KEMI
Swedish Chemicals Agency

Guidance on national chemicals control

Hazard and risk assessment and risk reduction of pesticides

GUIDANCE 1/20

kemikalieinspektionen.se

KEMI
Swedish Chemicals Agency

The Swedish Chemicals Agency is supervisory authority under the Government. We work in Sweden, the EU and internationally to develop legislation and other incentives to promote good health and improved environment. We monitor compliance of applicable rules on chemical products, pesticides and substances in articles and carry out inspections. We review and authorise pesticides before they can be used. Our environmental quality objective is A Non-toxic Environment.

Article number: 511 369

Preface

Chemicals contribute in many ways to improving our standard of living, but some of them are hazardous and can have serious adverse effects on human health and the environment. It is therefore necessary to use different means to protect human health and the environment from exposure to hazardous chemicals.

This guidance is part of a series of guidance documents developed by the Swedish Chemicals Agency and contains recommendations on risk management of pesticides in order to help authorities to take regulatory actions to reduce the negative impact of pesticide use.

The Swedish Chemicals Agency has developed this guidance with the financial assistance of the Swedish International Development Cooperation Agency (Sida). The views herein shall not be taken to reflect the official opinion of Sida.

Content

Summary

The aim of this guidance is to provide an overview of procedures and measures for hazard and risk assessment and risk management of pesticides in order to help authorities to take regulatory actions to reduce the negative impact of pesticide use on people's health and the environment. It is based on the approach of using information and assessments generated by authorities in other countries or by international agencies.

The International Code of Conduct on Pesticide Management has been developed by the Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO) and serves as a framework on pesticide management for all public and private entities engaged in, or associated with, the production, regulation, and management of pesticides. According to the Code, governments are strongly encouraged to establish regulatory schemes and infrastructures under which each pesticide product is registered before it can be made available for use.

Highly Hazardous Pesticides (HHPs), defined by their intrinsic properties and the risk they may pose to humans and to the environment, are a special focus area for the FAO in implementing the Code of Conduct. This area is particularly emphasised in this guidance document, which provides descriptions on how various information sources can be accessed. Sources like the harmonised classification of substances established according to the EU Classification, Labelling and Packaging Regulation is referred to. Because the EU Regulation is based on the United Nations' Globally Harmonised System for Classification and Labelling of Chemicals (GHS), the classification is also valid for other countries. Moreover, reviewed data and risk assessments conducted in various parts of the world, made in accordance with legal frameworks and established guidelines, will also add information to the assessment of whether a pesticide product fulfils the HHP criteria and can be handled safely or not.

In conclusion, governments with an aim to improve their management of pesticides will be guided on how already available information can be used to contribute to the protection of human and animal health and the environment. Information regarding intrinsic properties extracted from classification systems, the use of risk assessments conducted by various organisations, as well as proposals for relevant risk mitigation measures may all serve as a good starting point for countries that are in the process of improving the control of the trade and use of pesticides. The aim of this guidance document is to facilitate the work of evaluators and decision makers on how to access such information when taking regulatory action, with a special focus on HHPs.

Definitions and acronyms

Active ingredient/active substance means the biologically active part of the pesticide.

Authorisation of a pesticide product is used within the EU and means an administrative act by which the competent authority of a Member State in the EU authorises the placing on the market of a pesticide product in its territory before it can be sold and used.

Approval is used within the EU for active substances while authorisation is used for pesticide formulations. In this document approval has sometimes been used for pesticide formulations as an equivalent to pesticide registration.

Authorisation is mainly equivalent to **Pesticide registration**[1]**,** which means the process whereby the responsible national government or regional authority approves the sale and use of a pesticide following the evaluation of comprehensive scientific data demonstrating that the product is effective for its intended purposes and does not pose an unacceptable risk to human or animal health or the environment. Note that the definition of registration here differ from the definition of registration normally used in the context of industrial and consumer chemicals[2]

Chemicals (or chemical products) are usually defined and understood as chemical **substances** and **mixtures** of chemical substances.

GHS uses the following definitions of substance and mixture:
Substance means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurities derived from the process used, but excluding any solvent, which may be separated without affecting the stability of the substance or changing its composition.

Mixture means a mixture or solution composed of two or more substances in which they do not react.

Biocidal product means any substance or mixture, in the form in which it is supplied to the user, consisting of, containing, or generating one or more active substances with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on any harmful organism by any means other than mere physical or mechanical action.

Co-formulant means any substance (or mixture of substances) other than the active ingredient that is intentionally included in a formulation.

Competent authority means any authority or authorities of a Member State in the EU responsible for carrying out the tasks established under the EU Regulations regulating plant protection or biocidal products.

Formulation[3] means the combination of various ingredients designed to render the product useful and effective for the purpose claimed; this is the form of the pesticide purchased by users.

---

[1] FAO. (2010) *Guidelines for the Registration of Pesticides.* Retrieved 8 December, 2019 from: http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Code/Registration_2010.pdf

[2] KemI. (2019) *Guidance on national chemicals control - Access to information on primary suppliers and chemicals on the market.* Retrieved 23 March, 2020 from: https://www.kemi.se/en/global/guidance-on-national-chemicals-control/guidance1-19.pdf

[3] FAO. (2010) *Guidelines for the Registration of Pesticides.* Retrieved 8 December, 2019 from: http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Code/Registration_2010.pdf

Non-chemical methods mean alternative methods to chemical pesticides for plant protection and pest management based on agronomic techniques or physical, mechanical, or biological pest control methods.

Pesticide[4] means any substance or mixture of substances or micro-organisms, including viruses, intended for repelling, destroying, or controlling any pest, including vectors of human or animal disease, nuisance pests, and unwanted species of plants or animals causing harm during or otherwise interfering with the production, processing, storage, transport, or marketing of food, agricultural commodities, wood and wood products, or animal feeding stuffs, or which may be administered to animals for the control of insects, arachnids, or other pests in or on their bodies. The term includes substances intended for use as insect or plant growth regulators; defoliants; desiccants; agents for setting, thinning, or preventing the premature fall of fruit; and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport. The term also includes pesticide synergists and safeners when they are integral to the satisfactory performance of the pesticide.

Plant Protection Products are products intended for one of the following uses:

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

Rapporteur Member State means the Member State that undertakes the task of evaluating an active substance, safener, or synergist within the EU.

Risk[5] is a function of the probability of an adverse health or environmental effect, and the severity of that effect, following exposure to a pesticide.

Technical equivalence means similarity, as regards the chemical composition and hazard profile, of a substance produced either from a source different from the reference source or from the reference source but following a change to the manufacturing process and/or manufacturing location compared to the substance of the reference source with respect to the initial risk assessment that was carried out.

[4] FAO. (2010) *Guidelines for the Registration of Pesticides.* Retrieved 8 December, 2019 from: http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Code/Registration_2010.pdf
[5] Ibid

Acronym	Explanation
ADI	Acceptable Daily Intake
AEL	Acceptable Exposure Level
AOEL	Acceptable Operator Exposure Level
ARfD	Acute Reference Dose
BPC	The Biocidal Products Committee
CA	Competent authority within EU
CAR	Competent authority report (for biocides)
Cat.	Category
CMR	Substances which are **C**arcinogenic, **M**utagenic and toxic to **R**eproduction
DAR	Draft Assessment Report
DG SANTE	The EU Directorate-General for Health and Food Safety
EC	The European Commission
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	Good Agricultural Practice
GHS	Globally Harmonised System of Classification and Labelling of Chemicals
HHP	Highly Hazardous Pesticides
KemI	The Swedish Chemicals Agency
MRL	Maximum residue level
NOAEL	No-Observed-Adverse-Effect-Level
MS	EU Member State
OECD	Organisation for Economic Co-operation and Development
PNEC	Predicted No Effect Concentration
RAC	ECHA´s Risk Assessment Committee
RMS	Rapporteur Member State
US	United States
WHO	World Health Organisation

1 Introduction and scope

The aim of this guidance is to provide an overview of procedures and measures for hazard and risk assessment and risk management of pesticides in order to help authorities to take regulatory actions to reduce the negative impact of pesticide use on people's health and the environment. It builds on the approach of promoting the use of information generated by authorities in other countries or by international agencies. Extensive work has been carried out over the years when producing data and reports, this information may be valid for risk-management purposes in many countries. The use of peer-reviewed data and assessments will also contribute to the decreased need for conducting new animal studies and unnecessary duplication of work and costs.

This document is primarily intended to add some practical information to the global "Code of conduct on pesticide management"[6] developed by the Food and Agriculture Organisation (FAO) and to the "FAO Pesticide registration toolkit"[7], further described in Chapter 2. The guidance is built on experiences gained by the Swedish Chemicals Agency (KemI) during the work with the pesticide review programmes within the European Union (EU) from 1996 onwards. The guidance refers to data and reports based on the outcome and results from the review programmes for plant protection products[8] and biocidal products[9]. Although it is considered a stand-alone document it may be read together with the previously developed Swedish Chemicals Agency Guidance document "Practical guidance on how to access information from the EU pesticide registration process"[10].

In the following context, *plant protection products* are defined as products protecting plants or plant products while *biocidal products* are defined as products protecting humans, animals, materials, or articles against harmful organisms like pests or bacteria, including, for example, rodenticides, insect repellents, and insecticides. This guidance document has primarily been compiled for evaluators and decision makers working with pesticides management nationally.

The main aim of the guidance document is to facilitate the work of evaluators and decision makers on how to access peer reviewed data on pesticides for the identification of pesticides that might be the most harmful and for subsequent risk-mitigation activities. This document does not propose a decision-making framework for pre-market approval of pesticides. Nor does the document provide any detailed descriptions on how to perform a risk assessment for pesticides. For information on the general principles of how to make a risk assessment, a description is available in the Swedish Chemicals Agency guidance document "Hazard Assessment and Risk Assessment of Chemicals – an introduction"[11]. Information that is more detailed is also available in the EU guidance for plant protection products and biocidal

---

[6] FAO and WHO. (2019). *The International Code of Conduct on Pesticide Management*. Retrieved 4 October, 2019 from: http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Code/CODE_2014Sep_ENG.pdf

[6] FAO. (2019). *Pesticide Registration Toolkit.* Retrieved 29 October, 2019, from: http://www.fao.org/pesticide-registration-toolkit/en/

[8] European Commission. (2019). *Review programs for Plant Protection Products.* Retrieved 29 October, 2019 from: https://ec.europa.eu/food/plant/pesticides_en.

[9] European Commission. (2019). *Review program for Biocidal Products.* Retrieved 29 October, 2019 from: https://ec.europa.eu/health/biocides/overview_en

[10] Swedish Chemicals Agency. (2019). *Practical guidance on how to access information from the EU pesticide registration process.* Retrieved 29 October, 2019 from: https://www.kemi.se/en/global/guidance-documents/guidance-document-eu-pesticide-registration-process.pdf

[11] Swedish Chemicals Agency. Guidance on *Hazards Assessment and Risk Assessment of Chemicals – an introduction*. (To be published)

products, which can be found on the webpages of the European Chemicals Agency (ECHA), the European Food Safety Authority (EFSA), and the European Commission (EC).

