



Challenges and opportunities for increasing the use of low-risk plant protection products in sustainable production. A review

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Accepted: 6 March 2024 / Published online: 4 April 2024
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Abstract

Plant production systems worldwide are struggling to meet the diverse and increasing needs of humankind while also facing challenges such as climate change and biodiversity loss. This, combined with the desirable transition from the use of conventional pesticides to more sustainable plant protection solutions, has led to an urgent, and increasing, need for low-risk plant protection products (PPPs) to be developed, applied, and integrated into management practices across all types of plant production systems. Despite a high demand from end users and consumers together with joint political goals at the EU level to replace conventional pesticides, the number of low-risk PPPs on the European market remains low, in comparison to synthetic agrochemicals. In this review, we summarize knowledge about the policy, technical, and administrative issues hampering the process of bringing new low-risk PPPs to the European market. We present an overview of the challenges in using the low-risk PPPs that are currently available within the EU agricultural, horticultural, and forestry sectors. We describe the variation in modes of action and the limitations associated with different application techniques and give concrete examples of problems and solutions from Swedish plant production sectors, in contrast to global perspectives as demonstrated by examples from African agriculture. Finally, we conclude that trans-sectoral, multi-actor approaches are required and provide suggestions on how to address the remaining knowledge gaps related to efficiency, application, and economics of low-risk PPP use in Integrated Pest Management (IPM) solutions for plant protection to improve future food security in Europe.

Keywords Application techniques · Basic substances · Biological control agents · Integrated Pest Management (IPM) · Legislation · Low-risk substances · Plant production systems · Sustainable Development Goals

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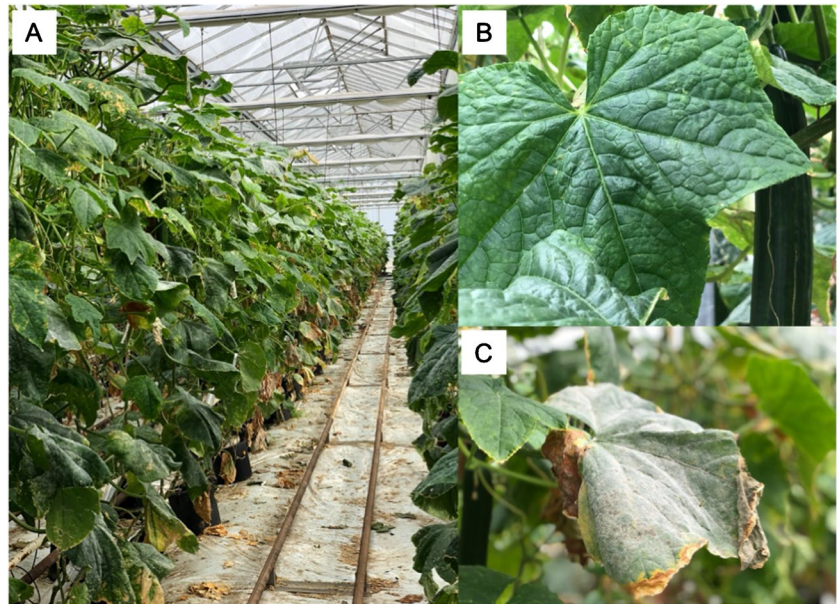
1 Introduction

Climate urgency (IPCC 2022), the accelerating loss of biological diversity (IPBES 2022), declining soil health, and the increasing need to support the global human population with food (The State of Food Security and Nutrition in the World 2021) and biomass for renewable energy and materials (IEA 2021) call for more sustainable and secure production systems. Worldwide, plant production systems, i.e., agriculture, horticulture, and forestry, are struggling to meet these diverse needs that are instrumental for achieving many of the Sustainable Development Goals defined by the UN (UN General Assembly 2015; Spaiser et al. 2017). At the same time, plant health in all production systems is increasingly threatened by native and introduced pests and pathogens (Spence et al. 2020; Chaloner et al. 2021; Sundh and Eilenberg 2021). Synthetic agrochemicals, including pesticides, have traditionally been used to secure yields (Jeschke 2016). However, because of the risk of harmful effects on the environment, biodiversity, and human health, the use of such compounds is not sustainable. Furthermore, continued use of synthetic pesticides

leads to an accumulation of pesticide resistance within pest populations, further limiting the usefulness of these agrochemicals (Gould et al. 2018; Hawkins et al. 2019). A transition to replace the most harmful synthetic pesticides with *low-risk plant protection products* (hereafter referred to as low-risk PPPs), i.e., plant protection products with little negative effects on human health, environment, and biodiversity, is therefore emerging as an urgent priority for policy, research, and practice (Buckwell et al. 2020). The REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) regulation and other similar EU and national policies are, for example, emerging as key drivers of the switch from hazardous to low-risk compounds (Coria et al. 2022).

In the EU, growing demands to reduce the use of agrochemicals and move towards more sustainable and diverse production systems have led to Integrated Pest Management (IPM) becoming mandatory within EU Directive 2009/128/EC (EC 2009a). In IPM, the goal is not to eradicate pests (here defined as all organisms harmful to the production system or human health, including insect pests and microbial diseases) but to manage populations to levels where their negative impacts are minimal (Barzman et al. 2015). The core concept of IPM is to prioritize preventive methods of pest control and the use of sustainable plant protection systems. Synthetic pesticides should be used as a last resort only (Stenberg 2017). Successful IPM approaches are based on different methods that can be combined in ways that maximize sustainability (Matyjaszczyk 2018). Chemical and biological plant protection products with low risks including low toxicity and other risks are particularly promising as components of IPM since they are generally expected to be less damaging to ecosystems than conventional synthetic pesticides. In some cases, these low-risk PPPs could be seen as full or partial replacements for those synthetic inputs, thereby helping to achieve one of the core goals of IPM, namely reducing synthetic inputs into agroecosystems (Dara 2019). Furthermore, they can be combined with other means of disease and pest control due to their low toxicity and thus are perfect candidates for use in IPM systems, which rely on combinations of control measures to achieve pest control with minimal negative impacts on the environment (EC 2009a). Yet, the use of low-risk PPPs as an integrated part of IPM strategies and practical plant protection approaches has remained limited (European Court of Auditors 2020). Some of the reasons for the low uptake of low-risk PPPs as identified by the European Court of Auditors (2020) are that the European Commission (EC) and its member states promote IPM but do little to enforce it. For example, farmers are not required to keep records of how they apply IPM. Furthermore, the current common agricultural policy does little to help enforce IPM since the application of IPM is currently

Fig. 1 Trial of alternative plant protection products to treat cucumber powdery mildew in commercial greenhouse production, Sanagården AB, Sweden 2018 (Rur et al. 2018). **A** Commercial cucumber production system within the trial. **B** Biological control treatment for disease control. **C** Symptoms of cucumber powdery mildew in untreated control plants. Photos by Laura Grenville-Briggs.



not a requirement for receiving subsidies under this policy. Thus, EU action provides weak incentives for farmers to adopt IPM strategies.

Sales of pesticides in the EU have remained more or less stable since 2011 (about 360 000 tons per year), and the rate of introduction for non-chemical pesticides to markets has been low (Eurostat 2021). In order to accelerate the urgently needed transition to more sustainable plant protection solutions, the regulatory, technical, and cultural barriers to the use and implementation of low-risk PPPs need to be better understood.

The overall aim of this review is to discuss emerging opportunities as well as challenges society is facing to increase the use of low-risk PPPs in agriculture, horticulture, and forestry (Fig. 1). Relying on the multi-sectorial expertise of the author team, we anchor our analysis in an EU context, leaning on the framework provided by the EC Regulation 1107/2009 (EC 2009b) and the recommendations from the European Court of Auditors (2020). We first set the scope by presenting how low-risk PPPs are defined, regulated, and act through different mechanisms. We then elucidate the complexity of how low-risk PPPs are used in practice within different cultivation systems—agriculture, horticulture, and forestry (mainly in tree seedling production in forest nurseries, as pesticides are generally not used in forestry), both in the EU and by presenting particular cases from Sweden, where all three systems are in transition to enable a more sustainable, climate-adapted future. Finally, we discuss how the use of low-risk PPPs could be increased, also considering global perspectives and the social dimension of the topic.

2 Definitions and legislation

2.1 Definition and criteria of low-risk PPPs

Several terms are currently used by different organizations and countries for describing alternatives to conventional pesticides (Table 1). Some of these definitions are based on the type of organisms used (e.g., microbial biological control agents, MBCAs), while others focus on the function, or origin (biological or synthetic). In this review, we will follow the terminology used by the European Union for legislation purposes and focus on substances and organisms classified as low-risk PPPs or basic substances (Table 2). Low-risk PPPs refer to products that contain only active substances (i.e., substances responsible for the impact on pests or pathogens) that have been approved and listed as having low-risk to human and animal health and the environment (EC 2009b; OEPP/EPPO 2017). The “PPP Regulation” defines low-risk active substances as distinct from traditional active substances (EC 2017). *Active low-risk substances* can be microorganisms, plant extracts, semiochemicals (behavior-modifying compounds, including pheromones), baculoviruses (viruses infecting insects), or certain active chemical substances (OEPP/EPPO 2017). Note that we do not consider macroorganisms (e.g., insects) (Table 2) in this review, as they are not considered active substances or basic substances.

