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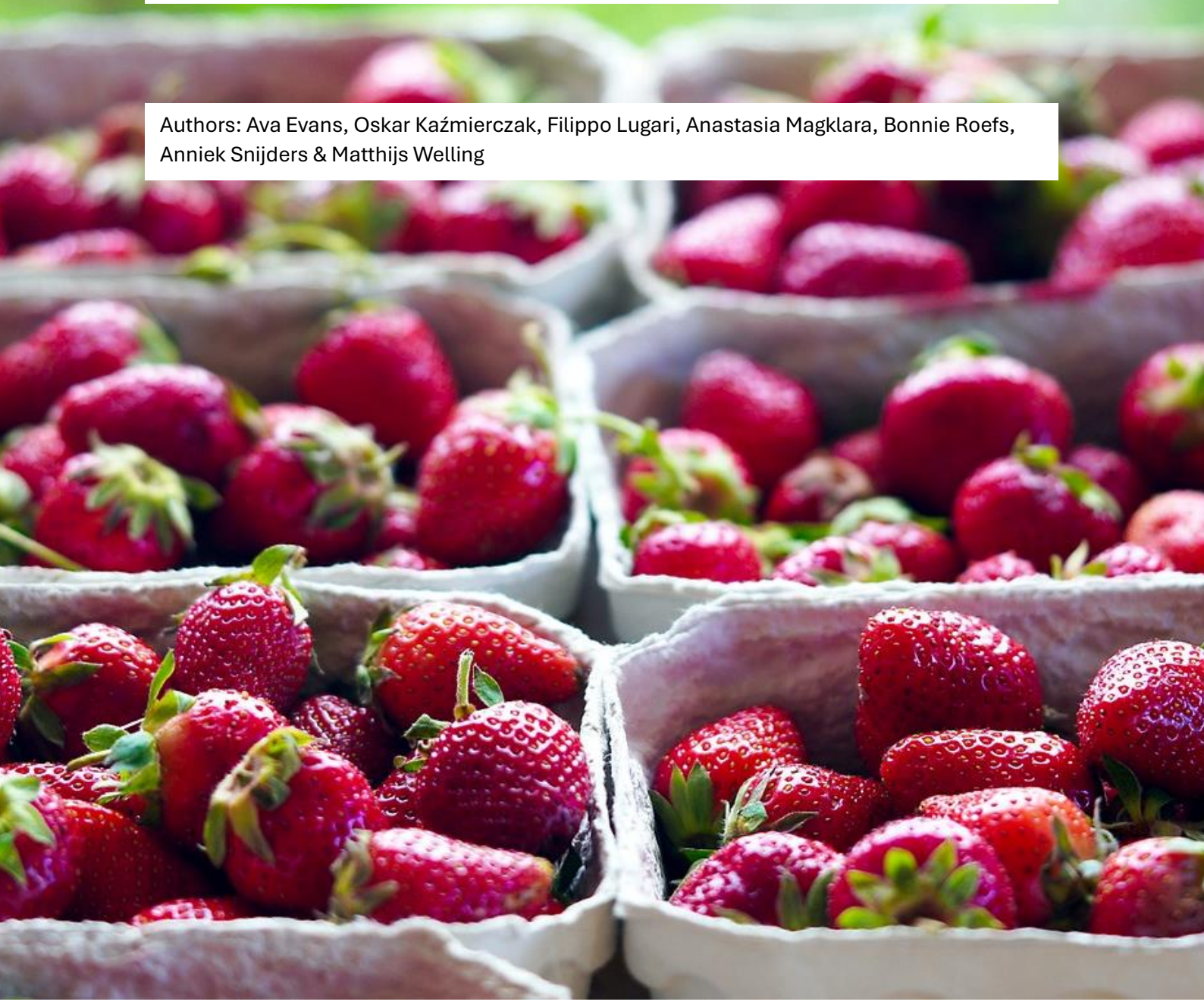

‘Essential’ PFAS for the future

Case study on the application of the concept of essential use to PFAS active substances in plant protection products

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28 June 2024 | ACT group 3294B

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Executive summary

Background on PFAS in plant protection products

Per- and polyfluoroalkyl substances (PFAS) represent a diverse group of anthropogenic chemicals characterized by the presence of fluorinated methyl groups (-CF3) or methylene groups (-CF2-). These compounds are incredibly resistant to degradation due to the strong carbon-fluorine bonds, making them prevalent in various applications, including plastics, lubricants, medical products, and pesticides. Their use is widespread in the European Union (EU), not least in agriculture, where they are often found in Plant Protection Products (PPPs). In the Netherlands, around 5% of PPPs contain PFAS, and testing of produce found PFAS in 14.0% and 7.1% of fruits and vegetables accordingly. PFAS can be used in PPPs as an active substance or an additive, meant to improve the properties of the product. Despite their utility, PFAS are persistent pollutants, accumulating in the environment and in living organisms, posing potential health risks such as genotoxicity, organ toxicity, and endocrine disruption.

Objectives

The primary objective of the study was to evaluate the essentiality of specific PFAS compounds used in PPPs within the Dutch agricultural sector. A secondary aim was to understand the perspectives of stakeholders on essentiality. Finally, we aimed to inform relevant policymakers on the possibilities of applying essential use to limit the use of PFAS.

Methods

The study employed a multi-faceted research design, including document analysis, stakeholder interviews, and a case study approach. The document analysis involved reviewing legislation, policy documents, substance evaluations and safety data sheets, and scientific literature to understand the regulatory framework and the properties of the selected PFAS compounds. Stakeholder interviews provided insights into the perspectives of various parties involved in the manufacturing, retail, use and regulation of PFAS. The case study focused on the application of fluopyram and lambda-cyhalothrin in strawberry and potato crops, respectively, assessing the essentiality of their use according to a framework developed based on the EU Commission's Communication on essential use.

Results

Fluopyram

Fluopyram is a fungicide, whose uses include the protection of strawberries from *Botrytis cinerea* — a pathogen that causes grey mold. The assessment revealed that fluopyram is not classified as a most harmful substance, not meeting the EU's stringent criteria, which in theory should prevent the application of the essential use concept and framework. Nevertheless, we continued with the evaluation to test the framework's application, looking at the difficulties, ambiguities and strengths in the application. Identified alternatives included synthetic and biological products and novel preventative management practices. However, the alternatives pose challenges in terms of performance, economic viability, and resistance management. None of the alternatives could be proven to meet all four criteria for substitution. Therefore, the analysis concluded that fluopyram's role in ensuring sufficient food supplies could justify its essentiality in certain contexts.

Lambda-cyhalothrin

Lambda-cyhalothrin is an insecticide whose uses include combating wireworms (*Agriotes* spp.) in potato cultivation. Based on available information, we classified it as a most harmful substance due to its endocrine disrupting properties and its high toxicity to aquatic invertebrates. Moreover, the EU recognizes the substance as a candidate for substitution. Alternatives such as neem oil, pyrethrins, and integrated pest management techniques were identified, but these alternatives also face limitations in terms of efficacy and practicality. The assessment determined that despite its harmful properties, lambda-cyhalothrin remains critical for protecting potato crops, indicating its essentiality in the absence of equally effective alternatives.

Stakeholder perspectives

Several stakeholders were interviewed through semi-structured qualitative interviews to gather their perspective on the concept of essential use, their perceived essentiality of (PFAS) PPPs, the current legislation of (PFAS in) PPPs, and the alternatives to (PFAS in) PPPs. Additional stakeholders provided written responses. They represented actors throughout the life cycle of a PPP: from manufacturer to professional user, with the addition of NGOs and implementing bodies.

Most stakeholders did not see much added value provided by the concept of essential use regarding PPPs. Several questioned whether it would even apply to PPPs. Solely an NGO had a positive impression; however, their rationale was based on its relevance to a broad group of the most harmful chemicals, rather than PPPs specifically. Views on the essentiality of (PFAS in) PPPs varied. Reasons for their proposed essentiality included: reduction or avoidance of pest resistance, lack of viable alternatives and proven safety of the substances. However, not all parties agreed; a speaker from an NGO made it crystal clear that they thought no use of PFAS in PPPs was essential. Overall, stakeholders appeared to have limited knowledge on the use of PFAS in PPPs and some even questioned established definitions of what constitutes a PFAS.

The views on PPP policy were largely aligned, wherein stakeholders thought they were strict (enough). Issues were raised with how costly and time-consuming the process of product approval is, which prevents new actors and substances entering the market. Additionally, concerns were raised about the disappearance of products from the market due to new regulations, reportedly leading to mismanagement of crop pests and pathogens. Solely an NGO claimed that the regulations were not stringent enough to protect human, animal, and environmental health.

Finally, there was broad recognition of biological and mechanical means of plant protection among interviewees. Reports of increased interest in non-synthetic PPPs were suggested as a driver of increasing interest and investment into the development of such alternatives. However, biological alternatives were not seen as a panacea. Interviewees expressed concerns about their efficacy in field conditions and their unsuitability or unavailability for chosen uses.

Conclusions

Since 2002, the EU has established comprehensive regulations for PPPs, covering active substances, safeners, and synergists. While these regulations are generally effective, they exhibit ambiguities and omissions, The addition of the PFAS label to PPPs does not introduce additional legal consequences, as current regulations do not classify all PFAS as persistent and bioaccumulative substances. This allows the use of many PFAS, despite their potential to produce long-lasting metabolites.

A proposed PFAS ban aims to prohibit their production and use, though the most acceptable scenario might permit their indefinite use in PPPs. The concept of essential use could regulate PFAS, yet it is not currently incorporated into EU legislation and, in its current state, may be time-consuming and ambiguous to apply.

Strengths of the essential use criteria include distinguishing between specific uses and recognizing non-chemical alternatives. However, the criteria face challenges such as being time-consuming and vague. As of June 2024, these criteria have not been officially legislated, potentially delaying their intended impact.

The study's implications highlight the need for ongoing research and stakeholder engagement to refine the criteria for essential use and to explore innovative solutions that could replace harmful PFAS without compromising agricultural productivity. By advancing the understanding of PFAS use in PPPs and their regulatory challenges, this research contributes to the broader discourse on sustainable agriculture and chemical safety in the EU.

Recommendations

After this broad analysis, we formulated some recommendations for future improvements in legislation, as listed below, but better illustrated in Chapter 9:

- **Redefine which substances are applicable for assessment under the essential use concept.** The use of a PPP ingredient is assessed only if it does fit the criteria for the "most harmful substances" identification; otherwise, it is not assessed under the essentiality criteria.
- **Reassess the practical implications of the essential use concept.** The criteria are too vague, risking undesirable interpretations and effects. Clearer definitions for terms like 'significantly safer' and 'similar level of performance' are needed to aid in testing, comparison and approval of alternatives.
- **Harmonize essential use concept directives with current PPP regulations.** The essentiality concept shares significant similarities with Regulation No 1107/2009 regarding harmful substances identification. This alignment facilitates a future harmonization between regulations but may lead to "double rulings" and regulatory loopholes, creating ambiguity in policy implementation.
- **Develop a streamlined method and platform for identifying and assessing alternatives for candidates for substitution.** This can serve as the framework used in identifying replacements for non-essential uses cases of PFAS in PPPs. A platform, such as the 'marketplace' from ChemSec or equivalent, would serve to expedite and ease the process of identifying and assessing the alternatives.
- **Ensure continued availability of emergency authorizations of PPP containing PFAS and PPP in general.** Even with potential bans and essentiality criteria for PFAS, emergency authorizations for PPPs should remain available. This is crucial for managing outbreaks of resistant or invasive pests when other control measures fail. A similar emergency authorization is already present in Reg. No 1107/2009 under article 53 and could function as a starting point for further discussion.
- We recommend that **for** any future change in **PPP** legislation**, the diverse** perspectives of stakeholders need to be **considered**. During our interviews, clear frustrations with the

current legislation were expressed and concerns about the safety of the PPPs currently on the market.

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1. Introduction

1.1. Context and multi-perspective problem analysis

PFAS is a collective description for per- and polyfluoroalkyl substances (see Figure 1), an incredibly broad group of compounds defined by the presence of one or more perfluorinated methyl groups (-CF_3) or perfluorinated methylene groups (-CF_2-), a varying number of carbon atoms and fluorination degree, and the existence of various secondary chemical groups (Panieri et al., 2022). The strength of the carbon-fluorine bonds renders PFAS very resistant to degradation. Furthermore, PFAS have unique properties that make them specifically well suited for a wide variety of applications. PFAS are ubiquitous, found in items ranging from plastics and lubricants to medical products and pesticides (European Chemicals Agency, n.d.).

Their use in European Union (EU) agriculture is widespread and increasing. In summer fruit, some 37% of strawberries, 35% of peaches and 31% of apricots in the EU have shown to be contaminated with PFAS. Moreover, fruits from Austria saw a near 700% increase in PFAS detections from 2011 to 2021, while the Netherlands noted a smaller but still considerable 70% increase across samples (PAN, 2024). As of 2022, an estimated 5% of plant protection products in the Netherlands contained PFAS (Adema, 2024).

PFAS are predominantly found in plant protection products (PPPs) or their formulations as active ingredients or additives. PFAS-based additives can be used to, for example, aid the dispersal and increase the uptake of the active ingredient(s) (Swedish Chemicals Agency, 2015). Recently, the US EPA (2022) found a further unintentional pathway of PFAS presence in PPPs—PFAS leaching from plastic barrels in which PPPs were stored. A further rationale for PFAS use in PPPs, as suggested by some industry groups, is the longer time they remain effective due to the stability of the compounds, meaning less PPPs must be applied to a crop. However, this incredible stability of PFAS compounds lies at the core of some concerns around their use (Wilcox, 2022).

The long degradation time of PFAS and of their by-products means they are persistent pollutants. Currently, PFAS are omnipresent; they occur in tap water, groundwater, freshwater, marine waters, soil, vegetation, animals (Ramírez Carnero et al., 2021; Sinclair et al., 2020), human blood, breast milk (So et al., 2006) and even in the placenta (Hall et al., 2022). Despite their prevalence, limited data is available on the effects of PFAS at environmentally relevant concentrations (Sinclair et al., 2020). However, what we do know is that some PFAS are genotoxic for humans, some are irritants, others are known to be toxic for kidney, liver, thyroid and the immune system (Lewis et al., 2016; Wilcox, 2022). Moreover, PFAS are known to increase the cholesterol levels in the blood. These compounds can act as hormones (Clark et al., 2024), rarely causing acute illness, but they accumulate in the animals and after years they can have chronic effects, in humans as well.

A plethora of conventions, directives, strategies, and regulations govern the manufacturing, use, and environmental availability of PFAS to protect human health. These measures vary in focus, ranging from setting allowable PFAS content in drinking water (European Commission, 2024a) to eliminate the production of the most harmful PFAS (Stockholm Convention, 2019) and requiring the registration and evaluation of chemicals being introduced in the market (REACH) (Human Biomonitoring for Europe, n.d.). Moreover, in 2023, several collaborating member states proposed a (full) ban on PFAS. However, the ban could permit time-unlimited exceptions for plant protection and biocidal products, as these are reportedly covered under their respective regulations (European Chemicals Agency, 2023a). Recently, in April 2024, the Directorate-

General for the Environment issued guidelines on the interpretation and application of the concept of "essential use" regarding chemicals, which includes PFAS. Nevertheless, the concept must be implemented in legislation to have any legal effect and its interpretation suggests that PFAS use might continue as it contributes to an activity critical for the functioning of society — provision of goods and services (European Commission, 2024b).

In the Netherlands there are several organizations that work with the national and international regulations on chemical substances, such as PFAS, in PPPs. For example, the Ctgb (College for the Admittance of Crop Protection Products and Biocides) and the NVWA (National Food and Safety Authority). However, the effectiveness of this legislation in protecting human health and the environment has become a disputed topic recently. Just this year, a report has been published by a civilian initiative, in which it is argued that the Ctgb does not require sufficient research on the neurotoxic effects on humans of pesticides when authorizing their introduction into the market (Buijs & Mantingh, 2024). Additionally, the report shows concentrations of pesticides in protected Natura 2000 areas.

With many international and national trends of concern about PFAS in PPPs, the determination whether these chemicals are harmful, and how harmful, is an interesting topic for research. This research focuses on how "essential" these chemicals are. The first step of this research is the definition of a research problem and the research scope. Next, the relevant stakeholders involved are discussed. The body of the research includes the results of document analysis and stakeholder interviews. Lastly, our research question is reviewed in the conclusions.

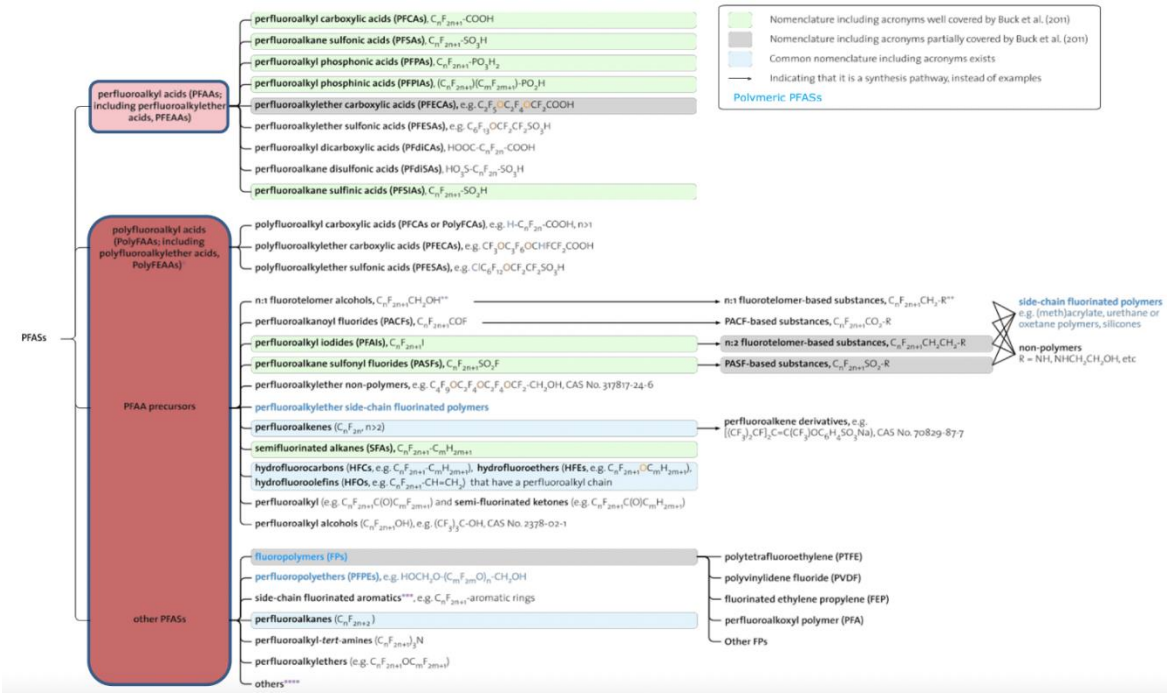

Figure 1. PFAS (sub)grouping and nomenclature (European Chemicals Agency, 2023). The range of what constitutes as a PFAS is very large.

1.2. Problem definition

Evidence is scarcely available, but new information on the dangers posed by PFAS emerges every day. Nevertheless, PFAS are included in a plethora of everyday objects and contribute to activities that lawmakers deem critical to the functioning of society. Therefore, a dilemma emerges. Should we continue using these functional and effective substances and risk future externalities, or should we outlaw their usage and risk social upheaval and economic losses?

Agriculture, and PPPs in particular, is one area that would evade regulation under a new proposed PFAS ban. Therefore, it is relevant to discover how this concept of "essential use" would be applied in practice.

1.3. Research scope

To tackle the research problem precisely and efficiently, the boundaries of our research had to be further specified. From the problem described above, we have decided to focus on PFAS in PPPs specifically. PPPs are products encompassing active substances, synergists, safeners, co-formulants and adjuvants (Regulation 1107/2009). A further explanation of these terms can be found in the glossary. PPPs were relevant to the commissioner, whose goal was – in a nutshell – to deepen the understanding of PFAS use in PPPs. Additionally, we limited the spatial scale of our research to the Netherlands, while taking important EU legislation into consideration where necessary.

We focus on fluopyram and lambda-cyhalothrin, both PFAS compounds found in PPPs, that are applied to strawberries and potatoes respectively. A case study has been conducted on the application of these specific PFAS, assessed according to the recent (April 2024) concept of "essentiality" as explained by the EU Directorate-General for the Environment. Then, stakeholders were interviewed on their perspectives on the assessment. Finally, stakeholder analysis was carried out to determine whether the EU definition of "essential" PFAS is an appropriate framework for assessing which PFAS compounds are essential in PPPs.

Our results are discussed with a perspective on the present and the future, while drawing on developments from the past. Our selection of stakeholders was influenced by the spatial scale. More information on stakeholders is provided in section 1.4. Our outputs include the following: (1) a report, including the assessment on the essentiality of the specific PFAS compounds and (2) a policy brief.

1.4. Stakeholders involved

Our focus is on all actors that are present within the supply chain of a PPP: from manufacturer to professional user. This includes researchers, legislators, NGOs and implementing bodies as well. This is because these groups influence the manufacture and use of PPPs.

To elaborate, most stakeholders relevant to our project scope are actors based in the Netherlands and belong to one of the following groups: users of PPPs, manufacturers, academics/NGOs, legislator or groups thereof. However, as will be discussed in following sections, EU legislative bodies are also included as they set PPP regulations that apply to all member states, including the Netherlands. Finally, multi-national companies producing and supplying PPPs are likewise included, as their products may be used in the Netherlands. The main

stakeholders involved in this project are summarised below. A fuller list of stakeholders involved in the issue can be found in Appendix A.

- Ctgb – College for the allowance of crop protection products and biocides (Ministerie van Landbouw, 2016)
  This Dutch organisation is an independent organisation that judges the safety of crop protection products and biocides. They operate within European and national jurisdictions. Additionally, they advise ministries on legislation and policy, based on technical, scientific knowledge. Based on this information, we judge them to be an important organisation with a relatively large power and interest in our project issue. The Dutch Ministry of Agriculture, Nature, and Food Quality (LNV) is responsible for the Ctgb; though, the Ctgb is an independent organisation.
- Professional users of PPPs (within the Netherlands).
  This group encompasses everyday users of PPPs and is central to the dilemma of the EU PFAS ban.
- NVWA – Dutch Food and Goods Authority (Nationale Voedsel en Waren Authoriteit, 2022).
  The NVWA checks whether companies that produce pesticides and biocides are adhering to the rules of the law, rules that are produced by the Ctgb.
- EFSA – European Food Safety Authority (European Food Safety Authority – EFSA | European Union, 2024)
  This group offers scientific advice on food-related risks. This advice can notify EU policy makers, to protect the public from emerging food-related risks.
- CropLife NL – Dutch Crop Protection Association (CropLife NL | Voor Gezonde Gewassen - Organisatie, n.d.)
  CropLife NL represents the interests of producers of crop protection products on the Dutch market. Companies affiliated with CropLife NL are therefore producers of PPPs (e.g. BASF).
- RIVM – National (Dutch) Institute for Health and Environment
  This organisation is an important, large Dutch research institute that also researches PFAS.
- ECHA – European Chemicals Agency
  The ECHA implements EU legislation on chemical use.
- PAN – Pesticide Action Network Netherlands (PAN, n.d.)
  The PAN has as a goal to ban the use of harmful pesticides. They work together with 20 NGOs.
- ChemSec – The International Chemical Secretariat.
  Non-profit organisation that aims to substitute harmful chemicals for safer alternatives. They conduct independent research and facilitate contact between researchers, companies and decision makers (The International Chemical Secretariat, 2024).

The above stakeholders are vital to our project due to their high interest in this topic and their diverse levels of power to determine decisions. The list is not exhaustive (see long list of stakeholders).

Regulatory regional authorities such as the Ministry of LNV are interested in securing regional accordance with environment and safety policies. They have high power, but it is likely that this topic does not really apply to their interests. We assume this because the regional authorities have many other goals on their agenda. The same reasoning goes for the RIVM, they are researching a variety of topics, not just PFAS in PPPs. Moreover, the ECHA has more chemicals than just PFAS under review. The Ctgb however, while less powerful than the authorities, have a

higher interest. This is because the regulation of PFAS in PPPs is one of their main focus points. Again, the same reasoning goes for the NVWA and the PAN.