It should be noted that within EU it is not possible to approve a pesticide product on the basis of another company´s data without a consent, according to specific rules on data protection. However, new information that leads to the conclusion that the risk caused by the pesticide product is greater than what has been shown by the applicant, can always be used to trigger different risk mitigation actions.

The initial part of this document aims to describe very briefly the work by the FAO and the World Health Organisation (WHO) on pesticide management globally, as well as relevant working procedures within the EU. The next parts of the document describe the risk management applied in the EU followed by some recommendations on how information can be used to identify HHPs, and how the risk that they may pose can be reduced. The last part of the document describes how the principles of a sustainable pest control may be applied in practice, followed by a few examples from Sweden.

2 The International Code of Conduct on Pesticide Management

This chapter refers to work currently on-going within the FAO and the WHO in terms of developing a framework that will guide government regulators, the private sector, civil society, and other stakeholders on best practice in managing pesticides throughout their lifecycle. The International Code of Conduct on Pesticides Management lays down the key principles for pesticides management, mainly for government authorities and the pesticide industry. The Code gives guidance on forming a legal national framework, which is a prerequisite for the reduction of the negative impact of pesticides on human health and the environment. The use of highly hazardous pesticides is still a serious concern in many parts of the world. The FAO and the WHO have created a definition of HHP that is described in the Code. The FAO pesticide registration toolkit serves as a good decision support system where the recommended starting point is the management of products that are considered highly hazardous.

2.1 The Code of Conduct on Pesticide Management and its principles

The International Code of Conduct on Pesticide Management was approved by the FAO Conference in June 2013. The Code and its listed guidance documents provide standards of conduct and serve as a point of reference in relation to sound life cycle management practices,

in particular for government authorities and the pesticide industry. Some of the key principles of the Code are the following:[12]

- Voluntary standards of conduct should be established for all public and private entities engaged in or associated with the management of pesticides, particularly where there is inadequate or no national legislation to regulate pesticides.
- The code is designed to be used within the context of national legislation as a basis whereby relevant entities addressed by the Code may determine whether their proposed actions and/or the actions of others constitute acceptable practices.
- Governments have the overall responsibility for regulating the availability, distribution, and use of pesticides in their countries and should ensure the allocation of adequate resources for this mandate.
- Governments should encourage and promote research on, and the development of, alternatives to existing pesticides that pose fewer risks such as biological control agents and techniques, non-chemical pesticides and pest control methods, and pesticides that are of low risk to human and animal health and the environment and that as far as possible or desirable are target specific and degrade into innocuous constituent parts or metabolites after use.

2.2 National legal frameworks to govern pesticide management

The Code is designed to be used within the context of national legislation. Relevant entities addressed by the Code may use the Code as a basis to determine whether proposed actions are considered acceptable. The governments have the overall responsibility for regulating the availability, distribution, and use of pesticides in their countries and should ensure the allocation of adequate resources for this mandate. It is stated that governments should establish regulatory schemes and infrastructures under which each pesticide product is registered before it can be made available for use. Furthermore, governments should allow for re-evaluation and should establish a re-registration procedure to ensure the regular review of pesticides, thus ensuring that prompt and effective measures can be taken if new information or data on the performance or risks indicate that regulatory action is needed. In addition, the FAO/WHO guidelines on pesticide legislation propose that a number of key elements for pesticide registration be included.

If your country is in the process of developing an approval system for pesticides FAO/WHO recommends that the pesticide law should:

- establish a mandatory registration system for pesticides
- set out the key elements of an application procedure for pesticide registration
- outline the information and data requirements to be included in the application
- provide the main criteria for decision-making
- require that registration decisions are communicated to the applicant and include a justification based on the decision criteria
- establish validity periods for registrations and provide information concerning re-registration
- clarify what changes require a new registration and what changes can be regarded as a modification of the existing registration

[12] FAO and WHO (2019). *The International Code of Conduct on Pesticide Management*. Retrieved 4 October, 2019 from: http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Code/CODE_2014Sep_ENG.pdf

- indicate that registration can be reviewed at any time when new information has become available and that a negative outcome of such a review can lead to cancellation of the registration
- regulate appeals procedures for cases in which the applicant believes a rejection, restriction, or ban is not sufficiently justified
- regulate how registration data will be stored and which part of the data package should be made publically available
- include provisions ensuring confidentiality and protection of intellectual property rights

2.3 FAO pesticide registration toolkit – a decision support system

Registration of pesticides is the process whereby the responsible national government or regional authority approves the sale and use of a pesticide following the evaluation of scientific data demonstrating that the product is effective for its intended purposes and does not pose an unacceptable risk to human or animal health or to the environment. The website "FAO pesticide registration toolkit"[13] serves as a decision support system for evaluators and decision-makers. The system is based on the "Code of conduct on pesticide management" and "FAO/WHO guidelines for the registration of pesticides". The toolkit contains technical advice on various processes and methods for pesticide registration, such as guidelines on pesticide legislation, data requirements, assessment methods for parts of the registration dossier, decision-making steps, etc. These are general methods and procedures applicable to all pesticides. The toolkit provides examples and support for different pesticide registration strategies where the strategy can range from basic to comprehensive.

2.4 Characteristics of Highly Hazardous Pesticides

The use of highly hazardous pesticides is still a serious concern in many parts of the world. The FAO and the WHO have created a definition of HHP that is described in the International Code of Conduct on Pesticide Management. The description is summarised as follows:

> "Pesticides that are acknowledged to present particularly high levels of acute or chronic hazards to health or environment according to internationally accepted classification systems such as the World Health Organisation (WHO) or the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) or their listing in relevant binding international agreements or conventions. In addition, pesticides that appear to cause severe or irreversible harm to health or the environment under conditions of use in a country may be considered to be and treated as highly hazardous".
>
> (International Code of Conduct, 2013)

[13] FAO. (2019). *The Pesticide Registration Toolkit.* Retrieved 10 November, 2019 from: http://www.fao.org/pesticide-registration-toolkit/en/

Criteria on HHPs according to FAO guidelines[14]

Highly hazardous pesticides should be defined as having one or more of the following characteristics:

Criterion 1: Pesticide formulations that meet the criteria of classes Ia or Ib of the WHO Recommended Classification of Pesticides by Hazard.

Criterion 2: Pesticide active ingredients and their formulations that meet the criteria of carcinogenicity Categories 1A and 1B of the GHS.

Criterion 3: Pesticide active ingredients and their formulations that meet the criteria of mutagenicity Categories 1A and 1B of the GHS.

Criterion 4: Pesticide active ingredients and their formulations that meet the criteria of reproductive toxicity Categories 1A and 1B of the GHS.

Criterion 5: Pesticide active ingredients listed by the Stockholm Convention in its Annexes A and B, and those meeting all the criteria in paragraph 1 of Annex D of the Convention; or

Criterion 6: Pesticide active ingredients and formulations listed by the Rotterdam Convention in its Annex III.

Criterion 7: Pesticides listed under the Montreal Protocol.

Criterion 8: Pesticide active ingredients and formulations that have shown a high incidence of severe or irreversible adverse effects on human health or the environment.

The Code also establishes the following regarding HHPs:

> "Prohibition of the importation, distribution, sale and purchase of highly hazardous pesticides may be considered if, based on risk assessment, risk mitigation measures or good marketing practises are insufficient to ensure that the product can be handled without unacceptable risk to humans and the environment."

3 Information on pesticides generated within the EU

This chapter contains information on what data are generated within the EU registration schemes and how such data can be accessed. The two regulations that lay down the principles and establish the requirements for placing pesticide products on the EU market are the Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market[15] and the Regulation (EU) No 528/2012 concerning the making available on the market[16] and use of biocidal products. In addition to the regulations, a number of guidance

[14] FAO. (2019). *International Code of Conduct on Pesticide Management. Guidelines on Highly Hazardous Pesticides.* Retrieved 10 November, 2019 from: http://www.fao.org/publications/card/en/c/a5347a39-c961-41bf-86a4-975cdf2fd063/

[15] EUR-Lex. (2019). *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* Retrieved 12 November, 2019 from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02009R1107-20181110

[16] EUR-Lex. (2019). *Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products* Retrieved 12 November, 2019 from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02012R0528-20140425&from=EN

documents have been developed both for use by the applicants and by the competent authorities. A harmonised classification should be performed and decided on for all active substances in pesticides according to the Classification, Labelling and Packaging Regulation (EC) No 1272/2008), which is based on the United Nations' Globally Harmonised System for classification and labelling of chemicals (GHS).

Available information on hazard and risk from other sources, such as authorities in other countries, may be used, either to trigger applicants to submit relevant data themselves or to use the data as a basis for risk-management decisions, depending on the allowances of your legislation. More specific risk assessments taking local conditions into consideration may be performed based on hazard and risk assessments conducted elsewhere in addition to any other information available in your country including local exposure data. Reviewed data and risk assessments made in accordance with established guidance and legal frameworks in other countries serve as a good starting point for countries with an aim to improve the control of the trade and use of pesticides and which do not yet have a robust regulatory system in place as described in chapter 6.

3.1.1 Information generated within the EU pesticide registration schemes

In order to be able to understand how information is generated within the different registration schemes for plant protection and biocidal products within the EU and how this information has been assessed, a short description of the procedure is provided. The EU Directorate-General for Health and Food Safety (DG SANTE) is responsible for the EU policy on food safety and health and for monitoring the implementation of related laws, which includes the work on plant protection products and biocides.

A plant protection product or a biocidal product usually contains more than one chemical component. The active component against pests and plant diseases is called *the active substance*. The pesticide company which would like to place a pesticide product on the market is responsible for compiling all information required for the active substance and the products containing that active substance. Each active substance is evaluated for safety and efficacy by the responsible authority before it reaches the market formulated as a product. The use of the substance must be proven safe for people's health, including exposure to residues of the substance in food, and to cause no unacceptable effects on animal health or the environment. The efficacy of the active substance should also be demonstrated in at least one representative product.

The assessment of the active substance is made within the EU in cooperation between the Member States, while the product assessment is performed in the country in which the product is going to be sold and used. Two EU agencies, the EFSA and the ECHA, play a key role in such assessments. They take part in the work on the review of the application for the active substance approval and put forward a proposal for decision to the EC. The decision is then taken together with the Member States. The EC takes the decision with support of a committee (The Standing Committee) consisting of representatives from the Member States.

An evaluating competent authority is appointed to assess the application for approval of the active substance. This work is organised in programmes, and the responsibility for the assessments is divided between the different Member States. The reason for this stepwise procedure is that the major part of the data produced by the pesticide companies is for the active substance, which makes the evaluation suitable for work sharing. The application for approval of products is accompanied by less data while taking local conditions (mainly exposure data) and product-specific properties into consideration. Although the decision on

product approval is made by each Member State, there are mechanisms intended to facilitate the placing of the products on the market such as mutual recognition of decisions between Member States. For biocidal products, some types of products can be granted an approval by the EC that is valid throughout the EU.

A database[17] of approved and non-approved active substances in plant protection products can be found on the EU Directorate-General for Health and Food Safety website. The database contains, among other things, information on approval status, residues, some toxicological information, and information on the classification and labelling of the active substance. Similar information on active substances in biocidal products can be found on the ECHA website where a list of approved active substances and corresponding background documents is available. The ECHA also hosts a list[18] of harmonised hazard classification and labelling of substances in which certain active substances can be found.