Basic substances are substances of different origins that are already approved for use in food, feed, and cosmetics (e.g., inorganic compounds, plant extracts) (Table 2). They do not possess an inherent capacity to cause endocrine disruption, or have neurotoxic or immunotoxic effects (Marchand 2017). While basic substances can be used as

Table 1 Terminology for alternatives to conventional chemical pesticides and their definitions and users of the definition.

Term	Definition	Used by
<i>Biopesticides</i>	<p>“Biopesticides include naturally occurring substances that control pests (biochemical pesticides), microorganisms that control pests (microbial pesticides), and pesticidal substances produced by plants containing added genetic material (plant-incorporated protectants) or PIPs.”</p> <p>“Biopesticides are plant protection products which contain biological control agents (microbials, pheromones, plant extracts etc) for use as agricultural, horticultural and home garden pesticides.”</p>	EPA (US) UK government
<i>Bioprotectants</i>	<p>“Bioprotection is used to protect against unwanted organisms including pests and pathogens and as such: it originates from nature, it can either be sourced from nature or is nature identical if synthesized and it has uses including in agriculture, forestry, amenity, home and garden, and public health.”</p> <p>IBMA Product categories within the scope of “Bioprotection” currently include the following: semiochemicals, microbials, natural substances, invertebrate biocontrol agents (macrobiols)</p>	IBMA (International Biocontrol Manufacturers Association)
<i>Biostimulants</i>	<p>“Products stimulating plant nutrition processes independently of the product’s nutrient content with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere; (i) nutrient use efficiency, (ii) tolerance to abiotic stress, (iii) quality traits, (iv) availability of confined nutrients in soil or rhizosphere.” Regulation (EU) 2019/1009</p>	EU
<i>Low-risk plant protection products</i>	<p>“Products that contain only low-risk substances can be authorized as a low-risk plant protection product.”</p>	EU
<i>Low-risk substances</i>	<p>“An active substance can be approved as a low-risk substance if it meets the regular approval criteria and in addition meets the low-risk criteria as specified in Annex II, point 5 of Regulation (EC) 1107/2009. There are specific criteria for chemical substances and for micro-organisms.”</p>	EU
<i>Microbial biological control agents (MBCA)</i>	<p>“Microbial biological control agents (MBCA) contain living micro-organisms such as bacteria, fungi or viruses for the control of weeds or pests and diseases of crop plants.” (Frederiks and Wesseler 2019)</p>	US
<i>Plant biologicals</i>	<p>“Plant Biologicals are naturally derived products that can serve as biostimulants, biocontrol agents, resistance inducers or biofertilizers. They derive from naturally occurring microorganisms, plant extracts or other organic matter. They include: macrobiols (predators and parasitoids: e.g. mites, spiders, bugs, lady beetles and wasps) microbials (bacteria, fungi, oomycetes and vira) and biologically derived products (plant extracts, lipopeptides, proteins).”</p>	Plant biologicals network, https://plantbiologicals.dk/what-are-plant-biologicals/

Table 2 Summary of the types of low-risk plant protection products (PPPs), their applications, and the relevant EU legislation.

Type	Definition and limitation	Application	EU legislation
<i>Macro-organisms</i>	Living insects, mites, nematodes and slugs/snails that are parasites, parasitoids or predators of crop plant pests. Classified as Biological Control Agents (BCAs). Considered low-risk, as they do not pose a threat to human health and no significant impact on environmental health.	Primarily greenhouse and orchard cultivation.	Macro-organisms do not fall under the biopesticide regulation EC 1107/2009, but under national regulations (if any are in place), since they are not plant protection products in the narrow sense (REBECA regulation).
<i>Micro-organisms</i>	Typically fungi, bacteria, oomycetes, protozoa and viruses. Mode of action differs from direct parasitism or inhibition of the target pest or pathogen, to elicitors which induce resistance in the plant. Classified as BCAs. Must be verified that their use is safe and will have no negative consequences for human or animal health or towards other non-target organisms. Risks of microorganisms should be evaluated depending on their biology and ecology, e.g. the presence of the organism in itself is not an obstacle for approval.	All production systems. Spray or seed treatments are typically used.	Micro-biological PPPs or BCAs have been regulated by the same EU legislation as chemical plant protection products (Regulation (EC) No 1107/2009) but can also be classified as low-risk substances. From Nov 2022, four implementing regulations (EU 2022/1438-1441) state that micro-organisms should be regulated depending on their biology and ecology. EU 2022/1438 states the criteria for approval. EU 2022/1439 modifies EU 283/2013 regarding microorganism data requirements. EU 2022/1440 modifies EU284/2013 regulating the requirements for PPPs containing microorganisms. EU 2022/1441 is linked to EU 546/2011 with the aim to unify principles for evaluation of PPPs containing microorganisms and ensuring high level of protection at the national level.
<i>Basic substances</i>	A new category of plant protection products. Substances with a main application outside of plant protection, but which may be useful in plant protection and that in some cases have traditionally been used by farmers. Must show an absence of dangerous properties or harmful effects for humans, animals and the environment. Must be applied with standard equipment.	Currently limited applications in greenhouse, open-field production and forestry.	Basic substances are approved through a simplified authorisation procedure according to Regulation (EC) No 1107/2009. The applications are submitted to the European Commission and the European Food Safety Authority (EFSA) carries out a scientific review. For registration as basic substance, no efficiency evaluation is required. For the substances to be eligible for organic production, they must be approved as foodstuff of plant or animal origin or on the list of approved substances for organic production.
<i>Low-risk substances</i>	Substances of microbial or other origin. Microorganisms with multi-resistance to antibiotics are not approved. Insect-pathogens must not affect non-target insects. Non-microbial substances must not harm humans, animals, or other aquatic animals. Half-life in soil must be less than 60 days with bioconcentration factor higher than 100.	Can be used in greenhouse, open field production and forestry. Currently most developed in greenhouse systems.	According to EC No 1107/2009, low-risk PPPs contain only low-risk substances and no other substances of concern. The registration as a low-risk substance follows the same procedure as the registration for chemical pesticides with the exceptions: (i) authorisation procedure for low-risk products must be completed within 120 days, instead of one year, (ii) period of first approval for low-risk substances is 15 years, instead of 10 years, (iii) up to 13 years data protection for the owner of the test or study. An evaluation of the efficiency of proposed low-risk substances is a requirement for the registration. Low-risk substances approved under the previous legislation (Directive 91/414/EEC) can be granted a renewal under the new directive.

part of a plant protection strategy, they are not approved *per se* as plant protection products, nor can they be sold or marketed as plant protection products. Basic substances are approved for the entire EU directly, which means that no further handling is required from the member states.

2.2 Authorization and registration of low-risk PPPs

Before an active substance can be placed on the market and used in a plant protection product, the Member States, the European Food Safety Authority (EFSA), and the European Commission evaluate its safety. This approval process provides the basis for the legal placing of PPPs on the market and for their appropriate use by end users (OEPP/EPPPO 2017). It implements the EU directive on sustainable use of pesticides (SUD; Directive 2009/128/EC) and is an important tool in IPM, which is currently requested from professional growers (Robin and Marchand 2022). In EU countries, registration of a PPP at a national level requires that the active substance in the product has first been approved at the EU level. Products that contain only low-risk active substances (i.e., do not contain any substance of concern, do not require specific risk mitigation measures, and that are sufficiently effective) can be authorized as low-risk PPPs (EC 2009b).

The authorization of low-risk substances follows the same procedure as the registration for chemical pesticides, although some adjustments have been implemented to favor registration of low-risk compounds (Table 2). These include development of a fast-track procedure that exempts the low-risk substances from obligations related to assessment of the need to set maximum residue limits for low-risk and basic substances. Thus, the authorization procedure for low-risk products must be completed within 120 days, instead of 1 year. In addition, the period of first approval for low-risk substances is 15 years, instead of 10 years, and up to 13 years of data protection is allowed for the owner of the test or study (previously this was 10 years). For approved substances under the previous legislation (Directive 91/414/EEC) that are potentially low-risk, a renewal of approval can be granted to designate them as low-risk. An evaluation of the efficiency of proposed low-risk substances is a requirement for the registration. Moreover, four implementing regulations (EU 2022/1438-1441) (EC 2022a, b, c, d) were adopted from November 2022 for microbial PPPs. Here, approval requirements for microorganisms are instead based on their biology and ecology (Table 2). A positive outcome of these new regulations is that the dossiers required for approval and authorization of microbial biocontrol agents have significantly fewer sections and subsections than their synthetic counterparts (Helepciuc and Todor 2022a). This includes lower requirements for residues, fate, behavior in the environment, and ecotoxicological data (Helepciuc and Todor 2022b).

As a measure to harmonize the authorization and to minimize the need for countries to carry out individual national evaluations, the EU has established a zonal authorization system (North, Central, and South) that reflects comparable agricultural and environmental conditions (EC 2022e). Within a zone, an EU country that acts as a zonal Rapporteur Member State (zRMS) is responsible for evaluation on behalf of other countries (concerned Member States, cMS) in the same zone. However, for use in greenhouses, as seed or post-harvest treatments, or as a treatment of empty storage rooms or containers, the EU is considered as a single zone (EC 2022e). Principles for assessment of efficiency and hazards as well as for decision making are provided in EU Regulation 2018/676 (EC 2018a).

