or on food and feed of plant and animal origin, which are linked to good agricultural practices and thereby also the original authorisations. Consequently, one might expect that there should be no concerns for P2GreeN, even if some residue PPP is in P2GreeN products. However, complications arise:²¹⁸

- i. Good plant protection practice and realistic conditions of use do not always occur, e.g., the PPPs might be over-utilised or changed in some form, or there might have been unexpected events that impacted the 'conditions of use;'
- ii. It is possible that treatments or steps undergone (by P2GreeN or earlier on in the cycle) might impact the PPPs either negatively or positively, as other substances and processes interact with the PPPs, e.g., what of the impact of dehydration/concentration?
- iii. Conditions might apply to any approval of the PPPs, e.g., not to be used on or near a protected site, near the habitat of a specific species, or at certain times or locations;
- iv. P2GreeN or those using P2GreeN products might also be using PPPs, thereby accumulating with any residues found within P2GreeN products.

Questions arise regarding what is the extent and nature of the PPPs present in any P2GreeN produce and whether the approval conditions still apply in some fashion to these.

The use of pesticides is currently governed by the Sustainable Use of Pesticides Directive.²¹⁹ This has been outlined in the section on soil and will not be repeated here. Following a review of that Directive, there is a current proposal for a Regulation on the sustainable use of plant protection products and amending Regulation 2021/2115,²²⁰ which is gradually going through the EU legislative process.²²¹ Key components under

²²⁰ <u>https://food.ec.europa.eu/system/files/2022-06/pesticides_sud_eval_2022_reg_2022-305_en.pdf</u>.

²¹⁷ E.g., Article 4(2) and (3).

²¹⁸ Comparisons can be seen here with the use of sewage sludge. e.g. Tayane C. R. Mesquita, Rizia R. Santos, Ane P. Cacique, Ludimara J. De SÁ, Flaviano O. Silvério & Gevany P. Pinho (2018) Easy and fast extraction methods to determine organochlorine pesticides in sewage sludge, soil, and water samples based at low temperature, Journal of Environmental Science and Health, Part B, 53:3, 199-206, DOI: <u>10.1080/03601234.2017.1405626</u>.

²¹⁹ Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides, [2009] OJ L 309/71.

²²¹ <u>https://www.europarl.europa.eu/RegData/etudes/BRIE/2022/739218/EPRS_BRI(2022)739218_EN.pdf</u>.

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this proposal include: banning all pesticides in sensitive areas, including urban green areas, sports grounds, Natura 2000 sites and any ecologically sensitive area to be preserved for threatened pollinators; and legally binding target for the EU of a 50% reduction in the use of and risk of chemical pesticides and a 50% reduction in the use of more hazardous pesticides by 2030 (complemented by national reductions targets also). An issue to be investigated here is to what extent these rules (might) apply where residues of PPPs are within water/fertiliser products spread on land. Does a *de minimis* approach apply or would, for instance, an absolute prohibition applies in the context of urban green areas and Natura 2000 sites?

Regulation 396/2005 establishes maximum residue levels of pesticides in or on food and feed of plant and animal origin which provides for maximum residue levels (MRLs) of pesticides, with details in its Annexes.²²² The MRLs are linked to good agricultural practices and thereby also to the original authorisation of the PPPs. However, it should be borne in mind that the PPPs will have gone through a full cycle before presence in the P2GreeN products (e.g., use, presence on/in food or water, consumption/ingestion by humans. digestion. defecation/urination. treatments/processing...), which may impact the nature and level of residues present. It would appear highly likely that there would be less PPPs present in a P2GreeN product than in the original PPP, but (i) processes could include something such as dehydration/concentration and (ii) if used in conjunction with the normal use of PPPs, the cumulative amount might exceed the permitted MRLs. This is an issue with using run-off also and not simply with human waste.

It is unclear to what extent this area of law will be relevant for P2GreeN or related activities. However, if the final products being added to the land fall within the definition of a pesticide or contain substances that could be deemed to be pesticides,²²³ then this could have significant consequences for the potential use of the products – especially in the long-term if the proposed Regulation is approved. This area also highlights the need to investigate elements such as the law on other residues that might be present, e.g., heavy minerals, pathogens, microplastics or pharmaceuticals. The legal frameworks in these fields are gradually becoming more onerous and complicated, as the long-term health and environmental implications become better understood. While they are relevant to broader frameworks, such as those regarding water quality or nature conservation, individual regimes are being developed and elements are also seen in, for instance, food law.

²²² [2005] OJ L 70/1. Regulation 1107/2009, Article 3(1) defines residues as meaning: 'one or more substances present in or on plants or plant products, edible animal products, drinking water or elsewhere in the environment and resulting from the use of a plant protection product, including their metabolites, breakdown, or reaction products'.

²²³ This has been the case for sewage sludge spread on land previously, e.g. Tayane C. R. Mesquita, Rizia R. Santos, Ane P. Cacique, Ludimara J. De SÁ, Flaviano O. Silvério & Gevany P. Pinho (2018) Easy and fast extraction methods to determine organochlorine pesticides in sewage sludge, soil, and water samples based at low temperature, Journal of Environmental Science and Health, Part B, 53:3, 199-206, DOI: <u>10.1080/03601234.2017.1405626</u>.

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10.7 Industrial Emissions

While the approach to EU environmental regulation is largely siloed from one area to the next (e.g., waste, air and water), even if a more holistic approach is then attempted within these areas (e.g., through the use of framework directives), a striking exception is that of the Industrial Emissions Directive,²²⁴ which deals with 'industrial activities'. The aim is to provide a more integrated, holistic approach to their operation²²⁵ and thereby 'achieve a high level of protection of the environment taken as a whole',²²⁶ in the knowledge that more extensive operations and operations of a specific kind²²⁷ are more likely to have impacts on a range of environmental media and thereby normally require a range of different environmental permits. It minimises the potential for pollution or degradation displacement. The Directive is not aimed at the local small craft shop but is focussed on potential heavy industrial polluters.

The Industrial Emissions Directive (IED) is the main EU instrument regulating pollutant emissions from industrial installations. Around 52,000 installations undertaking the industrial activities listed in Annex I of the Directive are required to operate in accordance with a permit (granted by the authorities in the Member States). This permit should contain conditions set in accordance with the principles and provisions of the Directive. The IED is based on several pillars:

- The integrated approach means that permits must take the whole environmental performance of the plant into account. This covers emissions to air, water and land, generation of waste, use of raw materials, energy efficiency, noise, prevention of accidents, and restoration of the site upon closure.
- The permit conditions including emission limit values must be based on the Best Available Techniques (BAT). In order to define BAT and the BAT-associated environmental performance at EU level, the Commission organises an exchange of information with experts from Member States, industry and environmental organisations. This work is co-ordinated by the European IPPC Bureau at the EU Joint Research Centre in Seville (Spain). This process results in BAT Reference Documents (BREFs); the BAT conclusions contained are adopted by the Commission as Implementing Decisions. The IED requires that these BAT conclusions are the reference points for setting permit conditions.

²²⁴ Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control), [2010] OJ L334/17. https://environment.ec.europa.eu/topics/industrial-emissions-and-safety/industrial-emissions-directive_en.
²²⁵ This reflects its earlier renditions in the form of the Integrated Pollution Prevention and Control Directive (Directive 2008/1/EC concerning integrated pollution prevention and control, [2008] OJ L24/8), which was amalgamated (and updated) with other Directives into the new IED.

²²⁶ Article 1 of the IED. Similarly, see for instance, Article 15(4) of the IED includes an obligation for the permitting regime that no significant pollution should be caused and that a high level of environmental protection should be achieved.

²²⁷ E.g., waste treatment facilities, poultry farms, combustion plants etc.

• Through the European Pollutant Release and Transfer Register (E-PRTR), emission data reported by Member States is made accessible in a public register. This provides environmental information on major industrial activities.

Although it requires more investigation, Annex I includes those engaging in chemical industries 'on an industrial scale' that include, for instance, the 'production of phosphorous-, nitrogen- or potassium-based fertilisers (simple or compound fertilisers). It also includes various large-scale waste activities, including the recovery of non-hazardous waste through biological treatment.²²⁸ It expressly encompasses anaerobic digestion,²²⁹ but excludes activities covered by the UWWT Directive (see the discussion above on UWWT). The Directive could easily apply to some P2GreeN operators – especially those that initially treat the human waste, but also potentially farmers that might avail of the products down the line.²³⁰ It is of particular relevance once the P2GreeN products have been successfully trialled and are then going to be commercialised, as the Directive does 'not apply to research activities, development activities or the testing of new products and processes'.²³¹ However, it is still of relevance at earlier stages because (i) some of the activities may fall outside this exclusion and (ii) the challenges at the commercialisation stage must be borne in mind at earlier stages in determining the long-term viability of the activities and outputs.

The core aspect of the Directive is the requirement of a permitting scheme – specifically, no industrial installation that falls within the scope of the Directive may operate without a permit.²³² The permit could be achieved through a single comprehensive permit²³³ granted by a single competent authority, or instead the application could be processed by multiple bodies provided that they are evaluated and granted in a coordinated, coherent manner that considers the environmental impacts as a whole.²³⁴ In determining and granting permits, a wide range of information is required²³⁵ and conditions applied,²³⁶ reflecting the integrated controlled approach. E.g. information and conditions regarding pollution levels and the potential for a pollutant to transfer from one environmental medium to another. Article 14 also expressly focusses on elements such as soil, groundwater and waste – all of which are crucial to P2GreeN activities (with the last depending on the applicability of the definition of waste or not). In countries where powers are divided up not merely horizontally across different bodies within the same

²³⁵ Article 12 of the IED.

²³⁶ Article 14 of the IED.

²²⁸ Where the industry has a capacity exceeding 75 tonnes per day.

²²⁹ However, the capacity threshold is raised to 100 tonnes per day. Activities with a capacity under this threshold are outside the scope of the IED.

²³⁰ To fall within this, the farmers would need to be using P2GreeN products on an intensive pig or poultry farm, which seems unlikely even if they simultaneously grow crops in light of the nutrients available from animal waste. However, it is technically a possibility.

²³¹ Article 2(2).

 $^{^{232}}$ Article 4(1) of the IED.

²³³ I.e. addressing elements such as emissions into air, water and land, as well as waste generation where relevant.

²³⁴ Article 5(2) of the IED required that the process be 'fully coordinated' to 'guarantee an effective integrated approach'.

jurisdiction, but also vertically, e.g., in the case of federalised states, this could be complex to identify, achieve and review.

As with much EU environmental law, the Member States are left with some flexibility in developing, implementing and enforcing the core elements of the Directive – most specifically the envisaged permitting scheme and potentially the creation of 'general binding rules' for 'certain categories of installations...'.²³⁷ However, first, the Member States must comply with a range of general principles²³⁸ and applicable environmental quality standards.²³⁹ Second, informing the domestic approaches (including permit conditions) are the concept of 'best available techniques' (BAT)²⁴⁰ and a wide range of soft law documents²⁴¹ in the form of BAT reference documents (BREFs)²⁴² and subsequently Commission 'BAT conclusions'. These BAT conclusions will be tailored for different sectors or activities and will identify elements such as the emission limit values for different pollutants.²⁴³ The precise balance between EU harmonisation and domestic flexibility depends in part on the nature of the industries in question. However, there is arguably a greater degree of (EU) standardisation in this regime than most other environmental regimes.

However, while the IED is focussed on an integrated approach and furthering a high level of environmental protection, the evaluation is focussed on the industry activities and processes rather than on the final product. The environmental credentials of the final products when being used in food production are of limited to no relevance for the IED under the current legislation – they do however remain relevant generally for aspects such as authorisation as a fertiliser and in food production, as well as there being the potential for the Member States to impose further controls themselves. In light of the role of both EU complementary legislation and soft law documents and domestic implementing measures, the full legislative report will need to consider both the legislative and non-legislative developments at the EU and domestic levels.

Finally, in 2022, the Commission adopted proposals to revise the IED and the E-PRTR,²⁴⁴ in order to enhance protections (including broader scope and higher

²³⁹ Article 18 of the IED. This can impose requirements beyond the use of BAT.

²³⁷ Article 6 of the IED.

²³⁸ Article 11 of the IED, e.g., prevention, no significant pollution, waste hierarchy, BAT, etc.

 $^{^{240}}$ E.g., Article 14(4) of the IED.

²⁴¹ I.e., documents technically without binding legal force, but nonetheless with legal effects due in particular to their role as interpretative tools.

²⁴² Article 13 of the IED. Although, it is debatable whether BREFs remain soft law documents currently or have shifted sufficiently to be a form of hybrid law or even part of hard law.