Because this guidance is referring to data and reports based on the outcome and results from the EU review programmes of active substances for plant protection and biocidal products, it may be read in conjunction with the documents on how to access EU information[19]. In Chapter 5, several general checklists are provided that refer to various documents and describe how they can be used for national and regional risk management and risk assessments. One checklist refers to the recommendations regarding highly hazardous pesticides found in the FAO and the WHO "Code of conduct on pesticide management". More detailed advice and tools are found in the Pesticide Registration Toolkit on the FAO website.

3.1.2 Plant Protection Products

As mentioned previously, the placing on the market of plant protection products in the EU is divided into two steps – the assessment and approval of the active substance is made on the EU level, and the authorisation of the products is made on the national level. The procedure is laid down in the legislation for plant protection products as well as in different types of guidance documents as illustrated in Figure 1. The different background documents that are generated by this process and that serve as the basis for the management of pesticides within the EU are found in Table 1.

3.1.2.1 Approval of active substances

A plant protection product usually contains more than one component, including one or several active substances along with one or several co-formulants. The EC takes a decision on approval or non-approval based on the evaluation by the Member States and the conclusions of the EFSA. Every active substance is evaluated for safety and efficacy before it reaches the market in a product. This evaluation consists of an assessment of the risk to humans, animals, and the environment and includes an assessment of the residues in food. The assessment is conducted for a representative product containing the active substance.

[17] Directorate-General Health and Food Safety. (2016). *EU - Pesticides database* Retrieved 12 November, 2019 from: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN
[18] European Chemicals Agency. (2019). *C&L Inventory* Retrieved 12 November, 2019 from: https://echa.europa.eu/information-on-chemicals/cl-inventory-database
[19] Swedish Chemicals Agency. (2017). *Practical guidance on how to access information from the EU pesticide registration process.* Retrieved on 29 October, 2019 from: https://www.kemi.se/en/global/guidance-documents/guidance-document-eu-pesticide-registration-process.pdf

3.1.2.2 Authorisation of a plant protection product

After approval of the active substance on the EU level, the product itself needs to be authorised in the Member State where it is going to be placed on the market or used. The risk assessment that was conducted for the approval of the active substance might not be entirely relevant for the product that is going to be authorised, and each application for a product authorisation contains a specific risk assessment taking the relevant crop, target organism, and local conditions into consideration.

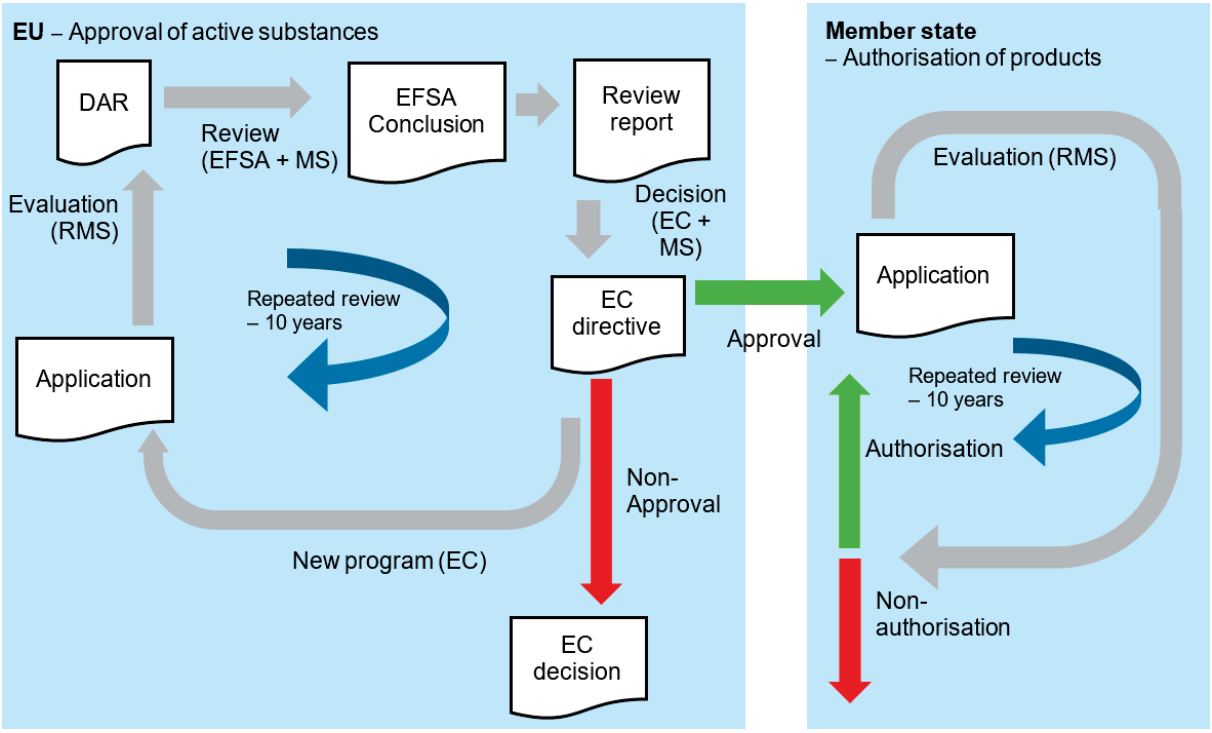
The Commission regulation (EU) No 546/2011[20] or the so-called "Uniform principles for evaluation and authorisation of plant protection products" states what is required in order to place a product on the market. Industry needs to provide the data for the following areas that will be assessed by the authorities:

- Phytotoxicity and efficacy
- Effects on plants or plant products
- Impact on target vertebrate species
- Impact on human or animal health
- Impact on human or animal health arising from the plant protection product
- Impact on human or animal health arising from residues
- Effects on the environment
- Fate and distribution in the environment
- Impact on non-target species
- Analytical methods
- Physical and chemical properties

The product assessment serves as a basis for the decision on whether to authorise, authorise with restrictions, or not authorise a product. Further guidance for decision-making is found in Chapter 6. Please note that this guidance document is only dealing with advice related to the impact on human and animal health and the environment.

[20] EUR-Lex. (2020). *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.* Retrieved 21 February, 2020 from: https://eur-lex.europa.eu/eli/reg/2011/546/oj/eng

Figure 1. The procedure for approval/non-approval of active substances in plant protection products within the European Union. The Rapporteur Member State (RMS) develops a draft assessment report (DAR) based on an application from the company. This is peer reviewed by the EFSA and other Member States (MS), and the conclusions serve as a basis for a decision by the European Commission (EC). The authorisation of a plant protection product in a Member State is based on the conclusions and provisions of such approval of the active substance. A new programme is initiated for a review of the decisions for active substances after approximately 10 years.



3.1.3 Biocidal products

The process for placing of biocidal products on the market in the EU is very similar to the process for plant protection products, i.e. the assessment and approval of the active substance is made on the EU level and then the products are authorised either on the national level or the EU level. The procedures for this process are laid down in the legislation for biocidal products as well as in different types of guidance documents and are partly illustrated in Figure 2. For a more detailed description of the different documents generated within the process, see Table 2.

3.1.3.1 Approval of active substances

Active substances need to be assessed and approved before they can be used in biocidal products in the EU. The assessment is done by an evaluating competent authority in an EU Member State and is followed by a peer review involving all EU countries coordinated by the ECHA. On the basis of the conclusions of this assessment, the Commission decides whether or not to approve the active substance in biocidal products through a vote of the Standing Committee on Biocidal Products. Where necessary to protect human health, animal health, or the environment, an approval may contain certain conditions to ensure that the risks identified are properly addressed. The conditions of the approval are found in the implementing regulation of the active substance, and the conclusions of the risk assessment are found in the assessment report. The active substance shall also be demonstrated to be efficacious in at least one representative product.

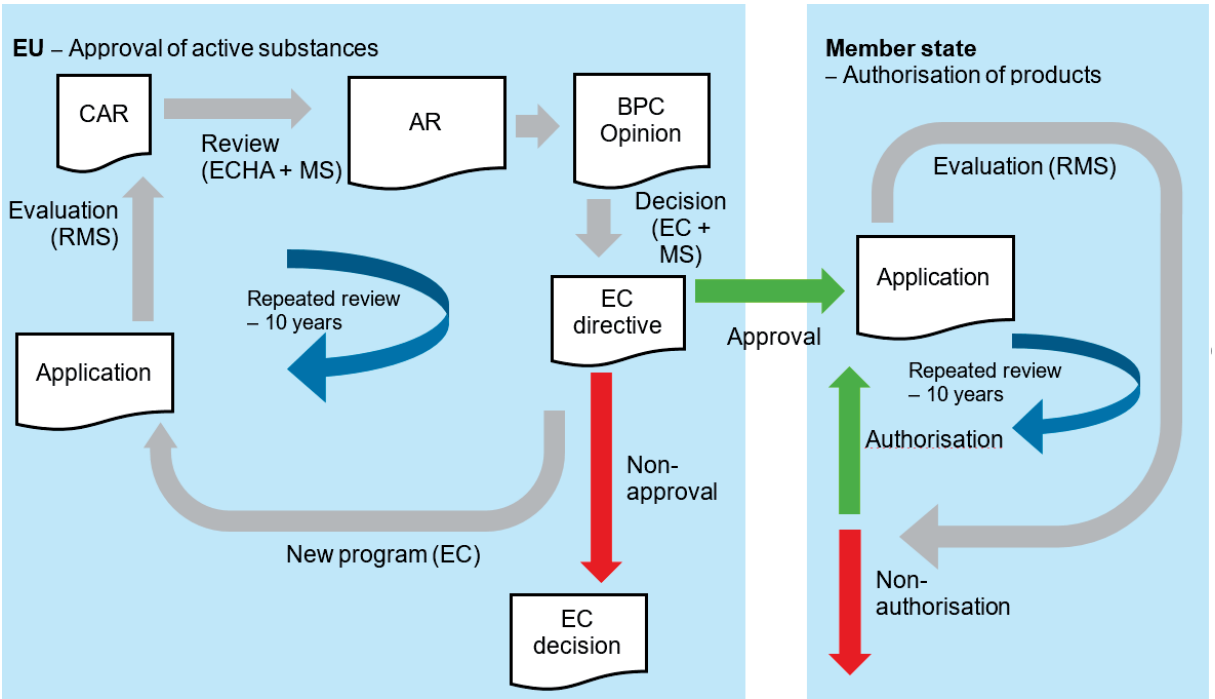
3.1.3.2 Authorisation of biocidal products

The EU "Regulation on biocidal products" requires all biocidal products to be authorised by the appropriate authority before they are placed on the market. Authorities can only authorise products if they have carried out an evaluation that shows that the use of the product is safe for human and animal health and the environment. The product must also be effective for its intended use(s). The "Regulation on biocidal products" sets out the different areas that need to be addressed before the product can be placed on the market. The Regulation also stipulates the data that companies need to provide to support the risk assessment.

The risk assessment shall determine:

- the hazards due to the physico-chemical properties of the product.
- the risk to humans and animals, including effects on target organisms and non-target organisms.
- the risk to the environment – including water, soil, and air – and the measures necessary to protect humans, animals, and the environment during the proposed normal use of the biocidal product and in a realistic worst-case situation.
- efficacy.