See below the Matrix of stakeholders for an illustration of this stakeholder categorisation (see Figure 2). The stakeholder's matrix is also known as power-interest structure is a tool of management and involving people and authorities from diverse areas. It classifies each stakeholder based on their interest and power to a vital issue (Polonsky & Scott, 2005).

To elaborate on Figure 2, the professional users of PPPs represent farmers of the Netherlands that use PPPs. They have a high interest in new regulations banning PFAS, as a ban could affect their farming practices drastically. However, this group has low power in comparison to other groups. CropLife NL represents the chemical industry around PPPs. It seems intuitive that the chemical industry would have considerable interest in the regulation of chemicals. New regulations and health standards can affect their practices and innovations, and ultimately their bottom line. We cannot say for certain how much power they have over regulators. However, we suspect that their power is relatively high. Lastly, ChemSec is assumed to have a high interest but low power. This is because they are not a regulatory or governmental organisation, but they do take high interest in the topic of PFAS. The EFSA is also assumed to have high interest but low power, whose responsibilities include providing scientific advice on emerging food risks. This advice informs EU policymakers; however, it is not possible for the EFSA to directly change policy.

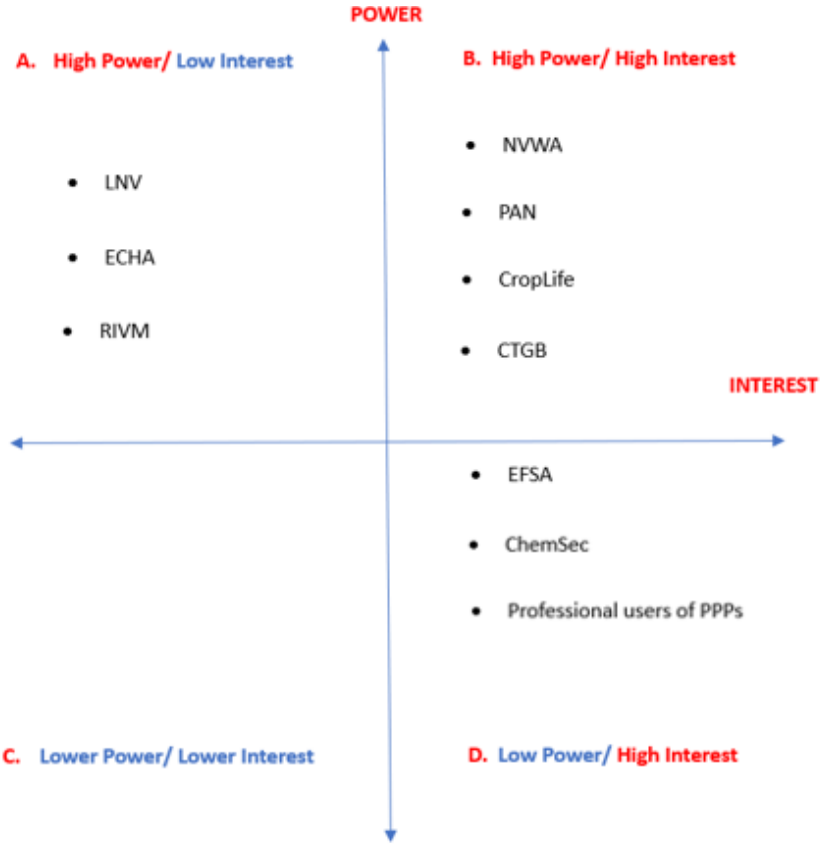

Figure 2. Matrix of crucial stakeholders for our research project.

2. Integrative project purpose and research questions

Our project is a case study on the essentiality of fluopyram and lambda-cyhalothrin in PPPs for strawberries and potato crops respectively, within the Dutch agricultural sector. The purpose of the project is to better understand whether the EU concept of "essential use" is an effective tool to assess which PFAS are essential, and which are not. Both fluopyram and lambda-cyhalothrin in PPPs have been examined according to regulations and definitions put forth by the EU. Furthermore, we have interviewed a variety of stakeholders to collect their interpretation of essentiality and their views on both the EU's definition and our method of examination.

2.1. Ethical considerations

For the ethical considerations of our project, we turned to the seven basic ethical principles in social research as defined by Hilton et al., (2019). First, in line with their work, we ensured that interviewees understood the methods, objectives of the research and the reason for their participation such that they were able to provide informed consent.

Second, we avoided deception when conducting interviews by emphasising transparency, sincerity, and principled conduct through the research procedure. More specifically, we clearly communicated our purpose of the interview and the goal of the research to the stakeholders in speech and in writing – via an information and consent sheet. Additionally, we encouraged the stakeholders to share their perspectives on the topic with us without pressuring them to adhere to our assumptions on the issue. Lastly, stakeholders had the opportunity to debrief their opinions on the topic by clarifying any misconceptions.

Third, privacy and confidentiality are crucial considerations for this report and for the policy brief. Therefore, we have not referred to individuals such that they could be individually recognised. Only with their consent, and when this was relevant to the outputs of the project, was their organisation mentioned in our output.

Fourth, in order not to cause physical or mental distress to interviewees, we took extra precautions to ensure comfort. For example, by making sure that interview questions were not leading in nature. The interview questions remained focused on establishing stakeholders' perspectives or inquiring about the activities and processes involved in their work. The issue of distress is pertinent, because participants may find certain subject matters upsetting given their direct involvement in the issue.

Fifth, we must note that the research is commissioned and funded by persons and organisations involved in projects whose basic assumption is that PFAS are inherently harmful and must be outlawed. However, starting with this assumption, we have gradually developed our own view on the situation.

Sixth, scientific misconduct and fraud are serious offences and can compromise the integrity of the project and undermine public trust in scientific research. Therefore, we have set standards for interviewing, ensuring that we were able to openly discuss intellectual property. Also, we have managed data safely and ensured transparency. Full interview transcripts are provided in a separate file such that it can be verified that no gross misrepresentations were made.

Finally, scientific advocacy must be considered. Advocacy becomes problematic when there is disagreement about facts and uncertainty about values. In our project, there are fundamental differences in values held by stakeholders. However, by including the diverse perspectives, we have attempted to represent the multi-faceted nature of the issue appropriately.

2.2. Project aim

The aim of our project consists of the following parts:

- Investigate the "essentiality" of specific PFAS compounds used in PPPs based on the EU definition. Two were the investigated PFAS: fluopyram and lambda-cyhalothrin.
- Collect different stakeholders' perspectives on this application of the concept of "essentiality" and on the concept itself.
- Give policy makers advice on the application of "essentiality" accounting for diverse perspectives, and on gaps in the current legislation on PPPs and PFAS use therein.

2.3 Research questions

1. **What is the current legislation on PPPs, and PFAS use therein, within the EU and the Netherlands?**

2. **To what extent do specific PFAS compounds used in PPPs meet the EU's criteria for "essentiality"?**
- What information is readily available to answer the two questions stated in the EU's criteria for essentiality?
- What information is still needed to be able to answer this question?

3. **What are the perspectives of users, manufactures, academics, and legislators on the EU's criteria of "essentiality" applied to specific PFAS in PPPs?**
- What do the different stakeholders consider "essential" for an effective PPP?
- What are the commonalities and differences between the stakeholders' perspectives?
- How do the different stakeholders' perspectives align with the recent (April 2024) conception of "essentiality" as explained by the EU Directorate-General for the Environment, and our analysis of this concept?

3. Methodology

3.1. Literature review

To answer research question one, a literature review was conducted on the legislation on PPPs within the EU and the Netherlands. For this, literature on policy from both the EU and the Netherlands that affects PPPs was reviewed. Additionally, attention was focused on the most recent policy developments regarding PFAS, and PFAS in PPPs. The majority of the documents that were reviewed were policy documents directly from the EU.

3.2. Framework application

On the 26th of April 2024, the European Commission published a communication document with guiding criteria and principles for the essential use concept (European Commission, 2024c). This document formed the basis of our framework. The criteria and guidelines in the document were transformed into a table, which could be used for the purpose of evaluating whether two specific PFAS compounds met the EU's criteria for "essentiality" (Appendix E).

Two specific PFAS compounds were selected based on several criteria: (1) it must be an active substance, safener, synergist or co-formulant used in an approved PPP on the EU market, (2) it has widespread use and (3) it must be potentially harmful.

The specific PFAS compounds selected were fluopyram and lambda-cyhalothrin. We focused on fluopyram used as a fungicide to protect strawberries from the destructive fungal pathogen *Botrytis* spp. (Bayer UK, 2023). Additionally, we investigated lambda-cyhalothrin as an insecticide used to protect potatoes against *Agriotes* spp. in their larval stage (wireworms) (Sipcam Oxon S.p.A., 2023).

Before applying the framework, it must be assessed if the substances are considered "most harmful". The ecotoxicological assessments of the substances were carried out in accordance with the communication (COM (2024) 2894 final). Informative websites were used to gather information, including the database of Lewis et al. (2016) and the International Agency for Research on Cancer (2024) database. The main documents consulted were those of US EPA or PAN. For each toxic property, sufficient literature was consulted to understand and take into consideration the level of toxicity of the substance (fluopyram or lambda-cyhalothrin). When all the properties were investigated, the final assessment was carried out by checking whether the substance has one or more of the listed properties found in the communication.

Details of the "Use of the substance" section of the framework were identified from relevant literature. Descriptor lists from ECHA (2015) were analysed and the relevant descriptors for both fluopyram and lambda-cyhalothrin selected for application into each technical function category. Details on the use of the substance and tasks involved in its use were provided by the manufacturers, including general precautions, specific use precautions, first aid measures and accidental release measures (Haas, 2023; Syngenta, 2023).

Essentiality assessment of the use was carried out to determine if the substance is necessary for the health or safety and critical for the functioning of society, and if there are acceptable alternatives (COM (2024) 2984 final). The manufacturers provide details on the technical function of the substance, from which it was assessed if the substance is required for the final product or service.

Alternative substances that could be used to control *Botrytis* spp. in strawberries, and wireworms in potatoes were identified via published research and government reports. Three groups of alternatives were identified following the guidance from the Communication. Lewis et al. (2016), an international database for pesticide risk assessments and management, was an invaluable source from which many of the identified alternatives were investigated. Substances that are both approved and not approved for use in The Netherlands under the EC Regulation 1107/2009 were included in the assessment to give a comprehensive overview of the existing alternatives. Alternative practices and techniques were also considered in the assessment.

The alternatives were then evaluated based on criteria adopted from Article 50 of Regulation 1107/2009. Alternative substances were deemed to be significantly safer for human or animal health or the environment, if they had no high alerts associated with them for environmental fate, ecotoxicity or human health according to Lewis et al. (2016). Additionally, alternatives that do not cause adverse health effects to humans and non-target organisms were identified from relevant literature. Again, alternatives that do not present significant economic or practical disadvantages, as well as alternatives that minimize the occurrence of resistance in the target organism were identified from literature.

In the assessment of alternatives, each alternative was assigned to the section of the framework that it fulfilled. In line with Regulation 1107/2009, the alternative must fulfil all four criteria of the assessment to be deemed an acceptable alternative to a candidate for substitution. In this way it could be assessed if there is an acceptable alternative available. If no acceptable alternatives are identified, the specific use case of the substance is considered essential.

3.3. Stakeholder analysis

The first step in the stakeholder analysis was identifying all relevant stakeholders (chapter 1.4). Our research is qualitative and focussed on a very specific area of interest – the application of the essentiality concept to PPPs containing PFAS essentiality, the PFAS including in PPPs, the legislation of (PFAS in) PPPs, and the alternatives to (PFAS in) PPPs. Therefore, a non-random purposive sampling technique has been used to select the interviewees. Interviewees were initially identified through literature research and an internet search. This was later supplemented by information gained from the project commissioner and recommendations from previously contacted stakeholders.

The initial contact with most of the stakeholders was either through email or a contact form found on their website. If a reply was not received within several days, we followed the email up with a call. In the cases that additional information was requested, an information sheet was sent (Appendix C1). After an interview was scheduled, we sent the stakeholder a consent sheet to review and sign in advance. The consent sheet can be found in Appendix C2.

In Appendix B, Table 3, a stakeholder response table can be found. This table provides an overview of all the stakeholders contacted during this project and the outcome of our correspondence.

A semi-structured interview style was chosen to ensure the interviewer had sufficient freedom to probe new leads introduced by the interviewee. This allowed the interviewer to follow the list of prepared questions (see interview guide in Appendix D) and navigate into new topics of interest identified during the interview. General questions were asked to all stakeholders, while additional specific questions were composed for each individual interviewee to gain as much expert

knowledge and perspective as possible. When it was not possible to conduct an interview in person, it was conducted online and recorded. Subsequently, all recordings were transcribed.

The interview transcripts were then subjected to an inductive code-based analysis in which responses from the interviewees were given a specific code based on their relevance to topics in the PFAS discussion.

Using the generated codes, it was possible to highlight the different types of answers stakeholders gave in response to the same questions. Coding of the specific questions lead us to gain a deeper understanding of the stakeholders' perspectives on the EU essentiality criteria, on the PFAS within PPPs, on the current legislation of (PFAS in) PPPs, and on the alternatives to (PFAS in) PPPs. Similarities and differences between the stakeholders' critiques of the essentiality criteria and adapted framework were identified and extrapolated on, giving a broad overview of the opinions of stakeholders on this matter. This information aided in the construction of new policy recommendations.

4. Current PPP legislation in the EU and the Netherlands

4.1. The development of EU legislation on pesticides

The foundational source of PPP policy in the European Union is found in its primary law—The Treaty on the Functioning of the European Union (European Commission, n.d.-c). Originally signed in 1957, Article 191 of this Treaty lays the groundwork for environmental policy within the EU, mandating that policy contribute to objectives such as the preservation, protection and improvement of environmental quality, and the protection of human health (Bourguignon, 2017; Treaty on the Functioning of the European Union, 2008). Moreover, policy should be based on a combination of scientific and technical data, considerations for environmental, social and economic conditions within EU regions, and cost-benefit analysis. Finally, it establishes several principles, such as the precautionary principle and principle of preventative action, that should be applied throughout environmental policymaking in the EU (Treaty on the Functioning of the European Union, 2008). These principles and objectives are pertinent to and reappear in EU PPP policy. See Figure 3 for an overview of how the groundwork for PPP policy was set.

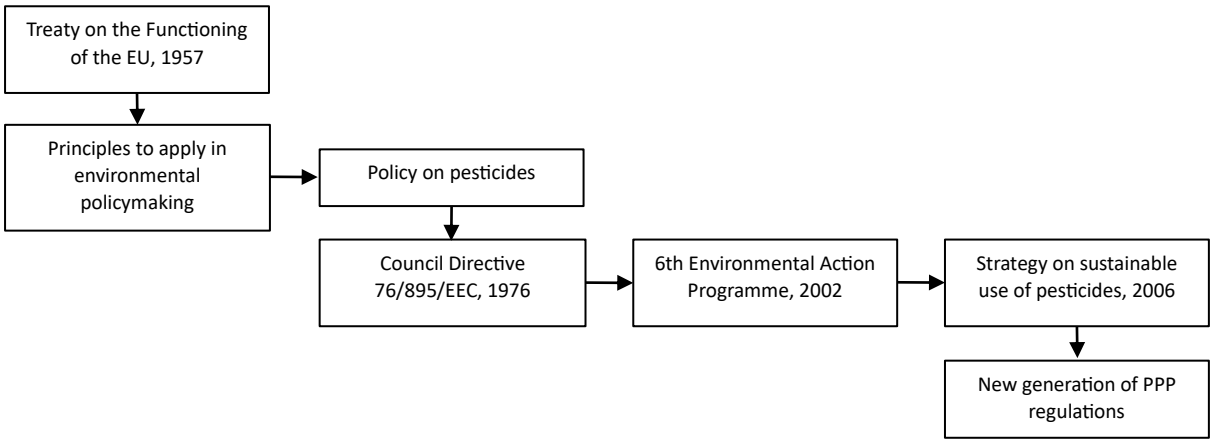

Figure 3. Illustration of how the groundwork for PPP policy was set.

Moving from broad principles to the development of harmonised EU policy on PPPs, we must return to the 1990s and 2000s. Prior to this, the EU had developed some policy on pesticides; however, it was sparse. A notable example included the 1976 Council Directive 76/895/EEC—the EU first attempted to harmonise pesticide regulations across the community—which set maximum pesticide residue levels in produce (Dinu & Karamfilova, 2018). Hence, arguably, instead of tackling the issue at its source, the regulation focused the end-stages of pesticide use.

However, it was the brink of the 21st century that saw the development of strengthened and broadened regulation (Dinu & Karamfilova, 2018). In 2002, the 6th Environment Action Programme of the EU was published. The programme established key environmental objectives based on an assessment of the state of the environment at the time. Specifically, it called for the reduction of the impact of pesticides on human and environmental health and of the risks associated with the use of pesticides. Moreover, the programme stipulated the development of a strategy on the sustainable use of pesticides in the EU (COM (2001) 31 final).

This strategy would arrive several years later in July 2006. The introduction to the strategy noted that while most member states and the EU as a whole had developed elaborate systems of evaluating and risks of pesticides on human health and the environment, further action was necessary as pesticide residues were still be found in the environment and food, exceeding established limits (COM (2006) 372 final) .(European Commission, 2006) The strategy prompted the development of a new generation of PPP regulations and now encompasses several legal acts on PPPs (Dinu & Karamfilova, 2018).

4.2. EU legislation on PPPs that is currently in force

The core legislation on PPPs that is currently in force is Regulation 1107/2009. The purpose of this regulation is to establish rules for authorisation of PPPs and their placement on the market. This serves to protect human health, animal health and the environment. Additionally, it improves market functioning through harmonised regulation. More concretely, the regulation describes the data requirements and the approval process for PPPs and their components (active substances, safeners, synergists, adjuvants and co-formulants). Following from the Regulation 1107/2009, a list of approved substances was published in 2011 (European Commission, 2011).

From this regulation we can glean that an active component, safener or synergist shall not be approved if:

- It is classified as a mutagen category 1A or 1B.
- It is classified as a carcinogen category 1A or 1B, unless exposure under realistic proposed conditions of use limits exposure to humans, it is used in a closed system or in other conditions which excluded contact with humans.
- It is classified as toxic for reproduction category 1A or 1B, unless exposure under realistic proposed conditions of use limits exposure to humans, it is used in a closed system or in other conditions which excluded contact with humans.
- It is considered to have endocrine disrupting properties which cause adverse effects in humans, unless exposure under realistic proposed conditions of use limits exposure to humans, it is used in a closed system or in other conditions which excluded contact with humans.

It should be highlighted that this is not an exhaustive list but covers the main criteria surrounding toxicity. Other regulations surrounding persistence and mobility also apply.

Another important element of current legislation is REACH (Regulation 1907/2006), which concerns professional activities that involve chemicals. PPPs, biocides and medicinal products are exempt from the REACH legislation because these substances are part of specific EU legislation (Ministerie van Landbouw, 2017). However, active substances in PPPs are included in the registered substances database from the REACH regulation, because these substances have multiple uses. This means that Regulation 1272/2008 on classification and labelling also has information on the labelling of PPPs.

The Netherlands is a Member State of the European Union. Therefore, the Netherlands adheres to the Regulation 1107/2009 on the data requirements for the placement of PPPs on the market (Rijksoverheid, 2023). After PPPs are placed on the market under this Regulation, they are subject to the Sustainable Use Directive (Directive 2009/128/EC). The Netherlands implements this directive with a National Action Plan, which supplements a previous legislation called the "*Implementation Programme for the Vision for the Future of Plant Protection 2030"*

(Rijksoverheid, 2023, p.3). Additionally, the National Action Plan takes into account the Water Framework Directive and the Dutch Plant Protection Product and Biocides Act.

Whilst the aforementioned policy documents do cover all compounds present within PPPs, care must be taken with regards to co-formulants. The original regulations regarding unacceptable co-formulants are given in the Regulation No 1107/2009 but this regulation does not go into depth on defining the specifics surrounding what is considered unacceptable and what data requirements are needed for this consideration. The initial list of unacceptable co-formulants from Annex III of Regulation 1107/2009 was amended by Regulation (EU) 2021/383, this document became available in March of 2021 and used the starting protocol supplied in Regulation 1107/2009.

This ruleset was reviewed and reworked with Regulation 2023/574. We can glean from this document that co-formulants are covered by Regulation 1907/2006 of the European Parliament and of the council ("REACH") and Regulation 1107/2009 if not already covered by any other criteria. This is of note as this would mean that co-formulants do not have a regulation dedicated to them specifically unlike active components, safeners and synergists. The above would allow any change made to the REACH protocol, such as the inclusion of the essentiality principle, to directly affect any co-formulants.

The following is a summary of the main criteria used in Regulation 2023/574 to identify unacceptable co-formulants.

- The co-formulant is classified as mutagen category 1A or 1B
- The co-formulant is classified as carcinogen category 1A or 1B
- The co-formulant is classified as toxic for reproduction category 1A or 1B
- The co-formulant is listed in Annexes I to V to Regulation 2019/1021 (Regulation on persistent organic pollutants).
- The co-formulant is classified in Article 59 (1) of Regulation 1907/2006 due to its identification as:
    - Persistent, bio accumulative and toxic.
    - Very persistent, and very bio accumulative.
    - A substance of high concern due to endocrine disrupting properties.

For an overview of relevant governing policy on PPPs and, more broadly, chemicals, refer to Table 1 below.

Table 1. Overview of governing EU policy on PPPs as active substances or co-formulants, and chemicals.