²⁴³ E.g., Article 15 of the IED.

²⁴⁴ Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) and Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste, COM/2022/156 final/3. See, https://environment.ec.europa.eu/publications/proposal-revision-industrial-emissions-directive en.

standards)²⁴⁵ and support more sustainable activities in accordance with the European Green Deal and the zero-pollution action plan. The proposals aim to improve the Directive by increasing the focus on energy, water and material efficiency and reuse, in addition to promoting the use of safer, less toxic or non-toxic chemicals in industrial processes. The revised Directive on industrial emissions will:

- Ensure full and consistent implementation of the IED across Member States, with tighter permit controls on air and water emissions;
- Increase investment in new, cleaner technologies taking into account energy use, resource efficiency and water reuse whilst avoiding lock-in to obsolete technologies;
- Support more sustainable growth of sectors that are key to building a clean, low carbon and circular economy;
- Cover additional intensive farming and industrial activities, ensuring that sectors with significant potential for high resource use or pollution also curb environmental damage at source by applying Best Available Techniques;
- Establish an Innovation Centre for Industrial Transformation and Emissions (INCITE);
- Integrate the previously separate requirements for depollution and decarbonisation so that future pollution control investments take better account of greenhouse gas emissions, resource efficiency and water reuse; and
- Enhance data transparency and public access to environmental information by making permit summaries available online and providing more opportunities for public participation in the setting and review of permits.

There is the potential for more extensive and burdensome obligations, but concurrently there is the potential for greater flexibility and support for P2GreeN activities since the proposals are focussed on elements such as sustainability, the circular economy and resource efficiency. Further, if farms are being more widely affected by this regime, it may have knock-on impacts on the desirability of products such as P2GreeN outputs.

Overall, environmental and human health issues are fundamental to the viability of P2GreeN (and similar) activities. Future research for the full legislative report will need to engage with how these EU frameworks are developed at a national and regional level, including the general regimes, permitting, exemptions (perhaps for trials, but not commercialisation) etc, as well as looking to domestic regimes/elements. Further, it will be essential to consider more directly elements that may pose particular challenges, drawing on insights from the P2GreeN regions and their activities, such as pharmaceuticals, salination, heavy metals, energy consumption, infrastructure requirements etc.

²⁴⁵ <u>https://environment.ec.europa.eu/topics/industrial-emissions-and-safety/industrial-emissions-</u> <u>directive_en</u>.

11 ANNEX V- DETAILED DESCRIPTION OF THE EXISTING POLICIES FOR COMMERCIALIZATION AND UPSCALING

Alongside the above issues come the longer-term commercial and upscaling considerations: how to ensure access to markets across the EU and potentially beyond? What constraints might be imposed and how can these be navigated? What supports might be available to farmers and those more generally engaged in agriculture? For the main part, these can and should be considered in detail at a later stage, but it is worth briefly sketching out some of the main considerations regarding four key issues here: (i) free movement of goods (FMG) and mutual recognition; (ii) the Common Agricultural Policy (CAP); (iii) food safety and (iv) organic foods. Other elements not addressed here, but potentially needing investigation for the full legislative report, include intellectual property law and international trade law.

11.1 The Free Movement of Goods

This is a brief introduction to the area of free movement of goods, as it is a vast and complex area that relies considerably on the judgments by the CJEU. The main law is founded in Articles 26 and 28-37 of the TFEU. It is supplemented by judgments and also by secondary legislation and soft law.

Once a good is authorised/in free circulation in one Member State, the principle is that it should be able to circulate freely across all Member States. Beyond prohibitions on the most obvious forms of restrictions such as customs duties (CDs) and quantitative restrictions (QRs), EU law aims to eliminate all hindrances to the free movement of goods across the EU. This includes measures having equivalent effect to CDs or QRs – with measures equivalent to QRs being most relevant to P2GreeN activities. A further aspect that will be of great significance for P2GreeN activities is that of mutual recognition – both the general principle and the legislative framework that has since developed. However, it must be recognised that Member States do have some leeway to impose restrictions for a range of objective justifications, as shall be seen.

The key Treaty provisions and some points from the jurisprudence are outlined here:

Articles 34 and 35 TFEU prohibit measures have an effect equivalent to quantitative restrictions (MEEQRs). This has been interpreted purposively by the CJEU,²⁴⁶ with the effect that 1) the prohibition encompasses any trading rules that 'are capable of hindering, directly or indirectly, actually or potentially, intra Community trade' and 2) the principle of mutual recognition requires 'that any product legally manufactured and marketed in a Member State in accordance with its fair and traditional rules... must be allowed onto the

²⁴⁶ E.g. the famous cases of *Cassis de Dijon* (Case 120/78 Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein [1979] ECR I-649) and *Dassonville*.

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market of any other Member State'.²⁴⁷ i.e. where the issues have not been harmonised, the EU Member States must still recognise the standards, rules and processes of other Member States, and thereby likewise authorise the product (without hindrance) in their own territories. This could obviously pose issues regarding reduced standards/a race to the bottom and also provide some countries/producers/operators with a competitive advantage.

However, it is done on the premise that some minimum standards already exist across the EU and, crucially, exceptions exist. Essentially, Member States may still impose restrictions that amount to MEEQRs where these are objectively justified, necessary and proportionate *stricto sensu*. This is facilitated by a combination of Article 36 TFEU and 'mandatory requirements' developed by the CJEU.

Article 36 contains a list of specific, exhaustive justifications including public morality, public policy, and the protection of health and life of humans, animals or plants. Although, with the caveat that 'Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States'. The CJEU developed the non-exhaustive mandatory requirements in cases such as *Cassis de Dijon* to complement these and they include, for instance, environmental protection more broadly and consumer protection.

Consequently, under the Treaty provisions, in conjunction with the case-law of the CJEU, the general approach would be that if a P2GreeN product were authorised in one Member State then it should be accepted across the EU in the same manner under the guise of FMG and mutual recognition. However, it would be possible for individual Member States to impose restrictions either in breach of EU law (which could be challenged but would take time) or through relying on the exceptions under Article 36 TFEU and/or mandatory requirements. To do so, they would have to identify a justification relevant to the issue and their country, which necessitated the measures in question. This could be a complete prohibition, or it could, for instance, include further labelling requirements or notifications.

This raises the question of whether an EU-level authorisation might be preferable instead or as well (irrespective of any increased initial costs or time delays) or alternatively whether it is desirable to consult with stakeholders across other Member States to see what issues or concerns might arise and how to address these in advance when seeking authorisation in the original Member State(s). It should however be noted that Article 36 TFEU and the mandatory requirements are not a free for all. Gradually processes were developed, via Regulations on Mutual Recognition, for the sharing of information and monitoring of their use, to ensure that they were not abused.²⁴⁸ These are complemented

 ²⁴⁷<u>https://www.europarl.europa.eu/RegData/etudes/fiches_techniques/2013/030102/04A_FT(2013)03010</u>
 <u>2 EN.pdf</u>, p.2.

²⁴⁸ See Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008 [2019] OJ L91/1.

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by a range of EU guidance documents,²⁴⁹ including on the application of the previous 2008 Mutual Recognition Regulation regarding 'fertiliser and growing media'.²⁵⁰ Further, if the area is harmonised and goods meet the relevant EU standards and especially where they are actively authorised under an EU process, then it is not a question of mutual recognition but simply one of general compliance with EU law.

This outline was kept very brief and general. Further examination of the cases regarding the mandatory requirements, for instance, could be very helpful, as well as the development of the EU legislation (and soft law) on the principle of mutual recognition. Likewise, some limited investigation into how the process works in practice, e.g., in the Commission Opinions on Mutual Recognition²⁵¹ including regarding fertilisers²⁵² and how individual Member States implement it could be useful. This will depend in part on the approaches taken by the pilot and follower regions, as well as how likely an EU-level authorisation appears for the P2GreeN products.

11.2 The Common Agricultural Policy (CAP)

Reference has already been made to a number of pieces of legislation that impact on the CAP, e.g. regarding water or pesticides. The final section (Policy Contribution) below also addresses relevant policies – i.e., the Green Deal and the Circular Economy Action Plan. The following discussion relates to the CAP more generally, sketching out briefly some of its main features in its most recent rendition.

The CAP establishes the EU's (evolving) approach to agriculture and uses financial support mechanisms to help deliver on the desired objectives. It has a long history and the discussion that follows does not address that history, but rather it examines the new approach to the policy resulting from Regulation 2021/2115.²⁵³ Articles 5 and 6 of this Regulation set the objectives for the National Strategic Plans which will form the core

goods_en#:~:text=The%20mutual%20recognition%20principle%20ensures,can%20be%20sold%20in%2 Oanother..

²⁵⁰ <u>https://ec.europa.eu/docsroom/documents/5825</u>.

²⁵¹ <u>https://single-market-economy.ec.europa.eu/single-market/goods/free-movement-sectors/mutual-recognition-</u>

<u>goods_en#:~:text=The%20mutual%20recognition%20principle%20ensures,can%20be%20sold%20in%2</u> <u>Oanother</u>.. E.g., it gave its first opinion in September 2021: https://ec.europa.eu/docsroom/documents/47254.

²⁴⁹ <u>https://single-market-economy.ec.europa.eu/single-market/goods/free-movement-sectors/mutual-recognition-</u>

 ²⁵² Opinion of 27.1.2022: https://ec.europa.eu/docsroom/documents/48574. And 3 opinions from January 2023: https://ec.europa.eu/docsroom/documents/52997;

https://ec.europa.eu/docsroom/documents/52958; and https://ec.europa.eu/docsroom/documents/53001.

²⁵³ Regulation (EU) 2021/2115 of the European Parliament and of the Council of 2 December 2021 establishing rules on support for strategic plans to be drawn up by Member States under the common agricultural policy (CAP Strategic Plans) and financed by the European Agricultural Guarantee Fund (EAGF) and by the European Agricultural Fund for Rural Development (EAFRD) and repealing Regulations (EU) No 1305/2013 and (EU) No 1307/2013, [2021] OJ L435/1, as amended by Commission Delegated Regulations 2022/648 ([2022] OJ L 119/1) and 2023/813 ([2023] OJ L 102/1).

means of implementing the new CAP. Of particular relevance to the P2GreeN project are Articles 5(a) and (b) which provide:

In accordance with the objectives of the CAP set out in Article 39 TFEU, with the objective to maintain the functioning of the internal market and a level playing field between farmers in the Union and with the principle of subsidiarity, support from the EAGF and the EAFRD shall aim to further improve the sustainable development of farming, food and rural areas and shall contribute to achieving the following general objectives in the economic, environmental and social spheres, which will contribute to the implementation of the 2030 Agenda for Sustainable Development:

(a) to foster a smart, competitive, resilient and diversified agricultural sector ensuring long-term food security;

(b) to support and strengthen environmental protection, including biodiversity, and climate action and to contribute to achieving the environmental and climaterelated objectives of the Union, including its commitments under the Paris Agreement;

More specific objectives are set out in Article 6 and of particular relevance to the P2GreeN project are the following:

(a) to support viable farm income and resilience of the agricultural sector across the Union in order to enhance long-term food security and agricultural diversity as well as to ensure the economic sustainability of agricultural production in the Union; ...

(d) to contribute to climate change mitigation and adaptation, including by reducing greenhouse gas emissions and enhancing carbon sequestration, as well as to promote sustainable energy;

(e) to foster sustainable development and efficient management of natural resources such as water, soil and air, including by reducing chemical dependency; (f) to contribute to halting and reversing biodiversity loss, enhance ecosystem services and preserve habitats and landscapes; ...

(i) to improve the response of Union agriculture to societal demands on food and health, including high-quality, safe and nutritious food produced in a sustainable way, to reduce food waste, as well as to improve animal welfare and to combat antimicrobial resistance.

By virtue of Articles 12 and 13 of the Regulation, an element of conditionality must be included by Member States in their CAP Strategic Plans, so that those farmers (and other beneficiaries) receiving direct payments or annual payments under a rural development programme must comply with the SMRs relating to climate and the environment, public health and plant health and animal welfare alongside standards for keeping land in GAEC.²⁵⁴

²⁵⁴ Relevant SMRs and GAECs for the P2GreeN project are listed in Annex VII (Chapter 13) to this Report.
Member States are given a range of policy measures to help to realise these objectives which include:

- Decoupled direct payments which take the form of basic income support for sustainability, or complementary redistributive income support for sustainability, or complementary income support for young farmers or schemes for the climate, the environment and animal welfare (Articles 20-31).
- Coupled income support for a limited number of products including a crop-specific payment for cotton (Articles 32-41).
- Specific programme aid for intervention in a limited range of products (Articles 42-68); and,
- Rural development intervention (Articles 69-84) including environmental, climaterelated and other management commitments (Article 70).