Figure 2. The procedure for approval or non-approval of active substances in biocidal products within the EU. The evaluating competent authority evaluates the dossier accompanying the application from the company and produces a competent authority report (CAR). An assessment report (AR) is developed after peer review by the Member States (MS) and ECHA, and approval by the biocidal product committee (BPC). The BPC delivers an opinion on which the European Commission (COM) can base a decision for approval or non-approval. The authorisation of a biocidal product in a Member State (MS) is based on the conclusions and provisions of such approval of the active substance. A new programme is initiated for a review of the decisions for active substances after approximately 10 years.



3.2 Documents generated within the EU pesticide registration schemes

The different documents that play a key role for the development of the decision for approval or non-approval of an active substance are listed in Table 1 and 2. The table describes the scope, content, and owner of the information generated during the EU review process for active substances in plant protection and biocidal products. These documents will be referred to in Chapter 5, which provides recommendations on how to use available information for the assessment of the active substance in pesticide products.

Table 1. Different types of documents generated within the EU programmes for plant protection products

Type of document	Responsible	Content/scope
Application	Applicant	The formal application including data/studies and a risk assessment (the dossier) to support the conclusion that the product or active substance is efficacious and can be used without causing any risk to human or animal health or the environment.
Draft assessment report	Rapporteur Member State	An evaluation, not peer-reviewed, presented as: 1) A hazard assessment of the active substance evaluating the following: - Identity and physical/chemical properties. - Classification and proposed labelling. - Fate and behaviour in the environment. - Ecotoxicology. - Mammalian toxicology. - Residues and analytical methods. - Efficacy. 2) A risk assessment for one product with one or several intended uses.
EFSA conclusion report	EFSA	Conclusion on the peer review of the active substance, the representative product, and its intended use(s) and the “List of end points” (established reference values) that should be used when carrying out risk assessments for products at the Member State level.
Review report	EC	A summary of the evaluation process that serves as a background for the decision on approval/non-approval of the active substance and contains the following: - data submitter - reference values (human health) - particular conditions to be taken into account by Member States in relation to the granting of authorisations of plant protection products - list of studies to be generated - list of supported uses For active substances without an EFSA conclusion, the review report also includes the “List of end points”.
Directive /Implementing Regulation	EC	Legal document for approved active substances. Contains e.g. - required purity - specific provisions - confirmatory data (for plant protection products)
Decision	EC	Legal document for non-approved active substances. Contains details about grace periods for withdrawal of products from the EU market.

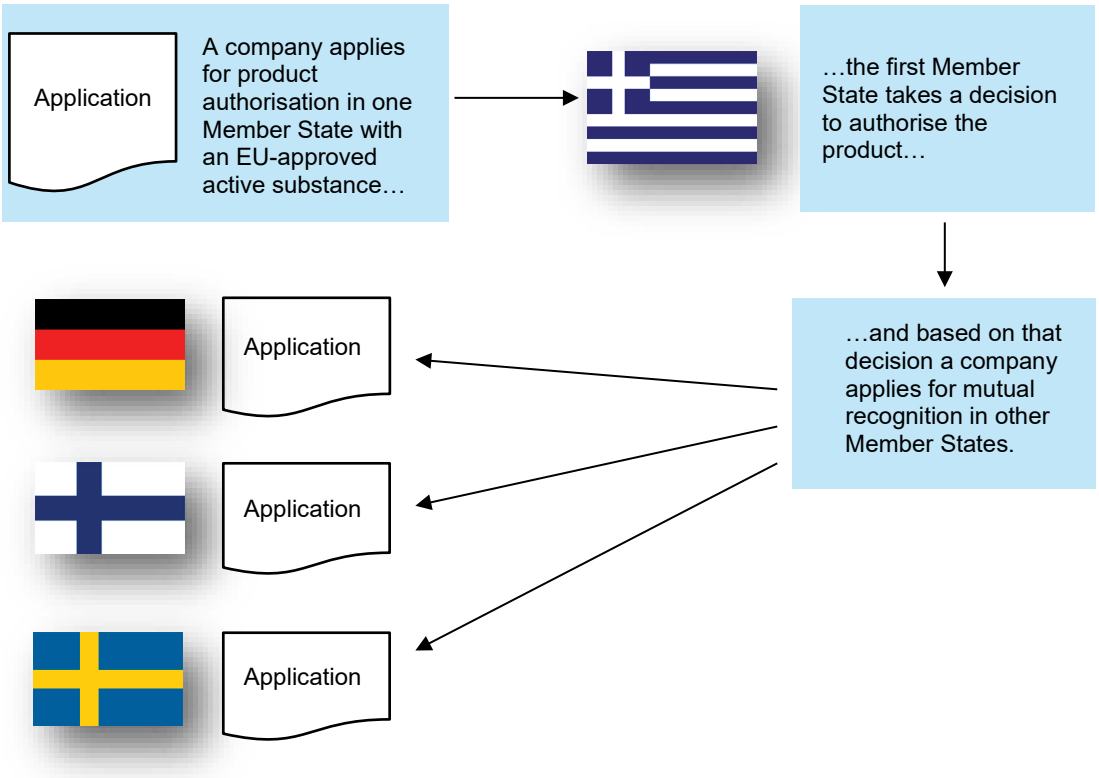
Table 2. Different types of documents generated within the EU programmes for biocidal products

Type of document	Responsible	Content/scope
Application	Applicant	The formal application including data/studies and a risk assessment (the dossier) to support the conclusion that the product or active substance is efficacious and can be used without causing any risk to human or animal health or to the environment.
Competent authority report	Evaluating competent authority	Study summary corresponding to the scientific areas listed above. The study summary includes a list of all studies used for the approval of the active substance, the risk assessment, and the conclusions drawn by both the applicant and the evaluating competent authority.
BPC opinion	ECHA	The opinion is based on the (draft) assessment report submitted by the rapporteur member state and relevant comments provided by other Member States and the applicant. The opinion serves as a basis for the decision on approval for an active substance, which is adopted by the European Commission and reflects the BPC agreements. In case confirmatory data are needed, this is stated in the BPC Opinion.
Assessment report	EC	A summary of the evaluation process and the overall conclusions. The aim of the assessment report is to support the opinion of the BPC and their decision on the approval and to facilitate the authorisation of individual biocidal products. It contains the “List of end points”.
Directive /Implementing Regulation	EC	Legal document for approved active substances. Contains, for example, the required purity and specific provisions for handling and use of a product containing the active substance.
Decision	EC	Legal document for non-approved active substances. Contains details about grace periods for withdrawal of products from the EU market.

3.3 Work-sharing

Due to the very extensive workload of the authorities that are responsible for the registration of pesticides before they can be sold and used, and in order to ensure harmonisation between countries, the EU legislation promotes the possibility to placing products on the market by mutual recognition of decisions for product authorisation. After approval of the active substance within the EU, industry applies for product authorisation in one Member State and may then, based on that first decision, apply for product authorisation in other Member States within the EU. One prerequisite that needs to be fulfilled when this procedure is followed is that the conditions of use and/or the agricultural practice are the same in the countries. For biocides, aspects such as public security or the protection of national treasures in a certain country may also be considered and allow for refusal or adjustment of the terms and conditions of the authorisation. For plant protection products, the EU Member States are divided into three geographical zones with the intention to facilitate work sharing and the mutual recognition of product authorisations.

Figure 3. After EU approval of an active substance, a company that wishes to place a product containing that active substance on the market can apply for a product authorisation in one Member State. The decision for authorisation in that Member State can then serve as a basis for the application and authorisation in the other Member States in which the company wishes to place the same product on the market.



Another way to decrease the workload in the EU is the establishment of simplified procedures for certain products that are considered to be of low risk to humans, animals, and the environment such as certain pheromones, substances used as food additives, or traditionally used substances of natural origin like lavender oil.

3.4 Information generated within the EU classification and labelling scheme

The EU Classification, Labelling and Packaging regulation[21] is based on the GHS. The regulation ensures that the hazards presented by substances and mixtures are clearly communicated to workers and consumers through classification and the use of pictograms and hazard statements on labels and via safety data sheets (to professional users). The Annex VI to the regulation contains a list of over 4,500 substances with EU-harmonised and legally binding classifications. These substances are also included in the classification and labelling inventory, a publically available database managed by the ECHA.

For hazards of highest concern (carcinogenicity, mutagenicity, reproductive toxicity and respiratory sensitisers) and for other effects on a case-by-case basis, classification and labelling will be harmonised throughout the EU to ensure adequate risk management. A

[21] EUR-Lex. (2019). *Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.* Retrieved 14 November, 2019 from https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32008R1272

proposal for harmonised classification is submitted to the ECHA by the Member States, the producers, the importers, or the "downstream users". Downstream users are defined as companies or individuals that use a substance, either on its own or in a mixture in their industrial or professional activities. In the case of plant protection products and biocides, the Rapporteur Member State shall submit such proposals.

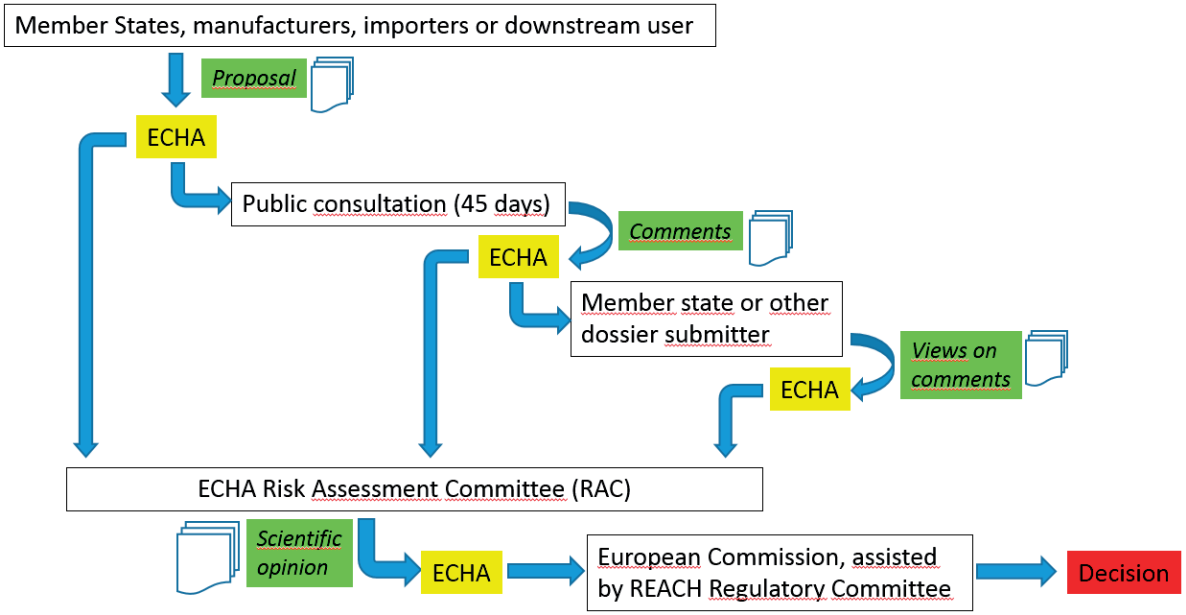
The harmonised classification report (dossier) includes information on

- producer of the substance
- uses of the substance
- hazardous properties
- justification for action at the EU level.

