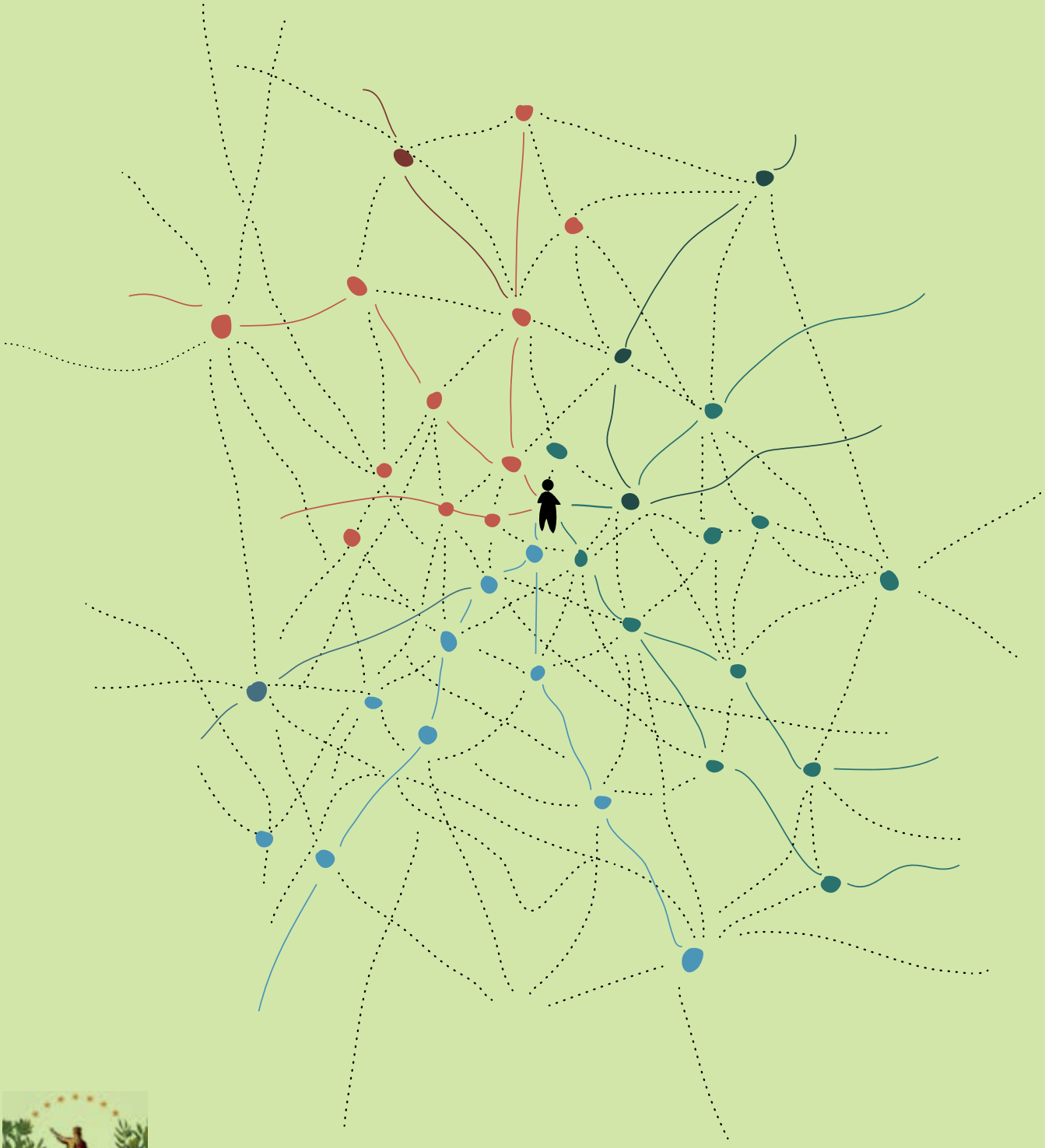
Focus on European Pesticide Policy and challenges ahead



OPERA

UNIVERSITÀ CATTOLICA del Sacro Cuore

OPERA is a research center and think tank of the Universitỳ Cattolica del Sacro Cuore. Since 2010, offers simple and pragmatic solutions to support European and national decision - working in a multistakeholder environment, with farmers, associations, NGOs, and governments, to integrate sustainability in the agri-food sector. Our vision is to provide high-quality information and analysis on the latest developments in EU agri-food policy and promote a balanced dialogue between stakeholders. So far, OPERA has been focused on the pressing issues of pesticide sustainability, the establishment of exposure prevention and mitigation measures, and pesticides risk management. In this document OPERA deals with European policies and the pesticide framework implementation.

Given the complexity of the topic, the broad array of regulatory chemicals risk analysis, performed under different sectorial regulatory, this document does not have the ambition to be exhaustive, but represent an attempt to provide a key to understanding the complex mechanism of the regulation of pesticides aimed to assure a sustainable use of pesticides also in view of the new strategies and ambitions targets of Europe toward a toxic free environment and climate neutrality by 2050.

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Extended Summary

The “umbrella” of the European food law: the Regulation (EC) No 1107/2009 for the authorization and the different actors role.

Europe, as is well known, has one of the most consistent and stringent legislative corpus aimed at ensuring food safety and environmental protection. Plant Protection Products (PPPs), as regulated product, falls under the umbrella of food law and need to be authorised and assessed before to be placed on the marked to assure a high level of protection of human health and the environment. The risk assessment is carried out through a scientifically based procedure by EFSA while the European Commission is responsible for a correct risk management, the analysis and the adoption of restrictive measures and appropriate preventive and control choices to protect human health. A dual system is in place, under which EFSA evaluates active substances used in plant protection products and Member States evaluate and authorize the products at national level. In this framework, Plant protection Products are regulated by Regulation (EC) No 1107/2009. All matters related to legal limits for pesticide residues in food and feed are covered by Regulation (EC) No 396/2005.

In this section information on responsibilities and procedure for PPPs risk analysis is provided.

Post authorisation phase. The Sustainable Use Directive 2009/128/EC (SUD).

But the marketing and use of PPPs is regulated by a large body of EU legislation. Regarding the Post Authorization and Use phase, the Sustainable Use Directive 2009/128/EC (SUD) represent an important driver to achieve a sustainable use of pesticides by reducing the risks and impacts of pesticide use on human health and the environment. These risks need to be assessed by appropriate risk indicators using statistical data collected in accordance with legislation concerning statistics on plant protection products and other relevant data.
Recently, two Harmonized Risk Indicators (HRIs) are used based on the quantities of active substances placed on the market in PPPs under Regulation (EC) No 1107/2009 and on the number of emergency authorizations granted for PPPs under Article 53 of the same regulation.

Regulation (EU) 2022/2379 of the European Parliament and of the Council of 23 November 2022 on statistics on agricultural input and output[1], should assure the collection of harmonized, updated and high-quality statistical data necessary for the development of agro-environmental indicators. This Regulation specifies technical elements of the data to be provided. Regulation (EU) **2023/1537 of 25 July 2023** laying down rules for the application of the Regulation (EU) 2022/2379 and shall enter into force the 1 January 2025. The data shall be transmitted to the Commission (Eurostat) by member State following the Annexes requirements (summarized in paragraph **3.3.1**)

Since the entry into force of the directive, article 15 on indicators, due to its ambiguity, has always been widely debated by the scientific community and by the experts of the individual member states. Indicators in this case reflect the hazard trend and not the risk, that is a combination of hazard and exposure.
Indeed, any indicator based on a quantity of active substances placed on the market typically fails to acknowledge the benefits that can be achieved by the implementation of precautionary measures, such as the role of field margins on biodiversity or innovative application techniques that can minimize pesticide losses to the environment. In such cases, risk reduction measures are not realistically assessed, or their impact evaluated.

Effectiveness and impact evaluation.

The effectiveness and impact of all these laws are regularly evaluated.