	Subject matter and purpose	Relevant definitions	Contents	Conclusions
(EC) Reg. No 1907/2006 (REACH)	1. The stated purpose of the legislation is to protect human health and the environment, encourage alternative methods of assessment of hazardous substances, while maintaining their unobstructed flow throughout the EU. 2. It establishes rules for the manufacture, placing on the market and use of chemicals and their mixtures. 3. The rules are supposedly based on the principle that it is the responsibility of manufacturers, importers and (professional) downstream users to ensure that substances do not adversely affect human health or the environment.	• Substance – a chemical or its compounds, including any additives necessary to maintain the substance's stability.	1. Obligates manufacturers and importers to register substances in quantities greater than one ton. 2. Requires that all substances subject to registration have a chemical safety assessment. 3. Lays out data requirements for the assessments, requiring more stringent testing as the imported/produced quantity increases. 4. Requires suppliers to provide safety data sheets to recipients of substances. 5. Called for the establishment of the European Chemicals Agency, which would manage and have oversight over the application of this legislation within the EU.	• REACH does not apply to active substances. Those are covered by respective regulation on plant protection products or biocides and are treated as already registered under REACH. • Still, it remains relevant for PFAS as their proposed ban is to be implemented under REACH. • Moreover, co-formulants in plant protection products are not exempt from REACH and must, therefore, be registered.
(EC) Reg. No 1107/2009	1. It establishes rules for authorizing PPPs, placing them on the market, their use and control within the EU. 2. Rules are applicable to active substances, safeners, synergists, co-formulants and adjuvants. 3. The regulation's purported purpose is to protect human and animal health, and the environment, while improving agricultural production and market functioning through harmonized regulation. 4. The regulation is reportedly underlined by the precautionary principle, wherein each member state should be permitted to apply the principle with regards to PPP authorisation.	• Synergist – does not show or shows little PPP activity, but it can enhance the activity of an active substance • Safener – meant to reduce or eliminate phytotoxic effects of the PPP on certain plants • Co-formulant – neither an active substance, safener, nor synergist but used in PPP • Adjuvant – substance or preparation containing, among other things, one or more co-formulants, that is sold separately from a PPP and is intended to be mixed with the PPP by the user to enhance effectiveness and pesticidal properties • Candidate for substitution – active substance that has established or presumed harmful effects (e.g. carcinogenicity, mutagenicity, endocrine disruption, etc.)	1. Set out the safety and ecotoxicology requirements for an active substance, safener or synergist to be approved. 2. Explains the application approval and renewal process for a substance. 3. Sets out data requirements on dossiers submitted for the approval of a substance. 4. Introduces the notion of "candidates for substitution" and how they are designated. 5. Establishes basic criteria that render co-formulants "unacceptable" for use in PPPs. 6. Permits derogation from the regulations for low-risk active substances and basic substances.	• Safeners and synergists must comply with the same requirements as active substances. • Co-formulants face scrutiny under Annex III, which specifies prohibited substances. Specific requirements regarding co-formulants are rudimentary. • Rules on adjuvants were yet to be developed as of the regulation's adoption. • Often, the regulation appears to refer to underlying value judgments and socio-economic analyses, but it does not (typically) provide guidelines on how to perform such analyses.
(EU) Reg. No 283/2013	1. Establishes rules and data requirements on active compounds in PPPs or veterinary medicines or biocides placed on the market to provide efficiency and human and environmental safety within the EU. 2. The data submitted on active substances should be comprehensive and scientifically sound. 3. Establishes rules and evaluation criteria to ensure animal health, human health and environment such as a) an acceptable daily intake (ADI) level for humans; b) establish acceptable operator exposure levels (AOEL); c) establish an acute reference dose, (ARfD) for humans.	• Good laboratory practice (GLP) – tests and analyses intended to acquire data on properties or safety related to human or animal health or the environment must be in accordance with EU regulations • Residue – one or more substances found in plants, plants or animal products, drinking water or in the environment, derived from the use of PPPs, among other metabolites and breakdown compounds.	1. Use of active substances must be provided on the label of PPPs or veterinary medicines or biocides. 2. Proposes residue definitions and maximum residue levels. Specifically, when selecting compounds to include, consideration should be given to the toxicological significance of the compounds (the amounts expected to be present) and the proposed analytical methods for post-approval control and monitoring. 3. Defines the residue level for risk assessment. The residue definition relevant for risk assessment for each compartment should include all the components (active substance, metabolites, breakdown and reaction products) that were detected.	The data requirements for an active substance include: • Composition, chemical identity and analytical methods • Stability, solubility and other physicochemical characteristics. • Mammalian toxicity such as genotoxicity, carcinogenicity, and reproductive toxicity • Residues in plants, soil, animals and the environment • Environmental fate of active substances such as degradation and mobility. • Bioaccumulation and the effects of active compounds in non-target species. • Measurements of efficiency of the active compounds for their intended use

(EU) Reg. No 284/2013	1. Establishes rules and data requirements for PPPs placed on the market, to provide efficiency and human and environmental safety within the EU. 2. The data provided submitted on PPPs should be comprehensive and scientifically sound. 3. Reinstatement and improvement of already established rules in PPPs intended for use within the EU.	No new, relevant definitions.	1. Use of PPPs should be given, including their composition and formulation. 2. Use of active substances should be provided on the label of PPPs. 3. Harmonization of all data requirements in all EU member states 4. Defines the residue level for risk assessment. The residue definition relevant for risk assessment for each compartment should include all the components of plant protection products (active substance, metabolites, breakdown and reaction products) that were detected.	• Comprehensive data requirements should be provided for PPPs to safeguard human and environmental safety. • Strengthen safety standards by setting out rigorous rules for data requirements for PPPs on the EU market of EU. • The EU prioritizes human and environmental health and safety by establishing strict criteria for PPPs. • The EU ensures the alignment of data requirements and evaluation processes of PPPs in all EU member states. • Provides less strict rules for minor use or low risk substances of PPPs. • Measures should be included for the efficiency and the safety of the PPPs should be confidential to protect the business. Although, they should be available for scientific evaluation.
(EU) Reg. No 2021/383	1. Provides a list of unacceptable co formulants identified by previously determined criteria from Reg. No 1107/2009. This falls under Annex III of Reg. No 1107/2009.	• CMR properties – the specific carcinogenic, mutagenic and reprotoxic properties of a compound.	a. Classification as "unacceptable co-formulants" uses guidelines established in Reg. No 1107/2009. This is of note as later regulations, particularly Reg. No 2023/574, set out a more detailed guideline around this classification. b. Clarifies that use of unacceptable co-formulants in adjuvants is also prohibited under Reg. No 1107/2009. c. Co-formulants listed may be present as unintentional impurities in other co-formulants, a concentration of 0,1% weight by weight or a specific concentration limit depending on CMR properties.	• The main use of this regulation is as a full implementation of the list of unacceptable co-formulants outlined in Annex III of Reg. No 1107/2009.
(EU) Reg. No 2023/574	1. Provides a detailed ruleset compared to one of Reg. No 1107/2009 for the identification of unacceptable co-formulants. 2. Specified rulings surrounding toxic effects, persistence and bioaccumulative properties are set out in this regulation.	No new, relevant definitions.	a. This regulation aims to futureproof the rulings surrounding co-formulants from Reg. No 1107/2009 by setting out a precise ruleset for this identification. b. Further clarifies that manufacturing, placing on the market and uses fall under both Reg. No 1907/2006 and REACH regulations when they are intended for use in PPPs. c. Applies approval criteria for active compounds, safeners and synergists set out in Reg. No 1107/2009 to co-formulants, if they are not already covered by another regulation. d. Specific mention is made that Members States can still prohibit or restrict application of co-formulants within its borders. e. Sets out CMR property as well as persistence and bioaccumulation criteria for the identification of unacceptable co-formulants	• The definitions and rulings surrounding an unacceptable co-formulant originally set in Reg. No 1107/2009 are further defined. Reg. No 2023/574 mainly works to bring co-formulant regulations in line with those of active compounds, synergists and safeners. • Of specific note is that the manufacturing, placing on the market and use are regulated **not by Reg No. 1107/2009 but by Reg No. 1907/2006 and REACH**
(EU) Reg. No 2024/1487	1. Provides detailed rulings about data requirements surrounding the approval of safeners and synergists. 2. Establishes a work program guiding the gradual review of safeners and synergists on the market in accordance with Reg. No 1107/2009.	No new, relevant definitions.	a. A specific list of safeners and synergists contained in at least one PPP authorized for placing on the market, will be provided on 19 July 2024. b. Regulation states that by 19 June 2028, approval of a safener or synergist shall be done via submission of application to the reporting Member state containing all data. Requirements for this data are set out in Article 11. c. Consideration is given to potential data protection and confidentiality. This can be claimed under Article 59(3) of Reg No. 1107/2009	• In essence, this regulation expounds on data requirements surrounding the criteria for approval set out in Reg. No 1107/2009.

4.3. Recent policy developments

The bulk of the aforementioned regulations have been in force for a decade or more now. Amendments have been introduced since then, but their scope, subject matter and content remains largely unchanged. However, some relevant developments have occurred in the 2020s.

Proposal for the restriction of PFAS under REACH

Starting in 2023, a group of (inter)national institutes and agencies from several EU nations, including Germany, the Netherlands, Sweden, Norway, and Denmark, submitted a proposal to ban PFAS within the EU. The scope of the ban is aligned with the OECDs definition of PFAS. Therefore, PFAS are defined as "any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it)" (European Chemicals Agency, 2023b, p. 2). However, the proposal does not cover substances that contain fully degradable PFAS subgroups, as they are not highly persistent (European Chemicals Agency, 2023b).

The ban proposed two restrictions options (ROs) that differed in their severity, length of transition period and permitted derogations. RO1 is a full ban with no exceptions (derogations) permitted and a transition period of 18 months. RO2 is a more lenient pathway, that nevertheless proposes a full ban on PFAS, but also permits time-limited, use-specific derogations (for an 18-month transition period and an additional 5- or 12-year derogation period). Moreover, RO2 foresees several time-unlimited derogations, for example in refrigerants, active substances of plant protection products and biocides, and medical products (European Chemicals Agency, 2023b). In simple terms, it would allow PFAS acting as active substances in PPPs to be used indefinitely, provided that they meet all other requirements of chemical and PPP regulations by the EU. Ultimately, RO2 is suggested as "the most balanced option" (European Chemicals Agency, 2023b), as it mitigates issues of the sudden unavailability of products.

Several pieces of rationale are provided to highlight the importance of the proposed ban. First, the authors refer to a Nordic Council report that estimates the annual costs of PFAS exposure in Europe at 52 to 84 billion euros. Second, they draw attention to the possibility of a severe underestimation of the amount of PFAS released into the environment, due to high uncertainties associated with products' waste phase. Finally, the report argues that the societal cost of inaction will always be greater than the cost of a PFASs ban, due to the persistence of PFASs and their degradation products (European Chemicals Agency, 2023b).

Between March and September of 2023, the 6-month consultation period for the proposal, the ECHA received over 5600 comments from 4400 unique parties. The majority, 68.5%, of the comments were submitted by companies or industry groups. Afterwards, the comments were directed to the Risk Analysis and Socio-Economic Analysis Committees of the ECHA, which were tasked with considering whether they contained relevant evidence-based information. The submitting member states could also update their original proposal based on the received input (European Chemicals Agency, 2023a).

Afterwards, in March 2024, after reportedly reviewing much of the comments, the ECHA announced a series of meetings (in March, June and September) where its scientific committees were to discuss various sectors involved with PFAS or products containing PFAS (e.g. petroleum

and mining, consumer mixtures, metal products, textiles). Subsequent steps have not been announced yet. However, ultimately, the ECHA is expected to deliver an opinion on the proposal to the European Commission "[...] in the shortest possible timeframe while ensuring their transparency, independence and high quality" (European Chemicals Agency, 2024a).

EU Commission Communication on "essential use"

Less than a month after the first meetings of the ECHAs committees, a potentially relevant development came from the Directorate-General for the Environment, who issued a set of guidelines and criteria for the application of the concept of "essential use" in EU policy. The purported aim of the concept is to "accelerate the phase-out of the uses of the most harmful substance that are non-essential" (COM (2024) 2894 final, p. 5), while providing time for the substitution of uses of harmful substances that are essential to society.

The Communication comes as a concrete deliverable for the Chemicals Strategy for Sustainability (European Commission, 2024), which requested that the Commission clarify the concept and underlying criteria for the characterization "essential use" of dangerous substances (COM (2020) 667 final). This notion of an essential use of a substance was to be used in conjunction with a generic approach to risk management — "the automatic trigger of pre-determined risk management measures (e.g. packaging requirements, restrictions, bans, etc.) based on the hazardous properties of the chemical and generic considerations of their exposure to protect consumers, vulnerable groups and workers from exposure to harmful substances in all but the proven essential uses for society, without the need or possibility to assess and take into account specific exposure levels for a specific situation or use (COM (2019) 264 final, p. 10). This combined framework is intended to protect consumers, vulnerable groups and workers from exposure to hazardous chemicals, while still allowing for the essential uses of the substances for society (COM (2020) 667 final).

In simple terms, the communication lays out a framework that should be used when deciding on whether a specific use of a most harmful substance is essential. The first step is the identification of a distinct and well-bounded use, as previously explained in section 3.2. Afterwards, the determination of essentiality can proceed based on two guiding criteria. First, the substance must be crucial to health and safety or critical to the functioning of society. Second, there must be no acceptable alternatives for the substance for a given use. Both criteria must be met for a use to be deemed essential (COM (2024) 2894 final). More information on the specific criteria is offered in Chapter 5 with the presentation of our application of the framework.

Notably for this report, if a most harmful substance was to be a PFAS included in a PPP, we interpret its use as necessary for health and safety by default, due to what the proposed qualifying uses are. No differentiation is made between active substances whatsoever, while the scope of the uses is incredibly broad. Put simply, a PFAS-based PPP is necessary for health and safety because it contributes to the provision of "secure sufficient and safe food and feed, such as uses in the production, processing, storage, distribution and delivery of food for human consumption" (COM (2024) 2894 final, p. 11). Moreover, due to the communication's concern with solely the "most harmful substances", many PFAS-based active substances would not qualify for assessment under this essentiality framework.

Ultimately, the communication has no legal effect at present; "[essential use] only has legal effect when introduced into specific legislation" (COM (2024) 2894 final, p. 2). Moreover, the

Communication suggests that essentiality is not a static concept. It can and will evolve over time as new (scientific) evidence emerges, societal challenges arise and change, and alternatives are revealed (COM (2024) 2894 final).

5. Essentiality analysis of specific PFAS

5.1. Framework outline

To assess the essential use of compounds found in PPPs, we consider both the Communication from the Commission covering the guiding criteria, and the established criteria for the approval of substances in PPPs. The framework was predominantly developed based on the guiding criteria from the Communication. Where necessary, criteria from other sources were utilised (e.g. Regulation 1107/2009 and 2023/574), following explicit suggestions in the Communication. The specifications in these regulations are largely similar to those set out in the Communication but include additional information. This allowed for the development of the adapted framework, through which active compounds, safeners, synergists and co-formulants found in PPPs, can be assessed for their essentiality.

Before applying the framework, it must be assessed if the substance is considered "most harmful". After this, there are two core sequential steps in the adapted essentiality framework. The first step of the framework is to assess whether the "most harmful substance" is essential or non-essential in terms of necessity for health and safety and availability of alternatives. The second step is an evaluation of the alternatives.

As previously mentioned, and in line with the Communication, a prerequisite to apply the essentiality framework is that a chemical is considered a 'most harmful substance'. To meet this requirement, the substance under investigation needs to have one or more of the following hazardous properties:

- Carcinogenicity category 1A and 1B;
- Germ cell mutagenicity Cat. 1A and 1B;
- Reproductive/developmental toxicity Cat. 1A and 1B;
- Endocrine disruption Cat. 1 (human health);
- Endocrine disruption Cat. 1 (environment);
- Respiratory sensitization Cat. 1;
- Specific target organ toxicity – repeated exposure (STOT-RE) Cat. 1, including immunotoxicity and neurotoxicity;
- Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative (PBT/vPvB)
- Persistent, mobile and toxic/very persistent and mobile (PMT/vPvM)
- Hazardous to the ozone layer Cat. 1

The detailed guidelines on what renders a substance as having one of the above properties can be found in Annex II to Regulation 1107/2009.

Recall that these criteria are very similar to the criteria that would render active substances (and safeners and synergists) and co-formulants unacceptable for inclusion in PPPs. The Commission specifically states that this list is not exhaustive; therefore, more stringent rulings may still be possible.

The first step in the assessment following the determination of a most harmful substance, is the establishment of a specific and well-bounded use of a substance. To describe the use, we sourced technical function descriptors from the ECHA (2015), following an explicit suggestion in the communication (COM (2024) 2894 final). The detailed description of a use is necessary for

the ensuing assessment of essentiality, because the notion of "essential" does not apply to any one substance in general but, rather, to a specific use case of that substance. For example, an active substance in a PPP could have multiple uses: in several types of crops and against several pests. Therefore, each combination of crop **x** pest constitutes a unique use that the framework may be applied to. By extension, finding a substance essential in one use does not imply that the substance is essential in any other use or is universally essential. Once this specific use is established, the de facto assessment of essentiality can occur. Set out in the communication are criteria that we have adapted to function within the framework. These criteria are the following:

- Necessary for health and safety:
  - Prevent, monitor or treat illness and similar health conditions
  - Sustain basic conditions for human or animal life and health
  - Manage health crises and emergencies
  - Ensure personal safety
  - Ensure public safety
- Critical for the functioning of society:
  - Provide resources or services that must remain in service for society to function (e.g. Ensure the supply of energy and critical raw materials or resilience to supply disruption)
  - Manage societal risks and impacts from natural crises and disasters
  - Protect and restore the natural environment
  - Perform scientific research and development
  - Protect cultural heritage

Second, if the substance is found to fulfil at least one of the above criteria (necessity or criticality), a two-part assessment of the alternatives is carried out to ultimately confirm or refute the essentiality of the substance in the use, depending on whether an acceptable alternative is available.

The initial step is the identification of alternatives. The Communication proposed three broad groups of alternatives that should be identified for the assessment. For all groups, the notion of "alternatives" is not limited to solely alternative substances. Where relevant, alternative technologies and farming techniques were also considered.

The first category covers products in the same product category that do not use the most harmful substance. No further guidance is offered. Therefore, we assumed that they could nevertheless be (highly) harmful synthetic substances.

The second category covers alternatives with lower performance, provided they are socially acceptable. Typically, this meant that natural, plant-derived compounds and mixtures were included within this category, given their generally lower efficacy. Published research and available accounts of their use were seen as implying a degree of societal acceptability. They may be safer than synthetic counterparts; however, this is not an absolute statement.

The third category covers alternatives that provide a similar technical function and a similar level of performance to those provided by or with the most harmful substance. Only alternatives for which published data proving their (near) identical performance were included. Importantly, no statement is made on the safety or ecotoxicology of an alternative by its inclusion under this category.

Lastly, once the alternatives are identified, the final step—their evaluation—can be performed. Following suggestions from the Communication on utilizing criteria from regulation relevant to that area (COM (2024) 2894 final), we used criteria from the 2009 Regulation on PPPs. However, as the regulation did not contain explicit mentions of acceptable alternatives and their determination, we adopted criteria from the most closely conceptually related notion of "candidates for substitution" (CfS). Information on this can be found in Article 50 of Regulation 1107/2009. The four criteria included in the adapted framework are: (1) significantly safer for human and animal health or the environment, (2) does not present significant economic or practical disadvantages, (3) minimises the occurrence of resistance in the target organism, and (4) consequences of minor use authorisations are taken into account.

Finally, based on the results of the evaluation, it can be decided whether an acceptable alternative has been found. If available, we can conclude that the specific use of a substance is not essential, and vice versa. If no acceptable alternatives are present, the use is deemed essential. The following sections (5.2 and 5.3) of the report present our application of the framework for two specific uses of PFAS acting as the main active ingredient of a PPP. Based on our adaptation of CfS from Regulation 1107/2009, an alternative is acceptable when it meets all four of the criteria. In our application, the presence of a substance in any criterion indicates that it meets this requirement.

5.2. Fluopyram

Substance background

Fluopyram is as a preventive broad-spectrum fungicide that is dispensed via foliar application (Bayer Hellas, n.d.; Veloukas & Karaoglanidis, 2012). We examined its use to protect the strawberry crop from grey mold (grey mould), a disease caused by a common fungus — *Botrytis cinerea* (Veloukas & Karaoglanidis, 2012). *Botrytis* spp. harm strawberries by infecting tissues that are already damaged or aging, leading to tissue decay (Petrasch & Wiley, 2019). This pathogen is classified as one of the most difficult diseases to manage, due to fungus' ability to readily develop fungicide resistance (Veloukas & Karaoglanidis, 2012). Following ECHA (2015) use descriptors, fluopyram has a technical function of a biocide and is included in the product category of plant protection products.

Regarding its mechanisms of action, fluopyram is an inhibitor of the complex II in the mitochondrial respiratory chain, known as succinate oxidoreductase (SQR) or succinate dehydrogenase (SDH). This enzyme is fundamental for both the tricarboxylic acid cycle and the mitochondrial electron transport chain (Matsson & Hederstedt, 2001).

General precautions for fluopyram involve using of personal protective equipment (PPE) and ensuring appropriate disposal of hazardous waste. First aid and accidental release measures are provided in the assessment table (see Appendix G).

Assessment of essentiality

Concerning the essentiality assessment of the use of fluopyram, it was found that the technical function of this substance can be, to some extent, replaced by trifloxystrobin in the final product. Luna Sensation (Bayer), which was the specific product under consideration, contains both active substances – fluopyram and trifloxystrobin – acting as fungicides (Bayer UK, 2023). For Luna Sensation (Bayer), both active substances are pertinent for the management of the pathogen. However, there are alternative formulations available in Netherlands for the

management of grey mold in strawberry crops, for example Luna Privilege. Luna Privilege contains fluopyram as its sole active compound. The existence of multiple formulations of fluopyram-based PPPs, could be seen as an indication of its vitality for human health and safety, by contributing to the provision of sufficient food supplies (COM (2024) 2894 final). However, this is solely an assumption. As the technical function is necessary and the substance is required for health and safety, an assessment of alternatives was conducted.

Identifying alternatives

The first category of alternatives, which includes products within the same category that do not use fluopyram, revealed several substances. First, isofetamid which is not approved for use in the Netherlands. However, it is still allowed in other EU member states (Lewis et al., 2016). This category also includes fenpyrazamine, which is approved in all EU countries. Finally, carbendazim is also available, but it is banned in the EU due to its diverse adverse effects on humans and honeybees (Lewis et al., 2016; Llanos & Apaza, 2018).

Next, we turn to alternatives with lower performance, but which remain socially acceptable. There we found Amylo-X WG a broad-spectrum bio-fungicide based on *Bacillus amyloliquefaciens* subsp. plantarum d747, which functions through a combination of diverse mechanisms of action (Ctgb, n.d.-a). Moreover, Polyversum is a bio-fungicide based on *Pythium oligandrum* strain m1, in which the fungus produces enzymes and actively feeds on *Botrytis* spp. (Ctgb, n.d.-b). Cerevisane is considered as another possible alternative to fluopyram. It is a purified extract obtained from the *Saccharomyces cerevisiae* strain las02, which can induce systemic resistance in the plant against foliar fungi (Ctgb, n.d.-c). Noli is a bio-fungicide formulated with *Metschnikowia fructicola*, used to prevent fruit decay, but it can also be applied in the final stages before harvest (en Rodenrijs, 2019). A range of integrated pest management (IPM) practices targeted at controlling *Botrytis* spp., including the removal of infected plants, using clean equipment, rotating crops, reducing humidity in the greenhouse and ensuring proper airflow (Government of Greece, 2013) show lower levels of performance than fluopyram.

Finally, alternatives that provide a similar technical function and a similar level of performance to those provided by or with the most harmful substance are identified.

First, we found iprodione, a post-harvest fungicide with endocrine disrupting properties and moderate alerts for environmental fate and ecotoxicity (Lewis et al., 2016). However, its authorisation expired in 2017 and was not renewed (European Commission, n.d.-b). The remaining alternatives with the similar technical function and level of performance are approved under EC Regulation 1107/2009 in all EU member states (Lewis et al., 2016; Llanos & Apaza, 2018). Fenhexamid, pyrimethanil and penthiopyrad are possible human carcinogens and have moderate environmental and ecotoxicity alerts. The category also features boscalid. Boscalid is persistent in the environment and has moderate ecotoxicity and human health alerts associated with it, with low risk for honeybees. Cyprodinil is a fungicide that is moderately persistent in soil and water systems. It has high alerts for environmental fate and ecotoxicity but has no serious human health concerns identified. Fludioxonil is a persistent bioaccumulative toxin. Pyraclostrobin has high ecotoxicity for certain aquatic organisms and can cause reproduction and development effects in humans. Trifloxystrobin is a commonly used fungicide and is not expected to be persistent in soil or water systems but may have negative effects on fertility in

mammals. It is very toxic to aquatic organisms but has an insignificant risk for honeybees. Captan is a dicarboxamide fungicide with low persistence in soil and water systems. It has low toxicity for mammals but may be carcinogenic and cause endocrine issues. It has a moderate ecotoxicity alert (Kim et al., 2016; Lewis et al., 2016).

Evaluating alternatives

While evaluating alternatives to fluopyram according to criteria adapted from Article 50 of (EC) Reg. No 1107/2009), isofetamid, fenhexamid, fenpyrazamine, and pyrimethanil were determined as significantly safer for human or animal health or the environment, due to their moderate persistence and their moderate or low alert for risks to human health, honeybees, and environment. There is no evidence of carcinogenic activity or promoting endocrine disruption (Lewis et al., 2016).

Regarding economic or practical disadvantage considerations, Abbey et al. (2019) stated that constant application of conventional fungicides, such as fluopyram, poses three major challenges: (1) growing public concern of contaminated produce and its impact on human health, (2) increased development of resistance in *Botrytis* populations, and (3) environmental impacts. Alternatives with lower performance, including bio-fungicides, can be highly affected by the microclimate and necessitate specific storage and usage conditions. Another challenge in product formulation is the application of the initial concentrations in microbial PPPs (Abbey et al., 2019).

Captan has been recorded as the chemical substance that can be used as alternative that minimizes the occurrence of resistance in the *Botrytis* spp. (Leroux, 2007). However, strains of *Botrytis* with less sensitivity to captan have been identified (Amiri et al., 2018). The polycyclic nature of *Botrytis* spp. facilitates rapid development of resistance to consistent and repeated application of fungicides (Abbey et al., 2019).

Finally, minor use authorisations can be granted for specific crops in the Netherlands, however none were identified in this instance. The importance of assessing the minor use of CfS in PPPs must be well supported by the regulatory authorities (European and Mediterranean Plant Protection Organization, 2019).