The report must contain sufficient information to enable an independent assessment of various physical, health, and environmental hazards.

The ECHA organises a public consultation with a commenting period of 45 days and forwards all comments received to the dossier submitter. The dossier submitter subsequently provides their view on the comments. The proposal, the comments, and the views of the dossier submitter are forwarded to the ECHA's Risk Assessment Committee (RAC) comprised of experts from the Member States. The RAC will issue a scientific opinion on the proposal, which is forwarded to the European Commission by the ECHA. The Commission, assisted by the REACH Regulatory Committee involving experts from the Member States, decides on the harmonised classification and labelling of the substance concerned.

Figure 4. The procedure of the ECHA and the EC following the submission of a proposal for harmonised classification and labelling.



3.5 Documents generated within the EU classification and labelling scheme

The different documents that play a key role for the development of a harmonised classification of an active substance are listed in Table 3, which describes the scope, content, and owner of the information generated during the EU classification and labelling process for

active substances in plant protection and biocidal products. As described in the previous section, the agreement on a harmonised classification is preceded by a robust process comprising scrutiny by a number of experts from several Member States as well as a public consultation before a decision is made. The harmonised classification in the EU can therefore serve as a basis for the assessment of whether a substance should be regarded as a highly hazardous pesticide or not. This information will be referred to in Chapter 5, which provides recommendations on how to use available information for the assessment of the active substance in pesticide products.

Table 3. Different types of documents generated within the EU programmes for the classification of pesticides

Type of document	Owner	Content/scope
Proposal	RMS (Dossier submitter of the classification report)	The harmonised classification report (dossier) includes information on - manufacture of the substance - uses of the substances - hazardous properties - justification for action at the EU level
Comments	The public	Public consultation including the dossier submitter (industry)
Views on comments	RMS (Dossier submitter of the classification report)	The RMS´s views on comments
Scientific opinion	ECHA Risk Assessment Committee (RAC)	RAC´s scientific opinion
Decision, included in Annex VI to Regulation ((EC) No 1272/2008	European Commission	Legal document on classification

4 Risk management within the EU

Risk management is defined by the WHO as a decision-making process that involves political, social, economic, and technical factors as well as a relevant risk assessment. It is recommended that risk management should be applied even without full scientific certainty for chemicals that might cause serious or irreversible damage to humans or the environment.

Risk management contributes to the protection of human and animal health and the environment from adverse effects caused by hazardous chemicals. Reduced cost for health care, more sustainable farmland, and increased trade of food and feed products that are recognised as safe are resource saving and will clearly have a positive financial impact in a country.

The use pattern of certain pesticides is of such a nature that exposure to the environment will more or less always occur, which means that risk reduction measures should be applied to the greatest extent possible.

4.1 The substitution principle and comparative assessment

Application of the substitution principle and a comparative assessment is a risk management tool applicable according to the Regulations on Plant Protection Products and Biocidal Products. This tool is applied both for active substances and for products. The substitution principle shall be applied for active substances that meet at least one of the exclusion criteria (further described in Chapter 5), but there are also a number of additional criteria that are listed in the EU regulations. Additional provisions may be cases where non-chemical control or prevention methods or other available substitutes exist that can be used instead, something that is highly recommended. Examples of such methods could be the use of special warehouses to avoid chemical post-harvest treatment or the heat treatment of bed bugs.

A comparative assessment of products shall be made before authorising a product that contains an active substance that meets the criteria for a candidate for substitution. A candidate for substitution is an active substance that fulfils the exclusion criteria but which has to be approved due to an extensive need that cannot be met by any alternative means. The purpose with the comparative assessment is either to replace hazardous active substances or products with less hazardous products (such as replacing powder formulations with wax blocks, suspensions, or ready-to-use products) or to replace the product with non-chemical control or prevention methods. Some examples on how the substitution principle has been applied in Sweden can be found in Annex 1.

4.2 Risk management for human health

Before performing a detailed risk assessment for a specific use of a pesticide, certain risk reduction measures can be worth considering as a more general way of reducing the risk to humans. When introducing such restrictions, it is of great importance that they are communicated both as part of the specific provisions of the authorisation of the product and included in the guidance for different stakeholders, particularly of the ones who will come in contact with the pesticide such as operators spraying a field or distributing bait stations with rodenticides.

4.2.1 Plant protection products

By lowering the dose rates or the number of applications, the exposure to humans can be reduced. Overuse of pesticides should be avoided and the aim should be not to apply more than what is required in order for the pesticide to be efficacious. For operators who are usually both mixing and loading and applying the plant protection product, risk reduction measures, such as the use of products that do not require mixing (like the use of seeds pre-treated with seed dressing or the use of ready-to-use packages) and appropriate personal protection equipment (like gloves, respiratory masks, and coveralls) will contribute to a reduced exposure. However, an assessment as to whether the required measures are feasible and affordable in a country or region needs to be made. For workers, the time before re-entry into a sprayed area and access to adequate personal protective equipment are other important factors that will affect the level of exposure.

Regarding bystanders, it is mostly a matter of information on when to avoid an area being sprayed or when it is acceptable to enter into a newly sprayed field. It may also be a matter of storage and handling of pesticides, like not storing the pesticide near housing areas and making sure that it does not come into contact with food or cooking facilities. The person handling exposed clothes or containers will also need to protect him or herself. The lowering

of dose rates and number of applications will also contribute to reduced amounts of residues and thereby result in a lower exposure to consumers.

4.2.2 Biocidal products

The same general principles also apply for biocidal products, although the risk mitigation measures vary quite extensively due to the wide variety of uses and types of biocidal products. It should be noted that many biocidal products, in particular those intended for the general public, are applied either without protective equipment or by using simple personal protective equipment such as gloves, etc.

However, industrial use of biocidal products or professional use in the service sectors may require specific equipment designed to minimise exposure (e.g. automated systems for wood treatment). Overdosing should be avoided and calibration of spraying equipment may be one way to reduce exposure and to ensure that the equipment is considered fit for its purpose. Certain restrictions or requirements are ensured by including specific conditions in the substance approval or in the product authorisation. If the use of appropriate dosing equipment is an important factor for the application of a biocidal product, other factors need to be considered as well in order to minimise exposure, such as the selection of the appropriate product, the weather conditions, and the level of infestation. These aspects also play a crucial role in minimising the risk for resistance and demonstrate the relevance and importance of making proper and specific use instructions available for the users of biocidal products.

4.3 Risk management for the environment

4.3.1 Plant protection products

Generally, the exposure of the environment can be reduced by lower dose rates, reduced numbers of applications, or application only using seed-dressing methods. The risk for contaminating groundwater can be lowered by different risk-reduction methods such as prohibition of application in areas used for abstraction of drinking water, application every third year (linked to rotation of certain crops), lowering dose rates, or restrictions to special seasons like autumn or spring spraying. Spray-free zones to protect surface water and terrestrial ecosystems and prohibition of spraying in flowering crops, or at times when bees are active, are examples of reducing risks to bees.

4.3.2 Biocidal products

Some of the risk-mitigation measures applied to minimise the direct exposure to humans may also be applicable in order to minimise exposure to the environment. Others may be more specific such as disposal of dead rodents exterminated by a rodenticide in order to minimise secondary poisoning of predators or avoiding the placing of bait stations near water drainage systems where they can come into contact with water. Other examples are specific instructions for storage of wood treated with a preservative in order to avoid leakage into the soil or water or specific use instructions for antifouling paints to reduce the leakage of active substances from boat hulls into the ocean. The use of bait stations for insecticides used to control certain ants in or around buildings is a way to limit the exposure of the biocide to non-target organisms.

5 Recommendations on how to identify highly hazardous pesticides

Highly hazardous pesticides are usually considered to be the most problematic pesticides and it is therefore recommended that an authority that wishes to decrease the risk to human health and the environment start by identifying them. This can be done with support from existing data, primarily data already available within your authority or in your country. Information generated within different approval schemes and information regarding classification and labelling in other countries could add valuable information, especially if data is scarce in your own country.

The aim of the recommendations below is to guide assessors on how reviewed data, generated within the EU system, can be used as an additional source besides the information you already have and information that could be found in international conventions and in literature. As described previously in this document, data (primarily animal studies) and risk assessments within the EU are generated on two levels, first for scrutiny of the active substance on the EU level, and then, for approved active substances, on the national level for the pesticide product. Because the study package is much more extensive for the active substance than for a single product, it is recommended that the assessment for the active substance is used to support the identification, prioritisation, and possibly some regulatory action of the most highly hazardous pesticides. These active substance assessments are also easily accessible in the EU databases, and may be relevant to consider, as long as the formulation type and the use and exposure of the product to be assessed is taken into consideration.

The Plant Protection Products Regulation and the Biocidal Products Regulation introduce formal exclusion criteria that apply to the evaluation of active substances. This means that an active substance meeting the exclusion criteria should, in principle, not be approved. These criteria are very similar to the FAO/WHO criteria for HHPs. The purpose of the exclusion criteria is to ensure a high level of protection of both human and animal health and the environment while making decisions on the approval or non-approval of active substances.

The exclusion criteria relate to the intrinsic hazardous properties according to the EU Regulation on Classification and Labelling and include but are not limited to the following:

- Carcinogens Cat. 1A or 1B
- Mutagens Cat. 1A or 1B
- Toxic for reproduction Cat. 1A or 1B
- Endocrine disrupting properties

- Persistent, bioaccumulative, and toxic (PBT)
- Very persistent and very bioaccumulative (vPvB)
- Fulfilling POP (persistent organic pollutant) criteria

5.1 Identification of highly hazardous pesticides based on available data

The criteria for HHPs refer both to the active substance and to the pesticide product. The product-related criteria are based on the intrinsic properties of the active substance and its concentration in a product. A certain concentration of a classified active substance in accordance with WHO[22] or GHS may lead to the classification of a product as highly hazardous. The criteria of relevance for the active substance mainly refer to listing of substances within certain conventions. The last HHP criterion, criterion 8 (see section 2.4 above), is used for active ingredients or pesticide formulations that may be problematic for other reasons than those mentioned above, e.g. other irreversible adverse effects on human health or the environment.

5.1.1 Checklist for pesticides fulfilling HHP criteria

The aim of the checklist in Table 4 is to present a stepwise approach to identifying and handling HHPs in your country. The checklist is based on the action plan suggested by the FAO in the guidelines on HHPs [23] (column 1) with some further recommendations on how to handle HHPs. The criteria refer both to the properties of the active substance and to the properties of the product.

The FAO toolkit contains a spreadsheet tool that can be used to document the HHP identification process. This can be done for individual pesticides or for lists of registered pesticides. A practical step to facilitate the identification of HHPs is to organise the products according to active substances before placing the data in the spreadsheet available in the FAO toolkit.