After the revision of Regulation (EC) No 1107/2009 by The European Commission’s Regulatory Fitness and Performance Programme (REFIT) that ensure that laws are “fit for purpose”, and two reports by the European Parliament, it was concluded that, despite marked improvements over the past in regulating PPPs, the implementation of the regulation is not satisfactory, Member States are not doing enough to reduce dependency on chemical substances for plant protection, and more transparency is requested to create trust in the overall framework. In response the Commission proposed an amendment of the General Food Law, which has been adopted by the Council and the European Parliament on 13 June 2019 (Regulation (EU) 2019/1381) on the transparency and sustainability of the EU risk assessment in the food chain applicable from 27 March 2021.

Weaknesses in the implementation, application and enforcement of the SUD have been highlighted, also in response of growing societal concerns highlighted in some European citizens’ initiatives, and European Parliamentary questions on sustainable use of pesticide.

In this framework, as part of the European Green Deal, the Commission’s Farm-to-Fork strategy, highlighting the need to transition to a fair, healthy and environmentally-friendly food system, make a proposal of a revision of the Sustainable Use Directive (SUD) moving toward a Regulation on the Sustainable Use of plant-protection products (also called SUR). In addition, setted the ambitious specific targets to reduce by 50% the use and risk from chemical pesticides as well as the use of the more hazardous pesticides by 2030 , monitoring the progress using the HRIs. On 22 June 2022 the Commission adopted the proposal that must be approved by Member States in the Council and the European Parliament, under the normal legislative procedure.

Actually, the Commission is decreasing the intensity of the efforts in the Sustainable use directive revision, due to geopolitical concerns caused by the recent Russia-Ukraine Crisis; but also following the opinion and scientific reports provided by different stakeholder involved in the food chain that put in evidence the potential negative impact on the overall Eu production and farmers income, accompanied by conseguent higher prices for agricultural raw materials and food.

Another aspect that emerge from the literature analysys is the important role of EU whose regulations and strategies are often taken as a reference even outside the European borders, and whose eventual adoption, particularly as regards the case of pesticide reduction targets, could create problems in ensuring global food security in the long term. Lesson of Sri Lanka’s unsuccessful transition to organic

[1] https://eur-lex.europa.eu/eli/reg/2022/2379/oj

farming in 2019, that abandoned its national experiment, after domestic rice production fell by 20% in the first six months, evidenced the importance of the timeline of a transition, that need a balance between immediate needs and long-term food security. Despite all, in February 2023, more than 85 NGOs ask the President to ensure that a strong proposal for an EU legislative framework for sustainable food systems is presented by September 2023 to achieve the EU's International commitments and the EU Green Deal and encourage the Commission keep environmental and social sustainability at the centre of the policy debate around food, agriculture and fisheries.

The new challenge: the EU's zero pollution and Chemical Strategy for Sustainability (CSS)

To coordinate hazard and risk assessments across EU several legislative proposals are available that could have horizontal impacts for chemicals regulatory regimes including REACH, biocides, and plant protection products.
As part of the **EU's zero pollution** ambition, a key commitment of the European Green Deal, on 14 October 2020 the European Commission published the **Chemical Strategy for Sustainability (CSS)** under which, with the aim to better protect citizens and the environment, and to boost innovation for safe and sustainable chemicals, the European Commission committed to publish a proposal to reform REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) by the end of 2022.

The commission also propose, to move towards a **'one substance, one assessment'** process for chemical safety assessments. The aims are to simplify the current arrangements for assessments, to improve the quality and consistency of safety assessments across legislation, and to ensure that resources are used more efficiently.

In this framework, and in response to the policy and societal ambitions, a strategic initiative called "the European Partnership for next generation, systems-based Environmental Risk Assessment (PERA)" was launched by the EFSA toward the adoption of a systems-based approach that initially, will focus on pesticides, after the consideration that there are many commonalities (e.g. hazard assessment, common parameters) for which a more coherent and harmonised approach would be beneficial when characterizing environmental risks. On the other side the **Safe and sustainable by design (SSbD)** concept of the **CSS** represent the effort to include better the socioeconomic aspects into the sustainability dimension that, at present mainly focus on the environment and safety.

1.
Introduction. The “umbrella” of the European food law.

Europe has one of the most comprehensive and protective regulatory frameworks for chemicals, supported by the most advanced knowledge base globally. EU chemicals legislation evolved with the development of new directives and regulations separated by market type. This is why, biocides, industrial chemicals, pesticides, medicines for human use and veterinary medicines are regulated independently. Pesticides belongs to the general framework of food law.
In response to the various food incidents that took place during the late 1990s, the European Parliament and the Council adopted Regulation (EC) No 178/2002[2] laying down the general principles and requirements of food law, that represents the overarching and coherent framework for the development of food and feed legislation both at Union and at Members States levels. The approach covers all sectors of the food chain, including feed production, primary production, food processing, storage, transport, and retail sales.

To this end, it lays down general principles, requirements and procedures that underpin decision making in matters of food and feed safety, covering all stages of food and feed production and distribution.

The general requirements of the food law are:
- Food should not be placed on the market, if it is unsafe.
- Feed should not be placed on the market or feed to any food-producing animal, if it is unsafe.
- Labelling, advertising and presentation should not mislead consumers (e.g. shape, appearance, packaging, packaging materials used, display, information).
- Food and feed business operators at all stages of production, processing and distribution within the businesses under their control should ensure that requirements of food law are satisfied and should verify that such requirements are met.

In order to achieve the general objective of a high level of protection of human health and life, food law shall be primarily based on **risk analysis**.

The Article 3. Reg.178/2002 clearly defines some important terms:
- “risk” means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard;
- “risk analysis” means a process consisting of three interconnected components: risk assessment, risk management and risk communication;
- “risk assessment” means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation;
- “risk management” means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options;
- “risk communication” means the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions;
- “hazard” means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect;
- “traceability” means the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution.

European Union legislation provides that the risk is identified by evaluating the probability and severity of the harmful effect of the food or feed on health, resulting from the presence of a hazard.

The risk assessment is carried out through a scientifically based procedure, which evaluates the exposure to the hazard and the risk, the probability and the severity of the harmful effect on health. This control is carried out by the European Food Safety Authority (EFSA), which collects communications from Member States or national authorities, consumers, businesses, the academic community, and those interested in food safety.

After the risk assessment, the European Commission is responsible for a correct risk management, the analysis and the adoption of restrictive measures and appropriate preventive and control choices to protect health.

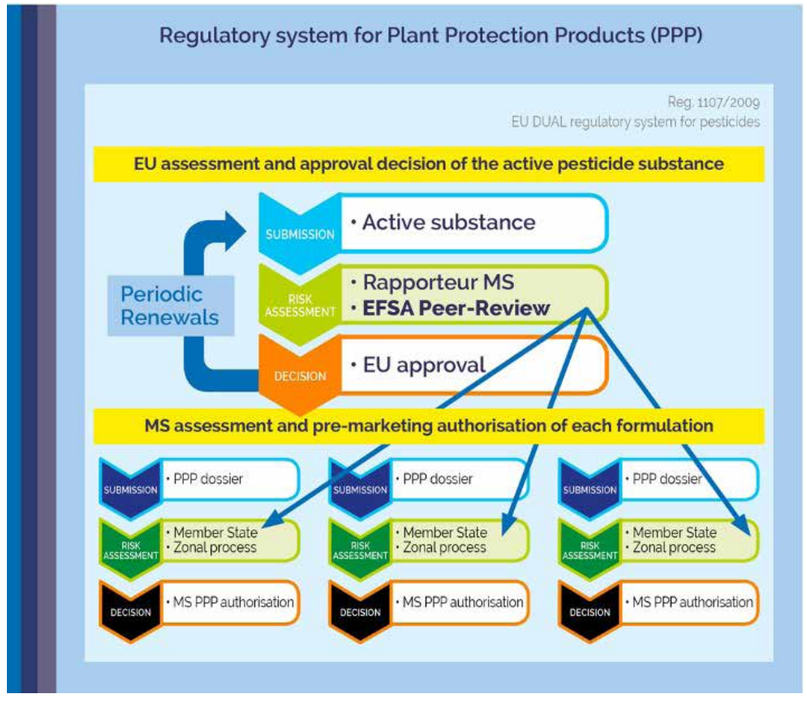

Figure 1 - Regulatory system for PPPs Source: Science Advice for Policy by European Academies (SAPEA) workshop 2017 (source www.sapea.info)

[2] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety - Official Journal L 031, 01/02/2002 P. 0001 - 0024.