Ecotoxicology

From the toxicological perspective, fluopyram is not considered carcinogenic by IARC (2024). The US EPA supports this finding with its 2021 and 2023 reviews (Davis et al., 2023; Turley et al., 2021), stating that fluopyram is “Not Likely to be Carcinogenic to Humans”. However, the EPA also reports that:

- Increased liver tumours were observed in female rats in the carcinogenicity study at the highest dose tested (89 mg/kg/day) with fluopyram.
- Thyroid effects (increased thyroid weight along with follicular cell hypertrophy and hyperplasia) were observed at dose levels similar to those that produced liver effects in rats and mice. In a male mice, there was an increased incidence of thyroid adenomas at the highest dose tested (105 mg/kg/day).
- Fluopyram induces liver enzymes following PXR/CAR activation, which causes increased metabolism of thyroid hormones. All these changes lead to liver and thyroid hypertrophy

and proliferation, eventually leading to liver tumours (female rat) and thyroid tumours (male mice).

- The CARC classified fluopyram as “Not Likely to be Carcinogenic to Humans” at doses that do not induce cellular proliferation in the liver or thyroid glands. This classification was based on convincing evidence that non-genotoxic modes of action for liver tumours in rats and thyroid tumours in mice have been established and that the carcinogenic effects have been demonstrated as a result of a mode of action dependent on activation of the CAR/PXR receptors. The CARC has determined that quantification of risk is not required. There is sufficient data to ascertain the mode of action of fluopyram.
- The chronic reference dose (RfD) is derived using the NOAEL of 6 mg/kg/day as the “point of departure” which is below the dose of 11 mg/kg/day that caused cell proliferation in the liver (i.e., a key event in tumour formation) and the subsequent liver tumours at a higher dose (89 mg/kg/day).

Back in 2012 in the US Federal Register (FR) considered fluopyram "likely to be carcinogenic”, but its stance changed in 2019 when it concluded that it is "not likely to be carcinogenic” (US Federal Register, 2012, 2019).

According to the European Chemicals Agency (2024b), FR (2019), the US EPA (2021), and Davis et al. (2023), fluopyram is not considered as a germ cell mutagen of Cat. 1A and 1B. There is no evidence about its toxicity (Cat. 1A and 1B) on reproduction and development (2019). Davis et al. (2023 and the FR (2019) said that “fluopyram did not elicit developmental or offspring effects, nor did it adversely affect reproductive parameters. No evidence of increased qualitative or quantitative susceptibility was observed in developmental or reproduction toxicity studies”. Furthermore, it is found that fluopyram is an endocrine disruptor in humans, but not of Cat. 1 (Wei et al., 2016); whilst, Lewis et al., (2016) report that no data are found about it. PAN explained that it has a potential endocrine disruptor effect in birds and fish, but no direct endocrine disrupting effects were evident in mammals; indirect effects observed on the endocrine system were not of concern for wild mammals. They occurred at higher doses than the endpoint used for risk assessment (Lyssimachou & Muilerman, 2019). In addition, Lewis et al,. (2016) reported that no data are found about fluopyrams’ effects on respiratory sensitisation. Therefore, it is not considered in the Cat. 1; to strengthen this statement, Davis et al. (2023) reported that fluopyram is considered in Cat. 4 as regards inhalation effects. Moving to the last hazardous properties, this molecule is not considered as a neurotoxin (Davis et al., 2023), apart from in rats (Turley et al., 2021); but it is not a neurotoxicant of Cat. 1. According to Lewis et al., (2016), the fluopyram neurotoxicity is still not clear: “Possibly, status not identified”. Besides, its DT_{50} (degradation half-life) in the field – which is 119 days (Lewis et al., 2016) – is lower than the threshold of 120 days posited in the (EC) Reg. No 1107/2009 to consider a compound as persistent in the environment. Lewis et al., (2016) reports that its DT_{90} is 833 days in the field, which is a value of persistent molecules, but it cannot be considered persistent. It can neither be consider bioaccumulative because it has a low potential of bioaccumulation (BCF = 18 l/kg); then, it shows a moderate toxicity in some animals (Lewis et al., 2016). Moreover, it is considered moderately mobile: it has a GUS leaching potential index = 3.23; it is higher than 2.8, thus it has a high leachability (Lewis et al., 2016). Finally, it does not appear in the list of ODS (ozone-depleting substances) of the US EPA (2015).

Overall, fluopyram is not considered a most harmful substances, as it does not meet any of the hazard criteria mentioned in section 5.1.

5.3. Lambda-cyhalothrin

Substance background

Lambda-cyhalothrin is an insecticide approved for use in all 27 EU member states and is a recognised candidate for substitution (European Commission, n.d.). The use we have considered is its application in potato farming, where it prevents root damage by insects from the *Elateridae* family (wireworms). To be effective, lambda-cyhalothrin must be applied into to the soil while sowing potatoes (Sipcam Oxon S.p.A., 2023; Syngenta, 2020). Following ECHA (2015) use descriptors, lambda-cyhalothrin has a technical function of a biocide and is included in the product category of plant protection products.

Regarding its mechanism of action, lambda-cyhalothrin is a non-systemic pyrethroid that becomes effective upon ingestion by insects (Lewis et al., 2016). Ingestion leads to a disruption of sodium channels that are responsible for nerve impulses and causes the eventual death of the insect (NPIC, 2001). The technical function of this product is required for the control of wireworms, as they cause significant damage to potato tubers leading to notable economic losses (Vernon & van Herk, 2022). General precautions when using lambda-cyhalothrin include the use of personal protective equipment (PPE) and the correct disposal of hazardous waste. Entry into waterways must be avoided as lambda-cyhalothrin is highly toxic to aquatic life. First aid and accidental release measures are included in the assessment table (see Appendix I).

Essentiality assessment

Regarding the essentiality assessment of the use of lambda-cyhalothrin, it was found that the technical function of this substance is required for the final product to deliver its services, as lambda-cyhalothrin is the sole active compound in the product (Karate 0.4% GR, Syngenta) with insecticidal properties. We also assessed that lambda-cyhalothrin is necessary for health and safety as it allows for “sustaining basic conditions for human or animal life and health” (COM (2024c) 2894 final, p. 14). As the technical function is necessary and the substance is required for health and safety, an assessment of alternatives was conducted.

Identifying alternatives

Identification of possible alternatives within the same product category that do not use lambda-cyhalothrin, yielded fosthiazate which is used as a nematicide for potatoes (European Commission, 2003) with a reported 57% efficacy (Bavarian State Research Centre for Agriculture, n.d.). Moreover, we found imidacloprid formulations could be used to treat tubers, but their efficacy is limited at around 20% (Bavarian State Research Centre for Agriculture, n.d.). Finally, calcium cyanamide, an “obsolete, post-emergence herbicide and defoliant”, was identified. However, it is not approved for use in the EU (Lewis et al., 2016) and likewise shows limited efficacy against wireworms — 34% (Bavarian State Research Centre for Agriculture, n.d.).

Alternatives to lambda-cyhalothrin with lower performance but that are socially acceptable include pyrethrins, neem oil and methods of IPM. Pyrethrins are naturally occurring insecticides that not acutely toxic, but they break down quickly and can be detrimental to beneficial insects such as bees (Dowle, 2021). Neem oil is another natural insecticide that has very low toxicity,

enabling safer control of pests. However, it readily photodegrades and has a short shelf-life, making large scale use challenging (Campos et al., 2016). IPM is a set of environmentally sensitive practices such as rotational cropping with brown mustard, a natural fumigant, or fallowing before sowing potatoes than can be effective in managing wireworms (Hughes, 2014; Wickwar & Wenninger, 2023).

No alternatives that provide a similar technical function and level of performance to those provided by lambda-cyhalothrin were identified. The Bavarian State Research Centre of Agriculture (n.d.) report that the identification of effective products against wireworms is unlikely, while the European Innovation Partnerships for Agricultural Productivity and Sustainability report that synthetic pesticides are becoming increasingly ineffective against wireworms (EIP-AGRI, 2022).

Evaluating alternatives

While evaluating alternatives to lambda-cyhalothrin according to criteria adapted from Article 50 of (EC) Reg. No 1107/2009), neem oil was determined as significantly safer for human or animal health or the environment, as it does not cause adverse health effects to humans or non-target organisms (US EPA, n.d.). Again, alternatives that do not present significant economic or practical disadvantages were not identified. The mentioned alternatives require more intensive applications and have greater rates of photodegradation.

Neem oil is cautiously suggested as an alternative that minimises the occurrence of resistance in the target organism, wireworms. Neem oil may limit resistance through its many active substances and modes of action (Siegwart et al., 2015). Nonetheless, low to medium resistance has been shown to occur in aphids (Feng & Isman, 1995). Finally, data on minor use authorisations in the Netherlands are lacking. Only the crops are provided and not the substances applied to those crops.

Ecotoxicology

Lambda-cyhalothrin is highly toxic to fish, bees and rats. However, it is not considered a carcinogen of Cat. 1A and 1B by Lewis et al., (2016) and IARC (2024). Hurley (2002) classifies lambda-cyhalothrin as a group D carcinogen: this means that its ability to cause cancer has not yet been determined (NPIC, 2001). Hurley (2002) explains that there is no indication of oncogenic activity but an increase in mammary tumours in female mice; and in the document of PAN (2017) it is reported that the molecule increases the growth of human breast cancer cells and has been found in association with dog mammary tumour. In addition, in the Stockholm Convention report (2013) it is explained that no evidence of carcinogenicity has been found in rats. Then, as illustrated by Hurley (2002), this molecule is not considered in the Cat. 1A and 1B of germ cell mutagens; in the prementioned report of Stockholm Convention, it is explained that no genotoxic effects have been observed in the standard in vitro test package. The adverse effects on reproduction and development of rats that have been reported are the decreased testes weights, degenerative histopathology in the testes, abnormal sperm morphology, decreased sperm count, motility and viability, increased semen lipid peroxidation, increased dead sperm, decreased testicular antioxidant enzyme activities, decreased semen volume, decreased plasma testosterone levels and decreased libido (PAN, 2017). However, it is not considered a toxicant for reproduction and development of Cat. 1A and 1B (Hurley, 2002). According to the Stockholm Convention report of 2013, no teratogenic or reproductive toxicity effects were observed within

developmental rat and rabbit studies or a 3-generation rat study. Furthermore, it was reported by NPIC (2001) that no data are available about reproductive and developmental toxicity of this molecule. Moving forward, the ECHA (2011) reported that lambda-cyhalothrin is an endocrine disrupter of Cat. 3 (while cyhalothrin is of Cat. 1), but in 2013 the report of Stockholm Convention explained that this molecule is listed in EU database within the Cat. 1; indeed, it is reported by the PAN (2017) that the evidence of these effects in vitro and in vivo experiments are a decreased plasma testosterone, increased serum corticosterone, decreased serum T3 and T4 levels, increased serum TSH levels, thyroid receptor binding antagonistic activity, oestrogenic activity, mammary and uterine tumours, and ovarian and testes effects. As regards effects on endocrine system animals and other organisms, there is no clear evidence (ECHA, 2011). Then, it causes respiration problems, but it is listed in Cat. 2 (Stockholm Convention Persistent Organic Pollutants Review Committee, 2013). Moreover, it is reported by Hurley (2002), it is neurotoxic for rats, mice and dogs. However, according to Lewis et al. (2016), it is possibly a neurotoxin in humans, but the status is yet to be confirmed. Finally, as it is explained in the PAN report of 2017, immunotoxicity has been detected in rats only at high doses, but only small studies demonstrated immunotoxicity in humans; more research is needed in this.

As it is highlighted in the PAN report (2017), there are potential risks caused by lambda-cyhalothrin to pollinators (including bees), beneficial arthropods, mammals, amphibians, aquatic invertebrates and freshwater and marine fish. Specifically, as reported by Lewis et al. (2016) and PAN (2017), the DT_{90} in laboratory at 20 °C (Degradation Time of the 90% of the initial concentration) is 1193 days which indicates that it is very persistent; but the DT90 in the field is 33.4 days. They also report that the BCF (bioconcentration factor) is 4982, just below the Stockholm Convention threshold of 5000 to be considered bioaccumulative. However, as reported in the Stockholm Convention document of 2013, the Persistent Organic Pollutants Review Committee (POPCR) explained that the lambda-cyhalothrin BCF (log Kow as 5-6.9) is above that threshold, therefore the debate is still opened. Then, it is not considered a mobile chemical in soil (WHO, 1990). Finally, it is not hazardous for the ozone layer since it is not in the list of the ozone-depleting substances (ODS) (US EPA, 2015); indeed, it is not volatile enough to reach the stratosphere – where the ozone layer is.

Overall, lambda-cyhalothrin can be considered in the list of the “most harmful substances” because it is an endocrine disruptor of Cat. 1.

6. Stakeholders' perspectives

After describing the governing policies and recent legislative developments and having performed detailed evaluations on fluopyram and lambda-cyhalothrin, we proceed to ascertain stakeholders' perspectives on the issue of the essentiality of (PFAS in) PPPs via qualitative interviewing. Thereby, we transition from research questions 1 and 2 to question 3: "What are the perspectives of users, manufactures, academics, and legislators on the EU's criteria of "essentiality" applied to specific PFAS in PPPs?".

6.1. Stakeholder overview

In total, we contacted thirty stakeholders with a request for an interview. The stakeholders were divided into categories, including legislators, academics/NGOs, manufacturers, retailers and professional users or associations thereof. Refer to Table 3, Appendix B for the detailed results of our contact efforts.

As per Table 3 in Appendix B, the response rate to our emails was 63%. However, few respondents agreed to an interview. Among the reasons for this were: staff shortages, time shortages or perception that they were not relevant to the topic of the research. Chosen respondents referred us to their colleagues or to different departments, although the communication typically ended there. All stakeholders that did not reply to the email correspondence were contacted via a follow-up telephone call. This sometimes led to new respondents.

An interesting general observation from the communication with stakeholders was the issue of compartmentalisation. In multiple instances, a potential interviewee questioned their fitness for an interview. This was generally because they either possessed knowledge on PFAS or PPPs. However, their expertise rarely covered both topics, and thus they felt uncomfortable discussing both topics in relation to each other.

Ultimately, interviews were conducted with the following stakeholders: ChemSec, LTO, CropLife NL, Bayer, Ctgb and Simons B.V. (see Table 2). Additionally, PAN Europe and NVWA did not want or did not have the time for an interview. Instead, they provided us with written responses to out questions. The interviews were transcribed verbatim and then coded. The results are reported in sections 6.2 and 6.3 below.

Table 2. Overview of interviewees and respondents.

Interviewee	Organisation	Sphere	Position
Interviewee #1	ChemSec (International Chemical Secretariat)	NGO	Policy advisor / external consultant to ChemSec
Interviewee #2	LTO (Agriculture and Horticulture Organization of the Netherlands)	Association (of farming professionals in the NL)	Employee
Interviewee #3	CropLife NL	Association (of agrochemical companies)	Director of Sustainability
Interviewee #4	Bayer	Manufacturer	Employee
Interviewee #5	Ctgb (Board for the admission of plant protection products and biocides)	Implementing body (Netherlands)	Policy expert in PFAS
Interviewee #6	Simonis B.V.	Retailer	Employee
Respondent			

Respondent #1	NVWA (Dutch Food Safety Authority)	Implementing body (Netherlands)	Employee (Crop protection supervision department)
Respondent #2	Pesticide Action Network Europe (PAN)	NGO	Communications Officer

6.2. Stakeholder perspectives

We have divided the presentation of perspectives into four unique sections: (1) essentiality, (2) PFAS in PPPs, (3) legislation of (PFAS in) PPPs and (4) alternatives to (PFAS in) PPPs. Within each section, the views of all six interviewees, and the two respondents are presented, distilling the commonalities and unique aspects of their perception.

Essentiality

Regarding the stakeholders' perception of essentiality, there were some differences. Only ChemSec viewed the essentiality criteria positively. Despite the limitations of the EU Commission communication, their representative thought that the current concept of essential use was a useful starting point for moving towards a sustainable future. However, their representative would have liked to see a future where the essential use criteria is also applied to suspected harmful substances in addition to the proven 'most harmful' substances. Although they mentioned that this could make the application of the concept unmanageable. Additionally, ChemSec was disappointed to find that due to the broad formulation of the criteria, it seemed that any use of PFAS in PPPs could be considered essential. In their opinion, no use of PFAS in PPPs is essential.

"We do not have control of the risks. We see that our groundwater and our fresh water is polluted by these substances [PFAS]"

- ChemSec

Speakers from the Ctgb and CropLife likewise thought that the essentiality criteria would have little to no impact on current PPP legislation. Ctgb reasoned that it would not enrich the current criteria used to assess the essentiality of a substance used in PPPs. CropLife also indicated how they thought that the essentiality criteria could help to simplify the authorization of formerly banned substances in emergency cases, e.g. sudden pest outbreaks.

Moving forward, every stakeholder had its own perspective on what was essential. According to LTO and CropLife, it was essential to use PPPs with diverse active ingredients to avoid pest resistance. Simonis B.V. based its viewpoint mostly on human health — a substance is safe when it is not harmful for the users (farmers) and when its residues are not harmful to consumers. Bayer assumed that the different perspectives of essentiality were related to society's perception of risk: when a useful product does not pose a significant hazard, there are greater chances that it would be considered essential. They illustrated this with the example of coffee. Despite its supposed dangers, they claimed that it is a known carcinogen, it is reportedly essential for society. However, PAN and ChemSec strongly considered PFAS in PPPs to be non-essential. PAN supported this opinion with the following statements:

"The persistence of PFAS chemicals poses an unacceptable risk to health and the environment"

- Pesticide Action Network Europe (written quote)

Lastly, the NVWA and Ctgb stated that as implementing bodies they simply carry out the law, and do not have any opinions on it.

PFAS in PPPs

"Chemical companies (...) want to make the most effective molecules that do their job in the least harmful way"

- Bayer

Aside from PAN, interviewees were generally unconcerned with or unaware of the presence of PFAS in PPPs. CropLife emphasized the difference between the PFAS used in their PPPs, which usually only contain a few CF3 sidechains, versus the 'typical long chain' PFAS.

CropLife also mentioned that they do not see a difference between PPPs containing PFAS and other PPPs, as they are subject to the same regulations. They were unconcerned with the PPPs containing PFAS as they thought they were "generally harmless", confirmed by their toxicology tests. Similarly, Simonis B.V. has no knowledge of the PFAS content of their products.

"We are commercial people, we only know a bit about the composition of our products"

- Simonis B.V.

The LTO mentioned that they were informed by CropLife that PPPs containing PFAS are used correctly. They are aware of the chemical properties of PFAS and stated that their farmers trust the Ctgb to safely approve PPPs. The Ctgb commented on our assessment of lambda-cyhalothrin and noted that at the time of approval, it was not recognised as an endocrine disruptor. The Ctgb stated that it may be assessed as an endocrine disruptor or as having other aspects that are not allowed during the next assessment and subsequently banned. The Ctgb is also aware of the number of co-formulants and active substances that adhere to the PFAS definition in the restriction proposal. Yet, they said they were unsure of how the restriction proposal will progress. They expect PFAS co-formulants and fluorinated packaging to be banned.

"It came to our attention that there are PFAS in a lot of PPPs. These PFAS were not on the list of PFAS that were regulated or banned before."

"Persistence, bioaccumulation and toxicity are already covered by the legislation that is in place. At the same time, it caused a discussion (...) to take persistence into account better"

- Ctgb

Finally, ChemSec expressed that they thought that PFAS were used as an aid rather than an active substance in PPPs. Both ChemSec and PAN stated that they did not believe that any use of PFAS in PPPs or agriculture is essential. They were especially concerned about TFA's, a common metabolite produced when PFAS compounds start to degrade. Additionally, PAN claimed that TFA's are currently polluting our water on an unprecedented scale, and then stated the following:

"We are only just finding out the damage this so far overlooked or neglected molecule can do. The pesticide industry narrative of 'not a real PFAS, does not stay in our body, harmless' is eroding fast."

- Pesticide Action Network Europe (written quote)

Legislation of (PFAS in) PPPs

Concerning the perspectives of stakeholders on the legislation of (PFAS in) PPPs, there were several perceptions. First, the interviewees from Bayer and Simonis B.V. claimed that no party is satisfied with the current legislation in EU for PPPs, noting that the high costs of authorization such as EFSA's requirements for effectiveness, human toxicology and ecotoxicology assessments pose an obstacle for newcomers to enter the market. They added to this that eventually only four multinational industries can afford the procedure. Simonis B.V. noted that in other parts of the world, manufacturers can refer to general data. But in Europe, companies have to produce their own. These types of studies can take over 10 years and may not be sufficient to guarantee safety. Furthermore, Simonis B.V. stressed that the government can be an unreliable partner for businesses due to their non-commitment to agreements.

"It takes over 10 years to do all the studies that are required for the dossier, and then people ask me if it is sufficient. It is never sufficient!"
- Bayer

"I sometimes say jokingly, companies who behave like that go bankrupt. No one wants to do business with them"
- Simonis B.V. (translated quote on the non-commitment of government procedures)

Moreover, Bayer, CropLife and Simonis B.V. agreed that the authorization process is extremely strict. It has become difficult for a formulation to reach the market. Additionally, LTO indicated that the high registration costs for new active substances under EU regulation 1107/2009 drive manufacturers to service non-European markets, leading to limited PPPs options in Europe.

"I do not think anyone is happy with the current situation, it is incredibly expensive (...) to get PPPs authorized, and that is (...) why there are more or less only four multinationals who can actually afford this"
- Bayer

Second, the interviewee for Ctgb and the NVWA respondent, reasoned that PPPs regulation covers most of the guidelines of essential use and questions what essential use would add to the current regulation. The NVWA respondent emphasized that the current legislation already includes a 'Comparative Assessment' for PPPs that contain an active ingredient that is on the list of 'candidates for substitution'. As well as EFSA's 'agricultural alternatives test' described in Article 4.7 of Regulation 1107/2009, that allows member states to (temporarily) allow PPP ingredients that would normally be banned by the 1107/2009 regulation. However, the Ctgb interviewee noted that their employees do not have concrete guidelines about the assessment of the "significantly safer alternatives". So, they had to develop a novel methodology to assess the "safer alternatives" by themselves. The interviewee from ChemSec expressed their excitement that the criteria for essential use had finally been made public. Because ChemSec had grown concerned that the concept of essential use had died, due to delays in publishing the communication after it was requested in the Chemicals Strategy. Additionally, the interviewee from ChemSec characterized the EU essential concept as vulnerable and "that needs to be developed into something practical". The LTO agreed that it is important to think about how to

translate this into something practical. He also stressed the importance of the Sustainable Use Regulation's goal of reducing farmers' dependence on chemical products.

Third, in contrast to the other stakeholders, PAN Europe stated that they believe that the regulation does not need to be amended; but simply implemented differently. Their respondent stated that according to the current PPP Regulation (1107/2009), pesticides authorised in the EU should cause no adverse effects to humans and no unacceptable effects on the environment. However, they believe that this is currently not implemented in practice, as harmful pesticide active substances such as PFAS are still approved. According to PAN Europe this would require updating guidelines to include and meet the current scientific insights. They believe that sufficient scientific and legal arguments exist to ban all PFAS pesticides under the current PPP regulation. They reinforced this argument with the following statement:

"The combination of being very persistent and very toxic and/or mobile should lead to a ban of all PFAS active substances under the pesticide regulation. Even if the authorities do not consider there to be enough proof for all individual PFAS pesticides, the precautionary principle required by law should lead to an immediate ban of all PFAS pesticides"
- Pesticide Action Network Europe (written quote)

Fourth, the interviewee from Ctgb shared the opinion that notably in the past 15 years, bringing environmental protection to the table has made PPPs regulation stricter and more complex. They mentioned that these improvements reflect a dynamic process. The interviewee supported their opinion by referring to the continuing discussions surrounding PFAS at the EU level, which underscores the importance of persistence in the environment as a major point in regulatory decisions.

Lastly, according to CropLife and Simonis B.V., the current regulations for PPPs are among the most stringent in the world, resulting in the banning of many PPPs. CropLife and Bayer said that they strongly believe that this rapid disappearance of products reduces the availability of (new) options to farmers and will not lead to efficient plant protection management. On the other hand, ChemSec criticized the current regulation as unsufficient to protect human and animal health, highlighting the lack of adequate oversight and monitoring of PFAS and TFA. LTO criticized the insufficient support for the farmers in adopting IPM techniques and moving away from these chemicals. LTO, Bayer and CropLife interviewees also emphasized that further limitation of the chemicals that are available could raise resistance risks in crops.