Table 4. Checklist on how to identify and handle highly hazardous pesticides

1) Issue according to the FAO action plan	2) Action	3) Comments
1) Identify the products registered on the market	List the current products registered in your country by using the Excel spreadsheet available in the FAO toolkit.	Also list when possible the use and crops for which the products are registered in the table. This information is useful when searching for alternatives in step 4.
2) Identify which registered pesticides are considered to be HHPs	Check criteria 1–4 against information available in your own country and in, for example, the ECHA Classification & Labelling	EU assessments for active substances can be of use when checking criterion 8.

[22] WHO. (2019). *The WHO Recommended Classification of Pesticides by Hazard.* Retrieved 18 December, 2019 from: https://www.who.int/ipcs/publications/pesticides_hazard/en/

[23] FAO. (2019). *International Code of Conduct on Pesticide Management Guidelines on Highly Hazardous Pesticides.* Retrieved 14 November, 2019 from: http://www.fao.org/publications/card/en/c/a5347a39-c961-41bf-86a4-975cdf2fd063/

1) Issue according to the FAO action plan	2) Action	3) Comments
	inventory[24] and the European databases on plant protection products and biocidal products for identifying active substances classified for CMR cat. 1a and 1b and acute toxicity. Substances fulfilling criteria 5–7 may be found on the Rotterdam and Stockholm convention and Montreal protocol websites[25]. Also check the EU Regulation concerning the export and import of hazardous chemicals[26]. Criterion 8 has to be checked nationally by consulting national poison control centres, hospitals, reports from institutions and universities, and EU risk assessments and/or by performing risk assessments for the actual use of the product.	
3) Take stock of the current uses of the HHPs and the reasons for their use	Collect information through consultations and interviews with other stakeholders such as user organisations.	
4) Determine to what extent the use of the HHP is actually needed (taking into account the availability of possible alternatives ideally listed in the same table)	Consult the guidance document on substitutions for plant protection products[27] and biocidal products[28], which outlines some principles on how to perform a comparative assessment between products. Collect information through consultations, interviews, and by sharing information with other relevant countries. Consult available efficacy trials that are performed in your country/region.	

[24] ECHA. (2019). *C&L Inventory.* Retrieved 18 December, 2019 from: https://echa.europa.eu/regulations/clp/cl-inventory

[25] UN ENVIRONMENT. (2019). *The Montreal Protocol.* Retrieved 14 November, 2019 from: https://www.unenvironment.org/ozonaction/who-we-are/about-montreal-protocol

[26] ECHA. (2019). *REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning the export and import of hazardous chemicals.* Retrieved 14 November, 2019 from: https://echa.europa.eu/regulations/prior-informed-consent/legislation

[27] European Commission. (2014). *Draft Guidance document on Comparative Assessment and Substitution of Plant Protection Products in accordance with Regulation (EC) No 1107/2009.* Retrieved 14 November, 2019, from:https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_aas_guidance_comparative_assessment_substitution_rev_1107-2009.pdf

[28] European Commission. (2014). *Comparative assessment for biocidal products.* Retrieved 14 November, 2019 from: https://circabc.europa.eu/sd/a/d309607f-f75b-46e7-acc4-1653cadcaf7e/CA-March14-Doc.5.4%20-%20Final%20-%20comparative_assmt_consolidated_version.doc

1) Issue according to the FAO action plan	2) Action	3) Comments
5) Investigate whether alternative products or methods are available	Check whether there are less hazardous products registered for the same use. Collect information through consultations and interviews with other stakeholders such as user organisations. If alternatives are available and the use of the product is going to be phased out, either by banning the active substance or by not granting an approval, phase out periods may be necessary. If no alternatives are available, determine the risks of the use of the products taking into account the actual conditions of use.	
6) Select and implement mitigating measures based on the risk assessment and depending on the different provisions as described in chapter 4.	If approving a product that eventually is going to be phased out, restrict the use and the time for the approval as much as possible while gathering experience from the use of better alternatives. Monitor and review the effectiveness of the mitigation measures.	Consider general risk mitigation measures as exemplified in Chapter 6; see also checklists below on health and environmental risk assessment and management.
7) Identify/encourage the development of better alternatives	Work together with different stakeholders to find/develop better alternatives. Set up task force groups.	Make sure that the task force groups contain members representing different sides of trading and handling and use of pesticides.
8) Promote less hazardous alternatives	Promote the less hazardous alternatives and phase out the HHPs when viable alternatives are in place.	Allow for relevant time periods to ensure the effectiveness of the less hazardous alternatives.

5.2 The applicability of an EU risk assessment for a country outside the EU

This section gives a brief description on how to check the approval status of an active substance in the EU and the background for that decision. This can be used to check if the active substance fulfils the HHP criteria. Moreover, there will be some guidance on whether there are any relevant impurities that need to be considered in the assessment and how to handle the situation when the same active substance may come from different manufacturing sources. If the risk management methods used in the EU are relevant there is also some advise on how to make use of this information when taking a decision according to provisions on regulating pesticides in your country, as further discussed in chapter 6.

5.2.1 Active substance approval in the EU

When assessing whether the active substance can be approved or not in the EU, the applicant needs to demonstrate that the risk of the active substance is acceptable during normal handling and use of a representative product containing that substance. Non-approval or restrictions of an active substance can also be based solely on the intrinsic properties of the active substance, should it fulfil the defined exclusion criteria. However, if the exposure is considered negligible the substance may be approved for restricted use(s) even when fulfilling the exclusion criteria. In addition, biocidal active substances fulfilling the exclusion criteria may also be approved in cases where not approving the substance would lead to serious danger to human or animal health or the environment or where the negative impact on society would be considered disproportionate. The approach below gives recommendations on where to find and how to use data on approval/non-approval generated within the EU. If the active substance is not approved, the reasons behind the non-approval should be scrutinised. Such refusal might be due to unacceptable risks, to lack of data, or to the fact that no application for approval was actually submitted.

5.2.2 Active substances fulfilling the HHP criteria

In addition to the scrutiny of the basis for the EU decision, it is recommended to check whether the active substance fulfils the HHP criteria. Section 5.1.1 contains a checklist for identifying and handling HHPs in a country with the intention of restricting or removing them from the market.

5.2.3 The manufacturing source of an active substance

Within the EU there is a requirement for the applicant to submit data on the specification of the active substance, such as data regarding the identity of any impurities and/or additives, including by-products of synthesis, the isomeric composition, and the method of manufacture and the manufacturing source. This information affects the toxicity profile of the substance and thereby the risk assessment and is included in the basis for the decision on approval or non-approval of the active substance. Companies that are going to apply for a product authorisation in an EU Member State has to be able to prove that the active substance in the product has the same specification as the active substance that is approved (the reference source), in order to be able to refer to the active substance approval. In case the manufacturing source is not the same, technical equivalence[29] has be established with the reference source. Due to confidentiality requirements, this kind of data is not very easily accessible.

5.2.4 Relevant impurities

Although information regarding the manufacturing source and the specification might not be accessible, certain data from the active substance assessment conducted within the EU can be accessed, if considered necessary. The minimum purity of the approved active substances within the EU as well as information on relevant (toxic) impurities, e.g. where the impurity renders a classification or the available information indicates that the impurity has a toxicological and/or ecotoxicological hazard, is available in the directive/implementing regulation of the active substance for plant protection products. For biocidal products this

[29] ECHA. (2018). *Guidance on the Biocidal Products Regulation, Volume V, Guidance on applications for technical equivalence, Version 2.0, July 2018.* Retrieved 15 January, 2020 from: https://echa.europa.eu/documents/10162/23036412/guidance_applications_technical_equivalence_en.pdf/18f72d37-98b6-47c8-98bb-941afeff6968

information is usually confidential. For plant protection products this information can also be found in the review report expressed as a maximum concentration of the impurity. One example of such information is found in the European Commission Implementing Regulation on the active substance 2,4-dichlorophenoxyacetic acid (2,4-D)30 and is expressed as follows:

> Purity: 960 g/kg
> Impurities: Free phenols (expressed as 2,4-DCP): not more than 3 g/kg.
> Sum of dioxins and furans (WHO-TCDD TEQ): not more than 0.01 mg/kg

Information on specifications can also be found on the FAO webpage[31] where specifications for pesticides and their related formulations are published in addition to the accompanying manual on the development and use of these specifications.

5.2.5 Guidance on how information for an active substance can be accessed and used

Despite the fact that information on the specification of the reference source is not easily accessible, it is still recommended that the EU risk assessments can be used for the purpose of screening of substances that may fulfil the HHP criteria, prioritisation and further risk management. The questions and answers in the boxes below are intended to serve as a guidance on how information for an active substance can be accessed and used. These may be consulted to check whether the EU risk assessments can be used for regulatory action in your country in combination with any other possible information that may be available.

1. Determine if the active substance is approved in the EU

- Check the EU databases whether the active substance in a plant protection product or a biocidal product is approved or not.

If the substance is approved in the EU

- Check the review reports and EFSA conclusions for a plant protection product.
- Check the ECHA website for the assessment report for the active substance and the BPC opinion for a biocidal product.

Use data and information to assess whether further restrictions are necessary in your country, see further guidance below.

If the substance is not approved in the EU

Use data and information as far as possible. Check the background for the non-approval, i.e. whether there was no application for approval, a lack of data, or if the active substance was not approved based on the outcome of the risk assessment.

Consider regulatory action if the reasons in the EU for non-approval are also relevant in your country. Information on non-approvals in other countries may also be relevant to consider.

---

[30] EUR-Lex. (2019).*COMMISSION IMPLEMENTING REGULATION (EU) 2015/2033 of 13 November 2015 renewing the approval of the active substance 2,4-D 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, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.* Retrieved 14 November, 2019 from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2015.298.01.0008.01.ENG

[31] FAO. (2020). AGP - Pesticide Specifications and Quality Control Standards page. Retrieved 22 January, 2020 from:

2. Does the active substance fulfil any of the HHP criteria?

- Check the C&L inventory on the ECHA website in addition to information checked in step 1 and information submitted as part of the application.
- Apply the criteria for HHP for the active substance.

If the active substance fulfils any of the HHP criteria

No further detailed risk assessment is necessary unless use of products containing the active substances is essential for a limited time period. The use should then be restricted as far as possible. Depending on the legal provisions in your country an end date should if possible be established, linked either to a restriction or a ban or when granting a re-approval.

An action plan should be designed that includes stakeholder involvement and a communication strategy – see checklist on HHP.

If the active substance does not fulfil any of the HHP criteria

Continue the work according to the recommendations in the boxes that follow below .

3. Is the manufacturing source of the active substance assessed within the EU the same as for the active substance in your product?

Ask the applicant if the source of the active substance in your product is the same as in the EU assessment or if there is a decision on technical equivalence within EU.

The manufacturing source is the same

The EU assessment is relevant for the active substance in your product.

- Check the EFSA conclusions (plant protection products)
- Check the ECHA website for the assessment report for the active substance (biocidal products)
- Use data and information as far as possible because the assessed dossier in the EU covers the impurities.

The manufacturing source is not the same

The EU assessment may be relevant for the active substance in your product but since the manufacturing source differs, the toxicity profile may also differ.

Consider how you can use the information in the EU assessment, for risk management purposes and/or to trigger the authorisation holder/the applicant to provide more information.