Belongs to the general framework of risk analysis, and in particular risk management, the Precautionary Principle.

It was first set out in a European Commission communication adopted in February 2000. It aims at ensuring a higher level of protection through preventative decision-taking in the case of risk and it has been recognized by various international agreements, notably in the Sanitary and Phytosanitary Agreement (SPS)/ WTO.

Presupposes that potentially dangerous effects deriving from a phenomenon, product or process have been identified, and that scientific evaluation does not allow the risk to be determined with sufficient certainty.

The implementation should start with a scientific evaluation, as complete as possible, and where possible, identifying at each stage the degree of scientific uncertainty. The transparent decision-making procedure should involve as early as possible all interested parties.

2.
Food law and Regulated products: pesticides and legal framework.

EFSA (European Food Safety Authority) delivers scientific advice on a wide range of issues such as food additives, allergenic food ingredients, genetically modified organisms, novel foods, and **pesticide**.

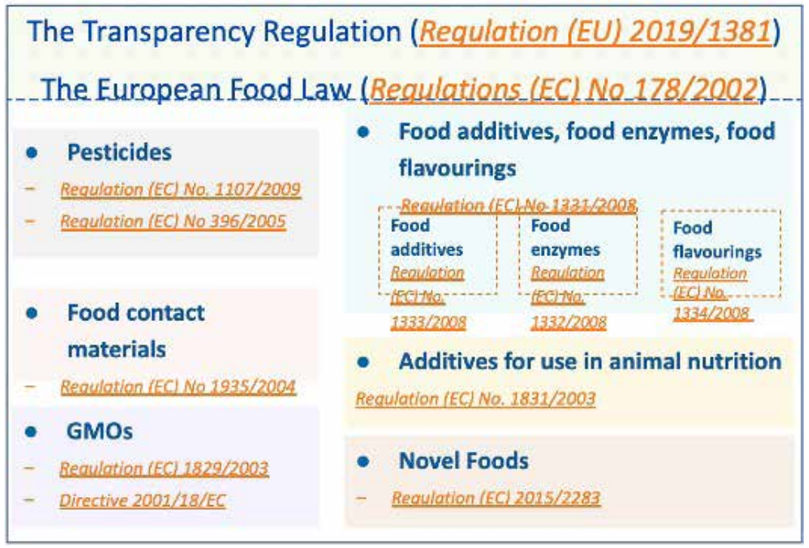

Figure 2 - Regulated products (from BTSF course on Food Safety Risk Analysis)

All these products are called **regulated product**, that means that, before to be used, these products need to be evaluated and authorized and for which there is a related product/specific european harmonized legislation pertaining to the safety and placement on the market.

Authorisation procedures are based on the principle that the applicant or the notifier have to prove that the subject matter of an application or notification complies with Union requirements.

The provision of the principles of food legislation in Regulation No. 178 of 2002 has allowed for the issuance of further regulations, directives and decisions governing various aspects of food safety, including Plant Protection Products (PPPs). These products cannot be placed on the market or used without prior an authorization. The marketing and use of PPPs is regulated by a large body of EU legislation. A dual system is in place, under which EFSA evaluates active substances used in plant protection products and Member States evaluate and authorize the products at national level.

Plant protection products are principally regulated by framework **Regulation (EC) No 1107/2009**.[3]

[3] 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 (OJ L 309, 24.11.2009, p. 1).

All matters related to legal limits for pesticide residues in food and feed are covered by **Regulation (EC) No 396/2005**.[4]
This regulation also contains provisions on official controls of pesticides residues in food of plant and animal origin that may arise from their use in plant protection (from EFSA).

Other important elements of the EU PPP regulatory framework are:
- Directive 2009/128/EC[5] establishes actions to achieve sustainable use of pesticides in the EU.
- Directive 2009/127/EC[6] deals with machinery for pesticide application and its design, construction and maintenance.
- Regulation (EC) No. 1272/2008[7] concerns product classification, labelling and packaging.
- Regulation (EC) No 1185/2009[8] and Regulation (EU) 2022/2379 concerns information on the annual amounts of pesticides placed on the market and the annual amounts of pesticides used in each Member State. Article 1(3) of Regulation (EC) No 1185/2009 requires that the statistics produced in accordance with that Regulation, together with other relevant data, serve the purpose of Articles 4 (the establishment of National Action Plans) and 15 of Directive 2009/128/EC, the calculation of indicators.

While an EU regulation is directly applicable, EU directives need to be transposed into national legislation. Directives, however, set common objectives; Member States can achieve these objectives by adapting the means to the local situation. This is the case for the Directive on Sustainable Use of Pesticides (whose acronym is SUD).

[4] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

[5] 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 (OJ L 309, 24.11.2009, p. 71).

[6] Directive 2009/127/EC of the European Parliament and of the Council of 21 October 2009 amending Directive 2006/42/EC with regard to machinery for pesticide application (OJ L 310, 25.11.2009, p. 29–33).

[7] 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 OJ L 353, 31.12.2008, p. 1–1355.

[8] Regulation (EU) 2022/2379 of the European Parliament and of the Council of 23 November 2022 on statistics on agricultural input and output, amending Commission Regulation (EC) No 617/2008 and repealing Regulations (EC) No 1165/2008, (EC) No 543/2009 and (EC) No 1185/2009 of the European Parliament and of the Council and Council Directive 96/16/EC PE/37/2022/REV/1OJ L 315, 7.12.2022, p. 1–29.

The **effectiveness and impact** of these laws are regularly evaluated.
For example, the Commission has commenced an evaluation of the sustainable use of pesticides directive and an impact assessment of its possible future revision and a proposal for a regulation on the sustainable use of plant-protection products (also called SUR) was started, following growing societal concerns about the use of pesticides highlighted in some petitions as the two European citizens' initiatives[9], and European Parliamentary questions on this issue.

Following the REFIT and the request of the Ex-Post Evaluation Unit of the European Parliamentary Research Service (EPRS), the implementation by EU Member States of the Plant Protection Product Regulation which governs the authorization of plant protection products (PPP) in the EU was evaluated.
These aspects will be covered in chapter 3.2 and 3.4.

[9] Initiative 'Ban glyphosate and protect people and the environment from toxic pesticides called on the Commission, under its third aim, 'to set EU-wide mandatory reduction targets for pesticide use, with a view to achieving a pesticide-free future' initiative Save bees and farmers! Towards a bee-friendly agriculture for a healthy environment calls on the Commission to propose legal acts to phase out synthetic pesticides by 2035, to restore biodiversity, and to support farmers in the transition.

3.
Overview of the regulatory context and the different actors' roles.

3.1. Authorization. Regulation (EC) No 1107/2009

Regulation (EC) No. 1107/2009 reflects the separation of risk assessment and risk management: approval and authorization are legislative acts based on a scientific assessment of the potential risk from the use of a PPP.

In this Regulation are mentioned:
- The criteria to ensure that active substances do not adversely affect human or animal health or the environment (Art 4);
- The approval processes. Both Active substances and PPPs undergo an intensive evaluation process before a decision can be made on approval.

Under this Regulation, Risk evaluation is performed in several steps:
1. Application for approval is submitted to an EU country called Rapporteur Member State (RMS);
2. RMS verifies if the application is admissible;
3. RMS prepares a draft assessment report;
4. EFSA issues its conclusions;
5. PAFF (Plant Animal Food and Feed) Committee votes on approval or non-approval;
6. Adoption by the Commission;

Publication of a Regulation in the EU Official Journal.