The process for approval of basic substances is simplified, with lower requirements on, for example, the efficacy evaluation (Table 2). Basic substances are regulated by the EC Regulation 1107/2009 (EC 2009b). Applications are submitted to the Commission, but EFSA performs the actual review. The documentation needed for an application is as follows: (1) a description of the properties of the substance and recommended usage; (2) an opinion on efficacy and security rating; (3) an opinion on human and animal safety; (4) an opinion on the hazard classification and acceptable effect on the environment; and (5) a list of references and necessary publications, evaluation reports, and studies.

At the time of writing this review (November 2023), 45 active substances are approved as low risk (excluding pheromones) and 24 compounds are approved as basic substances in the pesticide database in the EU (EC 2022f) (Table S11). Pheromones used for monitoring do not require authorization according to the Biocidal Products Regulation (EU) 528/2012 (BPR) (EC 2012). Basic substances are in most cases foodstuffs (e.g., vinegar, sucrose, calcium hydroxide). Moreover, out of the 71 active substances approved as microorganisms (EC Regulation No 1107/2009 (EC 2009b), EU 2022/1438-1441 (EC 2022a, b, c, d), only 27 are classified as low risk. The remaining 44 that are not low risk (EC 2022f) are therefore additional compounds to be used in plant protection (van Lenteren et al. 2018; Helepciuc and Todor 2022b). Additionally, potential low-risk active substances, i.e., substances previously approved as active substances (Directive 91/414/EEC) and expected to meet the low-risk criteria, but not yet approved as low-risk, are listed since 2018 (EC 2018b). These substances can be used for plant protection and are expected to be candidates for future approval of low-risk compounds.

2.3 Challenges with definitions and legislation

The EU directive on sustainable use of pesticides, (SUD) (Directive 2009/128/EC), aims at reducing the use of pesticides through IPM and increasing the use of alternatives to conventional pesticides. These aims are important steps

towards achieving the targets outlined in the European Green Deal (EC 2019a) and the Farm to Fork Strategy (EC 2020). In general, the goal of these pieces of EU legislation is to encourage the identification and use of less harmful active substances (including microorganisms) with general or specific action against harmful organisms and to facilitate the flow of plant protection products containing those substances to EU markets (Villaverde et al. 2014; Vekemans and Marchand 2020). However, despite these ambitions, the number of low-risk substances and products available is still low (Fig. 2, Table SII). For example, in contrast to the currently approved 45 active low-risk substances, the number of active substances classified as Candidates for Substitution (meant to be substituted by less toxic alternatives, cancelled or not-renewed) is 50 (EC 2022f). To some degree, the long lag period in implementation of the EU regulations may reflect the fact that the regulatory concept of low-risk substances is still relatively new and has not yet been concluded for all active substances on the market. However, some weaknesses and loopholes have been identified in the regulatory system that may also contribute by slowing down progress.

A profound shortfall in the current system is that EC Regulation 1107/2009 does not provide an explicit definition for a low-risk PPP but rather defines them based on hazard-based cut-off criteria (e.g., must not cause harm to humans, see Table 2). The dependence on the definition of the potential hazard obscures the scope of the regulation and complicates inter-sectorial and international communication among the involved actors (industries, sellers, growers, advisors, researchers, authorities, and non-governmental organizations (NGOs)). A clearer definition of low-risk PPPs could simplify the interpretation and implementation of the regulations and facilitate the exchange of knowledge related to low-risk PPPs. However, the new regulation of microorganisms from November 2022 may contribute to faster and more accurate risk assessments, as microorganisms should be evaluated depending on their actual risks to humans or animals rather than just their presence or absence. A potential drawback is that this work may be time consuming, as harmful behavior of certain microorganisms can be context dependent, i.e., switching to pathogenicity depending on environmental conditions (Porrás-Alfaro and Bayman 2011).

Another identified weakness is that the zonal authorization system is not working as expected, and the two-step approval process is slow. Many countries fail to take full advantage of the collaboration possibilities and audits have revealed massive duplication of work among member states (DG Health and Food Safety 2017). The overlap is largely caused by the failure of agreed standards to comply with the requirements of the national legislations that better correspond to the specific conditions in each country (DG Health and Food Safety 2017). This results in delays in processing of authorization and in the end also limits the spectrum of

products available on the market. According to Frederiks and Wesseler (2019), the two-step procedure consisting of registration of active substance at the EU level followed by registration of a PPP at member state level takes on average 65.7 months for a PPP based on microbial biological control agents. In contrast, registration within the US regulatory framework (accustomed to biopesticides) in which the PPP and active substance are evaluated simultaneously only takes 25.7 months on average (Frederiks and Wesseler 2019).

Ultimately, the slow progress is likely to be associated with the lack of efficient policy instruments (Lee et al. 2019). In addition to regulatory instruments, economic incitements are crucial. In order to approve a compound, investments in efficacy studies, environmental and health studies, and data requirements are needed from the company applying for approval (Helepciuc and Todor 2022a). This may be one reason why so few compounds are currently available on the market. Another limitation is the unfavorable tax rules that apply for these products because of proportionally higher tax when high amounts of a compound is needed (which is often the case for low-risk PPPs (Allmyr et al. 2019)). However, it is uncertain how efficient taxes are as a tool to reduce pesticides, as the relationship between pesticide tax and pesticide use is not always easy to predict (Böcker and Finger 2016). European legislations also differ between groups of low-risk PPPs, such that the basic substances can be used directly within the entire EU while those defined as low-risk PPPs are zone specific. Additional regulations are added at a national level, which adds to the complexity for industries and growers. Legal application is also generally limited to specific situations (e.g., greenhouse production), or to certain crop plants or pests/diseases, impeding the use of already registered products in new applications. The introduction of low-risk PPPs may also meet hesitation among growers who compete for market shares. While IPM is requested, a grower might hesitate in starting the transition from the use of pesticides to the use of low-risk PPPs unless the cost-efficiency of the latter has been convincingly demonstrated (in particular a reliable efficacy of low-risk PPPs): the transition could backfire if the competing farmers in non-EU countries continue using these chemicals (Citizens of Science in Pesticide Regulation 2018).

Moreover, even though Regulation EC/1107/2009 is regarded as one of the most stringent pesticide regulations in the world (Robinson et al. 2020), concerns have been raised regarding the transparency of the process and the scientific quality of the data upon which the approval relies (Robinson et al. 2020; Saltelli et al. 2022). In the current system, actors with commercial interests can choose the zonal Rapporteur Member State (zRMS) where they submit the dossier. This allows the industry to give priority to countries with the most industry-friendly policies. The data in the dossiers is provided by the companies who often produce it in their

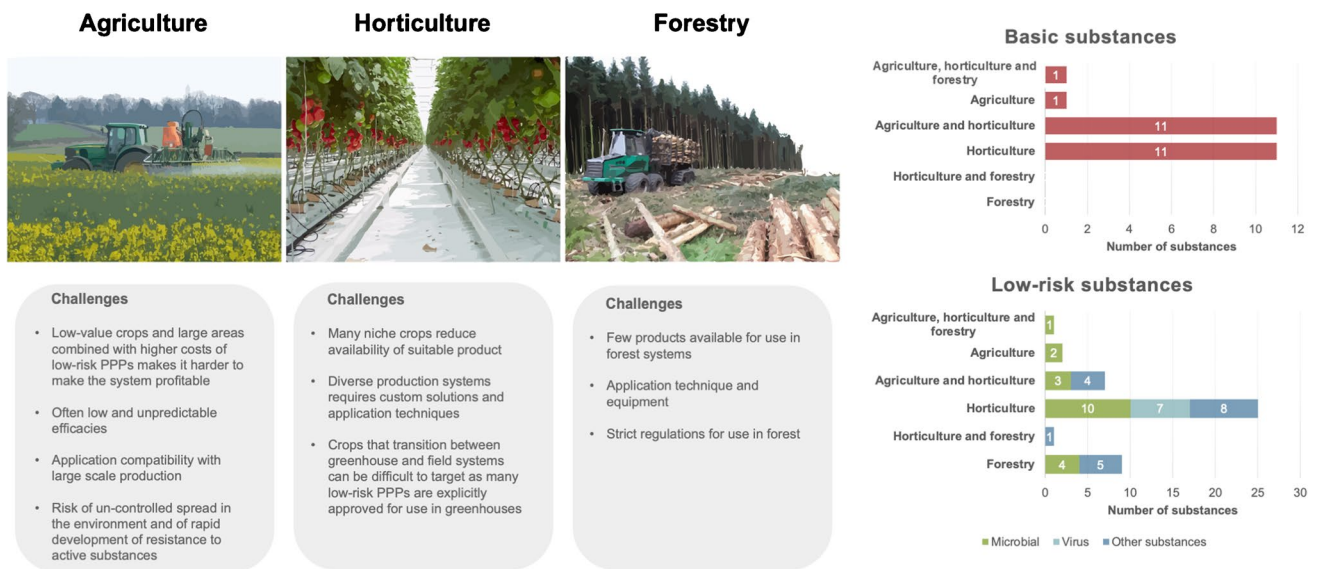


Fig. 2 Main challenges and number of low-risk PPPs classified as basic substances or low-risk substances in the EU for the plant production systems agriculture, horticulture, and forestry, respectively. The bar graphs are based on the situation in November 2023. Active substances = substances responsible for the impact on pests or pathogens. Photos have been modified in Adobe Photoshop using Agriculture: Brian Robert Marshall, Creative Commons Attribution-Share Alike 2.0 Generic https://commons.wikimedia.org/wiki/File:Crop_spraying_near_St_Mary_Bourne_-_geograph.org.uk_-392462.jpg; Horticulture: Goldlocki, Creative Commons Attribution-Share Alike 3.0 Unported https://commons.wikimedia.org/wiki/File:Tomato_P5260299b.jpg; Forestry: Peter McDermott, Creative Commons Attribution-Share Alike 2.0 Generic https://commons.wikimedia.org/wiki/File:Forestry_Equipment_at_Linn_Moss_-_geograph.org.uk_-542294.jpg.