By virtue of Article 10, the support offered by the Member State must be consistent with Annex 2 of the World Trade Organisation's Agreement on Agriculture – the Green Box in which there are no financial limits.

The choice of policy measures to realise the objectives will be influenced by a series of indicators related to output, result, impact and context which are set out in Annex I and which are part of the performance monitoring and evaluation framework that applies for the CAP from 2023 until 2027.²⁵⁵ A number of these will have an impact for P2GreeN, for example, to meet the objective "to foster sustainable development and efficient management of natural resources such as water, soil and air, including by reducing chemicals", the impact indicators include reducing soil erosion with the result indicator being an increase in the "share of utilised agricultural area under supported commitments beneficial for soil management to improve soil quality and biota." As for improving air quality impact indicators include improving air and water quality and a reduction in nutrient leakage.

Two particular aspects of the Regulation deserve especial attention, namely those schemes involving the climate and the environment. The first set of provisions here is Article 31 dealing with eco-schemes which may be summarised as support offered by the Member States for voluntary support schemes under which farmers make commitments to observe agricultural practices beneficial to the climate and the environment over and above those set out in the SMR and GAEC.²⁵⁶ More specifically, Article 31(4) requires that eco-schemes are to cover at least two of the following areas of action:

²⁵⁵ For more details see <u>CMEF (europa.eu)</u>.

²⁵⁶ Article 31(5) also provides that the payments covering commitments must also "(b) go beyond the relevant minimum requirements for the use of fertiliser and plant protection products, animal welfare, as well as other relevant mandatory requirements established by national and Union law;" and "(c) go beyond the conditions established for the maintenance of the agricultural area in accordance with Article 4(2), point (b)."

- (a) climate change mitigation, including reduction of greenhouse gas emissions from agricultural practices, as well as maintenance of existing carbon stores and enhancement of carbon sequestration;
- (b) climate change adaptation, including actions to improve resilience of food production systems and animal and plant diversity for stronger resistance to diseases and climate change;
- (c) protection or improvement of water quality and reduction of pressure on water resources;
- (d) prevention of soil degradation, soil restoration, improvement of soil fertility and of nutrient management and soil biota;
- (e) protection of biodiversity, conservation or restoration of habitats or species, including maintenance and creation of landscape features or non-productive areas;
- (f) actions for a sustainable and reduced use of pesticides, in particular pesticides that present a risk for human health or environment;
- (g) actions to enhance animal welfare or combat antimicrobial resistance.

Payments under the eco-schemes, which are to be annual and in addition to basic income support, are to compensate farmers for "all or part of the additional costs incurred and income foregone as a result of the commitments made." Article 31(9) references Article 70 which deals with rural development commitments in the areas of climate and the environment; eco-schemes must be consistent with such commitments.²⁵⁷

One final area of note is found in Article 127 of Regulation 2021/2115 allowing for European Innovation Partnerships (EIPs) for agricultural productivity and sustainability allowing funds from the CAP to complement those from Horizon to promote the take up by farmers of research. Each EIP (and their Operational Group) will be part of national and/or European CAP networks established under Article 126. One existing EIP of potential relevance to P2GreeN is that on Agricultural Productivity and Sustainability (EIP-AGRI) which was launched in 2012 and is designed "to foster competitive, sustainable farming and forestry to ensure a steady supply of food, feed and biomaterials."²⁵⁸

11.3 Food Safety

As a result of various food scares in the 1980s and 1990s, the EU introduced Regulation 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA) and laying down procedures in

²⁵⁷ It should be noted that Article 72 Regulation 2021/2115 allows for payments under rural development commitments for area-specific disadvantages arising from certain mandatory requirements. Article 74 also allows for investment in irrigation.

²⁵⁸ For further details see <u>Home | EIP-AGRI (europa.eu)</u>. See also the 2016 Evaluation of the scheme, available at <u>Evaluation study of the implementation of the European innovation partnership for agricultural productivity and sustainability - Publications Office of the EU (europa.eu)</u>

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matters of food safety; it is usually referred to as General Food Law (GFL).²⁵⁹ The Regulation seeks to promote a "high level of protection of human life and health" whilst seeking to eliminate those differences in the food laws of the Member States that "may impede the free movement of food, create unequal conditions of competition, and may thereby directly affect the functioning of the internal market."²⁶⁰ The GFL and the numerous related pieces of EU legislation, regarding labelling, food handling, maximum residues of PPPs on food/feed or otherwise, have considerable relevance to P2GreeN products, as these are intended to be used in food production.

For instance, one of these potential products is a liquid that could be applied to encourage the growth of agricultural products making it equivalent to water and as such. like water, it should be free from chemical and microbiological contaminants. This will require a scientific risk analysis of this product which will be conducted by EFSA;²⁶¹ such risk analysis will offer reassurance to producers (consumers and the EU's trading partners) that (based on scientific evidence) the product is safe to use throughout the production process – from farm to fork.²⁶² Consumer confidence will thus be ensured and to supplement this, GFL introduces a comprehensive system of traceability and improved the pre-existing rapid alert system established by Directive 92/59.²⁶³ It is worth highlighting that more specific regimes exist also, building upon the GFL. For instance, as noted above in the content on waste, Regulation 852/2004 on hygiene in foodstuffs²⁶⁴ sets criteria for the water used in the production of plant products to prevent contamination.²⁶⁵ While this example focusses on water (or the equivalent thereof), similar criteria apply to substances generally used in food production and risk analysis and considerations of the precautionary principle²⁶⁶ will be fundamental to any evaluation of P2GreeN products.

²⁶⁶ Reflected in Article 7 of the GFL.

²⁵⁹ [2002] OJ L 31/1. The Regulation has been amended on a number of occasions with the latest amendment being Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, [2019] OJ L231/1.

²⁶⁰ Ibid, Recitals 2 and 4.

²⁶¹ In this context, risk analysis involves risk assessment, risk management and risk communication but the other factors that can be taken into account include "societal, economic, traditional, ethical and environmental factors and the feasibility of controls." (Recital 19). National organisations may also conduct risk analysis.

²⁶² In the event of scientific uncertainty, the precautionary principle will apply.

²⁶³ [1992] OJ L 228/24. This Directive was later repealed and replaced by Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, [2001] OJ L11/4.
²⁶⁴ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs [2004] OJ L139/1.

²⁶⁵ Annex 1, Part A (II) (5)(c).

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11.4 Organic production

The essential difference between organic and conventional farming is that conventional farming relies on chemical intervention to fight pests and weeds and provide plant nutrition. That means synthetic pesticides, herbicides, and fertilisers. Organic production is a cultivation method that aims the production of food using natural substances and processes like biodiversity and composting instead to produce healthy, abundant food. In this way, organic production has a more limited environmental impact promoting responsible use of energy and natural resources and the maintenance of soil fertility, among other benefits. Miscellaneous organic materials, including animal manure, compost, grass turf, straw, and other crop residues, are applied to fields to improve both soil structure and moisture-holding capacity and to nourish soil life, which in turn nourishes plants. Biological pest control is achieved through preventive methods, including diversified farming, crop rotation, the planting of pest-deterrent species, and the use of integrated pest management techniques. Additionally, organic production rules encourage a high standard of animal welfare and require farmers to meet the specific behavioural needs of animals. Organic production is a fast-growing area in EU agriculture, which is a direct result of increased consumer interest in organic products. Also, the European Commission aims to achieve an increase in organic agriculture to 25% of total farmland by 2030 as part of the Farm to Fork (F2F) strategy.

The EU sets out a number of rules and regulations governing the production, distribution and marketing of organic products in the EU. They are designed to provide a clear structure to produce organic goods across the whole of the EU and to satisfy consumer demand for trustworthy organic products whilst providing a fair marketplace for producers, distributors and marketers. The first Regulations regarding organic production were related to general guidelines for organic production and labelling of organic products. Regulation 2092/91²⁶⁷ was repealed by the Regulation 834/2007.²⁶⁸ Regulation 889/2008²⁶⁹ was published to provide detailed rules for the implementation of the Regulation 834/2007.

However, in response to the challenges posed by the rapid expansion of organic production, and to provide an effective legal framework for the industry, the EU passed new legislation relating to the organic sector. For example, Regulation 2018/848 deals with the establishment of organic production principles and rules, certification procedure

²⁶⁷ Council Regulation (EEC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs, [1991] OJ L198/1.

²⁶⁸ Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91, [2007] OJ L189/1. Subsequently itself repealed by Regulation 2018/848.

²⁶⁹ Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control, [2008] OJ L250/1.

as well as the labelling and advertising claims and it entered into force on 1 January 2022 (repealing the Regulation 834/2007).²⁷⁰ In contrast to previous regulations:

- it strengthened the control system, helping to build further consumer confidence in the EU organic system;
- it sets out new rules for producers which will make it easier for smaller farmers to convert to organic production and new rules on imported organics to ensure that all organic products sold in the EU are of the same standard; and
- it expands the range of products that can be marketed as organic.

The legislation is supported by an Action Plan for the Development of Organic Production in the EU which was launched by the European Commission in March 2021.²⁷¹

More specifically, Regulation (EU) 2018/848 applies to every company that participates in the activities of any stage of production, manufacture and distribution of the following products:

(a) live or unprocessed agricultural products, including seeds and other plant reproductive material

b) processed agricultural products for use as food

c) animal feed

Examples of the changes made under the new organic legislation are listed below:

- a greater range of products that can be marketed as organic. This Regulation extends the scope of existing legislation on the production and labelling of organic products [regulation (EC) no. 834/2007] to cover products closely related to agriculture.
- the principles on which Organic Production and Organic Agriculture must be based are defined.
- revised rules for animal organic production, considering the experience gained, and established production requirements for new species, such as rabbits.
- new rules for producers which will make it easier for smallholder farmers to convert to organic production
- a strengthening of the control system, helping to build further consumer confidence in the EU organics system;
- specific conditions have been established that a product must meet to be imported from a non-EU country to be sold in the EU as organic.

This Regulation mentions that although methods such as tillage, cultivation practices and crop rotation can be used to increase yields in an organic production

²⁷⁰ Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 [2018] OJ L 150/1.

²⁷¹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on an action plan for the development of organic production COM (2021) 141. <u>https://agriculture.ec.europa.eu/farming/organic-farming/organic-action-plan_en</u>.

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system, they do not always suffice regarding meeting the nutritional needs of plants. So, in organic production, farmers can use fertilisers and soil improvers that have been authorized according to Article 24 to improve soil fertility only to the extent necessary. Regarding these products, operators should keep a register to guarantee that the foodstuff and related products have been produced in accordance with organic principles.

Regulation 2018/848 does not make any reference regarding the methods of crop irrigation in organic agriculture. However, there may be some sustainable agricultural approaches, such as the use of treated wastewater for crop irrigation. It is well known that the agricultural sector is the largest user of all water sources, so treated wastewater could be an applicable option for crop irrigation. This method could not only save drinkable freshwater but also reduce fertiliser dependence. However, more study is required regarding this irrigation method to have better knowledge. While there is no explicit mention of reclaimed water usage in organic production, it could remain a viable option as long as it aligns with the overarching principles of the Regulation. This includes preventing contamination with substances not authorized for use in organic production. So, further investigation is needed on the possibility of using reclaimed water for irrigation of organic crops.

Other legislation in this area includes Commission Implementing Regulation 2021/1165 authorising certain products and substances for use in organic production and establishing their lists.²⁷² So, for example, fertilisers, soil conditioners and nutrients are dealt with in Article 2 and Annex II,²⁷³ with the latter providing that they must comply with the relevant EU and national legislation on these substances (i.e. Regulation 2019/1009, the Fertiliser Regulation discussed above) and legislation on animal by-products (particular reference is made to Regulation 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and Annexes V and XI of the Commission Implementing Regulation, Regulation 142/2011).²⁷⁴ Annex II also specifies more restrictive conditions for specific products that could be used as fertiliser e.g. farmyard manure coming from factory farming is excluded from use.

²⁷² [2021] OJ L 253/13.

²⁷³ Article 2 of Regulation (EU) No 2021/1165 states: "Only the products and substances listed in Annex II to this Regulation may be used in organic production as fertilisers, soil conditioners and nutrients for plant nutrition, litter improvement and enrichment or algae cultivation or husbandry environment of aquaculture animals, provided that they are compliant with the relevant provisions of Union law... and, where applicable, in accordance with national provisions based on Union law." This Regulation also includes other types of products and substances authorised for use in organic farming.

²⁷⁴ Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal byproducts and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that, [2011] OJ L54/1.