I - Approval of an active substance
The rapporteur Member State (RMS) scientifically and technically evaluates the active substance and prepares an assessment report. RMS and The European Food and Safety Authority (EFSA) are in charge of risk assessment. EFSA conducts a public consultation and, together with the EU Member States, carries out a peer review of the assessment report prepared by the RMS. EFSA sends its conclusions to the European Commission.

The Commission is in charge of risk management and approves active substances for the use in PPPs, which are authorised by the Member States following EFSA evaluation. There is a list of approved active substances in the EU following the **Regulation EU 540/2011**[10]. The EU Pesticides Database provide information on active substances used in plant protection products, Maximum Residue Levels (MRLs) in food products, and emergency authorisations of plant protection products in Member States[11].

[10] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances Text with EEA relevance OJ L 153, 11.6.2011, p. 1–186.

[11] https://food.ec.europa.eu/plants/pesticides/eu-pesticides-database_en

II - ***Authorisation of a plant protection product (PPP)***
Member State is responsible for authorising PPPs. The Member State takes the final decisions on whether individual products with specific use recommendations are allowed on the market in their countries. Member State receives the application submitted from the industry related to PPP containing the approved active substance and makes the assessment taking into account the agricultural and environmental circumstances in their territory.

According to Commission **Regulation (EU) No 546/2011**[12], assessment and decision-making criteria to authorize a PPP containing an EU approved active substance are harmonized: these are the **uniform principles** for the assessment and the authorizations of PPPs.

However, Member States, shall "evaluate plant protection product in a range of agricultural, plant health and environmental (including climatic) conditions likely to be encountered in practice in the area of proposed use".
The EU is therefore artificially divided into 3 zones: North, Central and South to enable within each zone an harmonized and efficient system of mutual recognition of the authorization of a plant protection product between the Member States belonging to that zone.

Data requirements and Guidance documents
Data requirements for active substances and PPP are setting respectively by **Regulation EU 283/2013**[13] and **Regulation EU 284/2013**[14] and a list of test methods and guidance documents are provided by the Commission in accordance with Regulation (EC) No 1107/2009.

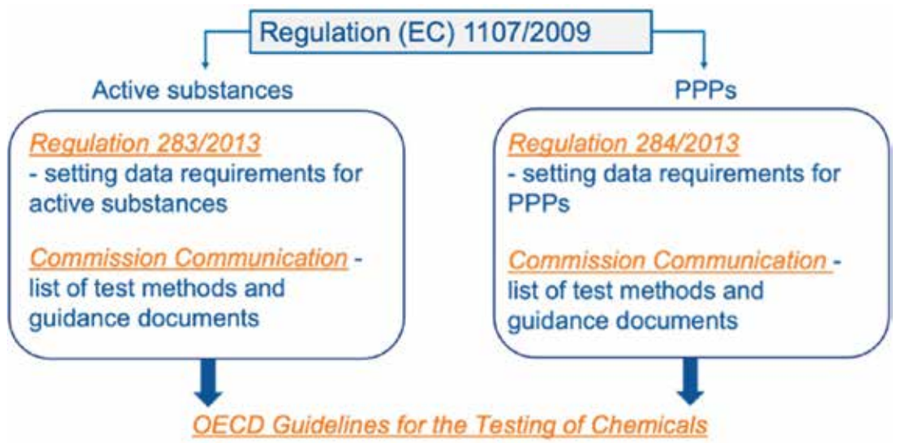

Figure 3 - Regulations that set data requirements for active substances and PPPs (from BTSF course on Food Safety Risk Analysis)

[12] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products Text with EEA relevance OJ L 155, 11.6.2011, p. 127–175.

[13] Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market Text with EEA relevance OJ L 93, 3.4.2013, p. 1–84.

[14] Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market Text with EEA relevance OJ L 93, 3.4.2013, p. 85–152.

Guidance documents provide details about the evaluation and decision procedure, to ensure a high level of harmonisation and interpretation.
These guidelines are not legally binding, however they represent the strongest interpretation of the existing legislation and are constantly updated.
Nowadays, the most comprehensive source of guidance and guidelines are the **Commission Communications.**

In the Communications are also included guidelines provided by other international organizations, such as the Organisation for Economic Co-operation and Development (OECD) and the European and Mediterranean Plant Protection Organization (EPPO).
Indeed, in the absence of suitable internationally or nationally validated test guidelines, test guidelines accepted by the European competent authority shall be used. But any deviations shall be described and justified. This aspect creates additional complexities.

Co-formulants-Annex III to Regulation (EC) 1107/2009
Regulation (EU) 2021/383 amending Annex III to Regulation (EC) No 1107/2009.

Co-formulants are substances or preparations used together with active substances in plant protection products and are thus equally spread in the environment. For this should be assessed using the same criteria concerning human health, the environment, ecotoxicity and groundwater and taking into account data on carcinogens, mutagens, toxicity to reproduction, persistency and bioaccumulation, endocrine disrupting properties.
Annex III is the list of co-formulants which are not accepted for inclusion in plant protection products or adjuvant.

Risk Mitigation
If the conditions for approval of active substance can provide for risk mitigation, the EU level only defines the risk reduction factors to be applied to reach an acceptable level of risks. This is up to the Member States to select the most appropriate Risk Mitigation Measure which fits best the local conditions and the farming practices when they assess the PPP dossier in view of their authorization at zonal and national level.

The selected RMM shall reach the level of risk reduction recommended in the EU review/renewal report accompanying the decision approving the active substance(s). However, a certain degree of flexibility remains for the Member States to adapt the recommended measures to local conditions as long as they are achieving the level of risk reduction required by the assessment.
Safety precautions phrases (SP-phrases) shall be put on the label to alert about certain hazards and to recommend certain precautions to ensure the protection of human or animal health or of the environment.

The Commission **Regulation (EU) No 547/2011**[15] refer to all information that shall be included clearly and indelibly on the packaging of plant protection products. In this regulation a list of safety precautions phrases is provided in to facilitate the harmonized enforcement of specific restrictions through labelling the plant protection products.

[15] Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products. OJ L 155, 11.6.2011, p. 176-205.

Emergency authorizations
Article 53 of Regulation (EC) No 1107/2009 allows, in special circumstances, Member States to authorize for a period not exceeding 120 days, the placing on the market of plant protection products, for limited and controlled use, where such a measure appears necessary because of a danger which cannot be controlled by any other reasonable means. In these cases, Member States may authorize plant protection products containing either approved or non-approved active substances. The increase oversight of emergency authorizations, due to Article 53 that gives the possibility to Member States to allow the use of PPP without regular authorization to address dangers to plant health was also noted. This influenced the development of the **Harmonized Risk Indicator 2** established under the Sustainable Use Directive that now **should take into account the area on which PPP under emergency authorisations are applied.**

3.2. Evaluation on the efficacy and implementation of the Plant Protection Products Regulation (EC) No 1107/2009

Industry is particularly affected by burdens and complexity of all the European rules and laws.

The European Commission's Regulatory Fitness and Performance Programme **(REFIT)**[16] *aims to ensure that EU laws deliver on their objectives at a minimum cost for the benefit of citizens and businesses and ensure that laws are still "fit for purpose".*

A report on Evaluation of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and of Regulation (EC) No 396/2005 on maximum residue levels of pesticides, covering the period of their respective entry into application until end 2018, was provided in May 2020[17].
The conclusion were that, *"despite an EU agriculture entirely without pesticides is not a realistic objective, Member States are not doing enough to reduce dependency on chemical substances for plant protection and that the potential of integrated pest management is not fully exploited".*

In addition, the Commission also considered two reports by the European Parliament. The first report[18], adopted in September 2018, concluded that,
despite marked improvements over the past in regulating PPPs,
the implementation of the regulation is not satisfactory.