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own or contracted laboratories, and these reports may be unpublished or published without the scientific peer-review system. The application dossiers are often large, and in many cases, the zRMS may not have the capacity or adequate expertise to review every detail or piece of raw data (Robinson et al. 2020). The approval system is thus prone to regulatory capture (Saltelli et al. 2022) where the interests of commercial actors may override the science-based societal benefits.

2.4 Opportunities within the framework of current and future legislation

With the adoption of the new regulations for the approval of microbial PPPs in November 2022 (discussed above), the information required for approval and authorization of these products has been greatly simplified (Helepciuc and Todor 2022b), which will hopefully speed-up these processes in the future. Thus, we are likely to see an increase in the numbers of biocontrol agents and other microbial PPPs registered for use in plant protection in the EU in the near future. Over the last decade the number of microbial PPPs has steadily increased globally (Kvakkestad et al. 2020; Helepciuc and Todor 2022a), with a disappearance of chemical PPPs in favor of biocontrol agents (Marchand 2023). The numbers of registered and approved low-risk PPPs are currently increasing (Marchand 2023), and this brings increasing possibilities

for growers to reduce their synthetic inputs and incorporate low-risk PPPs and biological control agents into their production systems. A recent survey of biocontrol experts across Europe identified the need for a common European framework on biocontrol (Lamichane et al. 2017) and suggested there is still a gap in knowledge and familiarity with biocontrol methods and other low-risk PPPs among practitioners. There have been other recent calls for evaluation of low-risk PPPs under one umbrella of bioprotection (Stenberg et al. 2023), to simplify policy and regulatory decisions, which will greatly aid in understanding and uptake of these PPPs.

At the EC level, specific guidance documents have been drafted to update SANCO/6895/2009, (applicable from 12 October 2023) to support understanding and interpretation of the current regulations for approval and use of low-risk PPPs. This revision includes new draft registration report (dRR) templates for PPPs containing microorganisms as active substances. This update aligns the dRR with the new requirements introduced in November 2022 through regulation 2022/1440 (information required to be submitted for PPPs containing microorganisms) and regulation 2022/1441, specifying uniform principles for evaluation and authorization of PPPs containing microorganisms (discussed above). Explanatory notes to this revision although not legally binding, have now been endorsed by the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) (October 2023)

with the aim being to provide support to dossier preparation and to help harmonize risk assessment and risk management work across member states (EC 2023a). A new EC database is also in progress to support these aims and at the OECD level, work is ongoing to make consensus documents on specific microbial species used as PPPs (EC 2023a). Thus, these revisions and supporting documents are expected to aid in the ease and speed of registration and approval of low-risk PPPs in the EU.

Another opportunity is presented by the creation of a new initiative designed to highlight the need to streamline the regulatory processes for biosolutions including low-risk PPPs in Europe is the European Biosolutions Coalition, a recently created coalition seeking to elevate the prominence of biosolutions on the European agenda. The Coalition is dedicated to championing the green transition, fostering more intelligent approaches within the industry, and creating enhanced prospects for companies working with biosolutions in the EU. For example, the European Biosolutions Coalition currently recommends that the EU should establish a fast-track system for the registration of microbial PPPs, to reduce both approval times and costs (EU Biocoalition 2023). Initiatives, such as this coalition, will facilitate multi-actor PPP solutions and will help support more low-risk PPPs entering the European market.

As growers become more familiar with low-risk PPPs, uptake increases and this in turn helps drive growth in the market. In fact, investments in low-risk PPPs are also growing worldwide. In 2021, 6% of global investment capital was invested in agbiotech including biopesticides, biostimulants, biofertilizers, and other plant biotech, compared with 5.1% in 2020 (Marrone 2023). At the EU level, there is also now a window of opportunity to get more low-risk PPPs onto the market and into practice. This was addressed directly by the current president of the European Commission Ursula von den Leyen in the state of the union address given in September 2023 followed by her letter of intent to the European parliament where she promised to make biotech and biomanufacturing a key priority for 2024 (EC 2023b). The global trend of investment and prioritization of green solutions and biotech will hopefully continue to support innovations in terms of both new low-risk PPPs and sorely needed new application techniques for low-risk PPPs, triggering a shift in how we protect our crops in the future.

3 Mode of action and application techniques

3.1 Mode of action of low-risk PPPs

The mode of action of an active substance is decisive for the regulatory framework under which the product is registered

and used. In general, if a product is to be considered as a low-risk PPP, its mode of action should be chemical or biological. Thus, the first criterion for low-risk PPPs is that the active substance is of a chemical or microbial nature. However, additional criteria on intended use need to be considered. These include an assessment of whether the product provides protection against pests curatively or preventively and whether it acts either as attractant (to capture the pest) or repellent (to prevent their colonization) (EC 2022g). A mechanical mode of action falls outside the scope of low-risk PPP concepts, even though several mechanical protection methods involve low risk. For instance, a polymer that physically prevents contact between the plant and a pest is not considered. A physical barrier placed around plants that prevents access of a pest to the plants is also not included in the scope of the PPP Regulation (EC 2022g). Biostimulants, i.e., products that act on plant vigor but not their resistance to pests or pathogens, are no longer under the PPP regulation but were moved to the purview of Fertilizing Products Regulation (FPR) in 2019 (EC 2019b; Ricci et al. 2019).

The mechanisms behind the plant protection effects of low-risk PPPs vary depending on the chemistry and biology of the products. According to OEPP/EPPO (2017), five mode of action categories can be designated for low-risk plant protection products: (1) low-risk (bio)chemicals with a direct mode of action, (2) low-risk (bio)chemicals with an indirect mode of action, (3) low-risk micro-organisms with a direct mode of action (e.g., parasites of insects, fungal pathogens (mycoparasites), baculoviruses), (4) low-risk micro-organisms with an indirect mode of action (e.g., host plant defense induction, endophytes), and (5) semiochemicals including pheromones. A *direct* mode of action occurs when the product targets the pathogen or pest *per se*. An *indirect* mode of action occurs, e.g., when the low-risk product elicits induced resistance or priming of a response in plants (ISR) (Pieterse et al. 2014; Robin and Marchand 2022). In addition, plant strengthening by stimulation of plant growth and increased nutrient storage by some low-risk agents or biostimulants provide an increased resource for defense responses (Huot et al. 2014). The major difference between induced resistance and primed ISR is that the former activates the plant defense immediately upon application of the low-risk agent, while primed ISR is only apparent when the plant is under attack (Pieterse et al. 2014). This also indicates that the different modes of stimulated defenses have different costs for the plant, where investments in defense usually compromise growth (Huot et al. 2014). The underlying plant systems that regulate resource allocation for defense and growth are very complex and to a large extent unknown, although light is an obvious parameter to provide energy (Pierik and Ballaré 2021).

The detailed mechanism of action at the molecular level is not known or investigated for many low-risk plant protection

products but may to a certain extent be deduced or inferred from available knowledge. Furthermore, because of the diversity of the modes of action of low-risk PPPs and/or several factors acting in concert, more knowledge about the biology and ecology of the products in cultivation systems and environments is also needed. These knowledge gaps also make it difficult to design appropriate application practices.

3.2 Application techniques

A proper application technique is crucial to ensure optimal delivery and function of PPPs, and some low-risk PPPs need special attention when applied to crops (Nilsson and Gripwall 1999). For example, microbial PPPs can be sensitive to physical influence and can easily be harmed during the application process with conventional spray techniques (Borges 1998; Garcia et al. 2008; Doruchowski et al. 2015). Microorganisms that are fragile cannot be applied to crops using the same equipment used for conventional (mainly chemical—spray based) PPPs, without adjustments. A challenge is also that the low-risk PPPs used in field applications must adequately resist environmental degradation and their cost-effective, precise application in time and space is a major challenge (Benelli et al. 2019).

Several growers use manual application of low-risk PPPs, or technology originally developed for chemical PPPs. In greenhouses with vegetable production, vertical booms are frequently used and vertical booms with air assistance are used in orchards. In smaller ornamental greenhouse production sites, manually held spray lances are commonly used. These technologies have weaknesses when it comes to their ability to cover the targeted areas of application. For example, it is difficult to apply low-risk products containing microorganisms to the abaxial leaf surface where pests are often located (Matthews 2001).