Regulation 2021/1165 divides products and substances into different categories based on the corresponding use. A list of authorised substances or products for use in organic production for each category is given in the Annexes, as described below:

- Active substances (Article 1, Annex I)
- Fertilisers, soil conditioners and nutrients (Article 2, Annex II)
- Non-organic feed material of plant, algal, animal or yeast origin or feed material of microbial or mineral origin (Article 3, Part A of Annex III)
- Feed additives and processing aids (Article 4, Part B of Annex III)
- Products for cleaning and disinfection (Article 5, Parts A, B, C of Annex IV)
- Food additives and processing aids (Article 6, Part A of Annex V)
- Non-organic agricultural ingredients to be used for the production of processed organic food (Article 7, Part B of Annex V)
- Processing aids for the production of yeast and yeast products (Article 8, Part C of Annex V)
- Products and substances for use in organic production of wine (Article 9, Part D of Annex V)
- Procedure to grant specific authorisations for the use of products and substances in certain areas of third countries (Article 10, Annex VI)

There is a transitional period for the Implementing Regulation 2021/1165 for certain points. Upon entry into force on the 1st of January 2022 it repealed the Regulation 889/2008, however, Annex VII of this latter Regulation regarding the list of allowed products for cleaning and disinfection of buildings and installations for, as well as Annex IX regarding the list of allowed ingredients of agricultural origin in processed organic food production which have not been produced organically continue to apply until 31st of December 2023.

A fertilising product can be used in organic production only if its ingredients are listed in Annex II and fulfil the specific conditions included therein (**Table 4**). These specific conditions could be more restrictive than those applied by the relevant legislative framework related to the market placement of the products. The Regulation undergoes constant amendments to update the list of authorised substances and products.

Table 4. Example of two entries in Annex II of Regulation 2021/1165. The fertilisers, soil conditioners and nutrients authorised for use in organic production are listed in Annex II.

Annex II of Regulation EE 2021/1165	
Name	Description, specific conditions and limits
Algae and algae products	as far as directly obtained by: (i) physical processes including dehydration, freezing and grinding (ii) extraction with water or aqueous acid and/or alkaline solution (iii) fermentation only from organic or collected in a sustainable way in accordance with point 2.4 of Part III of Annex II to Regulation (EU) 2018/848
Products or by-products of animal origin as below: Blood meal Hoof meal Horn meal Bone meal or degelatinised bone meal Fish meal Meat meal Feather, hair and skin meal ('chiquette') Wool Fur (1) Hair Dairy products Hydrolysed proteins (2)	 (1) Maximum concentration in mg/kg of dry matter of chromium (VI): not detectable (2) Not to be applied to edible parts of the crop

In conclusion, a fertilising product can be used in organic production if a) it is compliant with the relevant Union and national legislative framework, b) its ingredients are listed in Annex II of Regulation 2021/1165, and c) it fulfils the specific conditions included in Annex II of Regulation 2021/1165. Fertilising products, plant protection products and soil improvers derived from substances that have been authorized for use in organic agriculture pursuant to the Regulation 2018/848 can be labelled with phrases or logos that indicate their eligibility in organic production.

There are also private schemes that certify products as suitable for use in organic production. Products can be certified by a certification body like Ecocert or CAAE to attest their compliance to the EU organic regulation. However, national competent authorities also need to ascertain that the product is suitable for use in organic production, so required documentation must be submitted for evaluation. If the product is deemed suitable, it is listed in the respective registry of the ministry and the label can mention the suitability for use in organic production.

12ANNEX VI – DETAILED DESCRIPTION OF THE POLICY CONTRIBUTION

Policies and laws do not stand still. P2GreeN activities are occurring in a complex evolving context – one where multiple different issues and considerations are creating fresh challenges and opportunities on a daily basis. Policies are being developed and reviewed across the levels, but in particular at the EU level, that are directly relevant to P2GreeN activities. The key evolving EU policies of relevance to P2GreeN²⁷⁵ are the European Green Deal²⁷⁶ and the (second) Circular Economy Action Plan.²⁷⁷

As a multifaceted approach, the Green Deal encompasses the foundations for a range of other policies, including elements on biodiversity, farm to fork, circular economy etc. Further, although not the focus of a separate official policy document or a separate discussion here,²⁷⁸ considerations of sustainability (and also resilience) and the UN's Sustainable Development Goals²⁷⁹ are embedded across the Green Deal²⁸⁰ and environmental policies more generally. It is also important to note that, as these and other policies are evolving and in the process of being legislated for and implemented more generally, (i) it is essential to monitor these fields for new developments and (ii) it is worth noting some of the legal commitments that have already arisen. P2GreeN activities will both be affected by, and also have the opportunity to inform and shape, these policy developments. To this end, the following sections briefly outline the key elements of the European Green Deal and the Circular Economy Action Plan.

12.1 The European Green Deal (EGD)

Human life has made its mark upon the Earth through greenhouse gas (GHG) emissions, intense agriculture to feed an ever-growing population, over-consumption, and through the gradual chipping away of the environment. We face numerous crises, included biodiversity and climate crises, alongside growing populations (with increased food and energy needs, amongst others), widescale human migration and political instability. These pose significant challenges on a global scale, requiring consolidated responses – to address both the impacts and causes of these crises. The EU's primary response to these challenges is through the EGD presented in December 2019 by the European Commission, following considerable political challenges. It is an evolving work-in-progress, with individual policies and pieces of legislation gradually being developed.

²⁷⁵ Some other areas that are also under development are flagged above where they related to existing policies, e.g. soil, the CAP, nature restoration and pesticides.

²⁷⁶ 'The European Green Deal', Communication from the Commission, COM/2019/640 final, <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1588580774040&uri=CELEX%3A52019DC0640</u>.

²⁷⁷ 'A new Circular Economy Action Plan For a cleaner and more competitive Europe', Communication from the Commission, COM/2020/98 final.

²⁷⁸ This may be considered further at the full legislative report stage.

²⁷⁹ 'EU 'whole-of-government' approach: The EU comprehensive EU approach towards implementing the UN's 2030 Agenda for Sustainable Development', <u>https://commission.europa.eu/strategy-and-policy/sustainable-development-goals/eu-whole-government-approach_en</u>. The importance of the SDGs is flagged across the European Commission's policy areas.

²⁸⁰ E.g., 10 of the 17 SDGS are considered to be encompassed within the Green Deal, see ibid.

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The EGD 'aims to transform the EU into a fair and prosperous society, with a modern, resource-efficient and competitive economy where there are no net emissions of greenhouse gases in 2050 and where economic growth is decoupled from resource use. It also aims to protect, conserve and enhance the EU's natural capital, and protect the health and well-being of citizens from environment-related risks and impacts. At the same time, this transition must be just and inclusive....'²⁸¹

In order to succeed, the Green Deal has identified overarching policy areas under which policy, legislation, schemes and projects are to operate.

The EGD has identified eight policy 'regimes':²⁸² a zero-pollution ambition; the preservation and restoration of ecosystems and biodiversity; the Farm-to-Fork strategy; sustainable and smart mobility; environmentally and energy friendly building and renovation; a circular economy initiative; clean, affordable and secure energy; and an enhanced climate ambition. Underpinning these regimes is the need for adequate financing and the concept of a 'Just Transition', which will be explored within the framework of policy concerns. It is important to reiterate that some strategies, legislation, and action plans have been published, while others are either proposed or undergoing a feedback process. This increases the significance of monitoring the EGD's evolution and also provides significant opportunity for feeding into the development, including through evidence provided from projects such as P2GreeN.

However, due to its considerable complexity and wide scope, a full evaluation is neither feasible nor desirable within this Scoping Review. Therefore, this section will sketch out the main pillars of the EGD and flag some of the main areas of relevance to P2GreeN and similar activities. The key components will be highlighted, along with potential issues or concerns, and elements that merit further engagement at a later stage.

Within the EGD, there are several areas that are of particular relevance to P2GreeN activities, not simply those regarding food production *per se*, but also, for instance, those that address the use of waste, emission of GHGs and pollutants.

12.1.1 Climate Ambition

The EGD's climate ambition can be defined as the all-encompassing desire to reduce EU GHG emissions by 50-55% by 2030, and to curb emissions to net zero by 2050. It builds on the commitments in the Paris Agreement. This necessitates policy and statutory innovation and change in every sector. A European Climate Law,²⁸³ which came into effect on the 29th of July 2021, is the *principium* of the aforementioned goal of net-zero emissions by 2050, by enshrining it within statute. It imposes legally binding

²⁸¹ 'The European Green Deal', p.2.

²⁸² E.g., Figure 1 in the European Green Deal.

²⁸³ Regulation (EU) 2021/1119 of the European Parliament and of the Council of 30 June 2021 establishing the framework for achieving climate neutrality and amending Regulations (EC) No 401/2009 and (EU) 2018/1999, [2021] OJ L243/1.

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obligations on both the EU overall and Member States individually to contribute to this reduction. The Climate Law builds on the EGD and encompasses a range of measures to help achieve its objectives – included within its substantive provisions or operating in parallel and referred to in its recitals. These include: the enactment of a 55% reduction (as compared to 1990) of net GHG emissions by 2030;²⁸⁴ acknowledgement of the importance of carbon sinks,²⁸⁵ reflected in the subsequent amendment of legislation to enhance the use of land in this manner;²⁸⁶ the establishment of the European Scientific Advisory Board on Climate Change;²⁸⁷ a process for setting targets for 2040;²⁸⁸ a stronger coherence throughout Union policies to ensure climate neutrality;²⁸⁹ recognition of the need for the revision of legislation including elements such as land use and energy taxation²⁹⁰ and the introduction of a Carbon Border Adjustment Mechanism for selected sectors;²⁹¹ and stronger provisions on adaptation to climate change.²⁹² Developments can already be seen, e.g., through a proposal for a new Energy Taxation Directive²⁹³ and the adoption of the Carbon Border Adjustment Mechanism Regulation.²⁹⁴

12.1.2 Farm-to-Fork²⁹⁵

With agricultural resilience and stability under threat, the question of how to mitigate the effects on our food systems and as well as adapt to already disruptive weather patterns has come under the EU policy and legislation microscope. Agriculture is a leading source of GHG emissions within the EU, standing at 11% as of 2022,²⁹⁶ and

²⁸⁴ Article 4(1).

sector en#:~:text=Environment%20Agency%2C%202022-

²⁸⁷ Article 12.

²⁹⁴ Regulation (EU) 2023/956 of the European Parliament and of the Council of 10 May 2023 establishing a carbon border adjustment mechanism, [2023] OJ L130/52. Various provisions come into effect gradually over a period between 2023 and 2026. This was provided for in 'The European Green Deal', p.5. ²⁹⁵ 'The European Green Deal', s.2.1.6.

²⁹⁶ European Environment Agency, 'Annual European Union Greenhouse Gas Inventory 1990–2020 and Inventory Report 2022: Submission to the UNFCCC Secretariat' <Submission to the UNFCCC Secretariat> accessed 29 June 2023, p.IX.

²⁸⁵ Article 4(1).

²⁸⁶ Regulation (EU) 2023/839 of the European Parliament and of the Council of 19 April 2023 amending Regulation (EU) 2018/841 as regards the scope, simplifying the reporting and compliance rules, and setting out the targets of the Member States for 2030, and Regulation (EU) 2018/1999 as regards improvement in monitoring, reporting, tracking of progress and review, [2023], OJ L243/1. See for instance, <u>https://climate.ec.europa.eu/eu-action/land-use-</u>

[,]EU%20rules%20on%20land%20use%2C%20land%20use%20change%20and%20forestry,the%20period %20up%20to%202030.

²⁸⁸ Article 4(3), (4) and (5).

²⁸⁹ E.g. Article 5(3).

²⁹⁰ Recital 26.

²⁹¹ Recital 18.

²⁹² E.g. Article 5.

²⁹³ Proposal for a COUNCIL DIRECTIVE restructuring the Union framework for the taxation of energy products and electricity (recast), COM/2021/563 final. This continues to go through the EU legislative processes: <u>https://www.europarl.europa.eu/legislative-train/spotlight-JD22/file-revision-of-the-energy-taxation-directive</u>. This was provided for in 'The European Green Deal', p.5.