"What you see now, is that the number of products are decreasing so rapidly, that cultivations may start to disappear, because there are no alternatives left. While the rest of the world can still use these products because they are safe"

- CropLife NL (translated quote)

Alternatives

Five of the six interviewees, unprompted, mentioned the possibility for non-chemical/ biological alternatives to synthetic PPPs. Bayer, Simonis B.V. and CropLife noted that they experienced increased interest, demand and investment in the development of biological alternatives. LTO claimed that the enforcement of the adoption of alternative pest and pathogen management techniques is crucial.

"I think it is very important that it is not only the farmer who has to be in transition, but also their advisors, the industry, the suppliers, et cetera"

- LTO

However, they also mentioned several perceived drawbacks of (the switch to) biological alternatives to PPPs. Simonis B.V. and CropLife explained that their performance is limited by weather conditions. Reportedly, such products only work well under ideal circumstances, e.g. in greenhouse cultivation. Moreover, the interviewee from Bayer claimed that biological alternatives may not be available or feasible in all crops. However, PAN argues that implementation of alternative farming techniques and integrated pest management (which PAN stated are mandatory under the Sustainable Use Directive SUD) are viable alternatives.

Regarding the ban of PFAS, the interviewee from Bayer thought that the loss of PFAS products may increase the risk of crop failure, with the representative of LTO adding that synthetic products will remain important to combat pest resistance. CropLife drew attention to the fact that they saw no alternatives to PFAS pesticides in some uses, e.g. phytophthora in potato cultivation.

"Since, let's say the last 10-15 years, you see the tendency of farmers to (...) be less dependent on the chemical plant protection products. But having said that, for them it is still a struggle. (...) What kind of alternatives are there?"

- LTO

7. Discussion

7.1. PPP Policy

The current policy in place governing PPPs in the EU and the Netherlands is an older piece of legislation originating from 2009. Despite its age, this legislation remains the most up-to-date regulation and still gets quoted by the Dutch law. In this section we will discuss the strengths, weaknesses and idiosyncrasies of this regulation, contextualized by the PFAS in PPPs question.

The first challenge that we faced was related to the subjectivity and lack of specific guidelines surrounding the application of concepts seen in EU legislation. Of particular importance to us was the notion of candidates for substitution and their comparative assessment introduced in Regulation 1107/2009, which we applied when evaluating alternatives as part of the essentiality assessment. Candidates for substitution are ingredients of PPPs that are authorized for use but have suspected or proven safety concerns (see Annex II, Article 4). Such candidates are to be replaced by substances which carry lower risk or by non-chemical methods, as identified by a comparative assessment (Regulation 1107/2009).

An assessed substance must meet all four criteria as provided in Article 50. In short, these include greater safety, no significant economic or practical drawbacks, reduction of the chances of target organism resistance, and consideration of minor use authorizations. However, looking more closely at the criteria, three of them include expressions such as “adequate” or “significant”, whose meaning is not expanded upon, leaving room for subjective value judgements.

A set of more specific guidelines were developed and published in 2014 by the European and Mediterranean Plant Protection Organization (EPPO). This adapted version can now be found on the official EU website of the Directorate-General for Health and Food Safety. However, the cover page of that report, as published on the EU website, states that it “Does not necessarily represent the views of Commission services” (European Commission, 2014). Therefore, despite the apparent lack of other guiding principles, the Commission chose not to acknowledge the single source of such information that appears on their sites. Nevertheless, it appears that at least one EU member state — Spain — developed its own set of guidelines based on the EU version and EPPO standard (Molteni & Alonso-Prados, 2020). This indicates that member states have the discretion to develop their own assessment methods and other nations may likewise have national guidelines. We found further support for the discretion of member states to develop national guidelines in documents provided to us by the Ctgb, where they explained their methods. Interestingly, they too reference the EPPO standard (Ctgb, 2024).

Another challenge we encountered during our investigation into PPP legislation was the lack of specific rulings surrounding co-formulants. In the Regulation 1107/2009, a mention is made of a list of unacceptable co-formulants and some criteria to classify them as such. However, this list was made available on the 3rd of March 2021 in Regulation 2021/383, a full 11 years after the initial regulation was put into place. Furthermore, an amendment and detailing of the rather vague rules, surrounding the classification of unacceptable co-formulants – set out in the original 2009 regulation – was amended on the 13th of March 2023 in Regulation 2023/574. This clarified that co-formulants are regulated under the REACH protocol set out in Regulation 1907/2006. This allows the co-formulants, which by their nature are usually less critical in formulations of PPP, to be subjected to a PFAS restriction whilst not greatly affecting the functionality of the end product.

An additional challenge is the regional differences in PPP regulations between EU member states. The authorization of an active substance occurs at the EU level under EU regulations. However, the authorization of a PPP with an approved active substance occurs at the member state level. This leaves room for differences in implementation of the EU PPP regulations between member states. These differences could undermine the EU's ability to achieve its goal of preventing harm from dangerous chemicals across all member states. Additionally, it could pose an unnecessary obstacle to industry stakeholders who want spread products to multiple member states.

To mitigate this issue and ensure good administrative cooperation between the member states, EU created the principle of mutual recognition which guarantees the open movement in the community (Regulation 1107/2009). In different member states, different environmental conditions may occur, and subsequently different pathogens, pests and weeds may be more prevalent. For instance, Nordic countries have markedly different environmental and growing conditions compared to Mediterranean countries. Accordingly, the EU created geographical zones to support the cooperation between member states located in a designated zone. This aids the approval process of PPP by allowing them to be approved based on the aforementioned areas, instead of country borders, leading to a large degree of harmonisation in pest management systems (Cousins et al., 2021). Although this regulation is a step forward in ensuring effective cooperation between member states, we would like to see the EU revise some aspects of their essential use criteria to increase clarity; thus, mitigating misinterpretations.

7.2. Essential use

The concept of essential use is by no means new; however, its specific elements and interpretations have been updated. It was initially introduced in 1987 in the Montreal Protocol, which aimed to eliminate all but the essential uses of ozone-harming substances. Following the protocol, any ozone-harming substance had to meet two criteria to be considered essential: (1) "it is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects), and (2) there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health" (Figuière et al., 2023). At that time, examples of essential uses included ozone-harming substances in asthma inhalers, laboratory reagents and firefighting foams (COM (2024) 2894 final).

The European Commission's 2024 reconceptualization of essential use made subtle changes to the criteria and laid out a structure that can be used in the evaluation. Criterion 2 has been broadened to "there are no acceptable alternatives" (COM (2024) 2894 final, p. 3) to encompass a range of definitions for what alternatives are across EU legislation. Moreover, essential use is no longer viewed solely in relation to ozone-depleting substances — all most harmful substances are now enveloped, while ozone depletion remains one of the criteria for the determination of most harmful substances (COM (2024) 2894 final).

Below, we discuss some of the perceived strengths of working with the concept as well as challenges during its application. Where relevant, we make critical references to supporting literature.

Strengths

The recently proposed concept of essential use provides a standardised, structured and common method through which to perform an assessment of the essentiality of a substance. This avoids large discrepancies in methodology between organisations and individuals who are determining if a substance should be considered essential. Thus far, no legislation contains a definition of the essential use of a substance (COM (2024) 2894 final), hence this concept filled a crucial gap.

The concept of essential use is based on the Montreal Protocol from 1987. The adaptations made to the protocol led the proposed concept to have more detailed definitions for what acceptable alternatives are across EU legislation. This is advantageous as it allows the assessment to be appropriately and comprehensively used in various Member States of the EU. Additionally, is coherent with other EU policy objectives such as EU Green Deal and broader Sustainable Development Goals.

Another strength of the essentiality concept is that it considers specific uses of "most harmful substances". The concept facilitates efficient regulatory decision-making as it makes no discrimination between sectors (Bougas et al., 2023). It is not intended to assess the essentiality of sectors, but it is intended to assess the essentiality of specific uses of most harmful substances. Bougas et al. (2023) report that "the essential use concept is not a tool to discern whether chemicals themselves are essential or non-essential for society, rather it will apply to specific use(s) of substances". Indeed, as highlighted in the recent ChemSec article (2024), every use of a "most harmful" substance will undergo the assessment.

The concept of essential use not only considers other chemicals as alternatives but provides room for non-chemical alternatives to be considered. This is one of the main strengths of the concept as it allows alternative technologies and processes to be considered as alternatives to a most harmful substance. Although these alternatives often have a lower performance, they are generally safer for human and animal health, and the environment.

Chemsec (2024) claims that based on the Communication of the European Commission, nothing can be considered an "essential use", if safer alternatives are available. Moreover, they explain that an additional perceived strength of this concept and its interpretation is that it can prevent the mere substitution of one harmful substance with another harmful substance.

Lastly, the new essentiality concept considers the wider societal impact, stemming from the prohibition of the use of a substance. By assessing the degree to which the function of a substance is critical to society, the criteria imply that the socio-economic consequences for the different stakeholders of a hypothetical ban on a substance need to be analysed during the essentiality assessment. Thus, when banning a product, the role that that a substance has within society is considered. For example, in the case of PFAS used in PPPs, the consequences of a PFAS ban and its effects on manufacturers are considered. Consideration is also given to farmers who might rely on PFAS contained in PPPs to protect their harvest due to the lack of functional alternatives within the IPM system. These socioeconomic impacts of regulatory decisions must be carefully considered and are a key factor in the essentiality framework.

Drawbacks

First, at present, not a single active substance, safener or synergist authorized for use in plant protection products in the EU would be subject to assessment of its (essential) uses. The authorization for use in PPPs already implies that a substance is not a most harmful substance.

The hazard criteria used for establishing a most harmful substance are also criteria that would prevent the authorisation of a substance in the first place.

Moreover, one of the main issues we encountered was the broad scope of the essentiality criteria. We examined only one of the authorised fluopyram formulation (Luna Sensation) currently allowed on the Dutch market (Ctgb, 2024). However, other PPPs (e.g. Luna Privilege), which also includes fluopyram as an active substance, is authorised in the Netherlands for the management of *Botrytis* spp. in strawberry crops (Ctgb, 2024). Additionally, fluopyram acts as a nematicide To (Schleker et al., 2022). fully examine fluopyram and determine its essentiality as an active compound used to combat fungi and nematodes, we would need to evaluate approximately nine PPP formulations. It is apparent that this is a complex matter requiring in-depth knowledge of the functioning of the active compound.

According to Bougas et al., (2023) the essential use concept could facilitate more systematic comparisons of alternatives when evaluating CfS and facilitate approvals for derogations. We found that assessing essentiality is a time-consuming and labour-intensive process. In the evaluation of fluopyram alone, we found approximately thirteen distinct chemical alternatives for the use. Additionally, we identified and assessed four bio-pesticides and IPM strategies aimed to target this prominent phytopathogen. Gathering core information on the mode of action, optimal application timing during the crop life cycle, and potential resistance development can be considered as the "easy" part of the assessment. We draw the conclusion that these initial evaluations are less intricate compared to the extensive time required for subsequent socio-economic analysis (SEA) and chemical alternatives assessment (CAA). As highlighted by ChemSec (2024), the above-mentioned procedures can lead to "paralysis by analysis". At this point, we should consider the extent to which identification of data and alternatives should be pursued and determine when the collected data has been sufficiently explored. It is of major importance to the point at which all significant information is gathered, as well as the methods to explore these alternatives effectively. Exemplifying the potential for paralysis, Faust et al. (2014) analysed the burden that comparative assessment of candidates for substitution may have on regulatory authorities in Germany. They found that there were 351 products containing CfS and that, on average, each had 13 unique uses. When alternative products were added into the equation, a total of 18,479 cases (*product* x *use* x *alternative*) of comparative risk assessment would have been needed to evaluate the potential to replace all uses of CfS. Faust et al. conclude their article stating that: "This puts regulatory authorities under considerable pressure to develop appropriate strategies for efficient handling of the task" (2014, p. 9).

Another procedure that contributes to this pharaonic matter of time consumption is the possible conclusion of a socio-economic analysis (SEA). One of the main criteria for the essential use concept is that the substance must be "necessary for the health, safety and/ or critical for the functioning of the society" to be further considered in the assessment. This kind of information can be obtained by conducting a socio-economic analysis (SEA). This includes economic considerations, such as costs to manufacturers, importers, professional users and distributors (Bougas et al., 2023). Notably, SEA analysis takes a significant amount of time. Furthermore, it must be noted that SEA analysis could be significantly skewed in favour of PPP already on the market due to the advantage of established production lines. Introducing a new alternative would require a considerable time to scale production and reduce costs, potentially labelling it as less viable.

Another potential drawback regarding the application of the EU essentiality concept is the selection of a regrettable substitute. It is a priority for any substance labelled as a candidate for substitution to avoid "problem shifting" (replacing one problematic chemical with another problematic compound) (Cousins et al., 2021). For example, fluopyram is a component of Luna Sensation, along with another active substance, trifloxystrobin. Trifloxystrobin is considered as an efficient active substance against grey mould (Bayer_CropScience Limited, 2024). By applying the essentiality criteria to fluopyram, we defined and evaluated trifloxystrobin as an efficient alternative. However, trifloxystrobin is hazardous compound that can have negative effects on the fertility of mammals and aquatic organisms (Lewis et al., 2016). Markedly, trifloxystrobin was found in the list of the active compounds used in PPPs that are most often detected in both domestically grown as well as imported produce (PAN, 2024). This indicates that the execution of the assessment can be prone to problems (Cousins et al. 2021).

To address these pitfalls, Chemical Alternatives Assessment (CAA) was established. CAA supplies, establishes and alters methods used in the examination and selection of safer alternatives to substances of concern. If these procedures are followed strictly, the risk of "problem shifting" can be minimized. Unquestionably, there is the possibility of insufficient availability of information on the hazardous characteristics of the CfS. This gap in necessary knowledge should be considered carefully as it could lead to the issue of problem shifting (Cousins et al. 2021).

Lastly, current legislation on PPPs inadequately considers the prospective development of resistance in pathogens or pests, resulting from frequent application of certain effective PPPs. In the case of lambda-cyhalothrin as candidate for substitution, we found a limited number of alternatives available. More specifically, among the alternative products in the same category that do not use the most harmful substances, we identified three authorized active substances. For alternative products providing a similar technical function, we couldn't identify any active substances. As a result in this example, the criteria demonstrate their inadequacy due to the lack of viable alternatives. Because of the above, professional users in a potential ban of PFAS in PPPs, will have a restricted list of alternatives. they will start repeatedly applying the same PPP or even PPPs with the same mode of action. Consequently, these practices can promote the development of resistance among different wireworm's populations, by reducing its effectiveness over time.

7.3. Factors affecting the success of essential use in limiting the use of PFAS

Several challenges now lie ahead of essential use's implementation and success at eradicating non-essential uses of the most harmful chemicals. If essential use is to be effective at minimising PFAS use in PPPs, arguably even greater obstacles are in sight.

First, and perhaps most importantly, a question remains on how underlying concepts within the essential use framework will be interpreted, which will affect the concept's applicability to PPPs. Primarily, this is a concern regarding the elements that are proposed to indicate a use's necessity for health and safety. One of the proposed elements is "sustaining basic conditions for human or animal life and health" (COM (2024) 2894 final, p. 11). Its description, equally broad, explains that

a use is necessary for health and safety if it contributes to the provision of "secure sufficient and safe food", "secure sufficient and clean water", "secure clean air", or "secure heat and shelter" (COM (2024) 2894 final, p. 11). If a very literal interpretation is assumed, the entire ensemble of PFAS in PPPs may prove necessary for health and safety, due to its contribution to food production. A disclaimer is provided by the Directorate-General for the Environment, which states that the use of a most harmful substance for sustaining basic conditions must be critically evaluated as it could cause harm to human health or the environment. However, it is unclear to what extent this will be considered — how impactful it will be. This issue of interpretation is relevant, because if a use is found to be necessary for health and safety, we may then proceed to further stages of the evaluation of essentiality. Conversely, if a use is not necessary for health and safety or is not critical for the functioning of society, the assessment concludes there, and the use is deemed non-essential. No evaluation of alternatives is performed.

Second, at present, PFAS compounds may not meet the necessary prerequisites for a most harmful substance and, by extension, will not qualify for the evaluation of the essentiality of their use(s). PFAS entered widespread use in the 1950s (Brennan et al., 2021), hence their field of ecotoxicology is still continuously evolving. There remains much we do not know about the effects of PFAS exposure on human health (NIEHS, n.d.). Therefore, despite some founded concerns around the general safety of PFAS, the criteria may be stringent enough to prevent their qualification as a harmful substance. Where their safety has been investigated and described, PFAS may fall short of the established criteria. Such was the case with fluopyram which was not considered a most harmful substance in our assessment, according to currently available data. This could be viewed as a drawback of the essentiality concept with regards to PFAS, as it could hamper the implementation of the precautionary principle. However, the specificity of the criteria is what makes their application (more) feasible. As the interviewee from ChemSec suggested, the inclusion of more substances, apart from just the most harmful substances, could render the issue "too big [to handle]".

Third, currently, essentiality remains an isolated concept. It was called for in the Chemicals Strategy for Sustainability; however, its recent publication means that it has not been implemented into any governing policy yet. The road towards implementation is long and involves several EU bodies. First, the EU Commission must submit a proposal to Parliament. Parliament performs its first reading and may approve or amend it. Afterwards, the Council can approve or amend it. If both the Parliament and Council approve the proposal, the legislation is adopted. However, if the parties disagree, there may be second and third readings, and a final opportunity to adopt the proposal through a Conciliation Committee (European Parliament, n.d.) Therefore, at each step in the legislative process, there is the possibility of operationalizing the concept differently or amending it out of existence. This was a worry for the speaker from ChemSec who explicitly stated their major concern was "that it's [essential use] not used, not implemented".

Furthermore, related to the preceding concern, is the potential influence of lobbying activity within the EU on the shape and content of developing EU legislation. The Corporate Europe Observatory (2023) reported that major producers and lobby groups, including Bayer and CropLife, self-reported spending 15 million euro on lobbying activities in support of pesticides and agrochemicals in the EU. Should the lobby's past actions be an indication of future efforts, we can expect a concerted and targeted endeavour focused on weakening and undermining the implementation of the essential use concept. That was the case with the proposal of the 2022 Sustainable Use Regulation. While it may be difficult to prove causality, actions by the lobby may have contributed to the regulation being put on hold. Similarly, sowing doubt and uncertainty

surrounding the economic impacts of increasing pesticide regulation, may have impacted the stall and eventual withdrawal of the proposal for Sustainable Use of Plant Protection Products (Corporate Europe Observatory, 2023). Moreover, this is not a one-sided concern. At the opposite end of the spectrum, there are actors such as WWF, Greenpeace, ChemSec or Client Earth pursuing a (more) pesticide-free future. In the end, it remains difficult to predict what the results of such a clash of forces will be.

Additionally, if specific uses of PFAS pesticides were to be rendered non-essential or if PFAS were to be banned outright, the issue of monitoring their use becomes pertinent. The current Communication on essential use lacks clarity on how oversight will be conducted, and which entities will be responsible. It is conceivable that the European Chemicals Agency might assume this role. In the context of PFAS in PPPs, monitoring responsibilities in the Netherlands will likely fall to the NVWA, which oversees food safety monitoring. In both cases, the gargantuan task of monitoring a group as broad as PFAS poses practical and regulatory challenges. Furthermore, this issue extends beyond the EU's borders. To prevent the outsourcing of agricultural production to countries with more lenient plant protection regulations, the EU must establish stringent controls to ensure that imported produce is free from residues of banned or non-essential substances. This would necessitate robust international cooperation and comprehensive regulatory frameworks to maintain the integrity of EU standards and safeguard public health and the environment.

Finally, future crises are inevitable, and may affect the success of the essential use concept in limiting the use of PFAS. Economic and political climates oscillate depending on crises such as climate change, food security, and a growing world population. The global population is almost 8 billion people (United Nations Department of Economic and Social Affairs, 2019) and is rapidly growing (Sadigov, 2022). Factors such as food security and water scarcity are becoming urgent, and when present in the context of a growing population are the biggest threats to human life and health (Sadigov, 2022). Therefore, it could be argued that highly efficient PPPs containing PFAS are in fact essential, and their use must be continued to reliably supply food to the growing population.

Similarly, agricultural crises and climate change go hand in hand and certain situations may hamper the successful phase out of PFAS in PPPs. Climate change may cause unusual and unexpected agricultural difficulties in terms of pest and pathogen management. Should a new pest or pathogen become a problem that cannot be managed without the use of PFAS, emergency allowances will most likely be made repeatedly, rendering the essentiality concept somewhat void.

A general concern arising from climate change is the unexpected difficulties in terms of pest and pathogen management. Although IPM can be successful in managing many pests and pathogens, it is not available for all eventualities. For example, an increase in wet growing seasons can greatly affect the presence and pathogenicity of *Botrytis* spp. (Elad et al., 2007). In this case IPM could falter in its effectivity to control the pathogens leading to an increased application and need for pesticides. Thus, the changing climate might lead to an increased reliance on PPPs and might hamper the adoption of IPM strategies.

7.4. Stakeholder analysis

Essentiality. A variety of perspectives were ascertained through the series of interviews. In terms of stakeholders' perspectives on the concept of essential use, it was clear that their interpretation

of the concept varies greatly. ChemSec appeared to be the only interviewed stakeholder in support of the essential use concept. Although disappointed by the limitations of the communication and the fact that PFAS in PPPs can continue to be considered essential; they believed that it is a good starting point from which to ban harmful substances. However, the association of agrochemical companies, CropLife, along with the two implementing bodies in the Netherlands, the Ctgb and NVWA, believed that it would not impact the current PPP legislation. In fact, the Ctgb argued that the concept has no added value in assessing the essentiality of a substance. While CropLife believed that the concept may lead to a simplified authorisation process for emergency use of banned substances.

We found that essentiality carried a different meaning for each of the interviewed stakeholders. The justification for essentiality varied from human health and safety according to Simonis B.V. and the two NGO's, to needing substances with diverse active ingredients to avoid pest resistance according to CropLife NL. The manufacturer, Bayer, expressed that they base essentiality off the availability of alternatives. Bayer also expressed that they assume that the variability in the perception of essentiality is due to society's perception of risk. If risk is perceived to be low, the substance may more easily be perceived as essential.

Overall, it seemed that stakeholders were sceptical of whether the essentiality criteria would have any tangible impact on the reduction of the use of harmful chemicals in PPPs. Many interviewees expressed that the essential use concept was not directly related to the current legislation on PPPs. The general feeling around the impact of the essentiality concept is not optimistic. A lack of support and tangible confusion from stakeholders regarding the essential use concept may hamper the success of its implementation in the EU.

PFAS in PPPs. Despite the stakeholders conflicting views on the definition of essentiality and the impact that the concept of essential use would have, the interviewees were generally unaware or indifferent to the presence of PFAS in PPPs. While Simonis B.V. had no knowledge of the presence of PFAS in their PPPs, the LTO reported that their farmers trust the Ctgb to approve safe chemicals. This implied that the professional users of PPPs were satisfied with the perceived level of safety precautions the Ctgb were taking, and therefore accepted that the PFAS contained within their PPPs were safe. Similarly, the representative from CropLife expressed that they made no differentiation between PPPs containing PFAS and PPPs without PFAS because they are subject to the exact same regulations. They also considered all approved PPPs to be "generally harmless", as proven by their toxicology tests.

Modifying the definition of PFAS can lead to a reduced awareness of PFAS amongst stakeholders and professional users, subsequently leading to a potential increase in the use of PPPs containing PFAS. Our findings suggest that farmers generally trusted the approval system for PPPs and that manufacturers hoped to continue using PFAS in their PPPs. This is likely due to the desire to maintain profits in all involved sectors. However, this does not bode well for a future without PFAS.

The Ctgb were very aware of the rules and regulations surrounding PPPs and PFAS. They were unsure of how the restriction proposal would progress but believed that PFAS would be banned to some extent. Although this implementing body believed that the future of PFAS in PPPs is limited, the perspectives of the manufacturers and farmers told a different story. It is likely that there will be some resistance against a ban of PFAS in PPPs from the manufacturers and potentially from farmers too. However, as discussed below, farmers are generally in favour of biological and non-chemical alternatives, if profits can be maintained. ChemSec and PAN were

the only stakeholders who explicitly said that they believed no use of PFAS in PPPs is essential. They were acutely aware of the risks PFAS pose and support a ban of all PFAS. Although ChemSec were not expert in the field of PPPs, their role in supporting an EU ban on PFAS and in adopting and improving the essentiality criteria is imperative; furthermore, they were actively participating in the process.