5.3 Human health risk assessment

The purpose of a risk assessment is to provide technical support for decision makers. It should be recognised that a risk assessment deals with probabilities and always includes elements of uncertainty. Pesticides should only be registered/approved for use in a country when it has been demonstrated that they are not expected to have any harmful effects on human health under the local conditions of use. This is assessed by making risk assessments in which the exposure is compared with a reference value such as the acceptable (operator) exposure level (AOEL/AEL) [32]. If the exposure is higher than the AOEL/AEL, the pesticide is assessed to have a harmful effect on human health under that local use. AOEL/AEL values established by competent authorities can be found for many pesticides, e.g. in the EU databases. The AOEL/AEL is based on data for different endpoints (mainly from animal studies) that are

[32] EUROPEAN COMMISSION. (2017). *Guidance on the assessment of the exposure of operators, workers, residents and bystanders in risk assessments for plant protection products SANTE-10832-2015 rev. 1.7.* Retrieved 18 December, 2019 from: https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_tox_accpt-exp-levs-2015.pdf

submitted by industry. The AOEL/AEL is derived by dividing an adequate *No-Observed-Adverse-Effect-Level* (NOAEL) in an animal study by an assessment factor, usually 100. For certain types of application of the pesticide, the exposure can be calculated by using models. For further information on the basic principles of a risk assessment, please see the KemI introductory guidance on hazard and risk assessment[33].

5.3.1 Plant protection products

Guidance documents on the establishment of the AOEL and the assessment of exposure to operators, workers, residents, and bystanders for plant protection products can be found on the EFSA website along with an Excel calculator[34] for the exposure calculation. The exposure scenarios in the calculator are descriptions of the situations where exposure to the pesticides may occur and typically include:

- the type of application equipment used
- the pesticide formulation
- the application rate
- the work rate
- the level of personal protection.

The EFSA conclusions contain a table of representative uses that have been evaluated for a specific active substance. From this table, information on the type of crop, type of application, application equipment, and application rate can be extracted.

Human health effects in pesticide applicators (operators) or agricultural workers may occur both during and after use of the pesticides (risk following occupational exposure). However, human health effects may also occur in the general public after consumption of food or drinking water that has been exposed to pesticides (risk following dietary exposure) or when persons have been present close to pesticide applications (risk following bystander exposure).

Operators are persons who are involved in activities related to the application of a pesticide, such as mixing/loading the product into the application equipment, operation of the sprayer, and emptying or cleaning the sprayer and containers after use. Operators may be either professionals (e.g. farmers, contract applicators, commercial pest control operators, or government staff involved in vector control) or amateur users (e.g. home garden users).

Operators in agriculture will generally mostly be exposed to pesticides through contact with the spray cloud (via dermal or inhalation routes) or indirectly through contact with pesticide deposits (dermal). Operator exposures that are likely to occur under the proposed conditions of use should not have an adverse effect on persons using the pesticide.

An operator risk assessment should in principle be conducted for all pesticides and all proposed uses, unless it can be convincingly shown that operator exposure will be negligible. Such a risk assessment should take into account parameters like the dose, application method and frequency, climatic conditions, and personal protective equipment. The same applies for persons who are considered to be agricultural workers. Exposure of workers must be estimated for activities that involve contact with treated crops. Such contact may occur when

[33]Swedish Chemicals Agency, Guidance on *Hazard assessment and risk assessment – an introduction* (to be published)

[34] EFSA. (2015). *Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products.* Excel calculator to be found under supporting information. Retrieved 14 January, 2020 from: https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2014.3874

workers re-enter treated areas after the application of a plant protection product (e.g. for crop inspection, irrigation, or harvesting activities). In addition, worker exposure can arise from other activities such as sorting, bundling, and packaging crops treated with pesticides. For further guidance on how to access information on risk assessment for human health, please see the *Practical guidance on how to access information from the EU Pesticide Registration Process*.[35] General guidance on how to perform risk assessments at different resource levels is given in the FAO toolkit.

The questions and answers in the boxes below are intended to serve as a guidance on how information on risk to human health from an EU assessment for an active substance can be accessed and used.

1. Is the use of your product covered by the EU assessment?

Check the GAP (Good Agriculture Practice) in the dossier for the product in question to find out how the product is used. Check the summary of represented uses evaluated in the EU assessment. In case no GAP is available, efficacy trials may be used to get similar information.

If yes

Use data and information in the EFSA conclusions in addition to data available in your country. In the conclusions, a summary on the assessment of human health can be found, describing how the overall conclusions have been reached.

Examine the impact on human and animal health by checking the summary of the toxicokinetics, the toxicity, medical data, established limit values, dermal exposure, and exposure scenarios. Also check the section containing critical areas of concern for the assessed uses to see whether it is relevant for your product.

Default values on dermal absorption may have to be used unless data have been submitted in the dossier for your product or if the product is the same as in the EU assessment.

If no

Use toxicity data and established limit values if considered relevant. Default values on dermal absorption should be used unless data have been submitted in the dossier for your product. The EFSA exposure model for calculating the exposure of operators, workers, residents, and bystanders may be considered for the exposure assessment.

2. Are the risk mitigation measures relevant for your country/region?

Check the GAP (Good Agriculture Practice) in the dossier for the product in question or the efficacy trials for similar information. Check the summary of represented uses evaluated in the EU assessment.

If the risk mitigation measures are relevant, you could consider using similar requirements in your decision.

5.3.2 Biocidal products

Guidance on biocide legislation can be found on the ECHA website, more specifically guidance on how to perform risk assessments for various types of use of biocidal products. This guidance provides technical advice on how to perform the hazard and exposure

[35] Swedish Chemicals Agency. (2019). *The Practical guidance on how to access information from the EU Pesticide Registration Process.* Retrieved 18 December, 2019 from: https://www.kemi.se/en/global/guidance-documents/guidance-document-eu-pesticide-registration-process.pdf

assessment and risk characterisation for biocidal active substances and products with respect to human health. The Guidance on Exposure Assessment[36] should be read together with the Biocides Human Health Exposure Methodology Document[37]. Many of the principles described above for plant protection products apply also for biocides.

The questions and answers in the boxes below are intended to serve as a guidance on how information on risk to human health from an EU assessment for an active substance can be accessed and used.

1. Is the use of your product covered by the EU assessment?

Check the database for active substances on the ECHA website to see whether the active substance is approved and for which uses.

If yes

Use the data and information in the assessment report and in the BPC opinion in addition to data available in your country. A description of the health risks can be found in the summary of the risk assessment.

Examine the impact on human and animal health by checking the toxicokinetics, the toxicity, medical data, established limit values, dermal exposure, and exposure scenarios.

Default values on dermal absorption may have to be used unless data have been submitted in the dossier for your product or if the product is the same as in the EU assessment.

If no

Use toxicity data and established limit values if considered relevant. Default values on dermal absorption should be used unless data have been submitted in the dossier for your product. The EFSA exposure model for calculating the exposure of operators, workers, residents, and bystanders may be considered for the exposure assessment.

2. Are the risk mitigation measures relevant for your country/region?

Check the ECHA website to see whether the active substance is approved and for which uses.

If the risk mitigation measures are relevant, you could consider using similar requirements in your decision.

[36] ECHA. (2019). *Guidance on the Biocidal products Regulation, Volume III Human Health – Assessment and evaluation (parts B+C).* Retrieved 18 December, 2019 from: https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation

[37] ECHA. (2019). *Biocides Human Health Exposure Methodology Document.* Retrieved 18 December, 2019 from: https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups/human-exposure

5.3.3 Interpretation of the outcome

It is reasonable to believe that the AOEL for a pesticide in principle should be the same globally. It should therefore be possible to bridge operator risk based on differences in exposure between the existing risk assessment and the situation under review.

In principle, if the occupational risk in an existing assessment was considered to be acceptable, and exposure levels in the situation under review are likely to be similar or lower, then the risk for the situation under review is also acceptable. Alternatively, if the occupational risk in an existing assessment was considered not to be acceptable, and exposure levels in the situation under review are likely to be similar or higher, then the risk for the situation under review is also not acceptable.

In other cases, a valid extrapolation cannot be made and a local risk assessment should be carried out using an exposure model and/or exposure measurements. In Table 5, based on the FAO toolkit, the outcome of the bridging exercise is displayed.

Table 5. The bridging approach between existing data and the situation under review. The light grey colour indicates that the risk is controllable, and the dark grey colour indicates that the risk is unacceptable.

Is the risk in the existing assessment considered acceptable?	**What is the exposure level for the situation under review when compared to the existing assessment?**		
	Higher than the existing assessment	**Similar** to the existing assessment	**Lower** than the existing assessment
Yes	The extrapolation is not possible: carry out a local assessment	The risk for the situation under review is acceptable	The risk for the situation under review is acceptable
No	The risk for the situation under review is not acceptable	The risk for the situation under review is not acceptable	The extrapolation is not possible: carry out a local assessment

5.4 Pesticide residues in food, feed, and drinking water from use of plant protection products

In addition to the assessments described above, a dietary risk assessment shall also be made. This assessment is made to ascertain that consumers will not be at risk from pesticide residues in treated crops, animal products, processed food, or drinking water. A maximum residue level (MRL) is the highest level of a pesticide residue that is legally tolerated in or on food or feed when pesticides are applied correctly in accordance with what is stipulated in the Good Agricultural Practice (GAP).

The following key points should be noted:

- The amounts of residues found in food must be safe for consumers and must be as low as possible.
- The European Commission sets MRLs for all food and animal feed.

- The MRLs for all crops and all pesticides can be found in the MRL database[38] on the Commission website.

The data needed for a dietary risk assessment are the following:

- The toxicological reference values of acceptable daily intake (ADI) and acute reference dose (ARfD).[39]
- Residue estimates such as MRL.
- Food intake estimates (based on national food consumption data).

To assess whether or not the residue level expected to occur in commodities leads to unacceptable consumer risk, the available residue data are combined with information from national dietary surveys to estimate potential residue intake[40] by consumers, which is compared to toxicological reference values. Keeping residues at or below the MRL is of great importance in order to ensure safety for consumers and to enable the trade of commodities between countries.

Guidance on how to locate the result of this evaluation in the EU can be found in the KemI document *Practical guidance on how to access information from the EU Pesticide Registration Process*.

The question and answers in the box below are intended to serve as a guidance on how information on residues can be accessed and used.

1. Is the dietary risk assessment relevant for your country/region?

Check the EFSA conclusions.

If yes

Use the information as deemed appropriate for your country and include relevant risk mitigation measures in your decision.

If no

Check the Global Environment Monitoring System (GEMS)/Food cluster diets (WHO, 2006)[41] and use the relevant diet for the risk assessment. Include relevant risk mitigation measures in your decision.