Then a second report[19] was requested by The European Parliament in 2019 with the involvement of all key players. The conclusions were: request for more transparency, a strict application of the precautionary principle and of the
hazard-based approach, more incentives and research for low-risk alternatives, as well as the setting up of a negative list of prohibited co-formulants and an approval

[16] Available at https://commission.europa.eu/law/law-making-process/evaluating-and-improving-existing-laws/refit-making-eu-law-simpler-less-costly-and-future-proof_en

[17] REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL Evaluation of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and of Regulation (EC) No 396/2005 on maximum residue levels of pesticides COM(2020) 208 final.

[18] European Parliament (September 2018) Report on the implementation of the Plant Protection Products Regulation (EC) No 1107/2009 (2017/2128(INI)).

[19] European Parliament (January 2019) Report on the Union's authorisation procedure for pesticides (2018/2153(INI)) - Special Committee on the Union's authorisation procedure for pesticides.

procedure for safeners and synergists.

In 2019 the PEST, the Union's authorisation procedure for pesticides (PEST) special committee in response to concerns raised about the risk posed by glyphosate, concluded, that the public should be granted access to studies used in the authorisation procedure; the EU's framework should stimulate innovation and promote low-risk pesticides; scientific experts should review studies on the carcinogenicity of glyphosate; and data requirements for PPPs should include long-term toxicity.

In response the Commission proposed an amendment of the General Food Law, which has been adopted by the Council and the European Parliament on 13 June 2019 (Regulation (EU) 2019/1381) on the transparency and sustainability of the EU risk assessment in the food chain applicable from 27 March 2021.

In this regulation a general objectives and principles of risk communication, taking into account the respective roles of risk assessors and managers, are addressed.

In more details risk communication, taking into account risk perceptions of all interested parties, should better explain, in terms of accuracy, clearness, comprehension, coherence, how risk assessment findings are used to help inform risk management decisions. Information should be provided on how risk management decisions were reached and *on the factors, other than the results of the risk assessment, which were considered by the risk managers, as well as how those factors were weighed up against each other.*

Require to include representatives of all Member States, of the European Parliament and of the Commission as well as of civil society and industry organisations in the Management Board, while providing that those representatives should have experience and expertise not only in the fields of food chain law and policy, including risk assessment, but also in the fields of managerial, administrative, financial and legal matters and ensuring that they act independently in the public interest.

To ensure a higher level of transparency, the articles relating to the transparency of the data and the information that the authority is obliged to make public and the elements for which the notifier can request the confidentiality of the data are introduced or modified. A list of information and outcome that Authority shall make public is provided. The Authority may grant confidential treatment, upon the request of an applicant only with respect to items of information where is demonstrated by the applicant the potentially damage of its interests to a significant degree.

3.3. Post Authorization. The use phase. The Sustainable Use Directive 2009/128/EC (SUD)

This Directive[20] *establishes a framework to achieve a sustainable use of pesticides by reducing the risks and impacts of pesticide use on human health and the environment and promoting the use of Integrated Pest Management (IPM) and of alternative approaches or techniques, such as non-chemical alternatives to pesticides.*
The directive focuses on the pesticide **use phase.**

The main tools of the directive are:
- Training;
- Information and Awareness;
- Improvement of control of uses and PPP application equipment;
- Improvement of handling and storage of pesticides and treatment of their packaging and remnants;
- Integrated practices;
- Measuring the performance.

For each Member State a **National Action Plans (NAP)**[21] is compulsory to set quantitative objectives, targets, measures and timetables to reduce the time trend risks and impacts of pesticide use taking into account of the health, social, economic and environmental impacts of the measures envisaged, of specific national, regional and local conditions and all relevant stakeholder groups.

The Directive also includes:
- A list of principles to be followed for an IPM approach: from prevention to monitoring and intervention, with all the possible solutions (including anti-resistance strategies and biological control), targeting specifically the plant protection product to be used and its application. However the revision of SUD evidenced that the potential of integrated pest management is not fully exploited;
- The training subjects (in annex I) to ensure that those who use or will use pesticides are fully aware of the potential risks to human health and the environment and of the appropriate measures to reduce those risks as much as possible. Member States set up systems of both initial and additional training for distributors, advisors and professional users of pesticides and certification systems to record such training to ensure that all have sufficient knowledge, taking account of their different roles and responsibilities. Training activities aiming at fostering environmental and human health safe and sustainable use of pesticides, should concern aspects related either to the assessment evaluation process then the management requirements and should take present-day and future challenges into account to enable people to be better informed and able to better link knowledge, action, and sustainability. New farmers' generations in the upcoming few years necessary will deal with new technology that will collect data, will guarantee the traceability; pesticide-resistance. In this situation, different
partners (extensors, advisors, experts, distributors, etc.) could have "a role" to play in the knowledge generation process, as each group brings an important perspective.

[20] 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 (OJ L 309, 24.11.2009, p. 71).

[21] Available at https://food.ec.europa.eu/plants/pesticides/sustainable-use-pesticides/national-action-plans_en

● Health and safety and environmental requirements (in annex II) relating to the inspection of pesticide application equipment.

3.3.1. The big challenge of SUD: measuring the performance with indicators

The directive establishes a framework to achieve the sustainable use of pesticides by reducing the risk and impacts of pesticide use on both human health and the environment and promoting the use of integrated pest management and of alternative approaches or techniques. These risks thus need to be assessed using appropriate risk indicators. Article 15 of Directive 2009/128/EC requires the Commission to calculate risk indicators at Union level using statistical data collected in accordance with legislation concerning statistics on plant protection products and other relevant data to measure progress in meeting the main objective of the Directive.

The commission Directive (EU) 2019/782 of 15 May 2019[22] amending Directive 2009/128/EC as regards the establishment of harmonised risk indicators. Two Harmonized Risk Indicators (HRIs) were recently developed that take into account the statistics on the quantities of pesticide active substances placed on the market and the number of authorisations granted for plant protection products under Article 53, including if they are low risk active substances, candidates for substitution, or other active substances.

In detail:

Harmonized Risk Indicator 1: **based on the quantities** of active substances placed on the market in plant protection products under Regulation (EC) No 1107/2009.

Harmonized Risk Indicator 2: **based on the number of authorisations** granted for plant protection products **under Article 53 of Regulation** (EC) No 1107/2009.

[22] COMMISSION DIRECTIVE (EU) 2019/782 of 15 May 2019 amending Directive 2009/128/EC of the European Parliament and of the Council as regards the establishment of harmonised risk indicators OJ L 127/4 16.5.2019.

Table 1. Categorisation of active substances and weightings for the purpose of calculating Harmonised Risk Indicators 1 and 2

Row	Groups						
	1		2		3		4
(i)	Low-risk active substances which are approved or deemed to be approved under Article 22 of Regulation (EC) No 1107/2009, and which are listed in Part D of the Annex to Regulation (EU) No 540/2011		Active substances approved or deemed to be approved under Regulation (EC) No 1107/2009, and not falling in other categories, and which are listed in Parts A and B of the Annex to Regulation (EU) No 540/2011		Active substances approved or deemed to be approved under Article 24 of Regulation (EC) No 1107/2009, which are candidates for substitution, and which are listed in Part E of the Annex to Regulation (EU) No 540/2011		Active substances which are not approved under Regulation (EC) No 1107/2009, and therefore which are not listed in the Annex to Regulation (EU) No 540/2011
(ii)	Categories						
(iii)	A	B	C	D	E	F	G
(iv)	Micro-organisms	Chemical active substances	Micro-organisms	Chemical active substances	Which are not classified as: Carcinogenic Category 1A or 1B **and/or** Toxic for Reproduction Category 1A or 1B **and/or** Endocrine disruptors	Which are classified as: Carcinogenic Category 1A or 1B **and/or** Toxic for Reproduction Category 1A or 1B **and/or** Endocrine disruptors, where exposure of humans is negligible	
(v)	Weightings applicable to quantities of active substances placed on the market in products authorised under Regulation (EC) No 1107/2009						
(vi)	1		8		16		64

eurostat

Figure 4 - Table of categorisation and weighting for the purpose of calculating risk indicators Source: Eurostat

Member States are obligate to calculate the 2 HRIs as requested by article 15 of the directive for their national territory (NUTS0), the European Commission for the whole EU.