Legislation of (PFAS in) PPPs. Regarding perspectives on the legislation of (PFAS) PPPs, it was evident that opinions varied widely. Our findings noted a distinct divide between the interviewed NGO's and industry stakeholders. ChemSec believes that the current PPP regulations are insufficient in protecting human and environmental health. Whereas PAN believes the problem lies in the poor implementation of said regulations. In contrast, most of the industry stakeholders felt that the existing regulations on PPPs were already strict enough.

The Ctgb and ChemSec viewed the process of legislation development as a continuous endeavor. Although, Ctgb expressed disappointment with the unclear terms that they were tasked with implementing, such as "safer alternatives". Moreover, they interpreted the adding of the essential criteria to current legislation as an ambiguous intent. At the same time, ChemSec posed its concerns on the existing regulation as unsufficient to protect human and animal health.

The LTO stakeholders seemed to occupy a middle ground, by recognizing the importance of the Sustainable Use Regulation's goal of reducing farmers' dependence on chemical products. However, their primary goal is to achieve a good harvest with minimal cost and effort. LTO criticized the insufficient support from the EU legislation to the farmers in adopting IPM techniques and moving away from these chemicals. LTO is noting that many farmers would be flexible in adopting IPM techniques. Although, if other acceptable and efficient alternatives are not available on the market; then they are worried about resistance risks.

In the other side of the coin, Croplife NL, Bayer and Simonis B.V. appeared to be notably frustrated with the current legislation, finding it extremely strict. Their main arguments are the unreasonable requirements of EFSA that limit the market to only a few multinationals industries and the high registration costs for a novel PPP. CropLife and Bayer strongly believed that this rapid disappearance of certain PPPs reduces the availability of new options to farmers, hampering an efficient plant protection management.

Alternatives. Notably, all but one of the interviewed stakeholders gave some examples of alternatives – either biological or non-chemical – that can be adopted instead of synthetic PPPs. It is interesting to note that only LTO and PAN Europe emphasized the critical importance of using alternatives instead of conventional pesticides. However, many concerns about the alternatives were expressed, with particular apprehension regarding biological options. For instance, it was highlighted in two interviews that the performance of the latter alternatives is limited by weather conditions. Furthermore, Bayer argued that the biological alternatives are not a viable solution for all crops. These perspectives, although pragmatic, align with the current European landscape, where there is a significant resistance to ecological transition, especially to the transition within agriculture. To reinforce this, several stakeholders made statements regarding the ban on PFAS. For example, CropLife argued that no alternatives should be adopted in certain uses instead of PPPs containing PFAS, citing the example of their use against *Phytophtora* spp. in potato cultivation. Lastly, LTO affirmed that synthetic PPPs are necessary to prevent pest resistance. Overall, the different viewpoints consider alternatives important and effective under some

circumstances, but do not consider that they should become the main modus operandi in agriculture; in other words, they are sometimes essential, but less than synthetic PPPs.

8. Limitations

During this project, we encountered several obstacles. First, it proved challenging to find relevant stakeholders, who were willing to be interviewed. Some could only provide their perspective months in the future, while others thought they were not relevant for the subject matter of the report. Chosen stakeholders believed they did not have sufficient knowledge or were not permitted to speak on the topic. Our initial deadline for performing interviews was the end of the week 6 of the ACT project. However, necessary exceptions were made, extending this into week 7. This limited our ability to gather sufficient information from each category of stakeholders, as few interviewees per category were available and/or interested. Therefore, the number of perspectives we gathered for each category may not be enough to categorise the overall perspective of a specific group of stakeholders. However, as this research is an attempt to gather as much information as possible within the timespan available, the results are relevant for further examinations.

Furthermore, an effort to make the interviews as non-biased as possible was carried out by avoiding leading assumptions in every question. This method aimed to avoid prejudice-based answers; for example, by assuming during the interview that all PFAS need to be banned, some stakeholders may express their disagreement by not giving enough accurate information when answering. In addition, some stakeholders could perceive the interviews as an academic investigation, consequently sharing less important information.

Lastly, an important limitation of this project was also the time we had in relation to completing the assessments of fluopyram and lambda-cyhalothrin. The essentiality assessment needed to be carried out for every alternative and the legislative, political, social and ecotoxicological aspects about PFAS and alternatives require deep and long-term research that could have been carried out over a longer period. However, the core information is provided, and additional research was incorporated into the report and the policy brief (see Appendix J). This limitation is related to the “analysis of paralysis” as explained in the drawbacks in paragraph 7.2. It is the consequence of the huge number of assessments that are required for every chemical and alternative. Overall, during our ACT project we faced this issue of time limitation when assessing both the essentiality of fluopyram and lambda-cyhalothrin.

9. Conclusions and recommendations

Our research aimed to answer three questions regarding the European policy on PFAS in PPPs. In a nutshell, these questions encompassed (1) the current legislation on PFAS in PPPs, (2) the extent to which PFAS compounds apply for the "essentiality" concept from the European Commission and (3) the various perspectives of stakeholders on "essential" PFAS in PPPs. Specifically, we zoomed-in on the situation in the Netherlands, from the manufacturing to application of PPPs.

Through a policy review, we learned that the EU has, since the year 2002, developed an elaborate set of regulations, directives and communications to govern plant protection products (PPPs) and their underlying components. Generally, the regulations are fit for their specific purpose, establishing rules for the authorisation of active substances, their pre-approval testing, acceptable uses of the substances, as well as labelling requirements, amongst many other guidelines. Moreover, the regulations' coverage exceeds active substance alone. Safeners and synergists are likewise covered by much of the same requirements.

However, due to how inherently complex the issue of PPP regulation and oversight is, touching upon all aspects and political priorities (e.g. human health to economics, societal acceptance, food safety and the environment), there remain areas where we have seen inexact formulation of the regulations, leading to ambiguities and uncertainties in their application. Moreover, some aspects of PPP regulation appear to be missing entirely. Not only were these issues identified in our document analysis, but they were also voiced by the interviewees, which we treat as an indication of their relevance and consequence. Ultimately, these omissions and ambiguities may prove detrimental to the health and safety of the EU community, whose protection was the reported aim of much of the EUs plant protection product policy.

The addition of the PFAS label to a plant protection product does not appear to carry additional legal consequences beyond those already established for any active substance. There are paragraphs within the PPP regulations that could be seen as covering some of the predominant concerns around PFAS (see passages on PBT in Regulation 1107/2009). However, our analysis has shown that they are not restrictive enough to classify all PFAS as persistent and bioaccumulative substances. Therefore, the use of some less persistent PFAS is still allowed. Nevertheless, the inability to qualify them as a PBT substance alone, cannot be treated as an indication of their safety. They may give rise to (PFAS) metabolites whose half-life far exceeds that of the initially applied substance(s).

In light of PFAS' acceptability for use in PPPs and their established and presumed health and environmental hazards, the proposed PFAS ban emerges as a possible (extreme) solution to their regulation, by outright prohibiting their production and use. However, the ban foresaw multiple scenarios, wherein the reportedly most acceptable scenario would allow for indefinite use of PFAS in plant protection products. An interviewee involved in the European Chemicals Agency's deliberations on the ban indicated that the discussions tended towards exactly this scenario where PPPs are granted a time-unlimited derogation. Hence, we propose that the concept of essential use and its associated framework could emerge as another possibility of regulating the use of PFAS in PPP. Nevertheless, at present, essential use stems from a different branch of EU regulation and is not incorporated in any legislation, apart from the Montreal Protocol where it was originally posited. Even though the concept of essential use comes as an appreciated development, whose targeted deliberations may prove useful in limiting non-essential uses of the

most harmful substances, our attempts at applying essential use have shown that it may prove time-consuming at best and ambiguous at worst.

To answer our second research question, we applied the concept of essential use to two PPP active substances. The current landscape of PPP regulation is complex and requires in-depth research to fully understand. Below we note recommendations developed after analysing the strengths and weaknesses of the new essentiality principle when applied to PFAS in PPP, supplemented with policy recommendations from our review of the policy on PPPs.

- **Redefine which substances are applicable for assessment under the essential use concept.** Hazard criteria that prevent authorisation of a PPP ingredient (active substance, safener or synergist) are those which indicate a most harmful substance whose (essential) uses can be evaluated. For example, if an ingredient is a class 1A carcinogen, it cannot be authorised for use in a PPP. However, if it does not have the designation of a class 1A carcinogen (or other confirmed hazard), it is not considered a most harmful substance. Therefore, it will not be evaluated under the essentiality criteria.

- **Reassess the practical implications of the essential use concept.** The criteria are ambiguous and broad, which may lead to unexpected or undesirable interpretations and effects. Specifically, a change in the wording surrounding identification and approval of safer alternatives. More specific terminology should be used instead of the current wording of 'significantly safer' and 'similar level of performance'. This will aid in testing, comparison and approval of alternatives.

- **Harmonize essential use concept directives with current PPP regulations.** The current form of the essentiality concept only has marginal differences to Regulation No 1107/2009 concerning identification of harmful substances. While this allows for an easier transition to a harmonized set of rules regarding chemical substances, it still presents some pitfalls. For instance, similarities in the regulations could lead to unnecessary 'double rulings' where substances are covered under multiple legislations. These double rulings create uncertainty surrounding the application of policies and allow for loopholes in regulations.

- **Develop a streamlined method and platform for identifying and assessing alternatives for candidates for substitution.** This can serve as the framework used in identifying replacements for non-essential uses cases of PFAS in PPPs. A platform, such as the 'marketplace' from ChemSec or equivalent, would serve to expedite and ease the process of identifying and assessing the alternatives.

- **Ensure continued availability of emergency authorizations of PPP containing PFAS and PPP in general.** If the PFAS ban and essentiality criteria are accepted and written into EU law, care must be taken that specific temporary emergency use options of "harmful substances" stay available to allow for resistant or invasive pests to be dealt with when preventative measures and biological control have failed or are not effective at further controlling the outbreak. A similar emergency authorization is already present in Reg. No 1107/2009 under article 53 and could function as a starting point for further discussion.

For our third and last research question, we attempted to represent the perspectives of a diverse group of stakeholders. These perspectives provide necessary context to the debate on policy on PFAS in PPPs. The main take-aways from our stakeholder interviews are:

- Stakeholders were skeptical about whether the "essentiality concept" will have any tangible impact. Also, they did not consider the concept to be connected to PPP legislation. Furthermore, stakeholders had varying perspectives on what constitutes an essential PPP. One striking inconsistency was that ChemSec believed the "essentiality concept" to be a step in the direction of a future with less chemicals, while CropLife NL argued that it may lead to a more simplified authorisation process for PPPs.

- There exists debate among stakeholders on what constitutes as a "safe" or an "unsafe" PFAS. While manufacturers argue that the legislations are strict and that PPPs are safe, ChemSec and PAN claim the contrary. Additionally, the presence of PFAS in PPPs becomes less known as you move down the supply chain of PPPs. However, there has been an increase of awareness among farmers, and an increase in desire to move away from chemical PPPs. The Ctgb believes that the future of PFAS in PPPs is limited.

- There were two main opinions among stakeholders concerning the legislations of (PFAS in) PPPs: in favor or against the current legislation. The LTO, CropLife NL, Simonis B.V. and Bayer expressed their worries on the stringent nature of the legislation of PPPs. They warned for issues with disease and pest management (crop resistance), high barriers/costs for the development of alternatives, and insufficient aid for farmers to adapt. ChemSec and PAN however warned about the dangers of PFAS on nature and human health.

- Concerns about alternatives were expressed by the various stakeholders. These were, for example, the limitations of biological alternatives and the non-existence of alternatives for certain PPP uses.

We recommend that or any future change in the legislation on PPPs, these varying perspectives need to be taken into account. During our interviews, clear frustrations with the current legislation were expressed, as well as clear concerns about the safety of the PPPs currently on the market.

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Appendix A: Stakeholder long-list

- ACT student group(s)
- Wageningen University Science Shop – Freddy van Hulst (project coordinator)
- Stichting Huize Aarde (problem owner)
- **Regulatory Authority (regional)**
  EU Commission/ EU Council/ European Food Safety Authority (EFSA)/ European Chemicals Agency (ECHA)/ European and Mediterranean Plant Protection Organisation (EPPO)/ EU Pesticide Regulation/ European Environment Agency (EEA)/ European Federation of National Associations of Water Services (EUREAU)/ The European Environmental Bureau (EEB)/ Directorate-General for Environment
- **Regulatory Organisation (regional/international)**
  International Plant Protection Convention (IPPC)/ Food and Agriculture Organisation (FAO) of the United Nations/ World Trade Organisation (WTO)/ World Health Organisation (WHO)/ World Organisation for Animal Health (WOAH)/ International Standards Organisation (ISO)/ CropLife International/ United Nations Environment Assembly (UNEA)
- **Regulatory Authority (national)**
  Ministries of Agriculture/ Environment Affairs / Health, etc./ National Plant Protection Organisations (NPPOs): Netherlands Food and Consumer Products' Authority (NVWA)/ Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb).
- **Industry**
  Seed and Fertilisers Companies/ Pesticides Companies (e.g. Bayer, BASF, Adama, Syngenta)
- **Growers/ Growers Associations/ Distributors, Consultors, Agriculture Retailers/ Farmers' Union(s)/Organisation(s)**
  Committee of Professional Agricultural Organisations (Copa) & General Confederation of Agricultural Cooperatives (Cogeca)/ Customs & Border Control/Authorities / Non-governmental organisation (NGOs)/ Universities/ Private R&D entries, such as Contract Research Organisations (CROs)/ public lobby- or action groups.

Appendix B: Stakeholder contacts' overview

Table 3. Stakeholder contacts overview.

Organisation	Stakeholder category	Reply received (y/n)	Interview (y/n)
BASF	Manufacture	y	n
Bayer	Manufacture	y	y
CAV Agrotheek	Retail	n	n
Cebeco Agro	Retail	n	n
ChemSec	Academic	y	y
Corteva Agriscience	Manufacture	y	n
Cosun Beet Company	Agriculture	n	n
Croplife NL	Manufacture	y	y
CTGB	Legislation	y	y
ECHA	Academic	y	n
EEA	Academic	y	n
EEB	Academic	y	n
ESFA	Legislation	y	n
European Commision	Legislation	y	n
Fidra	Academic	y	n
Glastuinbouw Nederland	Agriculture	y	n
LTO	Agriculture	y	y
Ministry of LNV	Legislation	y	n
NFO	Agriculture	n	n
NVWA	Legislation	y	y
PAN	Academic	y	y
RIVM	Academic	n	n
Royal Brinkman	Retail	n	n
Simonis B.V.	Retail and manufacture	y	y
Syngenta	Manufacture	n	n
Toekomst Boeren	Agriculture	n	n
Van Iperen	Retail	n	n
Wageningen Universiteit Ecotoxicologist	Academic	n	n
Wageningen Universiteit SPRINT project	Academic	n	n
ZLTO	Agriculture	y	n
Frequency		19/30	8/19 (or 8/30)
Percentage		63%	42% (or 27%)

Appendix C1: Interviewee Information Sheet

European Union's criteria for essential use

Summary and our case study analysis results

Introduction

In 2020, the EU approved the European Green Deal. With this, the European Union made a commitment to – among other things – create a toxic-free environment. However, chemical use in the EU poses a dilemma. On the one hand, the most harmful chemicals can be very useful in for example green technologies. On the other hand, these chemicals can be problematic for human health and safety. This led to the idea of '**essential use**' of chemicals.

The 'essential use' concept has now been put in writing by the European Commission. The concept aims to classify the most harmful substances as non-essential or essential from a societal point of view.

Our research applies the concept of 'essential use' to two PFAS compounds that are often found in plant protection products. This allows us to be critical of the 'essential use' concept. **During the interview, this will be the topic surrounding our questions.**

You were invited to this interview to provide your perspective on this manner of making an assessment. Do you agree or disagree with how the EU is classifying chemicals as 'essential'? You are either professionally working with, producing, or researching chemicals in the EU. This is why your perspective matters!

Summary of the 'essential use' concept

1. First, to apply to the essential use concept, a chemical needs to be considered 'most harmful'.

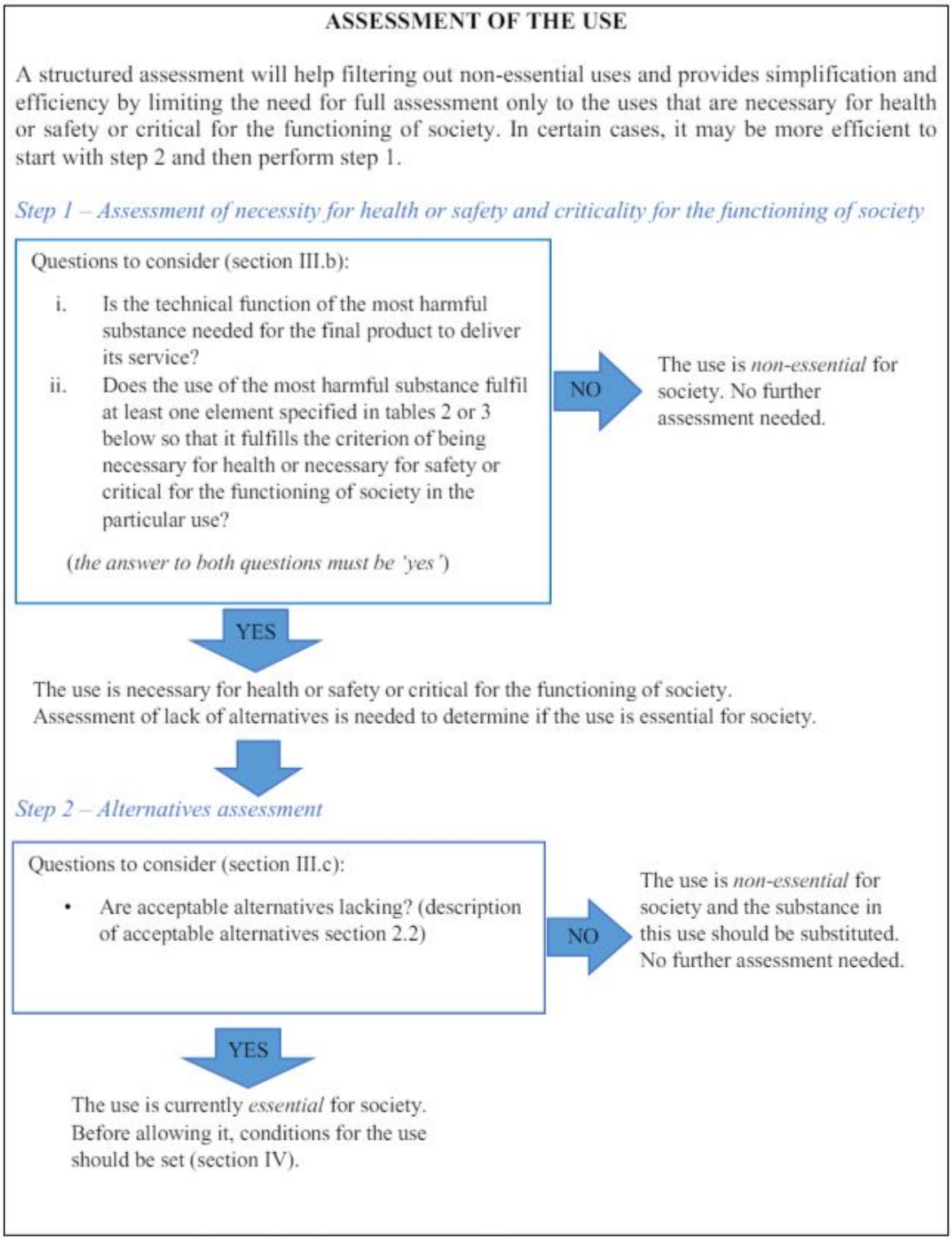
To this end, the substance must have one or more of the following hazard properties:

- Carcinogenicity (Category 1A and 1B)
- Germ cell mutagenicity (Cat. 1A and 1B)
- Reproductive/developmental toxicity (Cat. 1A and 1B)
- Endocrine disruption (Cat. 1 (human health or environment))
- Respiratory sensitisation (Cat. 1)
- Specific target organ toxicity (repeated exposure (STOT-RE) Cat. 1, including immunotoxicity and neurotoxicity)
- Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative (PBT/vPvB)
- Persistent, mobile and toxic/very persistent and mobile (PMT/vPvM)
- Hazardous to the ozone layer (Cat. 1)

2. Next, whether a "most harmful substance" is essential or non-essential is determined by two main criteria: (1) whether the use is necessary for health or safety or is critical for the functioning of society **and** (2) whether there are acceptable alternatives.

Of note is that the statement from the Commission does not define a specific notion of "acceptable alternative", instead suggesting that respective regulations typically define it. However, Reg. No 1107/2009 does not explicitly discuss the notion of acceptable alternatives. Therefore, we adapted criteria surrounding "candidates for substitution", which appeared as the most closely related and relevant set of criteria from the regulation on PPPs.

3. To assess whether the two criteria are met, a structured assessment must be made. Below, you can see the assessment that we applied to two PFAS compounds commonly used in plant protection products. The two PFAS compounds we assessed are: fluopyram and lambda-cyhalothrin.



Results of Fluopyram Assessment

- Fluopyram is a preventive fungicide of broad-spectrum (Veloukas & Karaoglanidis, 2011; Bayer, n.d.). It is a succinate dehydrogenase (SDH) (Matsson & Hederstedt, 2001).
- Protects against grey mould-*Botrytis* spp.
- Fluopyram is one of two active components of Luna Sensation (alongside trifloxystrobin), which is marketed as a fungicide (Bayer CropScience Limited, n.d.). Some of fluopyram's function could perhaps be replaced by trifloxystrobin. However, the effectiveness of the substance in dealing with specific fungal species will likely vary. To deliver nematocidal effects, fluopyram is needed in the final product.
- Fluopyram is necessary for health and safety, as it allows for "sustaining basic conditions for human or animal life and health" (COM (2024) 2894 final, p. 14), since it is a plant protection product contributing to the provision of sufficient food.
- A wealth of synthetic, as well as natural and biological alternatives are available to control *Botrytis*. Several synthetic alternatives have been shown to very effectively inhibit the fungus (e.g. pyrimethanil, fludioxonil, boscalid), with up to 100 % efficacy; however, testing was carried out in laboratory conditions and might not reflect field conditions (Kim et al., 2016; Llanos and Apaza, 2018).
- Fluopyram is not considered a most harmful substance because it has not any hazardous property listed in the EU's criteria for the "most harmful substances"

Results of Lambda-cyhalothrin Assessment

- Lambda-cyhalothrin is classified to non-systemic pyrethroid insecticide, which control insect population upon contact and ingestion (Lewis et al., 2016; NPIC, 2001).
- It is effective in preventing root damage by *Agriotes* spp. from the family *Elateridae* in their larval stage (i.e. wireworms) by causing paralysis and eventual death (Sipcam Oxon S.p.A., 2023; Syngenta, n.d.; NPIC, 2001)
- Lambda-cyhalothrin is necessary for "sustaining basic conditions for human or animal life and health" (COM (2024) 2894 final, p. 14) since it the active ingredient of plant protection products contributing to the keeping of insect population under economic threshold and eventually to the provision of sufficient food.
- We have identified few synthetic alternatives that target wireworms but do not use the most harmful substance (3 compounds, some of which are banned already), some alternatives with lower performance (Pyrethrins, Neem oil, Integrated Pest Management strategies), but there are not any alternatives with similar technical function. However, we still lack information on most of the alternatives regarding their economic impact, effects on humans or animals' health, and environmental consequences.
- Lambda-cyhalothrin is considered a most harmful substance because, within the hazardous property listed in the EU's criteria for the "most harmful substances", it is an endocrine disruptor of Cat. 1 for humans.

Appendix C2: Interviewee Information and Consent Form

Project: The application of the EU concept of "essentiality" / "essential use" to PFAS-based active substances and adjuvants in plant protection products

Project Team Manager: Bonnie Roefs (bonnie.roefs@wur.nl)

Project Supervisor: Freddy van Hulst (freddy.vanhulst@wur.nl)

Data Protection Officer: Wageningen University & Research DPO (functionarisgegevensbescherming@wur.nl)

Purpose of the study: The purpose of this study is to investigate the "essentiality" of PFAS compounds used in Plant Protection Products (PPPs) in the EU based on the recent conception of "essential use" as expressed by the Directorate-General for the Environment. To this end, we will be collecting stakeholder perspectives on "essentiality" and its application to specific PFAS compounds. Ultimately, this will contribute to a report and policy brief, which may be further used by the Project Supervisor in a broader EU project on PFAS.