The choice of application technique often depends on the chemical and physical characters of the products and on their specific mode of action, as well as the environmental conditions (e.g., field or greenhouse). For example, a slow-release wax pellet formulation has been used to apply methyl salicylate to control aphids in cereal fields (Ninkovic et al. 2003; Prinsloo et al. 2007).

Pheromone-mediated mating disruption is a semiochemical-based approach that is applied as a part of IPM in different cultivation systems, both in industrialized and in developing countries (Benelli et al. 2019). The success of the approach is highly dependent on the performance of the dispensers. Hand-applied dispensers deployed at densities ranging between 250 and 1000 dispensers per hectare are the most widely used devices for dispensing pheromones (Epstein et al. 2006; Trimble 2007). A novel

pheromone dispenser technology, based on electrospun mesofibers, has been developed for mating disruption pheromone application. The approach is labor-saving through mechanical deployment and environmentally sustainable, as the small pheromone-loaded fibers (0.6 to 3.5 μm) are fully biodegradable within 6 months (Hummel 2017). In recent years, high-release pheromone dispenser systems have been developed, using micro sprayers or aerosol puffers (Helsen et al. 2019). Aerosol delivery systems have several benefits over the passive dispensers: they are applied at lower density (2–5 units $\cdot\text{ha}^{-1}$ instead of 200–3000 units $\cdot\text{ha}^{-1}$ for passive dispensers), and they can be programmed to release the sex pheromones at selected times, covering the intervals when the target species is active, which increases the cost-efficiency (Benelli et al. 2019).

Despite the novel application and formulation methods being developed, there is a clear need for more research and development activities in this area. While it is generally known that low-risk PPPs have a lower field efficacy than chemical pesticides (Stridh et al. 2022), there is little data to support if this results from an inherent quality of the low-risk PPPs or if this is rather a consequence of poor application techniques, or other environmental factors. There is hope that development of new or improved application technologies can facilitate a greater use of low-risk PPPs. For example, use of drones in precision application of low-risk PPPs (spraying, or targeted release of microbial products) could make the application process more cost-effective and feasible also in larger agricultural field settings or in forests, as exemplified for macroorganisms (Filho et al. 2020; Martel et al. 2021; Moses-Gonzales and Brewer 2021). However, it is important to keep in mind that utilizing this type of technology also comes with other implications and costs. These include considerations such as local guidelines concerning licenses and regulations for registering, operating, and flying a drone (Filho et al. 2020).

4 Increasing the use of low-risk PPPs in the EU—challenges and possibilities

4.1 Availability of low-risk products

Despite the ambitions of policy makers in the EU to increase the development and use of low-risk PPPs to replace conventional pesticides, progress has been relatively slow. In Sweden, a recent analysis showed that despite a growing number of new low-risk substances being registered and approved, there is still a long way to go in order to meet the needs of consumers and to replace the functions earlier provided by conventional pesticides

(Allmyr et al. 2019). According to Lee et al. (2019), mixtures of regulatory, economic, and informative instruments, comprised of both incentivizing and discouraging instruments, would be needed in order to reduce the use of conventional pesticides. Thus, in addition to solving the purely technical challenges in application of the low-risk PPPs (see Section 3.2.), a multi-actor approach strategy is needed to identify and alter the structures that complicate the use of low-risk PPPs. To increase their use, it is crucial to ensure the availability of products with high efficacy, to establish strong support in policies and legislation, and to increase and secure the willingness of end users to integrate low-risk PPPs into their management practices. All this necessitates an updated scientific knowledge base and efficient uptake of research information to decision-making and practices (Fig. 3).

One of the crucial aspects challenging product availability is the fact that there is a small market potential in relation to registration costs for new low-risk PPPs. Recently, representatives of six companies specializing in plant protection products and operating in Sweden were interviewed about barriers to increased use of alternative pesticides in the country (Allmyr et al. 2019). The interviewees outlined that the high cost associated with registration of new products is often associated with the studies and trials that need to be completed to be eligible to apply and register new low-risk PPPs and not the application fee. They also emphasized that efficiency studies tend to cost more and take longer for low-risk PPPs compared to chemical pesticides, especially the ones containing microorganisms, since effectiveness often varies more between trials. The unforeseen requirement of additional studies can also make it difficult to estimate in advance what the final processing cost will be, which of course could cause further hesitation from an investor's perspective. For basic substances, the companies also stressed that driving the application process for registration seldom led to financial gain, as approvals ultimately benefit all actors independently of whether they have contributed to the registration process or not.

4.2 Supporting policy and legislation

The EU has taken several measures to facilitate the development and registration of new low-risk PPPs. These include exemptions from obligations related to assessment of the need to set maximum residue limits for low-risk and basic substances, and the recent change to start assessing the risks of microorganisms based on their biology and ecology. However, the regulatory framework in the EU is still not optimal, and there is a clear need to explore further possibilities to simplify the approval process for products containing potential low-risk substances. Another alternative to facilitate the

availability of more low-risk PPPs could be to completely exempt certain types of products from approval requirements. In Sweden, the possibility of exempting substances that have no toxic action and only work by attracting, repelling, or disrupting the chemosensory perception of certain insects (pheromones and kairomones) from the authorization requirements is currently being investigated by the Swedish Chemicals Agency.

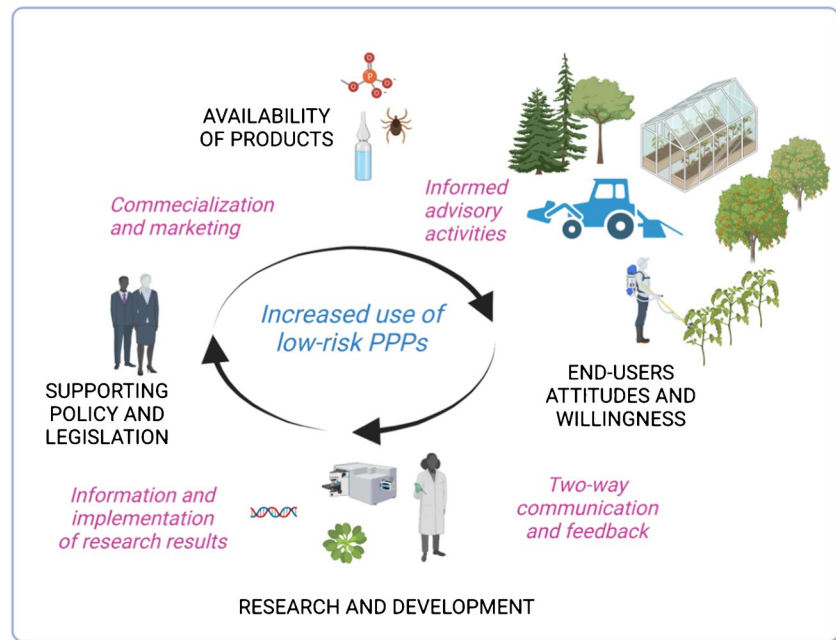
One of the challenges for farmers willing to make a transition from conventional pesticides to low-risk PPPs is the insecurity about the economic consequences: not only extra costs associated with having to apply the product multiple times, but also taxation. Low-risk PPPs are generally disadvantaged by the current tax legislation, as tax for pesticides is levied per kilogram of active substance used (independently of it being low-risk or not), and low-risk PPPs often require a higher dose per hectare compared to conventional pesticides (Allmyr et al. 2019). An opportunity to create an incentive to use low-risk PPPs could be to exempt their usage from this pesticide tax or to use some kind of environmental load indicator as basis for the taxation as in the Danish pesticide taxation system (Pedersen 2016).

4.3 The attitudes and willingness of growers to use low-risk PPPs

The willingness and skills of farmers will be the ultimate key to ensure successful implementation of low-risk PPPs as part of IPM strategies. Therefore, an important aspect of increasing the usage of low-risk PPPs is ensuring that their availability and application techniques are readily communicated to potential end users. Low-risk PPPs often have a short window for application, must be applied with good coverage, and have a reduced time-period during which they are effective, meaning that repeated applications are often needed. This is both time-consuming and expensive for the growers, and the potential negative effects on soil compaction and increased fossil fuel consumption have not been thoroughly investigated yet. One of the biggest challenges in increasing the use of low-risk PPPs is the insecurity of growers about how effective these products are, how to best apply them, and how they can be integrated into existing plant protection strategies. Advisors specialized in plant protection also point to a lack of clarity as to which products may be used, especially in organic production.

Expanded advisory activities involving decision support to assist integration of low-risk PPPs in IPM strategies and to influence attitudes of end users can be a powerful strategy to increase the use of low-risk PPPs in plant production systems. One way in which farmers can get assistance with implementing IPM practices to tackle pests, weeds, and diseases is through Decision Support System (DSS) platforms. A good example of an initiative like this is the

Fig. 3 Illustration of the central activities and focus areas leading to increasing use of low-risk PPPs. Created with BioRender.com.



IPM Decisions project (www.ipmdecisions.net) that receives funding from the European Union's Horizon 2020 research and innovation program. By providing end users with data, tools, and resources tailored to individual regions in a user-friendly online platform, the project aims to assist growers in both monitoring and managing pests and making informed decisions on how to implement IPM strategies.