Weightings are defined for a combination of 4 groups and 7 categories of active substances as in figure above.

A document to assist Member States in meeting their obligations under Article 15(2) of Directive 2009/128/EC was provided by the Commission[23].

The HRIs should always reflect the **current status of active substances**.
If an active substance changes Group or Category, due to a change in its approval status, or due to a change in its classification, the active substance shall be considered to be placed in its new Group/Category for the whole period of calculation of HRIs. The change to the new Group/Category will occur in the year following the change in classification/approval status.

Since the entry into force of the directive, article 15 on indicators, due to its ambiguity, has always been widely debated by the scientific community and by the experts of the individual member states. The Opera Research Center organized an expert working group and has had several consultations with stakeholders to identify a common way of thinking in evaluating and identifying the factors that should be considered in selecting each indicator[24].

[23] Eurostat, 2021 Methodology for calculating harmonised risk indicators for pesticides under Directive 2009/128/EC PDF: ISBN 978-92-76-36884-7 ISSN 2315-0815.

[24] Calliera et al, A process to provide harmonised criteria for the selection of indicators for pesticide risk reduction within the framework of the sustainable use directive. Pest Manag Sci 2013; 69: 451-456.

One conclusion of the debate was that any indicator based on a quantity of active substances placed on the market typically fails to acknowledge the benefits that can be achieved by the implementation of precautionary measures, such as the role of field margins on biodiversity or innovative application techniques that can minimize pesticide losses to the environment. In such cases, risk reduction measures are not realistically assessed, or their impact evaluated.

Another interesting example of how is important to consider the pros and cons of the use of HRIs is the Wageningen report on the impact of the Eu strategy and Farm to Fork. Indeed, the study results reveal that "increasing the area under organic production could contribute to the reduction of the overall use and risk of pesticides and the reduction of nutrient losses, assumed that the use and risk of pesticides in organic production measured by the HRI1 would be lower than in conventional production. For annual crops this is indeed the case, but some results suggest that for some perennial crops the opposite is true".
In such cases, there would be no reason to shift to organic production from a sustainability point of view.

Regulation (EU) 2022/2379 of the European Parliament and of the Council of 23 November 2022 on statistics on agricultural input and output[25], should assure the collection of harmonized, updated and high-quality statistical data necessary for the development of agro-environmental indicators.
This Regulation specifies technical elements of the data to be provided.
Those elements consist of the list of variables, the descriptions of the variables, the observation units, the precision requirements to be applied, the methodological rules to be applied, and the deadlines for transmitting the data. To keep the statistics on plant protection products consistent with regular updates of the list of approved active substances, they need to be aligned with Commission Implementing Regulation (EU) No 540/2011 (implementing Regulation (EC) No 1107/2009 as regards the list of approved active substances).

Recent Commission Implementing Regulation (EU) 2023/1537 of 25 July 2023 laying down rules for the application of the Regulation (EU) 2022/2379.
This Regulation shall enter into force the 1 January 2025.

The data shall be transmitted to the Commission (Eurostat) at national level by single active substance, by chemical classes (including plant protection products of microbiological or botanical origins, for harmonisation purposes), by categories of products and by major groups (as Fungicides and bactericides) and shall cover the crop areas with the indication of Non-organic area treated (ha) and Organic area (area under conversion and certified area) treated (ha), for the common list of crops, on agricultural holdings in the Member States, treated with plant protection products and the quantities of all active substances used on non-organic area (kg), quantity of all active substances used on organic area (area under conversion and certified area) (kg), during the reference period (the harvest year), including those used under emergency authorisations.
The data shall include all treatments from sowing/planting until end of harvest.

[25] https://eur-lex.europa.eu/eli/reg/2022/2379/oj

Annex II list the classification of active substances included in the plant protection products. **Soil sterilants (incl. nematicides)** are listed in "Categories of products" of the Major group "Other plant protection products".

Major groups	Categories of products	Chemical classes (1)
Total active substances in plant protection products		
Other plant protection products		
	Vegetal oils	
		Vegetal oils
	Soil sterilants (incl. nematicides)	
		Methyl bromide
		Biological nematicides
		Organophosphorous nematicides
		Other soil sterilants

Figure 5 - Classification of soil sterilants in Annex II- Source: Regulation (EU) 2023/1537 of 25 July 2023.

3.4. Evaluation on the implementation of the Directive on Sustainable Use (SUD) and the proposal for a Sustainable Use Regulation (SUR)

Weaknesses in the implementation, application and enforcement of the SUD have been highlighted and reported by the commission[26]; and several institutions as the Parliament, the Court of Auditors, the Council of European Union[27, 28, 29] and after several stakeholders consultation events.

Results evidenced that, despite the internal and external coherence of the SUD with other EU policies and instruments is generally strong and the objectives of the SUD were, and still are, highly relevant to address the risks that pesticide use poses to the environment and human health, the SUD has only been moderately effective.

Many Member States do not set quantitative targets or indicators in their NAPs to promote the sustainable use of pesticides or better protect human health and the environment. There is also no effective monitoring system, which has resulted in limited data on the use of pesticides. This has made it difficult to reach a conclusion on the extent to which the SUD has protected human health and the environment from the adverse effects of pesticides.

The recent evaluation of the SUD confirmed the long-standing difficulties identified *in its application, implementation and enforcement.*

[26] Report from the Commission to the European Parliament and the Council of October 2017 on Member State National Action Plans and on progress in the implementation of Directive 2009/128/EC on the sustainable use of pesticides – COM(2017) 587 final.

[27] Revision of Directive 2009/128/EC on the sustainable use of pesticides EPRS | European Parliamentary Research Service.

[28] European Court of Auditor, Special Report 05. 2020. Sustainable use of plant protection products: limited progress in measuring and reducing risks. https://www.eca.europa.eu/en/publications?did=53001.

[29] Council Conclusions on the report from the Commission to the European Parliament and the Council on the experience gained by Member States on the implementation of national targets established in their National Action Plans and on progress in the implementation of Directive 2009/128/EC on the sustainable use of pesticides. 13441/20 AGRI 447 PESTICIDE 41 SEMENCES 16 AGRILEG 157.

Commission compliance-monitoring index confirm that national transposition under a Directive has not worked to the extent envisaged by the original SUD proposal and the divergent and uneven enforcement of the SUD across Member States.

In June 2022 Members of the European Parliament (MEPs) discuss with the Commission the implementation of the EU pesticides legislation, and regarding the implementation of the SUD, evidenced concerns in particular on *suspected illegal aerial spraying in individual Member States, pesticide residues found in the environment (in specific EU regions, sites and animal species), delays in the submission and review of NAPs, pesticides statistics and HRIs.*

Problem evidenced in the implementation of the SUD urged the Commission to *introduce stricter rules, for example in the form of a regulation at EU level to increase coherence and introduce more effective policies in individual Member States.*

Aims of proposal for a Sustainable Use Regulation (SUR) are to replace the SUD in regulating the use of pesticides, and better align with the objectives of the European Green Deal and farm-to-fork strategy; to reduce impact and the risks from pesticide use on human health and the environment by pesticide-reduction targets linked to farm-to-fork strategy; promoting the use of IPM and alternatives to chemical pesticides.

A regulation is considered appropriate to ensure that the level of ambition in the farm-to-fork strategy is met and also remedy the problems identified with the implementation of the SUD, by providing clear and uniform rules.

In annex II of the proposal are indicated data to be provided in annual progress and implementation reports by 31 august of each calendar year to measure the progress towards achieving national 2030 reduction targets and other quantitative data.

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On 22 June 2022 the Commission adopted the proposal that must be approved by Member States in the Council and the European Parliament, under the normal legislative procedure

4.
The big challenge: the Green Deal and the Chemicals Strategy for Sustainability Towards a Toxic-Free Environment.

4.1. The green Deal and Farm-to-Fork strategy

The Green Deal aims to achieve a circular economy, restore biodiversity and reduce environmental pollution toward a toxic free environment and climate neutrality by 2050. Farm to Fork Strategy is part of the Green Deal and EU regulation on PPPs is a crucial tool to achieve the targets outlined in thit strategy.