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also contributes to biodiversity loss and further GHG emissions through the transportation, processing, packaging, and under-consumption of foodstuffs and other agricultural products. The provision of food which is environmentally sound and affordable while maintaining a high nutraceutical score is more important than ever. Hence, the EGD focusing on 'designing a fair, healthy and environmentally-friendly food system'.²⁹⁷ The main answer has been the Farm-to-Fork strategy,²⁹⁸ flagged in the EGD and highlighted in advance as seeking to reduce the use of fertilisers and antibiotics, as well as contributing to achieving a circular economy.²⁹⁹

Thus, the Farm-to-Fork strategy aims to tackle a number of problems which can reduce the nutritional and health value of food, as well as have negative biodiversity and environment implications, such as: nutrient leakage, chemical pesticide pollution, antimicrobial resistance, plant and seed quality, food waste prevention, and sustainable food processing and distribution, all the while ensuring that the key principles enshrined within the European Pillar of Social Rights³⁰⁰ are honoured. The strategy also aims to reduce the use of chemical pesticides by 50% by 2050, reduce nutrient loss by 50% while ensuring no deterioration in soil fertility, reduce the usage of fertilisers by 20% by 2030, reduce the sale of antimicrobials for farmed animals and in aquaculture by 50% by 2030, boost the development of organic production, and undertake a revision of food labelling.³⁰¹ To support and inform these changes, the EU is further expanding its data collection practices and has proposed developing the Farm Sustainability Data Network, or FSDN, which will collect further data relevant to agricultural activities and the Farm to Fork and Biodiversity Strategies' targets and other sustainability indicators, as well as providing advisory services.³⁰²

The Strategy which addresses the challenge of creating a sustainable food system is a central aspect of the EU's contribution to the realization of the United Nations' Sustainable Development Goals, especially Sustainable Development Goal 2 on Zero Hunger. So, in terms of objectives these include the reduction in the environmental impact of the EU food system which would become more resilient whilst ensuring food security. Among the twenty-seven actions proposals to realize the Farm-to-Fork Strategy, those of relevance to the P2Green project include:³⁰³

²⁹⁷ 'The European Green Deal', s.2.1.6.

²⁹⁸ A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system, COM (2020)381. ²⁹⁹ Ibid, p.12.

³⁰⁰ <u>https://ec.europa.eu/social/main.jsp?catId=1226&langId=en.</u>

³⁰¹ Farm to Fork Strategy, pp.9-11.

³⁰² Farm to Fork Strategy, p.17; and COMMISSION STAFF WORKING DOCUMENT STAKEHOLDER CONSULTATION - SYNOPSIS REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Council Regulation (EC) No 1217/2009 as regards conversion of the Farm Accountancy Data Network into a Farm Sustainability Data Network 2022.

³⁰³ Farm to Fork Strategy, Annex.

- A revision of the Sustainable Use of Pesticides Directive³⁰⁴ to reduce use and risk and dependency on pesticides and enhance Integrated Pest Management; this would be accompanied by a proposal to revise the Regulation on Pesticides Statistics to reduce gaps in data on pesticide use.³⁰⁵
- A revision of the Regulations implementing the Plant Protection Products framework to allow placing on the market of plant protection products containing biological active substances.
- A revision of the legislation on Food Contact Materials to improve food safety and to reduce the environmental footprint of the sector.

More generally, to promote policy coherence, the Commission suggested a proposal to develop a legislative framework for a sustainable food system which would allow all those involved in food production:³⁰⁶

... to transform their production methods more quickly, and make the best use of nature-based, technological, digital, and space-based solutions to deliver better climate and environmental results, increase climate resilience and reduce and optimize the use of inputs (e.g., pesticides, fertilisers).

The National Strategic Plans, which now form a central element of the CAP as noted above, will have to address how to meet the need to reduce the excessive use of nutrients, such as N and P in the environment. These aspects of the National Strategic Plans will be used by the Commission to "develop with Member States an integrated nutrient management action plan to address nutrient pollution at source and increase the sustainability of the livestock sector" which would address such matters as precise fertilisation techniques and the recycling of organic waste into renewable fertilisers.³⁰⁷ This is now addressed in Article 15(4)(g) of Regulation 2021/2115 on National Strategic Plans which provides:³⁰⁸

³⁰⁴ Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides [2009] OJ L 309/71.

³⁰⁶ Farm to Fork Strategy, p. 79. See European Commission, Directorate-General for Research and Innovation, Group of Chief Scientific Advisors, *Towards a sustainable food system – Moving from food as a commodity to food as more of a common good* (Publications Office, 2020) available at <u>https://data.europa.eu/doi/10.2777/282386</u>; SAPEA *A Sustainable Food System for the European Union* (Evidence Review Report No 7, 2021) available at <u>sustainable-food-system-report.pdf (sapea.info)</u> and Bock, A., Bontoux, L. and Rudkin, J., *Concepts for a sustainable EU food system*, (Publications Office of the EU, Luxembourg).

³⁰⁷ Farm to Fork Strategy, p. 7.

³⁰⁸ Council Directive 91/689/EEC of 12 December 1991 on hazardous wasteRegulation (EU) 2021/2115 of the European Parliament and of the Council of 2 December 2021 establishing rules on support for strategic plans to be drawn up by Member States under the common agricultural policy (CAP Strategic Plans) and

³⁰⁵ This latter proposal has been acted on with the adoption of Regulation 2022/2379 on statistics on agricultural input and output, [2022] OJ L 315/1 as part of the Strategy for Agricultural Statistics for 2020 and beyond.

The farm advisory services shall be adapted to the various types of production and farms and shall cover at least the following:

g) sustainable management of nutrients, including at the latest as from 2024 the use of a Farm Sustainability Tool for Nutrients, which is any digital application that provides at least:

(i) a balance of the main nutrients at field scale;

(ii) the legal requirements on nutrients;

(iii) soil data, based on available information and analyses;

(iv) data from the integrated administration and control system (IACS) relevant for nutrient management.

Sustainability may also be enhanced by the development of bio-based products, which could reduce dependency on pesticides, and in the Farm-to-Fork Strategy the Commission indicated that it would "put forward an Action Plan on organic production" that would "help Member States stimulate both supply and demand for organic products." ³⁰⁹

12.1.3 Circular Economy

A circular economy, if successful, would extend the life of products through recycling, repair, leasing, reuse, or transfiguration.³¹⁰ To illustrate, faeces or sludge can be transfigured into nutrient rich fertiliser, or urine can be transformed to a nutrient rich water and applied to farms in countries affected by drought and poor soil quality, decreasing the burden on water systems. A major aspect of the EGD is to ensure Europe's competitiveness in a global market while incentivizing a European and global diversion to a greener, non-polluting and energy-efficient future, including through: the right to repair, moving to sustainable products, food waste inhibition, and minimization of harmful chemicals in waste and the reduction of incineration amongst other initiatives.³¹¹ Additionally, with many resources being of a finite nature, resource stability and replacement becomes more crucial than ever. Resource stability is at the heart of resource efficiency, wherein existing resources are made to be more productive, while also enabling economic resilience. The circular economy is discussed further in the section below on the 'Circular Economy Action Plan'.

³¹⁰ E.g. 'The European Green Deal', pp.7-8.

financed by the European Agricultural Guarantee Fund (EAGF) and by the European Agricultural Fund for Rural Development (EAFRD) and repealing Regulations (EU) No 1305/2013 and (EU) No 1307/2013, [2021] OJ L435/1.

³⁰⁹ Farm to Fork Strategy, p. 8. See Moschitz, H, et al. "How can the EU Farm to Fork strategy deliver on its organic promises? Some critical reflections" (2021) 20(1) *EuroChoices* 30.

³¹¹ E.g. ibid, pp.7-8 and 11.

12.1.4 Biodiversity³¹²

Biodiversity is interwoven with ecosystems, with the former relating to the variety of flora and fauna in a particular area, and with the latter referring to a natural environment which includes the aforementioned plant and animal life. Biodiversity allows for healthy ecosystems, from the deep ground and mycorrhizal networks, to the invertebrates to the various vertebrates on our continent and beyond. Destabilized ecosystems through anthropocentric activities do not recover easily. Algal blumes caused by agricultural N and P run-off, wildfires, pollution can all cause the health of humans, animals, plants and fungi to disintegrate. To combat this, the EU has planned out the Biodiversity Strategy 2030³¹³ under the EGD, aiming to build resilience against the impacts of climate change, forest fires, food insecurity, and disease outbreaks.³¹⁴ Existing Natura 2000 areas will be expanded, with a new governance framework which will work to foster a deeper respect for our shared natural collective within both the public sector and various industry sectors. Elements are seen already with the proposed Nature Restoration Law discussed above.

12.1.5 Zero Pollution Ambition³¹⁵

Pollution is a large cause of premature deaths in humans, and it reduces the ability of ecosystems to operate as they should.³¹⁶ Building on the EGD, the Zero Pollution Action Plan,³¹⁷ focused primarily on the period of 2021-2030, aims to curb pollution of air, water, and soil within Europe. Based on the precautionary principle and on preventative action, it focusses on the need for a more effective 'zero pollution hierarchy' to deliver the zero-pollution ambition.³¹⁸ The Plan can be considered to have three major areas: the prevention of pollution at all stages, a chemical strategy, and measures to eliminate and remediate existing pollution of water and soils. To achieve this, the EU will revise measures to reduce pollution through legal frameworks on public health, air pollution, biodiversity, chemical management, environmental protection, and more - with numerous elements overlapping with strategies already mentioned in the context of the EGD or below regarding the CEAP. Crucially, the reviews of the UWWT and Sewage Sludge Directives are highlighted, with the importance of the treatment and reuse of substance being highlighted for 'more circular, less polluting farming', while flagging that these reviews will 'address emerging pollutants such as microplastics and micropollutants, including pharmaceuticals.³¹⁹ At the same time, data collection, research and innovation are flagged as essential for developing alternative, less-polluting, methods and products,

³¹⁵ 'The European Green Deal', section 2.1.8.

³¹⁸ Ibid, pp.3-4.

³¹² Ibid, section 2.1.7.

³¹³ 'EU Biodiversity Strategy for 2030 Bringing nature back into our lives', Communication from the Commission, COM/2020/380 final.

³¹⁴ E.g. <u>https://environment.ec.europa.eu/strategy/biodiversity-strategy-2030_en</u>.

³¹⁶ Philip J Landrigan and others, 'The Lancet Commission on Pollution and Health' (2018) 391 The Lancet 462.

³¹⁷ Pathway to a Healthy Planet for All EU Action Plan: 'Towards Zero Pollution for Air, Water and Soil', Communication from the Commission, COM(2021) 400 final.

³¹⁹ Ibid, pp.8-9.

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as well as in addressing pollution – this includes in fields relevant to agriculture and considerations of soil health.³²⁰ Concurrently, the polluter pays and rectification at source principles will also remain a staple of EU mitigation technique, applying to polluters within industry and agriculture and consumers.³²¹

12.1.6 Affordable Energy³²²

With 75% of the EU's GHG emissions resulting from the production and use of energy,³²³ the EU has engaged in a series of actions to ensure that the EU is within reach of its 2030 and 2050 targets: a hydrogen strategy,³²⁴ energy system integration strategy,³²⁵ an offshore renewable energy strategy,³²⁶ a methane strategy³²⁷ and a revised Trans-European Networks for Energy policy.³²⁸ With destabilizing events such as Russia's military attack on Ukraine and unstable energy prices, ensuring a stable and renewable source of energy for the Union has never been shown to be more paramount, particularly considering the nature of energy sources being primarily finite. The fewer resources there are, the more difficult and climate intensive will their retrieval be. With a smaller pool of resources, monopolization of certain fuel sources and their importance in various forms of industrial production, the cost of fuel and therefore energy is bound to increase.

12.1.7 Conclusion

Overall, the EGD provides a multifaceted roadmap to achieve its aims and foster a sustainable future for the EU and beyond. Several of its focus points are directly relevant to P2Green activities and products, meriting further examination in the full legislative report. This also raises the need to consider the cross-cutting elements regarding financing and a just transition. Some elements are already significantly developed at this point, but many are at the early stages and will continue to evolve.

323 Ibid.

³²⁰ Ibid, p.9.

³²¹ E.g., ibid, pp. 4-5 and 10-12.

³²² E.g. 'The European Green Deal', section 2.1.2.

³²⁴ A hydrogen strategy for a climate-neutral Europe, Communication from the Commission, COM/2020/301 final.

³²⁵ Powering a climate-neutral economy: An EU Strategy for Energy System Integration, Communication from the Commission, COM/2020/299 final.

³²⁶ An EU Strategy to harness the potential of offshore renewable energy for a climate neutral future, Communication from the Commission, COM(2020) 741 final.

³²⁷ EU strategy to reduce methane emissions, Communication from the Commission, COM/2020/663 final. This has been followed by a Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on methane emissions reduction in the energy sector and amending Regulation (EU) 2019/942, COM/2021/805 final, which at the time of writing was in the final stages of adoption by the EU institutions.