4.4 Research for effective use of low-risk PPPs

To increase the number of available low-risk PPPs and to make sure that they are properly used in the most efficient way, it is important to invest in both basic research that can provide new alternatives to pesticides, as well as applied research to refine methods of application and promote their use to farmers (Carlsson Ross et al. 2015). Currently, the scientific evidence regarding effectiveness of low-risk PPPs and candidates for products is generally scarce, and there is a clear need for application-oriented research, in particular to gain better knowledge of how alternative plant production products can function as a part of IPM strategies across cultivation systems and under field conditions. New studies are needed on the possible effects of combining different products and defining thresholds for initiating treatments. It is also important to establish and maintain efficient dissemination and knowledge exchange practices, for example through demonstration farms, where growers and advisers can acquire knowledge in practice or long-term field trials (Karlsson Green et al. 2021). These types of activities can reduce the gap between research and application and facilitate an open dialogue about existing needs and knowledge gaps.

One challenge is the limited amount of research funding available for this type of research. A crucial step to improve the situation is for research financiers to increasingly recognize this need and adjust their targeted funding accordingly. At the time of writing this review, a search in the EU research results database (CORDIS) using the key word “pesticide” resulted in 53 hits for the period from January 2020 to August 2022, and the phrase “plant protection products” captured 378 hits for the same period. Even though this result does not necessarily relate to relevant project outcomes in these subject areas, it indicates the integration of the topic within EU financing strategies. The specific highlighting of biological control as a key component of IPM and a key area for research within both EU legislation (such as the European Green Deal) and within recent Horizon Europe funding calls, demonstrates EU recognition of the importance of research into this topic and provides exciting opportunities for current and future research in the arena of microbial PPPs. Indeed, the EC has currently set aside €10 million to fund grants focusing on a priority review of biocontrol. More support would, however, be needed also from the national financiers, e.g., through targeted calls, to ensure availability of science-based information to end users.

The increase in available microbial and other low-risk PPPs presents several challenges and opportunities in terms of research. Indeed, a recent survey of biocontrol experts suggested that the primary requirement of research and innovation (R & I) in this sector is to enlarge the range of biocontrol solutions, primarily through investing in research to appropriately assess biocontrol methods, including their intended and unintended effects, to devise strategies to integrate biocontrol with other plant protection methods, and

thirdly to enlarge the scope of biocontrol research to include the socioeconomic factors influencing biocontrol adoption (Lamichane et al 2017).

As well as the hunt for new, suitable biocontrol strains, another challenge is to improve efficacy and consistency under field conditions by providing studies showing responses from the molecular to the ecological level, also ensuring that their use does not have unexpected side effects on the environment.

Another important aspect is the potential soil legacy effect due to the use of novel plant protection products. However, it is important to keep in mind how little we currently know about the natural variation and biodiversity of plant associated microbial communities in natural ecosystems (Pérez-Jaramillo et al. 2018; Cordovez et al. 2019) and how agricultural practices and domestication have impacted these (Pérez-Jaramillo et al. 2016; Berg and Cernava 2022). Without this background knowledge, it is hard to make accurate predictions about how microbiomes are and/or will be affected by the introduction of microbial inoculants (Hart et al. 2017; Cornell et al. 2021), and thus, these knowledge gaps present opportunities and possibilities for new research studies connecting both fundamental and applied research in this area with the practical needs of plant protection practitioners. The use of low-risk PPPs could have an impact on plant microbiomes in several ways; in crops, seed treatments could potentially interfere with pre-existing microbial inheritance (Berg and Raaijmakers 2018; Nelson 2018; Rodríguez et al. 2020), and in the environment, introduction of alien species with strong competitive abilities could alter the resident microbiomes (Litchman 2010), affecting which microbes plants are ultimately exposed to. A recent meta-analysis investigating studies of how bioinoculants affect resident microbial communities showed that bacterial and fungal communities respond differently to inoculations, with bacterial communities in general being more prone to change (Cornell et al. 2021). As a response to some of the observed negative anthropogenic effects on plant microbiomes (Berg and Cernava 2022), there are researchers calling for a “rewilding”—approach to manage plant microbiomes (Raaijmakers and Kiers 2022), with the idea of using and re-introducing microbial communities of wild ancestral plants in modern agriculture (Chen et al. 2021). However, more research is needed on all these topics in order to be able to make qualified and informed decisions about how to best manage inoculants such as microbial PPPs in large and diverse agricultural settings. This is recognized at the EU level, since the EC has recently made a request for services under the SANTE framework agreement for (1) a literature review on the occurrence and population levels in soil of microorganisms used in plant protection and (2) a review of the biology and ecology of microorganisms used in plant protection and this work is currently in progress.

Novel strategies to improve the utility of low-risk PPPs should be continuously developed, such as engineering of microbiomes (Busby et al. 2017). An important emerging research area is breeding of “microbe-optimized plants” (Syed Ab Rahman et al. 2018), since crop breeding efforts have focused on yield and quality parameters combined with pest and disease resistance, without considering compatibility with microbial PPPs for example. It is important to also remember that socio-economic factors are of the utmost importance in our farming systems, and thus, future research efforts should also include cost-benefit analyses and other measures of economic impacts. Moreover, successful development of applicable scientific information depends on close collaboration between the different actors and proper utilization of stakeholders’ knowledge. Multi-actor approaches (i.e., co-creation and sharing of knowledge among different types of actors with complementary expertise) are therefore particularly important in research concerning the efficacy, risks, and benefits of low-risk PPPs in different sectors. Directed resources are also needed to promote active collaboration between researchers and society. The research community has the major responsibility for testing and developing innovative approaches and disseminating the knowledge to inform policy decisions, as well as for provisioning of the evidence-based knowledge to advisors and growers that is sorely needed.

5 Use of low-risk PPPs in different plant production systems—examples from Sweden

5.1 Agriculture

Even though Sweden is one of the largest countries in Europe (by surface area), only about 6.5% of its land area is currently used for cultivation (data from 2022). Cultivation of lay (cultivated grassland) and cereals takes up the largest area (about 45% and 38%, respectively of all arable land), followed by rape seed production (4%), legumes (2%), and sugar beets and potatoes (1%, respectively) (Jordbruksverket 2023a). In 2017, the Swedish government set out a goal to convert 30% of all arable land to organic production by 2030 (Government Offices of Sweden 2022). Organic production systems typically require an increase in the use of alternative ways to combat pests and diseases, including the use of low-risk PPPs (Hillocks 2012). The latest estimations in 2020 show that about 20% of the total area of farmland in Sweden is under, or in the process of converting to, organic production; however, this fraction has declined by about 1% from 2019 (Jordbruksverket 2023).

Some of the biggest concerns for pest management and plant protection in Swedish agriculture are leaf blotch

(*Zymoseptoria tritici*) and yellow rust (*Puccinia striiformis*) in wheat, and late blight (*Phytophthora infestans*) in potato (Sundgren 2014; Eriksson et al. 2016). In open-field cultivation, there is a need for low-risk PPPs that can either be sprayed over larger areas, mixed into the soil, or applied as seed treatments. Currently, low-risk PPPs are mainly used in seed treatments in Swedish agriculture. One example of this is seed coating with the mycoparasitic fungus *Clonostachys rosea*, used against seed-borne and soil-borne fungi and oomycetes (e.g., *Fusarium*, *Pythium*, and *Phytophthora* spp.) (Table SI1). In total, only five of the 16 low-risk PPPs authorized for use in Sweden have documented effects on agricultural crops (EC 2022f) (Table SI1). A review performed by HIR Skåne (advisors south Sweden, Rural Economy and Agricultural Society) and the Swedish Plant Protection Council in 2020 found that out of the 49 low-risk or potential low-risk PPPs approved by the EU at the time, but not currently approved in Sweden, 20 would fill a unique or high need in Sweden (HIR Skåne 2020). However, only three of those had documented effects on agricultural crops, such as *Bacillus amyloliquefaciens* strain FZB24 (more recently classified as *Bacillus velezensis* FZB42 (Fan et al. 2017)) against potato late blight. The relatively low number of available products for agricultural cultivation in Sweden follows the same trend as for the EU, where a lower number of substances have shown documented effects in agricultural systems compared to horticultural systems (Fig. 2). In particular, the approved bacterial and fungal biocontrol agents that are not yet classified as low risk (EC 2022f) may prove useful in agriculture, such as *Pythium oligandrum* against potato late blight (Hashemi et al. 2022).

Another challenge for low-risk PPPs in agriculture is the use of large monocultures, which increases the risk of resistance development to the substance in insect pests or pathogens due to strong directional selection (Karlsson Green et al. 2020). Low-risk PPPs with multiple modes of action, such as biocontrol agents, are expected to present more of a challenge to pest populations in terms of resistance development, i.e., their use should reduce the risk of resistance development to the substance. However, this has yet to be systematically investigated for most microbial PPPs. This represents an important knowledge gap that should be investigated in the future, since we expect more commercial use of microbial and other low-risk PPPs in the future.