As part of the European Green Deal[30], the Commission's Farm-to-Fork[31] strategy highlights the need to transition to a fair, healthy and environmentally-friendly food system and proposes the ambitious specific targets to reduce by 50% the use and risk from chemical pesticides as well as the use of the more hazardous pesticides by 2030.

A range of actions are proposed to achieve the targets:
- Removing more hazardous pesticides from the market;
- Development and more widespread use of alternative pest control techniques in line with Integrated Pest Management, including in particular biological pesticides such as micro-organisms;
- Support from CAP for investments, advice as well as through area payments;
- Increase in organic farming;
- Precision agriculture and use of new technologies.

Harmonized indicators, using yearly basis data on the sales of PPPs reported by Members States to the Commission will be used to measure the progress. For some countries will be required to cut pesticide use even further 50% than the EU-wide goal, if the reduction targets remain tailored to individual countries.

The Commission decided to hold off the Sustainable use directive revision, citing geopolitical concerns caused by the recent Russia-Ukraine Crisis[32] ; in addition Sri Lanka's unsuccessful transition to organic farming in 2019 that abandon its national experiment, after domestic rice production fell by 20% in the first six months[33], evidenced the importance of the timeline of a transition that need of a balance between immediate needs and long-term food security. However the likelihood of policy depends upon the extent to which they are consistent with the interests of stakeholder groups.

[30] Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, 'The European Green Deal' COM/2019/640 final, EUR-Lex - 52019DC0640 - EN - EUR-Lex (europa.eu).

[31] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 'A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system', COM/2020/381 final.

[32] Oliver Moore, "EU Institutions - Productivity Now, Environment, Maybe Later", ARC 2020, 25 March 2022.

[33] Ted Nordhaus and Saloni Shah, "In Sri Lanka, organic farming went catastrophically wrong", FP, 5 March 2022.

In February 2023, more than 85 NGOs submit an open letter[34] to President of the EU Commission where signers, including ClientEarth, PAN Europe and WWF, ask the President to ensure that a strong proposal for an EU legislative framework for sustainable food systems is presented by September 2023 to achieve the EU's International commitments and the EU Green Deal and encourage the Commission keep environmental and social sustainability at the centre of the policy debate around food, agriculture and fisheries.

Leterature review on impact of farm to Fork targets
Several independent reports or opinion papers, and technical studies analysed the impact of the setted european targets from different perspective. Below a summary of some selected document results. Even if the bodies that have produced these evaluations represent different stakeholders interests, they are all in agreement regarding the positive impact on same environmental aspect and negative impact on the overall production, price, income growth and export.

1 - The study of the Panel for the Future of Science and Technology of the European Parlament[35]
Farmers recognise the need to reduce their dependency on agrochemicals but are reluctant to switch to alternative practices as in many cases, at present, those methods are still less efficient than chemical control. In addition, farmers are aware that more sustainable systems could poses heavy initial costs and increases the complexity of farm management and could requires additional decision-making.

On the other side the report highlight the role of the industry, committed to respond to demands to make product safety data more accessible to the public, to increase trust in the approval process and of the NGOs that represent societal concerns supporting or asking for more stringent regulations in a drive towards a pesticide-free Europe. Consumer perspective on crop protection could drive the reduction of pesticide use (althougt individual and regional differences) but on the other side, consumers may suffer from higher prices for food produced in the EU when the use of pesticides is restricted, unless alternative crop protection methods are available that do not depress yields or product quality. Following consumer perspective retailers and food processing companies have developed common practices or criteria for lower-pesticide products. Farmers may be more likely to make changes if they are supported by wholesalers, retailers and consumers paying higher prices.

[34] "Joint open letter on the need for a strong proposal on an EU legislative framework for sustainable food systems", Friends of The Earth, 10 February 2023.

[35] The future of crop protection in EuropeEPRS | European Parliamentary Research Service Scientific Foresight Unit (STOA) PE 656.330 - February 2021.

2 - European Landowners' Organization (ELO)[36] ***in the position paper*** declare that given the actual knowledge and tools, targets reduction are unreasonable and that farmers and landowners will be unable to reach the objectives of the proposed regulation, without *seriously prejudicing the viability of their businesses.*

Concerns are also expressed regarding the Farm to Fork timeline (less then 10 years), the lack of predictability regarding the values of the Harmonized Risk Indicators, interdiction to use plant protection products on 18% of EU's agricultural land (the total area under Natura 2000 - Habitats and Birds directives) and calls for *a more balanced approach in the Council and Parliament debates.*

3 - Technical report by the Joint Research Centre (JRC), the European Commission's science and knowledge service[37]
The report presents a modelled scenario of an ambitious implementation of the CAP reform proposals to measure the effects on EU agriculture including quantitative targets put forward in the Farm to Fork and Biodiversity Strategy for the greatest potential to affect agricultural environment and production The analysis includes a reduction of the risk and use of pesticides, a reduction of nutrient surplus, an increase of area under organic farming, and an increase of area for high-diversity landscape features. Based on the assumptions made and taking into account the limitations of the analysis, modelling results clearly indicate environmental benefits but also a decline in EU production and variations in prices and income for selected agricultural products, albeit in different degrees and highlight the need of effective instruments to support the sector during the transition towards a sustainable food systems.

4 - USDA Analysis on Economic and Food Security Impacts of Agricultural Input Reduction Under the European Union Green Deal's Farm to Fork and Biodiversity Strategies[38]
Results of the study reveals a reduction of agricultural production. This reduction would be accompanied by higher prices for agricultural raw materials and food and a decrease of European farmers competitiveness. In this document an economic analysis was provided in order to understand the implication of the adoption of European Strategy also beyond the EU. Results shows in both domestic and export markets *a driving up worldwide food prices, negatively affecting consumer budgets, and ultimately reducing worldwide societal welfare by $96 billion to $1.1 trillion, depending on how widely other countries adopt the strategies. Authors estimate that the higher food prices under these scenarios would increase the number of food-insecure people in the world's most vulnerable regions by 22 million (EU only adoption) to 185 million (global adoption).*

[36] https://www.europeanlandowners.org/images/The_Sustainable_Use_of_PPPs_Regulation_raises_serious_concerns_for_the_future_of_the_European_food_system_1.docx_1.pdf

[37] Barreiro-Hurle, J., Bogonos, M., Himics, M., Hristov, J., Pérez-Domiguez, I., Sahoo, A., Salputra, G., Weiss, F., Baldoni, E., Elleby, C. Modelling environmental and climate ambition in the agricultural sector with the CAPRI model. Exploring the potential effects of selected Farm to Fork and Biodiversity strategies targets in the framework of the 2030 Climate targets and the post 2020 Common Agricultural Policy, EUR 30317 EN, Publications Office of the European Union, Luxembourg, 2021, ISBN 978-92-76-20889-1, doi:10.2760/98160, JRC121368.

[38] Beckman, Jayson, Maros Ivanic, Jeremy L. Jelliffe, Felix G. Baquedano, and Sara G. Scott. November 2020. Economic and Food Security Impacts of Agricultural Input Reduction Under the European Union Green Deal's Farm to Fork and Biodiversity Strategies, EB-30, U.S. Department of Agriculture, Economic Research Service

5 - Wageningen Economic Research, Report[39] on Impact Assessment of EC 2030 Green Deal Targets for Sustainable Crop Production

This report explore the consequences of Farm to Fork and Biodiversity Stategy targets on the production volume of the crops in the EU, market prices, the international trade and indirect land use. In agreement with other studies results, the study reveals that the realisation of the objectives to reduce the risk and use of pesticides by 50% and to reduce nutrient losses (50%) have significant impacts on yield levels, all over EU and that negatively affects production and generates a decrease of supply in the EU home market and exports, which induces increases in commodity prices and conseguent EU imports.