Procedure: You are asked to participate in an interview of around 30 minutes to 1 hour, during which the Project Team Manager or their fellow teammates will ask questions to ascertain your perception. The interview will be recorded, and notes will be taken. Later, the audio recording will be transcribed, and its passages coded. Further analysis will be performed using the transcribed and coded interviews. By the end of the project, we expect to produce a report and policy brief, which will be disseminated to you.

1. I ---------- agree to take part in the study.
2. I understand that my consent is voluntary and can be withdrawn at any time during the interview, or within two weeks after the interview, without stating a reason.
3. I understand that I have the right to access and rectify my personal data upon request.
4. I understand that my participation in the research involves being interviewed by the project team manager or remaining team members, where I will be asked about my perception of "essentiality" / "essential use" regarding PFAS-based active substances / adjuvants of plant protection products.
5. I grant permission to the research team to take written notes and record my spoken responses during the interview.
6. I understand that all information I provide for this study will be treated confidentially.

7. I understand that my consent form will be archived indefinitely for academic integrity purposes.
8. I understand that original audio recordings will be retained in a secure, password-protected location until the full transcripts are prepared (no longer than 30 June 2024).
9. I understand that a transcript of my interview in which all identifying information has been removed will be retained until 31 July 2026.
10. I understand that excerpts from my interview may be used in the final products of this project—a report and policy brief.
11. I understand that I will not benefit directly from this research and no financial compensation will be offered.
12. I confirm that I have read and understood the information and consent form and have had the opportunity to ask questions which have been fully answered.
13. I understand that I am free to contact any of the people involved in the research to seek further clarification and information.
14. I understand that my anonymized data (including no direct identifiers and few indirect identifiers) can no longer be used to identify me and I waive my rights concerning personal research data.

Please select which applies to you. I agree / do not agree to my function and organization being used in the products.

The results of the project will be shared electronically. Please leave your preferred email address below to which the files will be sent.

Signature of research participant Date

---------- ----------

Signature of researcher Date

---------- ----------

Appendix D: Interview guide

General questions for all stakeholders

1. How familiar are you with PFAS and their applications in PPPs?
2. Are you familiar with the concept of essential use regarding harmful chemicals and what are your first thoughts on it?
3. Do you have any comments, questions or suggestions regarding our summary of the EU's criteria for essential use and our assessment of fluopyram and lambda-cyhalothrin?
4. Do you feel that the current legislation in place for (PFAS in) PPPs is sufficient to ensure the health and safety of society?
    a. What do you feel could be improved in the current legislation?
    b. Do you feel that mismanagement of PPP application is a significant issue?
5. What is your perspective on the EU guidelines for the determination of a "most harmful substance"?
6. Do you think that these criteria are useful for determining if a (most harmful) substance should be banned?
    a. What timeframe would you consider sufficient for this determination?
7. Would you like to revise the criteria and if so, how?
    a. How would you personally determine if a compound is essential?
    b. Do you have any PPPs containing PFAS in mind which you think are more essential and less essential?
8. Do you feel like the compounds assessed (fluopyram & lambda-cyhalothrin) are essential and if so why or why not?
9. How do you think EU should move forward regarding PFAS in PPPs?
    a. What consequences do you think this would have for society?
    b. What consequences do you foresee from continued use of these types of chemicals?
    c. Which consequences do you see for society and economy if a full ban on PFAS is implemented?
10. What are your thoughts on the alternatives we mentioned in the assessment?
    a. Have you heard of these alternatives before this assessment?
    b. Do you consider any of these alternatives feasible?
    c. Have you considered any other alternatives which we have not mentioned?
11. Do you believe that this framework, if implemented, can be effective in reducing the amount of PFAS and harmful chemicals used in PPPs?
12. Do you have any closing remarks on our application of essentiality or how to refine the framework?

Disclaimer: The following questions are divided by stakeholder group. The order in which they appear is not final. They will be asked at appropriate moments within the interviews.

I. **Manufacturers**
Are you willing to divulge if you are using any synergists, safeners or co-formulants, that could fall under the PFAS umbrella, in your products?
Economic Impact • What would the economic impact be for your company if this substance were banned and how would this affect the end users? • How much time and resources would it take for you to introduce a new product to the market? • What effects will the framework have on your company? • *Would this effect your products in markets within other continents.....?*
Research and Development • With all the new regulations and bans from EU, do you feel that the longevity of PFAS-containing PPPs are at risk and have you conducted research on potential alternatives to this chemical substance? If so, what were the findings?

II. **Legislators**
What measures are in place to facilitate farmers and manufacturers in adapting to new regulations? • Are there strategies or programs to motivate the development and adoption of more sustainable pesticide options? • Are there any future operations focused on promoting innovation in safer pesticide alternatives?

III. **Academics**
Do you think it is necessary to evaluate the adverse effects of the metabolite pathway for each PFAS? - At which point can we be confident that the degradation products are not hazardous? - Is it possible to forecast bad consequences of PFAS' degradation metabolites that we still do not know (referred to the metabolites, not the consequences)?

IV. **Professional Users**
Essential Practices in Agriculture that drive to high toxicity, etc.
Are you concerned with the effects that PPPs may have on your health and safety? • Do you use any forms of PPE when applying PPPs • Have you ever noticed adverse effects due to exposure to PPPs
Are you applying this product by itself/ or in combination with another PPP? If yes, do you consider the effects of pesticide residue on the consumer and if so what are your main concerns? Do you consider the effects/ fate PPPs are going to have on groundwater organisms, terrestrial mammals, soil-microorganisms and non-target plants and if so what criteria is most important?
Plant protection products
Would you be willing to share what plant protection products you use? **(individual farmer)** • How essential is Luna (Fluopyram) / Karate (Lambda-cyhalothrin) / (or equivalent product) for your cultivation? **Or** Would you be willing to share what PPPs are most commonly used in your area of agriculture? **(farmers' association)**
What made you chose the specific suite of plant protection products that you currently use? **(individual farmer)**
Do you already use alternatives to synthetic pesticides? If not, why? Do you feel you have sufficient information about them?

Appendix E: Blank essentiality assessment form

Use of the substance	
1. **Main characteristics of the use and process**	
2. **Technical function (following ECHA (2015) use descriptors)**	
a. Life cycle stage (LCS)	
a. Sector of use (SU)	

b. Product category (PC)	
c. Process category (PROC)	
d. Environmental release category (ERC)	
e. Article category (AC)	
f. Technical function (TF)	
3. **Context of the use**	
a. Final product or service resulting from the use	
b. Need for the substance in the use	
c. Need for the technical function of the final product	
d. Set of characteristics required to deliver the service and function provided by the use of the substance	
e. Details on how the use of a substance is performed and the various activities/tasks involved in the use (incl. exposure scenarios, risk management measures, and operational conditions)	
Essentiality assessment of the use	
1. **Necessity for health or safety and critically for the functioning of society**	
a. Is the technical function of the most harmful substance needed for the final product to deliver its service?	
b. Does the use of the most harmful substance fulfil at least one element specified in tables 2 or 3 below so that it fulfils the criterion of being necessary for health or necessary for safety or critical for the functioning of society in the particular use?	
If the answer to both questions is **"Yes"**, proceed to the assessment of alternatives to determine whether the use of the substance is "essential".	
2. **Assessment of alternatives**	
a. Identification of possible alternatives	
I) Products in the same product category that do not use the most harmful substance	
II) Alternatives with lower performance, provided it is socially acceptable	

III) Alternatives that provide a similar technical function and a similar level of performance to those provided by or with the most harmful substance	
b. Evaluation of alternatives (adapted from Article 50, Annex II to (EC) Regulation No 1107/2009)	
I) Significantly safer for human or animal health or the environment	
II) Does not present significant economic or practical disadvantages	
III) Minimizes the occurrence of resistance in the target organism	
IV) Consequences of minor use authorisations are taken into account	

Appendix F: Fluopyram ecotoxicology

Ecotoxicological elements	
Carcinogenicity cat. 1A and 1B	University of Hertfordshire (2024): “No, not known to cause a problem”. IARC - International Agency for Research on Cancer (2024): not in the list of carcinogenic substances. Davis et al. (2023) and Turley et al. (2021): fluopyram caused liver and thyroid hypertrophy and proliferation, eventually leading to liver tumors (in female rats) and thyroid tumors (male mice). In 2012, identified as "Likely to be carcinogenic” (Federal Register of USA, 2012), but 2019 update reported "Not likely to be carcinogenic” (Federal Register of USA, 2019)
Germ cell mutagenicity cat. 1A and 1B	No concern of mutagenicity (ECHA, 2024; Federal Register of USA, 2012, 2019; Turley et al., 2021)
Reproductive/development toxicity cat. 1A and 1B	No (Federal Register of USA, 2012). Davis et al. (2023): It did not elicit developmental or offspring effects, nor did it adversely affect reproductive parameters. No evidence of increased qualitative or quantitative susceptibility was observed in developmental or reproduction toxicity studies.
Endocrine disruption cat.1 (human health)	No data found (University of Hertfordshire, 2024). Endocrine disruptor but no cat. 1 (Wei et al., 2016)
Endocrine disruption cat.1 (environment)	Lyssimachou & Muilerman (2019): Potential endocrine disruptor effects in birds and fish. No direct endocrine disrupting effects were evident in mammals; indirect effects observed on the endocrine system were not of concern for wild mammals because they occurred at higher doses than the endpoint used for risk assessment.
Respiratory sensitisation cat. 1	PPDB: No data found (University of Hertfordshire, 2024) Davis et al. (2023): No, because it is of cat. 4
Specific target organ toxicity – repeated exposure cat. 1, including immunotoxicity and neurotoxicity	No neurotoxicity, apart in rats; but it is not cat. 1 (Turley et al., 2021; Davis et al., 2023).
Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative (PBT/ vPvB)	Persistence: According to PPDB (University of Hertfordshire, 2024) its DT_{50} in the field is of 119 days, which is lower than the threshold of 120 days illustrated in the Regulation n. 1107/2009 of the European Parliament and Council to consider a compound as persistent in the environment. However, the DT_{90} in the field is very high (833 days) but only the DT_{50} in the field is considered. Bioaccumulation and toxicity: Low potential of bioaccumulation (BCF = 18 l/kg) and moderate

	toxicity for some animals (University of Hertfordshire, 2024).
Persistent, mobile and toxic/very persistent and mobile (PMT/vPvM)	Not very persistent and moderately mobile (University of Hertfordshire, 2024)
Hazardous to the ozone layer cat. 1	Not in the list of ODS (US EPA, 2015).

Appendix G: Fluopyram essentiality assessment

Use of the substance	
1. **Main characteristics of the use and process**	Fluopyram is a preventive broad-spectrum fungicide applied by professional workers directly to the plant's leaf surface (Bayer Hellas, n.d.; Veloukas & Karaoglanidis, 2012). It is an inhibitor of the complex II in the mitochondrial respiratory chain, known as succinate oxidoreductase (SQR) or succinate dehydrogenase (SDH). This enzyme, located in the inner mitochondrial membrane of eukaryotes (in this case *Botrytis* spp.), is essential for the tricarboxylic acid cycle and the mitochondrial electron transport chain. The pest's cell energy cycle is disrupted by the inhibitors (Matsson & Hederstedt, 2001).
2. **Technical function (following ECHA (2015) use descriptors)**	
a. Life cycle stage (LCS)	PW (Widespread use by professional workers) / C (Consumer)* SL (Service life)
a. Sector of use (SU)	SU1 (Agriculture, Forestry, Fishery)
b. Product category (PC)	PC27 (Plant protection product)
c. Process category (PROC)	PROC5 (Mixing or blending in batch processes) PROC7 (Industrial spraying) PROC8a/PROC8b (Transfer of substance of mixture at dedicated or non-dedicated facilities)** PROC19 (Manual activities involving hand contact)
d. Environmental release category (ERC)	ERC8f (Widespread use leading to inclusion into/onto article (outdoor)) ERC10b (Widespread use of articles with high or intended release (outdoor))
e. Article category (AC)	AC0 (other)
f. Technical function (TF)	Biocide
3. **Context of the use**	
a. Final product or service resulting from the use	Inhibitor of the succinate oxidoreductase (SQR) or succinate dehydrogenase (SDH) (Matsson & Hederstedt, 2001).
b. Need for the substance in the use	It is the compound itself – fluopyram – that has fungicidal properties. However, there are countless other active substances with fungicidal properties, but their efficacy at combating specific fungal infections may vary.
c. Need for the technical function of the final product	Grey mould is one of the most precarious agricultural pathogens to manage. They damage the strawberry crops by infecting on already damaged or aging tissues, which

	directly leads to tissue decay (Petrasch & Wiley, 2019). Therefore, measures to control *Botrytis* spp., e.g. via fungicides such as fluopyram, are essential. Compared to other fungicides containing different active substances, fluopyram shows a lower tendency for resistance development. This is particularly evident when appliers alternate it with other fungicides (Veloukas & Karaoglanidis, 2012)).
d. Set of characteristics required to deliver the service and function provided by the use of the substance	The substance should be applied through spraying from the start of growth of the young plants (formation of the stolon) until full maturity, but no sooner than when the first symptoms of disease appear. The maximum suggested dose of application in strawberries is 200 g ha^{-1}. It should be applied no more than twice in any season and harvest is allowed at least one day after the final application (Bayer Hellas, n.d.).
e. Details on how the use of a substance is performed and the various activities/tasks involved in the use (incl. exposure scenarios, risk management measures, and operational conditions)	General precautions: Personal protective equipment must be worn when working with the substance (gloves, eye protection, face protection, protective clothing). Dispose of contents and containers through a licensed hazardous waste disposal contractor or collection site. Empty, clean containers can be treated as non-hazardous waste. Follow the usage instructions to minimize risks to human health and the environment. Specific use precautions: An aquatic buffer zone of 12 meters must be established from the application area. Root vegetables cannot be grown on a field directly after the application of fluopyram. First aid measures: In case of exposure, remove contaminated clothing and move to a well-ventilated area. Wash off residue with soap and water, and polyethylene glycol 400 (PEG 400). If ingested, call the poison center immediately and do not induce vomiting. No antidote is available; treatment is symptomatic. Activated charcoal and sodium sulphate are advisable. Accidental release measures: If spillage enters sewage system, immediately inform local water company. Substance should be cleaned up with inert absorbent (e.g. sand, sawdust, silica gel). Collect residue into a tightly sealed and labelled container and dispose according to local regulation (Haas, 2023).

Essentiality assessment of the use	
1. **Necessity for health or safety and critically for the functioning of society**	
a. Is the technical function of the most harmful substance needed for the final product to deliver its service?	Luna Sensation is marketed as a fungicide, with both its active substances–fluopyram and trifloxystrobin–acting as fungicides (Bayer UK, 2023). Therefore, some of fluopyram's function could be replaced by trifloxystrobin. However, the effectiveness of the substances in dealing with specific fungal species will likely vary. Additionally, fluopyram acts as a nematicide. Schleker et al., 2022) suggest that nematodes can cause considerable damage (estimated $100 billion globally) to crops and their control is necessary to produce food sustainably. To deliver such nematocidal effects, fluopyram is needed in the final product (Luna Sensation, Bayer).
b. Does the use of the most harmful substance fulfil at least one element specified in tables 2 or 3 below so that it fulfils the criterion of being necessary for health or necessary for safety or critical for the functioning of society in the particular use?	Yes, fluopyram is necessary for health and safety, as it allows for "sustaining basic conditions for human or animal life and health" (COM (2024) 2894 final, p. 14), since it is a plant protection product contributing to the provision of sufficient food.
If the answer to both questions is **"Yes"**, proceed to the assessment of alternatives to determine whether the use of the substance is "essential".	
2. **Assessment of alternatives**	
a. Identification of possible alternatives	
I) Products in the same product category that do not use the most harmful substance	**Isofetamid** is a botryticide (specific fungicide for *Botrytis* species (Fungi: *Sclerotiniaceae*) used on strawberries (Zuniga et al., 2020). It is a candidate for substitution, and it is not approved for use under EC Regulation 1107/2009 in the Netherlands, however, is approved in many EU countries (Lewis et al., 2016b). **Fenpyrazamine** is another botryticide and is approved for use under EC Regulation 1107/2009 in the Netherlands and many of the EU Member States (Lewis et al., 2016b). **Carbendazim** is a commonly used botryticide. It is not approved under EC Regulation 1107/2009 due to its possible genetic effects, likely human carcinogenic effects and endocrine disruption. Lastly, it has been found to be a

	reproduction toxicant and is toxic to honeybees (Lewis et al., 2016; Llanos and Apaza, 2018).
II) Alternatives with lower performance, provided it is socially acceptable	**Amylo-X WG** is a broad-spectrum bio fungicide based on *Bacillus amyloliquefaciens* subsp. plantarum d747 (Bacteria: Bacillaceae) with a preventive effect for treating fungal diseases and bacterial infections. It functions through a combination of diverse mechanisms of action (Ctgb, n.d.-a). **Polyversum** is a formulation based on *Pythium oligandrum* strain m1 (Oomycetes: Pythiaceae) and primarily used for preventative purposes. It has a unique mechanism of parasitisation, in which the fungus produces enzymes and actively feeds on *Botrytis* spp. It is considered as safe product for crops and beneficial insects (Ctgb, n.d.-b). The active ingredient **Cerevisane** of another bio fungicide, is a purified extract obtained from the *Saccharomyces cerevisiae* strain las02 (*Ascomycuta: Saccharomyceae*) (Ctgb, n.d.-c). The purified extract is the cell wall that can induce systemic resistance against foliar fungi. It is considered as less harmful to the environment and humans. **Noli** is a bio fungicide containing *Metschnikowia fructicola* (type strain nrrl y-27328, cbs 8853), which helps prevent fruit decay. It is designed for precautionary treatment, but it can also be used in the final stages before harvest (en Rodenrijs, 2019). **Alternative practices/techniques** for the control of *Botrytis* for whole crop (Government of Greece, 2013): - Reduce initial pathogen infection. - Remove infected plants and biological material. - Use clean machinery and equipment. - Practice crop rotation - Cover greenhouses with plastic that protects from UV radiation to reduce the production of spores. - Reduce humidity by planting sparsely. - Ensure sufficient airflow. - Balance fertiliser use
III) Alternatives that provide a similar technical function and a similar level of performance to those provided by or with the most harmful substance	**Carbendazim** is a commonly used botryticide. It is not approved under EC Regulation 1107/2009 due to its possible genetic effects, likely human carcinogenic effects and endocrine disruption. Lastly, it has been found to be a reproduction toxicant and is toxic to honeybees (Lewis et al., 2016b). **Fenhexamid** is another chemical compound that targets the above species. It is approved under EC Regulation 1107/2009 in the Netherlands (Lewis et al., 2016; Llanos and Apaza, 2018).

	Pyrimethanil is a botryticide and is approved for use under the EC Regulation 1107/2009 in the Netherlands and most EU Member States (Lewis et al., 2016b). **Iprodione** is a post-harvest fungicide that is a likely carcinogen and is an endocrine disruptor. It has moderate alerts for environmental fate and ecotoxicity. It is approved for use in the Netherlands and in Malta under the EC Regulation 1107/2009 (Lewis et al., 2016; Kim et al., 2016). **Boscalid** is a botryticide that is persistent in the environment and has moderate ecotoxicity and human health alerts associated with it, with low risk for honeybees. It is approved for use under the EC Regulation 1107/2009 in all EU Member States (Lewis et al., 2016; Kim et al., 2016). **Cyprodinil** is a fungicide that is moderately persistent in soil and water systems. It has high alerts for environmental fate and ecotoxicity but has no serious human health concerns identified. It is approved under the EC Regulation 1107/2009 in all EU Member States (Lewis et al., 2016b). **Fludioxonil** is a broad-spectrum fungicide. It is a persistent bioaccumulative toxin. It is approved under the EC Regulation 1107/2009 in all EU Member States (Lewis et al., 2016; Kim et al., 2016). **Pyraclostrobin** is a broad-spectrum fungicide. It has high ecotoxicity for certain aquatic organisms and can cause reproduction and development effects in humans. It is approved for use under the EC Regulation 1107/2009 in all EU Member States (Lewis et al., 2016b). **Penthiopyrad** is a fungicide approved for use in the Netherlands under the EC Regulation 1107/2009. It is a possible human carcinogen and has moderate environmental and ecotoxicity alerts (Lewis et al., 2016b). **Trifloxystrobin** is a commonly used fungicide. It is not expected to be persistent in soil or water systems but may have negative effects on fertility in mammals. It is very toxic to aquatic organisms but has a low risk for honeybees. It is approved for use under the EC Regulation 1107/2009 in the Netherlands and most EU Member States (Lewis et al., 2016b). **Captan** is a dicarboxamide fungicide with low persistence in soil and water systems. It has low toxicity for mammals but may be carcinogenic and cause endocrine issues. It has a moderate ecotoxicity alert. It is approved for use under the EC Regulation

	1107/2009 in the Netherlands and many EU Member States (Lewis et al., 2016b).
b. Evaluation of alternatives (adapted from Article 50, Annex II to (EC) Regulation No 1107/2009)	
I) Significantly safer for human or animal health or the environment	**Isofetamid** is considered as moderately persistent and has a moderate alert for human health. **Fenhexamid** has been assessed as a low-risk chemical for honeybees, humans, and mammalian health. It is not known to be carcinogenic or to promote endocrine disruption (Lewis et al., 2016). **Fenpyrazamine** found with no confirmed health concerns and with only moderate environmental and ecotoxic alerts. **Pyrimethanil** has only moderate environmental, ecotoxic and human health alerts. It has low risk for honeybees. For the alternatives with lower performance there are not any known cases that cause problems in the environment and human health.
II) Does not present significant economic or practical disadvantages	It has been reported that the continuous application of synthetic fungicides encounters three vital challenges: (1) enhancing public concern of contaminated fruits and their impact in human health, (2) increased development of resistance in *Botrytis* populations, (3) impact on environment (Abbey et al., 2019). However, those also are applicable for fluopyram. As far for alternatives with lower performance such as bio fungicides can be highly influenced by the microclimate and require specific storage and usage. Another challenge in product formulation is the application of the initial concentrations in microbial PPPs (Abbey et al., 2019).
III) Minimizes the occurrence of resistance in the target organism	**Captan** is a dicarboxamide fungicide that is not typically susceptible to resistance development by *Botrytis* (Leroux, 2007), however strains of *Botrytis* with less sensitivity to Captan have been identified (Amiri et al., 2018). *Botrytis* is a high-risk pathogen as it has a polycyclic nature, allowing it to quickly become resistant to commercial fungicides (Abbey et al., 2019).
IV) Consequences of minor use authorisations are taken into account	**None identified*** *In the Netherlands, minor use authorisations are granted for specific crops (i.e. minor crops). However, the research

	team has not found the actual products authorised for use in minor crops.