Moreover, to be able to use low-risk PPPs in practical agriculture, it is essential to have demonstrated good field efficacies that are economically feasible for farmers. These kinds of data are often lacking for specific diseases and crops or where the effects are promising in greenhouse studies but poor under field conditions (Stridh et al. 2022). However, there are some exceptions, such as phosphite salts (phosphonates), e.g., potassium phosphite, which have shown efficient activity against several diseases in various crops, especially

oomycete diseases, e.g., potato late blight caused by *P. infestans* (Thao and Yamakawa 2009; Huang et al. 2018; Manghi et al. 2021). Due to its low toxicity, and since it has previously been used as a fertilizer for many years, potassium phosphite could potentially be considered as a low-risk PPP. Phosphite seems to have both a direct inhibiting effect on growth and sporulation of oomycetes (Grant et al. 1990) and an indirect effect by acting as an inducer of plant defense responses (Lim et al. 2013; Burra et al. 2014). Several studies have shown that potassium phosphite has a good efficacy against potato late blight (Kromann et al. 2012). Long-term field trial data has recently shown that potassium phosphite has an almost equivalent effect against natural *P. infestans* infections as the application of conventional fungicides (Liljeroth et al. 2016, 2020). By replacing half of the fungicides used with phosphite, these experiments showed that it was possible to obtain the same level of disease control and yield as when using fungicides only. Thus, phosphite can be integrated into disease control programs and thereby reduce the dependence on conventional fungicides.

In both the USA and Canada, phosphite is approved for use in potato cultivation, and there are commercial products available. However, in the EU, it is not approved for potato due to concerns about residues and potential long-term risks for frugivorous birds. Phosphites have been marketed either as fungicides, fertilizers, or biostimulants, which is confusing for both distributors and growers (Thao and Yamakawa 2009). It is now clarified that phosphite does not provide the plant with the nutrient phosphorous, since plants cannot oxidize phosphite to phosphate. Many studies have shown positive crop responses to phosphite, and these responses are likely due to disease suppression (Thao and Yamakawa 2009). Phosphonite has been approved as an active ingredient in plant protection products by the EU commission (EC 2013). Thus, it is not listed as a low-risk PPP or as a basic substance and can no longer be marketed as a fertilizer.

5.2 Horticulture

Horticulture in Sweden is divided between greenhouse and open field cultivation, where crops are commonly germinated in greenhouses before transfer to fields. For greenhouse cultivation, the main crops in Sweden are cucumbers, potted salads, and herbs, as well as tomatoes and ornamental plants. The principle horticultural crops grown under open field cultivation are strawberries, carrots, and apples (Jordbruksverket 2020).

In field vegetables, the main pests are carrot fly (*Psila rosae*) (Sundgren 2014; Virić Gašparić et al. 2022) and carrot psyllid (*Trioza apicalis*) (Sundgren 2014; Cotes et al. 2018), downy mildew (*Bremia lactucae*) (Sundgren 2014), and aphids in lettuce (e.g., *Myzus persicaria*) (Sundgren 2014). In the Brassica family, large white butterflies (*Pieris*

brassicaceae) (Alcalá Herrera et al. 2022) are a widespread problem, and in recent years, the spread and damage from cabbage whiteflies (*Aleyrodes proletella*) has also become more problematic (Daniel et al. 2016; Hansson et al. 2021). For berries, the main problems are grey mold (*Botrytis cinerea*), downy mildew (*Podosphaera aphanis*) and pests such as thrips (*Thysanoptera* sp.), strawberry blossom weevil (*Anthonomus rubi*), and strawberry mite (*Phytonemus pallidus*) (Mozūraitis et al. 2020; Iqbal et al. 2021). For other fruits, such as apple, the main pests are codling moth larva (*Cydia pomonella*) and apple scab (*Venturia inaequalis*) (Sundgren 2014).

The majority of low-risk substances approved in Sweden (11 out of 16) have documented effects in horticultural crops, which follows the general pattern for the EU (Fig. 2). Among these, ferric phosphate is one of the most widely used, and it is mainly used against snails in agricultural and garden crops (Table SI1). Besides ferric phosphate, a large proportion of the low-risk PPPs approved for use in horticulture are microbial (7 out of 11), which is also the case at the EU level (Fig. 2). One of the most commonly used microbial PPPs is the bacterium *Bacillus thuringiensis* which is of potential low risk (i.e., approved but not yet classified as low-risk). This bacterium is used to protect against butterfly and moth larvae in the cultivation of several important crops in Sweden, e.g., cucumbers, cabbage, and tomatoes (Andersson et al. 2022). In the review performed by HIR Skåne and the Swedish Plant Protection Council in 2020, it was concluded that among the 49 low-risk and potential low-risk substances not approved in Sweden at the time, 17 were judged to have an important contribution to horticultural plant protection (HIR Skåne 2020). For example, *Bacillus* spp. against powdery and downy mildews (Table SI1). However, it is clear that even with these additional substances, more substances are needed to cover the diversity of horticultural crops and their associated insect pests and diseases.

One potential reason for a larger proportion of low-risk PPPs approved for use in horticulture (Fig. 2) could be the fact that horticultural systems tend to be more easily contained than agricultural fields or forest systems. It is also easier to execute more precisely targeted applications of substances and organisms in horticultural crops, something which is often needed for organismal low-risk PPPs. As horticultural crops span different cultivation systems and environments (e.g., greenhouses, cultivation tunnels and open fields), the low-risk PPPs used for these crops need to be approved for use in the specific contexts. For example, if there is a high risk of wind dispersal, substances can still be approved for use in greenhouse systems. Additionally, some entomopathogenic fungi (e.g., *Isaria fumosorosea*) are only approved for use in greenhouse settings due to problems with efficiency when applied under field conditions (Table SI1).

5.3 Forestry

Forests cover almost 70% of the land area in Sweden, comprising a large green infrastructure where forests provide multiple benefits, including carbon sequestration and production of renewable biomass and energy (Felton et al. 2022). Forests are also an important element of urban areas and frequently used for recreation. Planting material for forest regeneration is generally produced in nurseries (greenhouses and out in the open field) under conditions similar to those used in horticulture.

The economically most important pests of forest trees are bark beetles (*Ips typographus*) (Schroeder 2001) and large pine weevils (*Hylobius abietis* L.) (Nordlander et al. 2003). Of the fungal diseases, root and stem rot of conifers, caused by *Heterobasidion* species, is the economically most significant one (Oliva et al. 2017). Ungulate browsing is another major problem in Swedish forestry (Ezebilo et al. 2012). Additionally, the ecologically important broadleaved trees are suffering from introduced, invasive pathogens, such as *Hymenoscyphus fraxineus* (causal agent of ash disease) (Cleary et al. 2016), *Ophiostoma novo-ulmi* (causal agent of Dutch elm disease) (Martin et al. 2010), and soil-borne *Phytophthora* species (Cleary et al. 2017). Pest control is needed not only in woodlands, but also in forest tree nurseries, orchards, and in urban green areas dominated by trees. The current use of PPPs in the Swedish forest sector is low and low-risk PPPs even lower, which mirrors the low availability of such products in the EU (Fig. 2). In future climate and management regimes, however, the need for low-risk PPPs is expected to increase (Keskitalo et al. 2016). In the list of the 49 low-risk substances and potential low-risk substances approved in the EU, but not approved in Sweden in the review performed by HIR Skåne and the Swedish Plant Protection Council in 2020 (HIR Skåne 2020), three were judged to have a potential important role in Swedish forestry.

The Swedish Forest Stewardship Council (FSC) has one of the strictest policies for pesticide use in Europe, and it expects certificate holders to entirely abstain from the use of chemical pesticides in FSC certified forest management units (FSC 2020). Therefore, there is great potential for application of low-risk PPPs in the different forest production settings, including to protect seedlings during production (Capieau et al. 2004). Despite this obvious niche, alternative PPPs based on active substances approved as low risk for the forest sector are still scarce, and only a few products based on microbes and pheromones are in use. For example, to prevent root rot of conifers, a product with a saprotrophic fungus *Phlebiopsis gigantea* as an active substance is used for stump treatment (Oliva et al. 2017). In addition, a product based on *Verticillium albo-atrum* isolate WCS850 is accepted as a preventive treatment (vaccine defense inducer) against Dutch elm disease (Postma and Goossen-van de

Geijn 2016) and mainly used in urban trees. Due to recent massive outbreaks of spruce bark beetles (*Ips typographus*), The Swedish Chemicals Agency has recently allowed a derogation for the use of products containing semiochemicals (2,3,2 methylbutenol, (S)-*cis*-verbenol, and ipsdienol), to combat these outbreaks, despite the active substances not being approved in the EU.

The relatively small market size for specific products is one of the obstacles for increased use of low-risk PPPs in Swedish forestry. For instance, a nuclear polyhedrosis virus prepartate for control of the European pine sawfly *Neodiprion sertifer* was registered and successfully utilized, but the registration has not been extended since the market is limited. However, Swedish authorities aim to continue to promote the use of low-risk plant protection methods. For example, some of the acute problems that were earlier solved using pesticides, such as the control of the large pine weevil (*H. abietis*) on pine seedlings have recently made use of alternative low-risk innovations, e.g., protective coatings that are now widely used. In 2021, a principally important court verdict was issued in Sweden denying a company's application for renewed approval of a neonicotinoid pesticide which is used against the large pine weevil on seedlings of coniferous trees. The verdict was given because a non-chemical control method or a preventive method that is in general use was available. The verdict was one of the first of its kind in the EU based on the fact that chemical authorities may decide on the substitution of chemical plant protection products even in cases where they do not contain a candidate substance for substitution. This verdict may also provide some guidance on the possibilities of using substitution in other areas to further promote progress towards low-risk PPPs in the field of plant protection.