³²⁸ Regulation (EU) 2022/869 of the European Parliament and of the Council of 30 May 2022 on guidelines for trans-European energy infrastructure, amending Regulations (EC) No 715/2009, (EU) 2019/942 and (EU) 2019/943 and Directives 2009/73/EC and (EU) 2019/944, and repealing Regulation (EU) No 347/2013, [2022] OJ L152/45.

12.2 The Circular Economy Action Plan

Around half of all greenhouse gas emissions and 90% of biodiversity loss and water stress come from the extraction and processing of resources, while waste is not managed efficiently leading to pollution as well as potential resource waste.³²⁹ Additionally, climate change is becoming particularly challenging to the agricultural sector; erratic weather patterns elicit heat stress or cold snaps have implications for pest die-off as well as crop health. Additionally, with the global population set to only rise, food systems are bound to be strained. It is time to look for low-waste yet high-yield solutions.

As already explained, P2GreeN's goal is to extract value from human waste in the form of nutrients and water. The very core of the project is circular, with valuable inputs re-entering the agricultural sector as opposed to being lost, while waste is minimized. Therefore, it is conceivable that Circular Economy Action Plan will impact upon the project implementation. Under the Action Plan, the EU endeavours to develop a more sustainable economic framework to support the Green Deal's carbon neutrality by 2050 objective.³³⁰ The Circular Economy Action Plan is the first EU plan to consider large-scale legislative innovation for the introduction of circularity by-design, rather than as an afterthought. The Action Plan is separated into three interlinked parts:

- (i) A sustainable product framework;³³¹
- (ii) Key value chains and products;³³² and
- (iii) Schemes for less waste and higher value.³³³

The purpose of this section will be to outline briefly the Action Plan in light of P2GreeN's alignment with a circular economy, while also identifying key areas which are of interest to the particularities of the P2GreeN project.

12.2.1 Sustainable Product Framework

The sustainable product framework, which may be considered the crux of the action plan outlines an initiative for circularity and sustainability of products produced and consumed within the EU as a vehicle for higher-quality and environmentally friendly produce. Furthermore, a clear link is established between product information and consumer trust and, importantly, choice. It is worth highlighting that seven of the 35 action points in the CEAP fall directly within the sustainable policy framework heading, including most fundamentally the creation of a 'legislative proposal for a sustainable product policy

³²⁹ Communication, 'A new Circular Economy Action Plan For a cleaner and more competitive Europe' COM [2020] 98 final, 2

³³⁰ Commission, 'The European Green Deal' (Communication) COM (2019) 640 final, ch 1, page 2 ³³¹ COM [2020] 98 final (n 1) 3

³³² Ibid., 6

²²² IDIO., O

³³³ Ibid., 12

initiative'. In conjunction with a review of the earlier Ecodesign Directive,³³⁴ this has led to a Proposal for an Ecodesign for Sustainable Products Regulation (ESPR).³³⁵ This sets requirements for various product groups to improve their environmental impact and merits close monitoring.

12.2.2 Key Products and Value Chains

In order to achieve a circular economy, various value chains are highlighted which are of particular concern and generate challenges pertaining to material use and waste throughout a product's lifecycle. In order to achieve economic circularity, these lifecycles will have to be altered to allow for reuse, remanufacturing, or recycling. Of particular concern to circularity and by extension climate change mitigation, are the following: electronics, ICT, batteries, vehicles, packaging, plastics, textiles, construction, buildings, food, water and nutrients.³³⁶ While electronics, ICT, packaging, construction and buildings have some relevance to P2GreeN, those of most significance are clearly nutrients, food and water. Consequently, this sub-section outlines some of the key considerations relevant to these three focus points.

Water as a resource is being depleted; with all components of the global water cycle having been impacted by climate change, e.g., with changing precipitation patterns impacting upon how much annual or seasonal precipitation a region receives.³³⁷ Furthermore, empirical evidence supports the conclusion that climate change has affected global patterns of soil moisture and land surface aridity.³³⁸ Critically, hydrological drought can result in shortages of drinking water, while agricultural drought can threaten food production, damage crops, and decrease crop yield.³³⁹ This has consequences on the price of produce and availability of foodstuffs. This has already been observed in Europe, with Southern Regions facing water stress conditions which result in all possible water being used, as well as non-renewable groundwater.³⁴⁰ In order to counteract this and ensure food security within a changing environment, the Commission has noted that it will aim to "ensure the sustainability of renewable bio-based materials, including through actions following the Bioeconomy Strategy Plan and Action Plan".³⁴¹ The Action Plan directly considers the Water Reuse Regulation, which has entered into force as of June

³³⁴ Council Directive (EC) 2009/125/EC of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products, [2009] OJ L 285/10.

³³⁵ Proposal and Annexes for a Regulation establishing a framework for setting ecodesign requirements for sustainable products and repealing Directive 2009/125/EC, COM/2022/142 final.

³³⁶ Ibid., 7-12

³³⁷ Caretta, M.A., A. Mukherji, M. Arfanuzzaman, R.A. Betts, A. Gelfan, Y Hirabayashi, T.K. Lissner, J. Liu, E. Lopez Gunn, R. Morgan, S. Mwanga and S. Supratid, 'Climate Change 2022: Impacts, Adaptation and Vulnerability' in H.O. Pörtner and others (eds), *Sixth Assessment Report of the Intergovernmental Panel on Climate Change* (Cambridge University Press 2022), ch 4.1

³³⁸ Ibid ³³⁹ Ibid

 ³⁴⁰ Bisselink B and others, 'JRC Technical Report: Climate change and Europe's water resources' (Luxembourg Publications Office of the European Union 2020) ch 3.2
 ³⁴¹ COM (2020) 98 final (n 1), 12.

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26 2023.³⁴² While the date of implementation does not allow for much interpretation, the Regulation has standardized minimum water quality requirements for the safe reuse of treated urban wastewater for use in agricultural irrigation, the monitoring requirements and risk management provisions for assessment of health risks, permitting requirements and provisions on transparency.³⁴³ P2GreeN will have to monitor how this legislation is interpreted by the CJEU in order to ensure alignment. It also once more highlights the relevance of the Action Plan to P2GreeN activities.

The Circular Economy Action Plan only briefly mentions the development of the Integrated Nutrient Management Action Plan as a response to inefficiencies within the nutrient cycle.³⁴⁴ While the plan has undergone a public consultation and a Commission adoption is expected, how the INMAP will manifest is uncertain. What is certain, however, is that nitrogen and phosphorus, being key to the maintenance of biological productivity and environmental health, will be considered. Importantly, the call for evidence explicitly mentions that the Action Plan will complement the Zero Pollution Action Plan for Air, Water and Soil and will build on legislation such as the Sewage Sludge Directive.³⁴⁵ Thereby, a direct link from 'fork to farm' (and thereby food) has been herein established, and vice versa.

Finally, within this heading, it is worth flagging that one of the value chains highlighted is that of packaging and a key action point is a 'Review to reinforce the essential requirements for packaging and reduce (over)packaging and packaging waste'. This has led to a Proposal for a Packaging and Packaging Waste Regulation (PPWR)³⁴⁶ to minimize packaging waste and promote the use of environmentally friendly alternatives.

12.2.3 Preventative Waste Policies

As discussed previously, improved fertilisers and waste in themselves create a waste issue that also impacts on the potentiality of a future circular economy. The Circular Economy Action Plan has implemented policy and promised future legislative action in order to counter waste prospectively, such as waste reduction targets, implementation of responsibility requirements for producers and the harmonization of different waste collection streams.

In a related matter, the Commission has noted that its plan to ensure credence of secondary raw materials by supporting the development of solutions for high-quality sorting and removal of contaminants from waste as well as methodologies for the

 ³⁴² Regulation (EU) 2020/741 of the European Parliament and of the Council of 25 May 2020 on minimum requirements for water reuse, [2020] OJ L 177/32.
 ³⁴³ Ibid.

 ³⁴⁴ 'A New Circular Economy Action Plan for a Cleaner and More Competitive Europe', 12.
 ³⁴⁵ Ibid.

³⁴⁶ Commission, 'Proposal for a Regulation of the European Parliament and of the Council on packaging and packaging waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904, and repealing Directive 94/62/EC, COM (2022) 677 final.

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minimization of substances which pose problems to health or the environment in recycled materials while co-operating with the industrial sector to develop harmonized systems for the tracking of substances, particularly those with 'chronic effects'. Additionally, the Commission has proposed amendments to the annexes of the Persistent Organic Pollutants regulation and notably, intends to improve on the 'classification and management of hazardous waste' to 'maintain clean recycling streams'. This implies that hazardous waste (human waste is automatically considered as such) will be classified and managed in order to maintain recycling streams free from contamination. These amendments are mostly related to pollutants which are present in trace amounts in human waste, such as dioxins or pesticides. Notably, these are typically present in low concentrations and may not pose significant health risks, the main significance lies in EU willingness to regulate the matter. P2GreeN must therefore anticipate legislation and policy which will impact the presence of substances that pose risks to health in recycled material. This will be interwoven with the Chemicals Strategy for Sustainability which aims to address the interaction of chemicals, products, and waste legislation and thereby, "strengthen synergies with the circular economy". 347

It is worth noting that this reflects broader changes in EU law, e.g. the proposals to amend lists of priority substances in the area of water protection.³⁴⁸ As scientific knowledge develops, as technology improves and as concerns increase regarding long-lasting environmental and human health impacts, changes to existing risk regulatory regimes can be expected to enhance protections. This is accentuated when considering not just recycled waste, but any form of waste that is maintained or re-integrated within supply chains as intended by the Circular Economy Action Plan. Consequently, one might expect that the proposed developments as identified under the Action Plan are only a starting point and that further policy and legislative changes will be introduced over time.

12.2.4 Consumers and Transparency

Although not one of the three core pillars of the CEAP, a key aspect of the Action Plan and the sustainable product policy framework is that of empowering consumers and ensuring that they have cost-saving opportunities which may incentivize them to participate effectively in a circular economy. The Commission intends to both propose a revision of EU consumer law to ensure the consuming public have access to trustworthy and relevant information on products. Additionally, there is intention to set minimum requirements for sustainability labels and logos and information tools, which would safeguard consumers from greenwashing and planned obsolescence. While legislation targeting planned obsolescence may not be necessarily relevant for the purposes of P2GreeN, greenwashing and transparency concerns certainly are.

³⁴⁷ 'A New Circular Economy Action Plan for a Cleaner and More Competitive Europe', 14.

³⁴⁸ Commission, 'Proposal for a Directive of the European Parliament and of the Council amending Directive 2000/60/EC establishing a framework for Community action in the field of water policy, Directive 2006/118/EC on the protection of groundwater against pollution and deterioration and Directive 2008/105/EC on environmental quality standards in the field of water policy, COM (2022) 540 final.

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Transparency in itself will be of vital importance to both P2GreeN and EU initiatives of this nature, particularly at a time in which disinformation is rife. The EU has already shown that it will legislate for transparency, as illustrated by the Water Reuse Regulation example; key information on every water reuse project must be made available to the public. This has aggregate benefits: product legitimacy, accountability and awareness, to consider a few. Transparency is also linked to greenwashing, as companies will find it more troublesome to exaggerate or otherwise falsely claim commitment to their environmental responsibility.

Lastly, it should be noted that social cohesion is a driver for societal change. It promotes collective responsibility and encourages collaboration between all stakeholders, government or public. In order for a circular economy to succeed, participants must be drawn together to solve common issues affecting them, such as waste. Information on products stemming from the P2GreeN project may increase knowledge about EU projects and contribute to the aforementioned collaboration for common goals.

12.2.5 Conclusion

The Circular Economy Action Plan is a novel project endeavouring to transition to an economic model which encourages regenerative production, including in the face of a changing climate and related agricultural pressures. The central idea is to ensure policy and legislative changes facilitate the reuse of materials and stronger product design. The Action Plan makes particular reference to food, water and nutrients as worthy of consideration for the purposes of a Circular Economy. Simultaneously, the EU has various legal and regulatory regimes for the management of these key products and value chains, which, as noted, have been, or will be amended to account for current and future challenges. It is also possible to infer that the future will bring further changes in respect of nutrients, water and food, beyond those that are already on the horizon.