Appendix H: Lambda-cyhalothrin ecotoxicology

Ecotoxicological elements	
Carcinogenicity cat. 1A and 1B	No, according to Lewis et al. (2016) and IARC (2024). The US EPA (2015a) classifies lambda-cyhalothrin as a group D carcinogen: it means that its ability to cause cancer has not been determined (NPIC, 2001). There is no indication of oncogenic activity but increase in mammary tumours in female mice (Hurley, 2002). Increases the growth of human breast cancer cells and it has been found in association with dog mammary tumour (Pesticide Action Network, 2017). Stockholm Convention (2013): no evidence of carcinogenicity in rats.
Germ cell mutagenicity cat. 1A and 1B	No, it tested negative in reverse mutation assays (Hurley, 2002). No genotoxic effects were observed in the standard in vitro test package (Secretariat of the Stockholm Convention, 2019).
Reproductive/development toxicity cat. 1A and 1B	No (Hurley, 2002). Possibly in humans, status not identified. (Secretariat of the Stockholm Convention, 2019): With cyhalothrin no teratogenic or reproductive toxicity effects were observed within developmental rat and rabbit studies or a 3-generation rat study. Data are not available from occupational exposure, accidental poisonings, or epidemiological studies regarding the reproductive and developmental toxicity of lambda-cyhalothrin in humans; no effects were observed in rats and rabbits (NPIC, 2001).
Endocrine disruption cat.1 (human health)	No, it's cat. 3 (ECHA, 2011), but cyhalothrin is cat. 1. Yes, cat. 1 (Secretariat of the Stockholm Convention, 2019).
Endocrine disruption cat.1 (environment)	Not for animals, cat. 3 (ECHA, 2011).
Respiratory sensitisation cat. 1	It causes respiration problems, but it is Cat. 2 (Secretariat of the Stockholm Convention, 2019).
Specific target organ toxicity – repeated exposure cat. 1, including immunotoxicity and neurotoxicity	Neurotoxicity in rats, mice and dogs (Hurley, 2002). Possibly in humans, status not identified

	(Lewis et al., 2016). Immunotoxicity in rabbits at high doses (Morgan & Osman, 2007) ; only small studies demonstrated immunotoxicity in humans (Pesticide Action Network, 2017).
Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative (PBT/ vPvB)	In soils, DT_{90} (lab at 20 °C) = 1193 days (very persistent), but DT_{90} (field) = 33.4 days (Lewis et al., 2016; Pesticide Action Network, 2017). Bioaccumulation: BCF = 4982, which is below the e Stockholm Convention threshold of 5,000 (Lewis et al., 2016; Pesticide Action Network, 2017). According to the Stockholm Convention (2013), Persistent Organic Pollutants Review Committee (POPCR) gave its BCF (log Kow as 5-6.9) above the Stockholm threshold for bioaccumulation.
Persistent, mobile and toxic/very persistent and mobile (PMT/vPvM)	In soils, DT_{90} (lab at 20 °C) = 1193 days (very persistent), but DT_{90} (field) = 33.4 days (Lewis et al., 2016; Pesticide Action Network, 2017). It is a non-mobile chemical in soil (WHO, 1990).
Hazardous to the ozone layer cat. 1	No: it is not volatile enough to reach the stratosphere. It is not in the list of the Ozone-depleting Substances (ODS) of US EPA, 2015a.

Appendix I: Lambda-cyhalothrin essentiality assessment

Use of the substance	
1. **Main characteristics of the use and process**	Lambda-cyhalothrin is an insecticide broadcast by professional workers (farmers) directly into the soil while sowing potatoes. It is particularly effective in preventing root damage by insects from the family *Elateridae* in their larval stage (i.e. wireworms) (Sipcam Oxon S.p.A., 2023; Syngenta, 2020)
2. **Technical function (following European Chemicals Agency (2015) use descriptors)**	
a. Life cycle stage (LCS)	PW (Widespread use by professional workers) / C (Consumer) SL (Service life)
a. Sector of use (SU)	SU1 (Agriculture, Forestry, Fishery)
b. Product category (PC)	PC27 (Plant protection product)
c. Process category (PROC)	PROC8a/PROC8b (Transfer of substance of mixture at dedicated or non-dedicated facilities) PROC19 (Manual activities involving hand contact)
d. Environmental release category (ERC)	ERC8f (Widespread use leading to inclusion into/onto article (outdoor)) ERC10b (Widespread use of articles with high or intended release (outdoor))
e. Article category (AC)	AC0 (other)
f. Technical function (TF)	Biocide
3. **Context of the use**	
a. Final product or service resulting from the use	Lambda-cyhalothrin belongs to (the pyrethroids, a group of synthetic chemicals that closely resemble natural insectides – pyrethrins (NPIC, 2001). It is a non-systemic insecticide effective upon contact and ingestion (Lewis et al., 2016). It disrupts sodium channels responsible for generating and conveying nerve impulses, causing insect paralysis and death (NPIC, 2001).
b. Need for the substance in the use	Lambda-cyhalothrin is a pair of isomers of cyhalothrin (NPIC, 2001). It is the substance itself that has insecticidal properties. However, there are countless other active substances with insecticidal properties, but their efficacy at combating specific insect infestations may vary.

c. Need for the technical function of the final product	Wireworms are reportedly some of the most difficult agricultural pests to manage, not least due to their subterranean nature. They damage the potato plant by feeding on its roots or tubers, which directly impacts the quality and marketability, and crop yield. Since the 1990s, wireworms have been seen as a major pest (Vernon & van Herk, 2022). Therefore, measures to control wireworms, e.g. via insecticides such as lambda-cyhalothrin, are vital.
d. Set of characteristics required to deliver the service and function provided by the use of the substance	The substance must be applied directly into the soil with a granulate spreader during sowing (Syngenta, 2020). Application must occur from April until June at a maximum dosage of 15 kg ha^{-1} of product per growing season, equivalent to 60 g ha^{-1} of active substance (Sipcam Oxon S.p.A., 2023).
e. Details on how the use of a substance is performed and the various activities/tasks involved in the use (incl. exposure scenarios, risk management measures, and operational conditions)	General precautions: Personal protective equipment must be worn when working with the substance (gloves, eye protection, face protection, breathing mask, protective clothing). Dispose of contents and containers through a licensed hazardous waste disposal contractor or collection site. Follow the usage instructions to minimise risks to human health and the environment. Specific use precautions: Prevent entry into waterways; lambda-cyhalothrin is acutely and chronically toxic to aquatic life. The substance may cause an allergic reaction. First aid measures: In case of exposure, remove contaminated clothing and move to a well-ventilated area. Wash off residue with water. If ingested, call the poison center immediately and do not induce vomiting. Inhalation may cause pneumonia and pulmonary oedema. No antidote is available; treatment is symptomatic. Accidental release measures: If spillage enters sewage system or surface water, immediately inform local water company or local authorities respectively. Substance should be cleaned up with non-sparking vacuum or by mopping. Do not use solvents for cleanup. Collect residue into a tightly sealed and labelled container and dispose according to local regulation (Syngenta, 2023).

Essentiality assessment of the use

1. **Necessity for health or safety and critically for the functioning of society**

a. Is the technical function of the most harmful substance needed for the final product to deliver its service?	Lambda-cyhalothrin is the active component in Karate 0.4% GR (Syngenta). The biocidal property of the active substance is necessary for the product to deliver its final service, as no other active substances are found in the product.
b. Does the use of the most harmful substance fulfil at least one element specified in tables 2 or 3 below so that it fulfils the criterion of being necessary for health or necessary for safety or critical for the functioning of society in the particular use?	Yes, lambda-cyhalothrin is necessary for health and safety, as it allows for "sustaining basic conditions for human or animal life and health" (COM (2024) 2894 final, p. 14), since it the active ingredient of plant protection products contributing to the provision of sufficient food.
If the answer to both questions is **"Yes"**, proceed to the assessment of alternatives to determine whether the use of the substance is "essential".	
2. **Assessment of alternatives**	
a. Identification of possible alternatives	
I) Products in the same product category that do not use the most harmful substance	**Fosthiazate**, approved as a nematicide in potatoes (European Commission, 2003) , can be applied and incorporated into the soil prior to planting to combat wireworms. Its efficacy was found to be 57 % (Bavarian State Research Centre for Agriculture, n.d.). **Imidacloprid** formulations, e.g. Gaucho 600 FS, typically used to treat tubers against aphids, can be used in higher doses to combat wireworms. However, their efficacy is limited, with trials putting their efficacy at around 20% (Bavarian State Research Centre for Agriculture, n.d.). **Calcium cyanamide** is an "obsolete, post-emergence herbicide and defoliant". It is not approved for use in the EU under Reg. No 1107/2009 (Lewis et al., 2016). The Bavarian State Research Center for Agriculture (n.d.) tested the substance, finding it 34 % effective in reducing wireworm attacks, when applied after ridging.
II) Alternatives with lower performance, provided it is socially acceptable	**Pyrethrins** are a group of naturally occurring compounds, found in plants such as Chrysanthemum, used in Europe for their insecticidal properties since the 18th century. The great demand for insecticides triggered the development of synthetic alternatives –pyrethroids– in the 20th century, to which lambda-cyhalothrin belongs (Hodoşan et al., 2023). Pyrethrins are highly effective, not acutely toxic, but they break down relatively quickly (Dowle, 2021) – less photostable and more biodegradable (Hodoşan et al.,

	2023). However, their efficacy also threatens beneficial insects such as bees (Dowle, 2021). **Neem oil** is a natural insecticide, pressed from the seeds of the Azadirachta indica tree, whose efficacy can be very good even at low concentrations but will depend on the azadirachtin content of the oil (Kovaříková & Pavela, 2019). Among plant-derived insecticides, it displays some of the lowest toxicity to humans and beneficial organisms. However, it has limited stability, as it readily photodegrades, and a short residence time major challenge of agriculture is to increase food production to meet the needs of the growing world population, without damaging the environment. In current agricultural practices, the control of pests is often accomplished by means of the excessive use of agrochemicals, which can result in environmental pollution and the development of resistant pests. In this context, biopesticides can offer a better alternative to synthetic pesticides, enabling safer control of pest populations. However, limitations of biopesticides, including short shelf life, photosensitivity, and volatilisation, make it difficult to use them on a large scale. Here, we review the potential use of neem oil in crop protection, considering the gaps and obstacles associated with the development of sustainable agriculture in the not too distant future (Campos et al., 2016). **Integrated pest management (IPM)** is a set of environmentally sensitive practices to manage agricultural pests (US EPA, 2015b). For wireworm management, practices such as rotational cropping with brown mustard, a natural fumigant, or fallowing before sowing potatoes can be effective (Hughes, 2014; Wickwar & Wenninger, 2023).
III) Alternatives that provide a similar technical function and a similar level of performance to those provided by or with the most harmful substance	**None identified**. The Bavarian State Research Centre for Agriculture (n.d.) reports that the development and registration of new products that are highly effective against wireworms is unlikely. Moreover, the European Innovation Partnerships for Agricultural Productivity and Sustainability claim that synthetic pesticides are increasingly ineffective against wireworms (EIP-AGRI, 2022).
b. Evaluation of alternatives (adapted from Article 50 of (EC) Reg. No 1107/2009)	
I) Significantly safer for human or animal health or the environment	The EPA deemed that the use of **neem oil** according to label directions will not cause adverse health effects to humans and non-target organisms (US EPA, n.d.).

II) Does not present significant economic or practical disadvantages	**None identified**. The presented alternatives largely display shorter residence times, greater rates of photodegradation and require much greater applications per hectare.
III) Minimises the occurrence of resistance in the target organism	A cautious suggestion is made that **neem oil** could potentially limit resistance through its wealth of active substances and modes of action (Siegwart et al., 2015). However, it has still been shown to result in the development of low to medium resistance in aphids (Feng & Isman, 1995). Research on biopesticide resistance remains scarce. **(None identified)**
IV) Consequences of minor use authorisations are taken into account	**None identified*** *In the Netherlands, minor use authorisations are granted for specific crops (i.e. minor crops). However, the research team has not found the actual products authorised for use in minor crops.

Appendix J: Policy brief

AGRICULTURE

POLICY BRIEF NO 1/2024

Towards a PFAS-free future

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Key messages

- Increased societal and scientific attention on the impacts of perfluoroalkyl and polyfluoroalkyl (PFAS) substances on human and environmental health call for legislative action and renewed assessment of their use.
- The legislation of PFAS in Plant Protection Products (PPP) is currently at risk of falling behind.
- The "essential use" concept as proposed by the European Commission in April 2024 is a promising concept to integrate within PPP legislations.
- We propose the following recommendations to aid in the merging of the "essential use" criteria and the current PPP regulations. This may ensure continued functioning of EU food production in light of the looming PFAS restriction proposal.
    - **Reassess the practical implications of the essential use concept.**
    - **Harmonize essential use concept directives with current PPP regulations.**
    - **Develop a streamlined method and platform for identifying and assessing alternatives for candidates for substitution.**
    - **Ensure continued availability of emergency authorizations of PPPs containing PFAS and PPPs in general.**

What is the issue?

The EU is currently wrestling with an environmental problem on a massive scale, and it is not climate change. In this case, we are talking about the widespread use of perfluoroalkyl and polyfluoroalkyl substances also known as PFAS. This group of chemicals is increasingly appearing in news headlines, reflecting a general increase in society's concern on its safety. Some 14% of fruit and 7.1% of vegetables tested in 2021 across the EU were contaminated with at least one PFAS pesticide (Lysimachou & Roynel, 2024) (see Figure 1). PFAS can enter our environment in a variety of ways, but this policy brief focusses on just one: their use within European agriculture as plant protection products (PPPs).

Perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA), both members of the PFAS chemical family, have already been banned in the EU for close to ten years. Other PFAS chemicals

are still approved for use in a variety of industries. A restriction proposal submitted by Denmark, Germany, the Netherlands, Norway and Sweden in 2023 aims to further reduce the presence of PFAS. This proposal underlined the persistence of PFAS, which will over time lead to an increased exposure to people, plants and animals (ECHA, 2023). This exposure, if releases are not minimized in time, will reach levels high enough to potentially induce negative effects for human, animal and environmental health (ECHA, 2023).

The main focus of this policy brief is the use of PFAS in Plant Protection Products (PPPs). Currently, some of the active compounds used in PPPs fall under the umbrella of PFAS compounds. Therefore, they are affected by the above-mentioned regulation. However, this regulation writes that PPPs may require additional evaluation to determine to what extent their use can be or should be restricted. This is because this group of products already has its own regulations. For example, Regulation 1107/2009 on the placement of PPPs on the market.

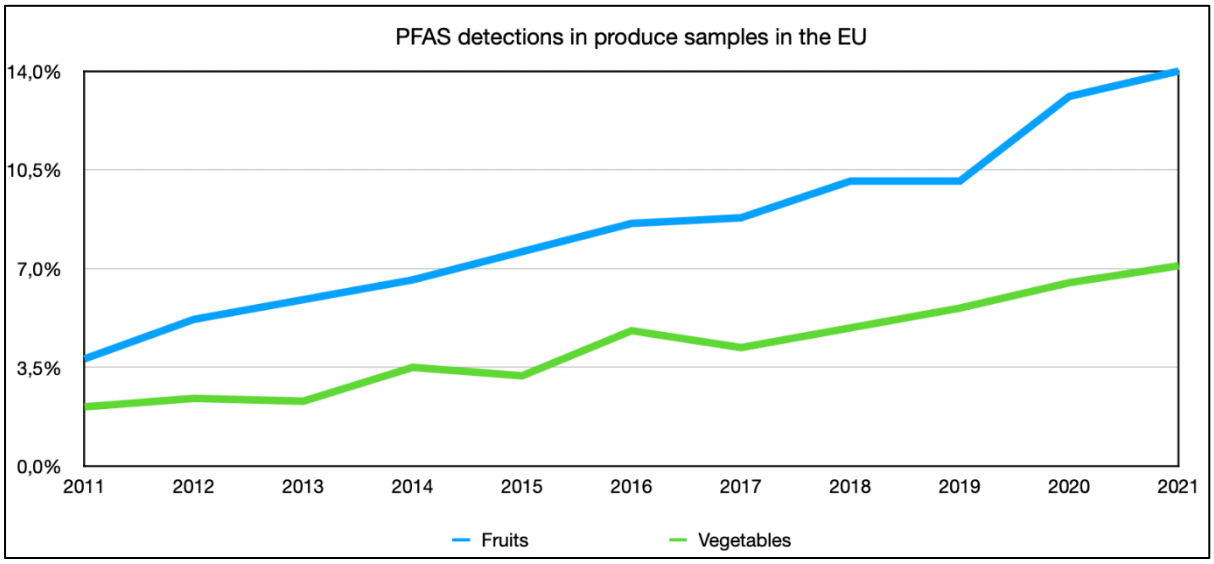

Figure 1. PFAS detection in fruits and vegetables in the EU.

Determining the essentiality of PFAS in PPPs

A recent communication from the European Commission (22nd of April, 2024) could be of use in determining if the use of PFAS is necessary. The communication outlines specific guidelines of "essential use" of most harmful substances. These guidelines state simply that a most harmful substance shall only be allowed for use if:

1. The use is necessary for health or safety or is critical for the functioning of society,
   And
2. There are no acceptable alternatives

While the guidelines are still in active development, the "essential use" concept could have interesting to applications in the case of PFAS in PPPs.

In our research, we have analysed the current and upcoming policies and regulations regarding Plant Protection Products and PFAS, and have interviewed stakeholders on their views and ideas on the developing landscape and their place within it. The core of our work is a conceptual exercise where we critically reviewed the idea of "essential" and "non-essential" use of PFAS in PPPs. For this, we evaluated two PFAS compounds found in PPPs with this concept.

In the table below we show the policy strengths and weaknesses of the essential use concept (table 1).

Table 1. Essentiality concept when tested on PFAS in PPPs: strengths and weaknesses.

Strength	Weakness
Implementation	
• The essentiality concept is a step closer to a stronger implementation of the precautionary principle across multiple industries. • Overlap between the "most harmful substances" criteria and the "unacceptable active substances, safeners and synergists" criteria. This is an opportunity for harmonization.	• Incorporating the essential use criteria into legislation may be a difficult and lengthy process. • Overlap between the "most harmful substances" criteria and the "unacceptable active substances, safeners and synergists" criteria. Risk of inefficient double regulation. • Implementation in current form requires excessive monetary and time investments to check and verify every possible combination of chemical/alternative and pest.
Content: essentiality assessment criteria	
• The criteria distinguish between specific uses of a substance. Thus, acknowledging that the same substance may be essential in one, but not essential in another use. • The concept of essential use provides a standardised, structured and common method for assessment of most harmful substances. • The essentiality concept recognizes non-chemical alternatives (alternative processes and technologies). • Ecotoxicology has become more important within the essentiality assessment.	• The criteria to assess essentiality for health and safety or critical to the functioning of society are broad and ambiguous. This could lead to differences in interpretation and a weaker implementation. • There is a lack of clarity on at what point a "sufficient" number of alternatives have been identified. This fosters the risk of "paralysis by analysis". • Any chemical can be considered non-essential if a safer alternative with an acceptable level of effectiveness is available for that same use. This does not take into account the potential need for a back-up options for product uses. • The concept of essentiality contains ambiguous criteria for the identification of "safer" alternatives. This could lead to an increase in "problem shifting" in which one harmful chemical is replaced with another.

What can policy makers do?

The current landscape of PPP regulation is complex and requires in-depth research to fully understand. Below we note recommendations we developed after analysing the strengths and weaknesses of the new essentiality principle when applied to PFAS in PPP, supplemented with policy recommendations from our review of the policy on PPPs.

- **Redefine which substances are applicable for assessment under the essential use concept.** Hazard criteria that prevent authorisation of a PPP ingredient (active substance, safener or synergist) are those which indicate a most harmful substance whose (essential) uses can be evaluated. For example, if an ingredient is a class 1A carcinogen, it cannot be authorised for use in a PPP. However, if it does not have the designation of a class 1A carcinogen (or other confirmed hazard), it is not considered a most harmful substance. Therefore, it will not be evaluated under the essentiality criteria.

- **Reassess the practical implications of the essential use concept.** The criteria are ambiguous and broad, which may lead to unexpected or undesirable interpretations and effects. Specifically, a change in the wording surrounding identification and approval of safer alternatives. More specific terminology should be used instead of the current wording of 'significantly safer' and 'similar level of performance'. This will aid in testing, comparison and approval of alternatives.

- **Harmonize essential use concept directives with current PPP regulations.** The current form of the essentiality concept only has marginal differences to Regulation No 1107/2009 concerning identification of harmful substances. While this allows for an easier transition to a harmonized set of rules regarding chemical substances, it still presents some pitfalls. For instance, similarities in the regulations could lead to unnecessary 'double rulings' where substances are covered under multiple legislations. These double rulings create uncertainty surrounding application of policies and allow for loopholes in regulations.

- **Develop a streamlined method and platform for identifying and assessing alternatives for candidates for substitution.** This can serve as the framework used in identifying replacements for non-essential uses cases of PFAS in PPPs. A platform, such as the 'marketplace' from ChemSec or equivalent, would serve to expedite and ease the process of identifying and assessing the alternatives.

- **Ensure continued availability of emergency authorizations of PPP containing PFAS and PPP in general.** If the PFAS ban and essentiality criteria are accepted and written into EU law, care must be taken that specific temporary emergency use options of "harmful substances" stay available to allow for resistant or invasive pests to be dealt with when preventative measures and biological control have failed or are not effective at further

controlling the outbreak. A similar emergency authorization is already present in Reg. No 1107/2009 under article 53 and could function as a starting point for further discussion.

Further reading

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Glossary

Pesticides: product that prevents, protects and destroys an injuring organism for the plant or the plant products before and after harvest.

Plant Protection Products (PPPs): products structured in a way that been provided to the users, containing active substances, synergistic or safeners, and designed for the above aims:

I. Protecting plants or plant products in defiance of injurious organisms or inhibiting the action of these organisms, unless there is a hygiene-related reason for their use.
II. Affecting the living process of plants, for instance affecting the plant growth and not its nutrition.
III. Safeguarding the plant products, except substances or products that are conditioned to special Community preservatives.
IV. Annihilating unfavourable plants or parts of plants, without algae except are used in soil or water for plant protection reasons.
V. Diminishing or preventing unfavourable growth of plants, without algae except are used in soil or water for plant protection reasons.

Residues: are referred to on one or more substances found within plants, plant products, animal products for human consumption, drinking water or the wider environment due to application of PPPS, containing their metabolites, breakdown products or reaction process.

Substances: are referred to chemical elements and their compounds, as they are existing in nature or by manufacture, encompassing any impurity due to manufacturing process.

Metabolite: is referred to any chemical compound as result of degradation of active substances, synergistic or safeners, created in the environment or in living organism.

Impurity: is referred to any chemical compound apart from the pure active substance and/or its variant which is current in the technical product, involving elements from the manufacturing process or degradation due to storage conditions.

Synergist: is a chemical compound that does not show or shows little PPP activity, but it can enhance the activity of an active substance.

Safener: is a chemical compound that meant to reduce or eliminate phytotoxic effects of the PPP on certain plants

Co-formulant: is a chemical compound that is neither an active substance, safener, nor synergist but used in PPP

Adjuvant: is a chemical substance or preparation containing, among other things, one or more co-formulants that are sold separately from a PPP and are intended to be mixed with the PPP by the user to enhance effectiveness and pesticidal properties (Regulation 1107/2009).

Abbreivations of EU communications, directives and regulations

COM (2001) 31 final – Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on the Sixth Environment Action Programme of the European Community, "Environment 2010: Our future, Our choice". Available at: https://eur-lex.europa.eu/EN/legal-content/summary/sixth-environment-action-programme.html

COM (2006) 372 final – Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions - A thematic strategy on the sustainable use of pesticides. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52006DC0372

COM (2019) 264 final – Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – Findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH) and identified challenges, gaps and weaknesses. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2019%3A264%3AFIN

COM (2020) 667 final – Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – Chemicals Strategy for Sustainability; Towards a Toxic-Free Environment. Available at: https://circabc.europa.eu/ui/group/8ee3c69a-bccb-4f22-89ca-277e35de7c63/library/dd074f3d-0cc9-4df2-b056-dabcacfc99b6/details?download=true

COM (2024) 2894 final – Communication from the Commission – Guiding criteria and principles for the essential use concept in EU legislation dealing with chemicals. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52024XC02894

Directive 2009/128/EC – 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. Available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:309:0071:0086:en:PDF

Regulation 1907/2006 or (EC) Reg. No 1907/2006 – Regulation (EC) No 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. Available at: https://eur-lex.europa.eu/eli/reg/2006/1907/oj

Regulation 1272/2008 or (EC) Reg. No 1272/2008 – Regulation (EC) No 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 1907/2006. Available at: https://eur-lex.europa.eu/eli/reg/2008/1272/oj

Regulation 1107/2009 or (EC) Reg. No 1107/2009 – Regulation (EC) No 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. Available at: https://eur-lex.europa.eu/eli/reg/2009/1107/oj

Regulation 2019/1021 or (EU) Reg. No 2019/1021 – Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (recast). Available at: https://eur-lex.europa.eu/eli/reg/2019/1021/oj

Regulation 2021/383 or (EU) Reg. No 2021/383 – Commission Regulation (EU) 2021/383 of 3 March 2021 amending Annex III to Regulation (EC) No 1107/2009 of the European Parliament and of the Council listing co-formulants which are not accepted for inclusion in plant protection products. Available at: https://eur-lex.europa.eu/eli/reg/2021/383/oj

Regulation 2023/574 or (EU) Reg. No 2023/574 – Commission Implementing Regulation (EU) 2023/574 of 13 March 2023 setting out detailed rules for the identification of unacceptable co-formulants in plant protection products in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council. Available at: https://eur-lex.europa.eu/eli/reg_impl/2023/574/oj