The need for low-risk PPPs in forestry is likely to increase as the use of conventional pesticides is gradually restricted, especially in nurseries. New low-risk PPPs for this sector are also on the horizon. For instance, the bacterium *Streptomyces lydicus* has been found to be effective as a control agent against soilborne pathogens in forest nurseries in the USA (Weiland 2014), and the strain WYEC 108 has been approved as a low-risk active substance in the EU. Although it has not yet been registered for forest-seedling production in Sweden, it could be a promising new product to use in the IPM toolbox for the Swedish forest sector.

6 Global outlook on increasing the use of low-risk PPPs—examples from Africa

A rapid transition to the use of sustainable agrochemicals is crucial to increase our possibilities to achieve several of the targets of the UN Sustainable Development Goals under Agenda 2030 (UN General Assembly 2015). This is especially urgent in low-income countries where adverse health

effects from synthetic pesticides are common (Kesavachandran et al. 2009; Jørs et al. 2018).

In most countries in the world, there have been efforts to improve national standards for pesticide legislation and even to harmonize the rules between countries, such as within the EU (Handford et al. 2015). In Africa, however, there are still many countries lacking efficient legislation even if there are agreements in both West and Central Africa and in East Africa to harmonize pesticide legislation and policies (Handford et al. 2015). Even if there are less pesticides used per hectare in Africa compared to other regions in the world, they are often poorly regulated and the use of hazardous substances that could even be illegal, without proper protection or storage is still all-too common. For example, it is estimated that fraudulent pesticides of dubious quality now account for approximately one-third of all pesticides sold across West Africa (Hagblade et al. 2022). There is thus an urgent need for less harmful plant protection products in the region. Both biopesticide use and development are, however, still underdeveloped in Africa although there are several compounds registered across the continent (Srinivasan et al. 2019; Akutse et al. 2020). There are, however, also initiatives to develop biopesticides, especially in South Africa and Kenya (Srinivasan et al. 2019; Akutse et al. 2020). A promising development in South Africa is the development of new guidelines for the registration of biopesticides, along with both bans and restrictions of harmful products (Hatting et al. 2019).

There is a high potential for developing plant-derived pesticides in Africa, due to the large number of native pesticidal plants in the region (Stevenson et al. 2017). The possibility for farmers to produce low-risk PPPs from locally available plants may also be an important factor when considering the cost-benefit balance between conventional pesticides and biopesticides (Amoabeng et al. 2014). Until now, empirical research on the effectiveness of such plant-derived products from field trials is, however, lacking (Stevenson et al. 2017) and development and commercialization of new products generally take time. Experiences from the International Centre of Insect Physiology and Ecology (*icipe*) in Kenya show that the process could be considerably shortened if it is streamlined based on experience of previous product development (Akutse et al. 2020). Experience also shows the importance of public-private partnerships in product development (Srinivasan et al. 2019; Akutse et al. 2020). In addition, there are pilots of community-based production of biopesticides which could give additional economic support to women and young farmers (Srinivasan et al. 2019).

Rapid development of low-risk PPPs may be especially important to control invasive species that could have devastating impacts on food security in the region and that often are resistant to available pesticides. One recent example is the fall armyworm (FAW) *Spodoptera frugiperda*, a polyphagous moth that invaded Africa in 2016 from South America

and since then has spread rapidly across the Sub-Saharan part of the continent where it inflicts significant damage on maize production. The initial outbreaks of FAW led to a huge increase in the use of pesticides by African farmers (Murray and Jepson 2019). FAW is resistant against several of the conventional pesticides, and efforts have been made to develop biopesticides based on plant-derived compounds (Rioba and Stevenson 2020) or insect pathogens (Akutse et al. 2020).

The emergency situation caused by the invasion of FAW in East Africa, triggered a review of the legislation and pathways to use of low-risk PPPs in the region, since new control measures had to be found and approved for use rapidly. With the lack of specific registration and guidelines for low-risk PPPs at the time, the East Africa Community (EAC 2019) partner states of South Sudan, Uganda, Kenya, and Tanzania agreed there was an urgent need to harmonize the guidelines for the safe use of low-risk PPPs and to fast-track this work (EAC 2019). This was a pivotal point, since it meant that, for the first time in many decades, key policy makers from governments across Africa became aware of the intensive strain on the regulatory agencies and the significant threat to agricultural production, food security, and human health from both FAW but also from the lack of clear and implementable policies around low-risk PPPs (Haggblade et al. 2022). The new EAC harmonized guidelines provide a framework for microorganisms, macro-organisms (excluding those that are genetically modified), and biochemical pesticides (defined by the EAC as botanicals and semiochemicals) that are classified as low-risk PPPs.

The guidelines provide four registration use categories, designed to allow end users access to new products as fast and as safely as possible, thereby facilitating rapid responses to invasive species or serious pest outbreaks as and when needed (EAC 2019). Thus, products can be registered under four different categories: experimental use, full registration, temporary or emergency registration (allowing immediate use, while the full registration process is ongoing), and provisional registration which allows agencies to seek further biosafety data before full registration. These guidelines were adopted by the 13th Sectoral Council on Agriculture and Food Safety in September 2019 and by most partner states shortly afterwards (EAC 2019). The response to the FAW outbreak in Africa illustrates the proactive thinking that needs to be adopted within the EU to provide legislation that supports the uptake of low-risk PPPs rather than hindering the process and further demonstrates the essential role these products are likely to play in the future of plant protection globally.

7 Conclusion

As the demand for more sustainable plant protection solutions is urgent and increasing, we investigated the current status of low-risk PPPs for the European market regarding

legislation, availability of products, their mode of action, use, and application techniques. Our review highlights the importance of a seamless connection between science, policy, and practice to enable and support a successful transition from the use of harmful pesticides to low-risk alternatives. Knowledge exchange through cross-sectorial dialogue, multi-actor approaches, and investments in holistic, application-oriented research are the cornerstones of this connection. EU policy development is heading in the right direction, so that approval and registration processes for low-risk PPPs, particularly biocontrol agents, are being simplified. This change would boost interest and investment in agbiotech companies providing jobs and strengthening competitiveness in this sector. As a result, this should pave the way for an increase in the availability and uptake of low-risk PPPs within the EU. While predominantly focusing on the EU, we also compared this to African agriculture, to bring in a more global perspective. The speed of development of a harmonized response to the emergency presented by the FAW outbreak in East Africa, which utilized low-risk PPPs and expedited their approval, regulation, and use in practice, can be seen as an example of how we should respond to similar events in the EU in the future.

Based on our analysis, we identified urgent knowledge gaps to be addressed through research. These include how to optimize the efficiency of low-risk PPPs, how to best apply them, investigating the impacts and interdependencies within and on the plant microbiome, and how low-risk PPPs can be successfully integrated into current and future plant protection strategies. We believe that the latter should also include the use of breeding programs to develop plants better able to induce resistance in response to low-risk PPPs or to better host microbial PPPs that are able to induce resistance. In addition to efficiency and environmental consequences, we also conclude that the socio-economic aspects need to be considered in search of cost-efficient solutions to practical plant protection problems in agriculture, horticulture, and forestry. For example, cost-benefit analyses should be carried out wherever possible to weigh up the risks of crop losses against the benefits of treatments in terms of yield and quality. In many cases, producers and consumers will need to be more accepting of minor, often cosmetic, damage present in plant produce. Low-risk PPPs are likely to dominate our plant protection products in the future, and investments into research and development in this area are of the utmost importance and will pave the way for the development of more resilient and sustainable plant production systems in the future.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s13593-024-00957-5>.

Acknowledgements The authors thank members of the focus group “Low-risk compounds in plant protection” funded by Swedish

University of Agricultural University (Plant Protection Platform) 2017–2019, who contributed with important discussions that inspired us to write this review.

Authors' contributions Conceptualization: Å Lankinen, J. Witzell; writing—original draft preparation: Å. Lankinen, J. Witzell, K. Aleklett, S. Furenhed, K. Karlsson Green, M. Latz, E. Liljeroth, R. Larsson, K. Löfkvist, J. Meijer, V. Ninkovic, L. Grenville-Briggs; writing—review and editing: Å. Lankinen, L. Grenville-Briggs, A. Menkis, Å. Olson with input from all authors. All the authors approved the final version of the manuscript. Project coordination: Å Lankinen. Figure preparation: L. Grenville-Briggs (Fig. 1), Å. Lankinen, M. Latz, K. Aleklett, J. Witzell (Fig. 2), J. Witzell (Fig. 3)

Funding Open access funding provided by Swedish University of Agricultural Sciences. This work was supported by a grant from Swedish University of Agricultural Sciences (Plant Protection Platform) for the focus group “Low-risk compounds in plant protection” to ÅL, JW, EL, VN, the Swedish Research council (grant nr 2018-04354) to ÅL. Financial support to ÅO, AM, and RL from the Swedish Foundation for Strategic Research (grant ID18-0025), to LGB from Swedish Research council, Formas, (grant nr 2019-00881) and from SLU GroGrund, is also acknowledged.

Data availability Not applicable.

Code availability Not applicable.

Declarations

Ethical approval Not applicable.

Consent to participate Not applicable.

Consent for publication Not applicable.

Conflict of interest The authors declare no competing interests.

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