Awareness of and adherence to legislation and standards as they evolve is essential for P2GreeN and future related activities and products. This may also help support trust, which is pivotal if produce which utilizes reclaimed water or human waste (in any form) is to enter the EU market. Poor consumer relations management may risk unwillingness to either participate in the project or to buy products derived from human waste. In contrast, as flagged in the Action Plan, enhancing trust and building social cohesion through a shared understanding of the importance of a circular economy and projects such as P2GreeN, may enhance uptake and provide a foundation for further endeavours in this field. While serving as a pilot, P2GreeN allows for low-cost and lowrisk experimentation and research to establish potential costs, both environmental and fiscal, as well as examine cultural and social features of circularity at a consumer and producer level. Furthermore, it can serve as a model which highlights potential legislative and policy barriers to nutrient retrieval which can then serve as precursors for further investigation.

13 ANNEX VII – the CAP's Statutory Requirements (SMRs)

- 1. **SMR 1 Water** Directive 2000/60 establishing a framework for Community action in the field of water policy Articles 11(3)(e) and (h):
 - (e) controls over the abstraction of fresh surface water and groundwater, and impoundment of fresh surface water, including a register or registers of water abstractions and a requirement of prior authorisation for abstraction and impoundment. These controls shall be periodically reviewed and, where necessary, updated. Member States can exempt from these controls, abstractions or impoundments which have no significant impact on water status;
 - (f) ...
 - (g) ...
 - (h) for diffuse sources liable to cause pollution, measures to prevent or control the input of pollutants. Controls may take the form of a requirement for prior regulation, such as a prohibition on the entry of pollutants into water, prior authorisation or registration based on general binding rules where such a requirement is not otherwise provided for under Community legislation. These controls shall be periodically reviewed and, where necessary, updated.
- 2. SMR 2 Nitrates Directive 91/676, Articles 4 and 5:

Article 4 1. With the aim of providing for all waters a general level of protection against pollution, Member States shall, within a two-year period following the notification of this Directive:

- (a) establish a code or codes of good agricultural practice, to be implemented by farmers on a voluntary basis, which should contain provisions covering at least the items mentioned in Annex II A;
- (b) set up where necessary a programme, including the provision of training and information for farmers, promoting the application of the code(s) of good agricultural practice.

2. Member States shall submit to the Commission details of their codes of good agricultural practice and the Commission shall include information on these codes in the report referred to in Article 11. In the light of the information received, the Commission may, if it considers it necessary, make appropriate proposals to the Council.

Article 5 1. Within a two-year period following the initial designation referred to in Article 3 (2) or within one year of each additional designation referred to in Article 3 (4), Member States shall, for the purpose of realizing the objectives specified in Article 1, establish action programmes in respect of designated vulnerable zones.

2. An action programme may relate to all vulnerable zones in the territory of a Member State or, where the Member State considers it appropriate, different programmes may be established for different vulnerable zones or parts of zones. 3. Action programmes shall take into account:

(a) available scientific and technical data, mainly with reference to respective nitrogen contributions originating from agricultural and other sources;

(b) environmental conditions in the relevant regions of the Member State concerned.

4. Action programmes shall be implemented within four years of their establishment and shall consist of the following mandatory measures:

(a) the measures in Annex III;

(b) those measures which Member States have prescribed in the code(s) of good agricultural practice established in accordance with Article 4, except those which have been superseded by the measures in Annex III.

5. Member States shall moreover take, in the framework of the action programmes, such additional measures or reinforced actions as they consider necessary if, at the outset or in the light of experience gained in implementing the action programmes, it becomes apparent that the measures referred to in paragraph 4 will not be sufficient for achieving the objectives specified in Article 1. In selecting these measures or actions, Member States shall take into account their effectiveness and their cost relative to other possible preventive measures.

6. Member States shall draw up and implement suitable monitoring programmes to assess the effectiveness of action programmes established pursuant to this Article. Member States which apply Article 5 throughout their national territory shall monitor the nitrate content of waters (surface waters and groundwater) at selected measuring points which make it possible to establish the extent of nitrate pollution in the waters from agricultural sources.

7. Member States shall review and if necessary, revise their action programmes, including any additional measures taken pursuant to paragraph 5, at least every four years. They shall inform the Commission of any changes to the action programmes.

3. SMR 3 and 4 Natura 2000 – Directive 2019/147 and Directive 92/43

Directive 2009/147 on the conservation of wild birds - Article 3(1), Article 3(2), point (b), Article 4(1), (2) and (4)

Article 3

- 1. In the light of the requirements referred to in Article 2, Member States shall take the requisite measures to preserve, maintain or re-establish a sufficient diversity and area of habitats for all the species of birds referred to in Article 1.
- The preservation, maintenance and re-establishment of biotopes and habitats shall include primarily the following measures: ...(a);
 - (b) upkeep and management in accordance with the ecological needs of habitats inside and outside the protected zones; ...

Article 4

- 1. The species mentioned in Annex I shall be the subject of special conservation measures concerning their habitat in order to ensure their survival and reproduction in their area of distribution. In this connection, account shall be taken of:
 - (a) species in danger of extinction;
 - (b) species vulnerable to specific changes in their habitat;
 - (c) species considered rare because of small populations or restricted local distribution;
 - (d) other species requiring particular attention for reasons of the specific nature of their habitat.

Trends and variations in population levels shall be taken into account as a background for evaluations.

Member States shall classify in particular the most suitable territories in number and size as special protection areas for the conservation of these species in the geographical sea and land area where this Directive applies.

2.Member States shall take similar measures for regularly occurring migratory species not listed in Annex I, bearing in mind their need for protection in the geographical sea and land area where this Directive applies, as regards their breeding, moulting, and wintering areas and staging posts along their migration routes. To this end, Member States shall pay particular attention to the protection of wetlands and particularly to wetlands of international importance.

4. In respect of the protection areas referred to in paragraphs 1 and 2, Member States shall take appropriate steps to avoid pollution or deterioration of habitats or any disturbances affecting the birds, in so far as these would be significant having regard to the objectives of this Article. Outside these protection areas, Member States shall also strive to avoid pollution or deterioration of habitats.

Directive 92/43 on the conservation of natural habitats and of wild flora and fauna - Article 6(1) and (2)

1. For special areas of conservation, Member States shall establish the necessary conservation measures involving, if need be, appropriate management plans specifically designed for the sites or integrated into other development plans, and appropriate statutory, administrative or contractual measures which correspond to the ecological requirements of the natural habitat types in Annex I and the species in Annex II present on the sites.

2. Member States shall take appropriate steps to avoid, in the special areas of conservation, the deterioration of natural habitats and the habitats of species as well as disturbance of the species for which the areas have been designated, in so far as such disturbance could be significant in relation to the objectives of this Directive.

4. SMR 5 – Food Safety – Regulation 178/2002, Articles 14 and 15, Article 17(1), Articles 18, 19 and 20

Article 14 Food safety requirements

- 1. Food shall not be placed on the market if it is unsafe.
- 2. Food shall be deemed to be unsafe if it is considered to be:
 - (a) injurious to health;
 - (b) unfit for human consumption.
- 3. In determining whether any food is unsafe, regard shall be had:

(a) to the normal conditions of use of the food by the consumer and at each stage of production, processing, and distribution, and

(b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.

4. In determining whether any food is injurious to health, regard shall be had:

(a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;

(b) to the probable cumulative toxic effects;

(c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.

5. In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration, or decay.

6. Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.

7. Food that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.

8. Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe.

9. Where there are no specific Community provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.

Article 15 - Feed safety requirements

1. Feed shall not be placed on the market or fed to any food-producing animal if it is unsafe.

2. Feed shall be deemed to be unsafe for its intended use if it is considered to: — have an adverse effect on human or animal health;

- make the food derived from food-producing animals unsafe for human

consumption. 3. Where a feed which has been identified as not satisfying the feed safety requirement is part of a batch, lot or consignment of feed of the same class or description, it shall be presumed that all of the feed in that batch, lot or consignment is so affected, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment fails to satisfy the feed safety requirement.

4. Feed that complies with specific Community provisions governing feed safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.

5. Conformity of a feed with specific provisions applicable to that feed shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the feed is unsafe.

6. Where there are no specific Community provisions, feed shall be deemed to be safe when it conforms to the specific provisions of national law governing feed safety of the Member State in whose territory the feed is in circulation, such provisions being drawn up and applied without prejudice to the Treaty, in particular Article 28 and 30 thereof.

Article 17 - Responsibilities

1. Food and feed business operators at all stages of production, processing, and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.

• • •

Article 18 - Traceability

1. The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing, and distribution.

2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed. To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.

3. Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.

4. Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions. 5. Provisions for the purpose of applying the requirements of this Article in respect of specific sectors may be adopted in accordance with the procedure laid down in Article 58(2).

Article 19 - Responsibilities for food: food business operators

1. If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection.

2. A food business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the food-safety requirements and shall participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.

3. A food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health. Operators shall inform the competent authorities of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce, or eliminate a risk arising from a food.

4. Food business operators shall collaborate with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied.

Article 20 - Responsibilities for feed: feed business operators

1. If a feed business operator considers or has reason to believe that a feed which it has imported, produced, processed, manufactured, or distributed does not satisfy the feed safety requirements, it shall immediately initiate procedures to withdraw the feed in question from the market and inform the competent authorities thereof. In these circumstances or, in the case of Article 15(3), where the batch, lot or consignment does not satisfy the feed safety requirement, that feed shall be destroyed, unless the competent authority is satisfied otherwise. The operator shall effectively and accurately inform users of the feed of the reason for its withdrawal, and if necessary, recall from them products already supplied when other measures are not sufficient to achieve a high level of health protection.

2. A feed business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the feed shall, within the

limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the feed-safety requirements and shall participate in contributing to the safety of food by passing on relevant information necessary to trace a feed, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.

3. A feed business operator shall immediately inform the competent authorities if it considers or has reason to believe that a feed which it placed on the market may not satisfy the feed safety requirements. It shall inform the competent authorities of the action taken to prevent risk arising from the use of that feed and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce, or eliminate a risk arising from a feed.

4. Feed business operators shall collaborate with the competent authorities on action taken in order to avoid risks posed by a feed which they supply or have supplied

5. **SMR 7 – Plant Protection Products** – Regulation 1107/2009, Article 55 first and second sentence

Plant protection products shall be used properly. Proper use shall include the application of the principles of good plant protection practice and compliance with the conditions established in accordance with Article 31 and specified on the labelling.

6. SMR 8 – Pesticides – Directive 2009/128, Articles 5(2), 8(1) to (5), 12, 13(1) and (3)

Article 5 (2) By 26 November 2013, Member States shall establish certification systems and designate the competent authorities responsible for their implementation. These certificates shall, as a minimum, provide evidence of sufficient knowledge of the subjects listed in Annex I acquired by professional users, distributors, and advisors either by undergoing training or by other means. Certification systems shall include requirements and procedures for the granting, renewal, and withdrawal of certificates.

Article 8 Inspection of equipment in use

- 1. Member States shall ensure that pesticide application equipment in professional use shall be subject to inspections at regular intervals. The interval between inspections shall not exceed five years until 2020 and shall not exceed three years thereafter.
- By 26 November 2016, Member States shall ensure that pesticide application equipment has been inspected at least once. After this date only pesticide application equipment having successfully passed inspection shall be in professional use. New equipment shall be inspected at least once within a period of five years after purchase.
- 3. By way of derogation from paragraphs 1 and 2 and, following a risk assessment for human health and the environment including an assessment of the scale of the use of the equipment, Member States may:

a. apply different timetables and inspection intervals to pesticide application equipment not used for spraying pesticides, to handheld pesticide application equipment or knapsack sprayers and to additional pesticide application equipment that represent a very low scale of use, which shall be listed in the National Action Plans provided for in Article 4.

The following additional pesticide application equipment shall never be considered as constituting a very low scale of use:

- i. spraying equipment mounted on trains or aircraft;
- ii. boom sprayers larger than 3 m, including boom sprayers that are mounted on sowing equipment;
- b. exempt from inspection handheld pesticide application equipment or knapsack sprayers. In this case the Member States shall ensure that operators have been informed of the need to regularly change the accessories, of the specific risks linked to that equipment, and that operators are trained for the proper use of that application equipment in accordance with Article 5.
- 4. The inspections shall verify that pesticide application equipment satisfies the relevant requirements listed in Annex II, in order to achieve a high level of protection for human health and the environment. Pesticide application equipment complying with harmonised standards developed in accordance with Article 20(1) shall be presumed to comply with the essential health and safety and environmental requirements.
- 5. Professional users shall conduct regular calibrations and technical checks of the pesticide application equipment in accordance with the appropriate training received as provided for in Article 5.

Article 12 - Reduction of pesticide use or risks in specific areas.