[39] Johan Bremmer, Ana Gonzalez-Martinez, Roel Jongeneel, Hilfred Huiting, Rob Stokkers, Marc Ruijs, 2021. Impact Assessment of EC 2030 Green Deal Targets for Sustainable Crop Production. Wageningen, Wageningen Economic Research, Report 2021-150. 70 pp.; 11 fig.; 33 tab.; 15 ref.

4.2. The Zero Pollution Strategy and the 2020 Chemical Strategy for Sustainability (CSS)

The **Chemical Strategy for Sustainability (CSS)** aims to set out a new toxic-free hierarchy in chemicals management, prioritizing the use of safe chemicals and minimizing exposure to harmful ones. Specific revisions promised in the Chemical Strategy include:

- Zero tolerance approach to non-compliance;
- Banning the most harmful chemicals, such as PFAS chemicals, unless their use is deemed essential;
- Accounting for combined exposures to multiple chemicals instead of just looking at one at a time in order to assess real-life chemical hazards and risks;
- Incentivising innovation and the development of chemicals that are safe and sustainable by design;
- Ensuring that hazardous chemicals banned in the EU will not be exported to other countries.

This strategy is in line with the Green Deal target and the **Zero Pollution Strategy.**

One target of the Zero Pollution Strategy is the reduction by 2030 of 50% nutrient losses, the use and risk of chemical pesticides, the use of the more hazardous ones, and the sale of antimicrobials for farmed animals and in aquaculture.

Action plan also sets out key actions for 2021-2024 to complement the many relevant actions in other European Green Deal initiatives, including the chemicals strategy for sustainability.

A key action defined in the CSS is the development of **Safe and Sustainable by design (SSbD) criteria** for chemicals, that require for the integration of safety-based considerations with life cycle-based consideration, ensuring that all chemicals and materials are designed, manufactured and (re-)used in a way that they are ‘safe and sustainable-by-design’ and then ensuring the respect of all the sustainability pillars along the entire value chain.

The Safe and sustainable by design (SSbD) concept of the CSS also represent the effort to include better the socioeconomic aspects into the sustainability dimension that, at present, mainly focus on the environment and safety dimension. The Joint Research Centre (JRC), the European Commission’s
science and knowledge service, published a technical report[40] with the purpose of a better definition of criteria.

Under the 2020 Chemical Strategy for Sustainability (CSS), with the aim to better protect citizens and the environment, and to boost innovation for safe and sustainable chemicals, the European Commission committed to publish a proposal to reform REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) by the end of 2022 and propose, to simplify the current arrangements for assessments, improve the quality and consistency of safety assessments across legislation and ensure that resources are used more efficiently, to move towards

[40] Caldeira C., Farcal R., Moretti C., Mancini L., Rasmussen K., Rauscher H., Riego Sintes J., Sala S. Safe and Sustainable by Design chemicals and materials - Review of safety and sustainability dimensions, aspects, methods, indicators, and tools. EUR 30991 EN, Publications Office of the European Union, Luxembourg, 2022, ISBN 978-92-76-47560-6, doi:10.2760/879069, JRC127109.

a ‘one substance, one assessment’ process for chemical safety assessments. This approach aims to streamline the scientific and technical work undertaken by EU agencies such as ECHA and the European Food Safety Authority (Efsa). The Commission adoption of the proposal is planned for the second quarter 2023[41]. In response to the policy and societal ambitions a strategic initiative called “The European Partnership for next generation,
systems-based Environmental Risk Assessment (PERA)[42] was launched by the European Food Safety Authority (EFSA)[42] that initially, will focus on pesticides.

[41] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13161-Chemicals-making-best-use-of-EU-agencies-to-streamline-scientific-assessments_en

[42] European Food Safety Authority (EFSA), Devos Y, Auteri D, de Seze G, Fabrega J,Heppner C, Rortais A, Hugas M, 2022. Building a European Partnership for next generation, systemsbased Environmental Risk Assessment (PERA). EFSA supporting publication 2022:e200503. 9 pp. doi:10.2903/sp.efsa.2022.e200503.

5.
Conclusions

Besides pesticides, authorization procedures cover medicines for human use, veterinary medicines, biocides and industrial chemicals. Overall, the function of the current frameworks is similar, but important differences exist between the frameworks’ environmental protection goals and risk assessment strategies.

To coordinate hazard and risk assessments across EU chemicals several legislative frameworks are in place and after several evaluation on the effectiveness and impact several proposals have done that could have horizontal impacts for regulatory regimes including REACH, biocides, and plant protection products.

To simplify the current arrangements for assessments, to improve the quality and consistency of safety assessments across legislation and to ensure that resources are used more efficiently, a new method called ‘one substance, one assessment’ for chemical safety assessment is proposed and EFSA started, with the establishment of a partnership systems-based Environmental Risk Assessment (PERA), an evaluation of the proposed approach analyzing, as first case study, pesticide.

In addition, Safe and sustainable by design (SSbD) concept of the Chemical Strategy for Sustainability is a proposal for to integrate safety and sustainability considerations into the design and evaluation of chemicals.

We can conclude after our review that, despite EU has a very robust regulatory framework in place to protect citizens and the overall environment, there is a general agreement that EU current regulation of chemicals can be further improved to achieve the ambitious target of climate neutrality by 2050 of the Green Deal and some approach are proposed for a better harmonization/synchronization of different framework aimed to better use of the data, economic recourses and expertise, as a systems-based approach and the Safe and sustainable by design (SSbD) concept.

However, taking into account that also some natural pesticides authorized for organic production have negative impacts on the environment and human health (eg copper), and that the way to measure the progress toward a reduction of the risk rely on indicators based only on a quantity of active substances placed on the market, the ambitious pesticide-free objective cannot be limited to top-down approaches but should also value the expert knowledge and know-how of all stakeholders and the transition towards a chemical “life cycle perspective” seem very relevant in order to put in evidence actual environmental burdens and benefits.

In addition, to fulfill the ambitious targets, it is opinion of the author of the document that strengthen the role of exposure science is needed.
Indeed, within European chemicals legislation, exposure assessment together with hazard identification and hazard characterization is a fundamental regulatory pillars of risk assessment and at present European chemicals risk assessment is being mainly hazard (or toxicity) driven and guidance and tools for exposure assessment have evolved sector-specifically, designed to meet the needs of specific policy domains[43]. But chemicals safety is strictly connected with exposure and chemicals management. This last aspect, in particular, is also mentioned in the SDG 12 on responsible production and consumption and, more specifically, target 12.4, that focuses on the *“environmentally sound management of chemicals and all wastes*

throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimize their adverse impacts on human health and the environment"[44].

Working on better address the effectiveness of pesticide mitigation measures and on the concept of 'safe and sustainable-by-design' (SSbD), could help to ensure that that exposure to substances and other stressors of concern are minimized. Different priority areas of exposure science to successfully support the ambitions across European strategies are evidenced by the Europe Regional Chapter of the International Society of Exposure Science (ISES Europe)[45] as exposure modelling, exposure data production and analytics, human biomonitoring, uptake of exposure knowledge into policy, education and training of exposure knowledge, and funding and international collaboration to establish exposure science as a scientific field[46].

Considering that reducing pesticide use has become a goal shared by several institution, is an important issue in public policies and, also considering the growing public awareness on pesticide risks, monitoring the impact of the new strategies and regulations becomes very relevant for the socioeconomic sustainability dimension.

[43] Yuri Bruinen de Bruin et al, Journal of Exposure Science & Environmental Epidemiology (2022) 32:513–525; https://doi.org/10.1038/s41370-021-00388-4

[44] https://sdgs.un.org/goals (accessed 10 august 2023) - https://ises-europe.org (accessed 10 august 2023).

[45] Peter Fantke et al, The European exposure science strategy 2020-2030, Environment International 170 (2022) 107555, https://doi.org/10.1016/j.envint.2022.107555

https://operaresearch.eu/it/