Member States shall, having due regard for the necessary hygiene and public health requirements and biodiversity, or the results of relevant risk assessments, ensure that the use of pesticides is minimised or prohibited in certain specific areas. Appropriate risk management measures shall be taken, and the use of low-risk plant protection products as defined in Regulation (EC) No 1107/2009 and biological control measures shall be considered in the first place. The specific areas in question are:

- (a) areas used by the general public or by vulnerable groups as defined in Article 3 of Regulation (EC) No 1107/2009, such as public parks and gardens, sports and recreation grounds, school grounds and children's playgrounds and in the close vicinity of healthcare facilities;
- (b) protected areas as defined in Directive 2000/60/EC or other areas identified for the purposes of establishing the necessary conservation measures in accordance with the provisions of Directives 79/409/EEC and 92/43/EEC;
- (c) recently treated areas used by or accessible to agricultural workers.

Article 13 - Handling and storage of pesticides and treatment of their packaging and remnants

- 1. Member States shall adopt the necessary measures to ensure that the following operations by professional users and where applicable by distributors do not endanger human health or the environment:
 - (a) storage, handling, dilution and mixing of pesticides before application;
 - (b) handling of packaging and remnants of pesticides;
 - (c) disposal of tank mixtures remaining after application;
 - (d) cleaning of the equipment used after application;
 - (e) recovery or disposal of pesticide remnants and their packaging in accordance with Community legislation on waste.
- 2. ...
- 3. Member States shall ensure that storage areas for pesticides for professional use are constructed in such a way as to prevent unwanted releases. Particular attention shall be paid to location, size, and construction materials.

14 ANNEX VIII – LIST OF EU LAWS INVESTIGATED

Regulations

Council Regulation (EEC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs, [1991] OJ L198/1.

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, [2002] OJ L31/1.

Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, [2004] OJ L139/1.

Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC, [2005] OJ L70/1.

Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, [2006] OJ L396/1.

Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91, [2007] OJ L189/1. [since repealed by Regulation 2018/848]

Commission Regulation (EC) 415/2008 of 8 May 2008 on the division between 'deliveries' and 'direct sales' of national reference quantities fixed for 2007/08 in Annex I to Council Regulation (EC) No 1788/2003, [2008] OJ L125/22.

Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control, [2008] OJ L250/1. [technically repealed by Regulation 2021/1165, but with some elements still continuing to apply temporarily]

Council Regulation (EC) 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1997/2006, [2008] OJ L 353/1.

Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) [2009] OJ L 300/1.

Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC [2009] OJ L 309/1.

Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that, [2011] OJ L54/1.

Regulation (EU) 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, [2012] OJ L167/1.

Regulation (EU) 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008, [2013] OJ L 347/549.

Council Regulation (EU) 1385/2013 of 17 December 2013 amending Council Regulations (EC) No 850/98 and (EC) No 1224/2009, and Regulations (EC) No 1069/2009, (EU) No 1379/2013 and (EU) No 1380/2013 of the European Parliament and of the Council, following the amendment of the statute of Mayotte and with regards to the European Union, [2013] OJ L354/86.

Regulation (EU) 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC, [2014] OJ L189/1.

Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429

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and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/ EC and Council Decision 92/438/EEC (Official Controls Regulation), [2017] OJ L95/1.

Regulation (EU) 2018/841 of the European Parliament and of the Council of 30 May 2018 on the inclusion of greenhouse gas emissions and removals from land use, land use change and forestry in the 2030 climate and energy framework, and amending Regulation (EU) No 525/2013 and Decision No 529/2013/EU, [2018] OJ L 156/1.

Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 [2018] OJ L 150/1.

Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008, [2019] OJ L91/1

Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003, [2019] OJ L 170/1.

Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union, [2019] OJ L198/241.

Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, [2019] OJ L231/1.

Regulation (EU) 2020/741 of the European Parliament and of the Council of 25 May 2020 on minimum requirements for water reuse, [2020] OJ L177/32.

Regulation (EU) 2021/1119 of the European Parliament and of the Council of 30 June 2021 establishing the framework for achieving climate neutrality and amending Regulations (EC) No 401/2009 and (EU) 2018/1999, [2021] OJ L243/1.

Commission Implementing Regulation (EU) 2021/1165 of 15 July 2021 authorising certain products and substances for use in organic production and establishing their lists, [2021] OJ L253/13.

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Regulation (EU) 2021/2115 of the European Parliament and of the Council of 2 December 2021 establishing rules on support for strategic plans to be drawn up by Member States under the common agricultural policy (CAP Strategic Plans) and financed by the European Agricultural Guarantee Fund (EAGF) and by the European Agricultural Fund for Rural Development (EAFRD) and repealing Regulations (EU) No 1305/2013 and (EU) No 1307/2013, [2021] OJ L435/1.

Regulation (EU) 2022/869 of the European Parliament and of the Council of 30 May 2022 on guidelines for trans-European energy infrastructure, amending Regulations (EC) No 715/2009, (EU) 2019/942 and (EU) 2019/943 and Directives 2009/73/EC and (EU) 2019/944, and repealing Regulation (EU) No 347/2013, [2022] OJ L152/45.

Regulation 2022/2379 on statistics on agricultural input and output, [2022] OJ L 315/1.

Commission Regulation (EU) 2023/163 of 18 January 2023 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for DDT and oxathiapiprolin in or on certain products, [2023] OJ L23/1.

Commission Regulation (EU) 2023/923 of 3 May 2023 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards lead and its compounds in PVC, [2023] OJ L123/1.

Regulation (EU) 2023/956 of the European Parliament and of the Council of 10 May 2023 establishing a carbon border adjustment mechanism, [2023] OJ L130/52.

Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and of the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council Directive 87/357/EEC, [2023] OJ L135/1.

Directives

Council Directive 79/409 of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds [1979] OJ L103/1.

Council Directive 86/278/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture, [1986] OJ L181/6.

Council Directive 91/271/EEC of 21 May 1991 concerning urban waste water treatment [1991] OJ L 135/40.

Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources, [1991] OJ L375/1.

Council Directive 91/689/EEC of 12 December 1991 on hazardous waste, [1991] OJ L377/20.

Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora [1992] OJ L 206/7.

Council Directive 92/59/EEC of 29 June 1992 on general product safety, [1992] OJ L228/24. [Repealed by Directive 2001/95/EC]

Commission Directive 98/15/EC of 27 February 1998 amending Council Directive 91/271/EEC with respect to certain requirements established in Annex I thereof, [1998] OJ L67/29.

Council Directive 99/31/EC of 26 April 1999 on the landfill of waste, [1999] OJ L182/1.

Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of-life vehicles, [2000] OJ L 269/34.

Council Directive 2000/60/EC of 23 October 2000 establishing a framework for Community action in the field of water policy, [2000] OJ L327/1.

Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment, [2001] OJ L197/30.

Directive 2001/81/EC of the European Parliament and of the Council of 23 October 2001 on national emission ceilings for certain atmospheric pollutants, [2001] OJ L309/22.

Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, [2001] OJ L11/4.

Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003 providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment and amending with regards to public participation and access to justice Council Directives 85/337/EEC and 96/61/EC, [2003] OJ L156/17.

Directive 2004/35/CE of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage, [2004] OJ L143/56.

Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration, [2006] OJ L372/19.

Directive 2008/1/EC of the European Parliament and of the Council of 15 January 2008 concerning integrated pollution prevention and control, [2008] OJ L24/8. [Repealed by Directive 2010/75/EU].

Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe, [2008] OJ L152/1.

Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive), [2008] OJ L164/19.

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, [2008] OJ L 312/3.

Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council, [2008] OJ L348/84.

Council Directive (EC) 2009/125/EC of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products, [2009] OJ L 285/10.

Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides, [2009] OJ L 309/71.

Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds, [2009] OJ L 20/7.

Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes, [2010] OJ L276/33.

Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control), [2010] OJ L 334/17.

Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment, [2011] OJ L26/1.

Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) [2012] OJ L 197/38.

Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy, [2013] OJ L226/1.

Directive 2014/52/EU of the European Parliament and of the Council of 16 April 2014 amending Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment, [2014] OJ L124/1.

Directive (EU) 2016/2284 of the European Parliament and of the Council of 14 December 2016 on the reduction of national emissions of certain atmospheric pollutants, amending Directive 2003/35/EC and repealing Directive 2001/81/EC [2016], OJ L 344/1.
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Commission Directive (EU) 2019/782 of 15 May 2019 amending Directive 2009/128/EC of the European Parliament and of the Council as regards the establishment of harmonized risk indicators, [2019] OJ L127/4.

Decisions of the European Commission

Commission Implementing Decision (EU) 2022/1307 of 22 July 2022 establishing a watch list of substances for Union-wide monitoring in the field of water policy pursuant to Directive 2008/105/EC of the European Parliament and of the Council, [2022] OJ L197/117.

15 ANNEX IX – LIST OF ABBREVIATIONS

BATBest available techniquesBOD5Biological Oxygen DemandBREFsBAT reference documentsCAAECertification Body in Spain	
BOD₅Biological Oxygen DemandBREFsBAT reference documentsCAAECertification Body in Spain	
BREFs BAT reference documents	
CAAE Certification Body in Spain	
CAP Common Agricultural Policy	
CDs Customs duties	
CEAP Circular Economy Action Plan	
CIEU Court of Justice of the EU	
CMC Component Material Category(/ies)	
COD Chemical Oxygen Demand	
Corg Organic carbon	
D3.8 Deliverable 3.8	
DEOS Environmental Quality Standards Directive	
EAERD European Agricultural Fund for Rural Development	
EAGE European Agricultural Guarantee Euro	
EEA European Economic Area	
EFSA European Food Salety Authonity	
EGD European Green Deal	
EGD European Green Deal	
EIA Environmental impact assessments	
EIP-AGRI EIP on Agricultural Productivity and Sustainability	
EIPS European Innovation Partnersnips	
E-PRIR European Pollutant Release and Transfer Register	
EQSD Environmental Quality Standards Directive	
ESPR Ecodesign for Sustainable Products Regulation	
EU European Union	
F2F Farm to Fork (strategy)	
FAQ Frequently Asked Questions	
FMG Free movement of goods	
EDD Exatilizione Descharte Desculatione	
FPR Fertilising Products Regulation	
GAEC Good Agricultural and Environmental Conditions	
GAEC Good Agricultural and Environmental Conditions GFL General Food Law	
FPRFertilising Products RegulationGAECGood Agricultural and Environmental ConditionsGFLGeneral Food LawGHGGreenhouse gas	
FPRFertilising Products RegulationGAECGood Agricultural and Environmental ConditionsGFLGeneral Food LawGHGGreenhouse gasGWDGroundwater Directive	
FPRFertilising Products RegulationGAECGood Agricultural and Environmental ConditionsGFLGeneral Food LawGHGGreenhouse gasGWDGroundwater DirectiveHDHabitats Directive	
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FPRFertilising Products RegulationGAECGood Agricultural and Environmental ConditionsGFLGeneral Food LawGHGGreenhouse gasGWDGroundwater DirectiveHDHabitats DirectiveIACSIntegrated administration and control systemICTInformation & Communications TechnologyIEDIndustrial Emissions DirectiveINCITEInnovation Centre for Industrial Transformation and EmINMAPIntegrated Pollution Prevention and ControlJRCJoint Research CentreKPotassiumKPIKey Performance Indicators	nissions

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LULUCF	Regulation on land use, land use change and forestry
MRLs	Maximum residue levels
MSDS	Material Safety Data Sheet
N	Nitrogen
NAPCP	National air pollution control programme
NECD	National Emissions Reductions Commitments Directive
P	Phosphorus
PAH16	16 Priority Polycyclic Aromatic Hydrocarbons
PFC	Product Function Category
PM	Particulate matter
PPPs	Plant Protection Products
PPWR	Packaging and Packaging Waste Regulation
QRs	Quantitative restrictions
REACH	Regulation on the registration, evaluation, authorisation and restriction of chemicals
RMP	Risk management plan
SACs	Special Areas of Conservation
SDS	Safety Data Sheet
SEA	Strategic Environmental Assessment Directive
SFT	Smart Fertigation Tool
SIEF	Substance Information Exchange Forum
SMR	Statutory Management Requirement
SMRs	Statutory Management Requirements
SPAs	Special Protection Areas
SPS	Sanitary and Phytosanitary
SUP	Sustainable use of pesticides
TBT	Technical Barriers to Trade
TFEU	Treaty on the Functioning of the European Union
TSS	Total Suspended Solids
UDDT	Urine Diverting Dry Toilet
UDFT	Urine Diverting Flush Toilet
UN	United Nations
UVCB	Substances of unknown or variable composition
UWWT	Urban Wastewater Treatment
UWWTPs	Urban Wastewater Treatment Plants
WBD	Wild Birds Directive
WEEE	Waste Electrical and Electronic Equipment
WFD	Waste Framework Directive

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