[38] EUROPEAN COMMISSION. (2016). *EU Pesticides database.* Retrieved 18 December, 2019 from: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN

[39] EUROPEAN COMMISSION. (2001). *Guidance for the setting of an Acute Reference Dose (ARfD) 7199/VI/99 rev. 5 05/07/2001.* Retrieved 18 December, 2019 from: https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_tox_acute-ref-dose.pdf

[40] EFSA. (2019). *Pesticide Residue Intake Model- EFSA PRIMo revision 3.1.* Retrieved 18 December, 2019 from: https://www.efsa.europa.eu/en/supporting/pub/en-1605

[41] WHO. (2019). *Global Environment Monitoring System (GEMS)/Food cluster diets (WHO, 2006).* Retrieved 18 December, 2019 from: https://www.who.int/nutrition/landscape_analysis/nlis_gem_food/en/

5.5 Environmental risk assessment

5.5.1 Environmental exclusion criteria

An assessment is always made in order to conclude whether the active substance fulfils the decision-making criteria as being PBT, vPvB, or a POP. These criteria are agreed upon by the EU Member States and are laid down in the Commission Regulation on the uniform principles. A conventional hazard assessment of the long-term effects and the estimation of the long-term exposure cannot be carried out with sufficient reliability for substances meeting the PBT and vPvB criteria. Therefore, a separate PBT and vPvB assessment is required (see the criteria in the boxes below).

The box below shows the criteria for the assessing whether a substance meets the P (half-life), B (bioaccumulation potential), T (toxicity) criteria[42].

Persistence (P)

An active substance fulfils the persistence criterion when

- the half-life in marine water is longer than 60 days
- the half-life in fresh or estuarine water is longer than 40 days
- the half-life in marine sediment is longer than 180 days
- the half-life in fresh or estuarine water sediment is longer than 120 days
- the half-life in soil is longer than 120 days.

Bioaccumulation (B)

An active substance fulfils the bioaccumulation criterion when the bio-concentration factor is greater than 2,000.

Toxicity (T)

An active substance fulfils the toxicity criterion when

- the long-term no-observed effect concentration for marine or freshwater organisms is less than 0.01 mg/l
- the substance is classified as carcinogenic (category 1A or 1B), mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B or 2) pursuant to Regulation (EC) No 1272/2008
- there is other evidence of chronic toxicity, as identified by the classifications STOT RE 1 or STOT RE 2 pursuant to Regulation (EC) No 1272/2008.

[42] EUR-Lex. (2020). *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.* Retrieved 21 February, 2020 from: https://eur-lex.europa.eu/eli/reg/2011/546/oj/eng

The box below shows the criteria for assessing whether a substance meets the vP (half-life), or the vB (bioaccumulation potential) criteria[43].

Persistence

- the half-life in marine, fresh, or estuarine water is longer than 60 days
- the half-life in marine, fresh, or estuarine water sediment is longer than 180 days
- the half-life in soil is longer than 180 days.

Bioaccumulation

- the bio-concentration factor is greater than 5,000.

The same criteria apply for active substances in biocidal products according to the Biocidal Products Regulation. However, active substances fulfilling the criteria may be approved in cases where it has been shown that the exposure to the active substance in a product is negligible or where the active substance has proven to be essential to prevent a serious danger or when not approving the substance would have a disproportionate negative impact on society. Availability of suitable and sufficient alternatives (substances or technologies) shall be considered in this context. In case an active substance meets one of the exclusion criteria but is approved anyway for any of the above-mentioned reasons, the time for approval shall not exceed five years. The active substance will then be regarded as a so-called candidate for substitution.

5.5.2 Plant protection products

Pesticides should only be registered/approved for use in a country when it has been demonstrated that they are not expected to have any harmful effects on the environment under the local conditions of use. Specific studies according to OECD test guidelines are performed in order to detect possible hazardous effects in the following organisms:

- Birds and other terrestrial vertebrates
- Aquatic organisms (fish, aquatic invertebrates, sediment-dwelling organisms, algae, aquatic macrophytes)
- Bees and other pollinators
- Non-target arthropods other than bees
- Non-target soil meso and macrofauna
- Soil nitrogen transformation
- Terrestrial non-target higher plants
- Earthworms

If risks are still of concern, higher-level studies, such as field studies, should be required.

For the exposure assessments, the example models from the EU or the "Primet"[44] or other relevant models can be used. Estimation of environmental exposure can be expressed as the predicted environmental concentration – which is the estimation of the concentrations/doses

[43] EUR-Lex. (2020). *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.* Retrieved 21 February, 2020 from: https://eur-lex.europa.eu/eli/reg/2011/546/oj/eng

[44] Wageningen university and research (2019). *Primet, Alterra rapport 1648, ISSN, 1566-7197.* Retrieved 18 December, 2019 from: https://library.wur.nl/WebQuery/groenekennis/1867573

that organisms in environmental compartments are or might be exposed to. There are different models available to calculate/estimate these concentrations in soil, groundwater, surface water, and sediment. Exposure scenarios are also available to calculate the secondary exposure of birds and mammals via the food chain such as seeds, plants, or insects.

The risk characterisation is done by comparing the toxicity effect concentrations with the estimated concentration in the environment, which results in a so-called toxicity exposure ratio (TER). The calculated value must be above the cut off TER values, and these values include safety factors to increase the protection of the environment. The TER values are not strictly scientifically based, but they have been agreed upon by all EU member states, they are specified in the legislation, and they are used for decision-making.

Examples:

1. Acute toxicity to aquatic organisms (TER 100)
2. Acute toxicity to algae (TER 10)
3. Acute toxicity to earthworm (TER 10)
4. Long-term toxicity to birds (TER 5)

The questions and answers in the boxes below are intended to serve as a guidance on how information on risk to the environment from an EU assessment for an active substance can be accessed and used.

1. Does the active substance fulfil the PBT criteria?

If yes

Conclude whether these decision-making criteria are relevant for your country. Make a decision on restriction or withdrawal if the criteria are applicable.

If no, or if the criteria do not apply for your country

Continue with the environmental risk assessment.

2. Is the use of your product covered by the EU assessment?

Check the GAP (Good Agriculture Practice) in the dossier in question (plant protection products) or the efficacy trials for similar information. Check the summary of represented uses evaluated in the EU assessment.

If yes

Use data and information in the EFSA conclusions in addition to data available in your country. The conclusions contain a summary of the assessment of the risk to the environment that describes how the overall conclusions have been reached.

Also, check the section containing critical areas of concern for the assessed uses to see whether it is relevant for your product. Use fate and behaviour data, toxicity data for aquatic and terrestrial organisms, and established TER values, if considered relevant.

If no

Use fate and behaviour data from the applicant´s dossier and toxicity data for aquatic and terrestrial organisms from the EU assessment and perform a national risk assessment.

5.5.3 Biocidal products

Guidance on biocides legislation can be found on the ECHA website, more specifically guidance on how to perform risk assessments for various types of use of biocidal products.

This guidance provides technical advice on how to perform the hazard and exposure assessment and risk characterisation for biocidal active substances and products with respect to the environmental risk assessment. Many of the principles described above for plant protection products also apply for biocides.

The risk assessment for biocides is carried out by using the toxicity effect concentrations from tests on different aquatic and terrestrial organisms which results in a so-called PNEC value (Predicted No Effect Concentration), using assessment factors between 1 and 1000, depending on the available data in the dossier. The PNEC value is not strictly scientifically based, but it has been agreed upon by all Member States and is specified in the legislation to be used for decision making.

The risk characterisation for biocides is done by comparing the toxicity effect concentrations for different aquatic and terrestrial organisms with the estimated concentration in the environment (PEC). The risk is acceptable if the PEC/PNEC is less than 1.

The questions and answers in the boxes below are intended to serve as a guidance on how information on risk to the environment from an EU assessment for an active substance can be accessed and used.

1. Does the active substance fulfil the PBT criteria?

Check the European database for identifying active substances assessed as fulfilling the criteria. The PBT assessments are available in the CAR and the BPC Opinion.

If yes

Conclude whether these decision-making criteria are relevant for your country. Make decision on restriction or withdrawal if the criteria are applicable.

If no or if the criteria do not apply for your country

Continue with the environmental risk assessment.

2. Is the use of your product covered by the EU assessment?

Check the ECHA website to see whether the active substance is approved and for which uses.

If yes

Use data and information in the assessment report as far as possible in addition to data available in your country. In the summary of the risk assessment, a description of the risk to the environment can be found. Use PNEC values, if considered relevant.

If no

Use fate and behaviour data from the applicant´s dossier and toxicity data for aquatic and terrestrial organisms from the EU assessment and perform a national risk assessment.

A description of the risk to the environment can be found in the summary of the respective risk assessments.

6 Recommendations on risk reduction

Once the use of highly hazardous pesticides has been identified in a country, it is recommended that measures are taken to reduce the exposure. In order to avoid that these pesticides at some point become a problem to the environment or to the society, it is recommended that the pesticide products as far as possible are regulated upstream in the

supply chain. Which risk reduction measures that can be taken in a country depends on the legislation in the country. As pointed out in chapter 2 in the Code of Conduct on Pesticide Management, it is stated that governments should establish regulatory schemes and infrastructures under which each pesticide product is registered before it can be made available for use. This is highly recommendable and if such provisions are not in place in your country you should consider introducing that kind of legislation. As this may take quite a long time there may be other options to start taking action against highly hazardous pesticides that are being used in your country. Some possible legal options that may be available in a country and which can be used to take regulatory action with the purpose to reduce the negative impact of the most hazardous pesticides are described below. Your legislation might contain one or more of the following provisions:

1) **Pesticide products need to have a pre-market approval before they can be placed on the market and used (i.e. the kind of system that is described in chapter 2.2.).** Such approval is usually preceded by a process, whereby a company, wishing to place the product on the market, has applied for an approval and has provided certain scientific data, demonstrating that the product is effective for its intended purposes and does not pose an unacceptable risk to human or animal health or the environment. This information is then evaluated by the responsible national government or authority which takes a decision to approve the product or not.

   In case such requirements are in place, this guidance document provides you with some recommendations on how you can take regulatory actions by using already available and accessible information, in addition to information submitted as part of the application for the pesticide product. Depending on how much scientific data the application dossier contains you may want to consider the results from risk assessments conducted by other authorities or information from the open literature. Should this additional information lead to the conclusion that the product may pose an unacceptable risk, you could consider to use it as part of the basis for your decision, either not to grant an approval or grant an approval with certain restrictions. You could also use it to trigger further information from your applicant which either agrees with the conclusion based on the additional information or has to argue for why it is not relevant.

   However, in order to be able to use additional information as part of your assessment, a couple of criteria need to be met. First of all, this operation has to be concurrent with the pesticides legislation in your country, which means that the legislation must allow data, indicating a risk to human health or to the environment, obtained from other sources than from the applicant, to be used for taking action. Second, the information has to be deemed relevant for the product or the active substance in question.

   Our recommendations are relevant in a situation when an authority would like to use additional information to restrict the use of a product. Another way to use the additional information is to trigger the applicant to provide more information or arguments for why this information may not be relevant or only partly relevant.

   a) **Approvals are limited in time**
      In many countries, the approval of a product is set for a limited time, which means that the approval expires after a certain period. Enabling the review of existing approvals at any point in time facilitates the use of new information on the hazards and risks of a product and will simplify the work to reduce the negative impacts of pesticides.

In case there are provisions in your legislation regarding the possibility to re-assess the risk of the use of a pesticide product at the time when the approval expires, this guidance document can be used in the same way as described for an application for a new product. Depending on the outcome of the re-assessment, the product can either be re-approved with or without certain restrictions or not re-approved. In case the law stipulates that the approval should be prolonged without any possibility to re-assess the risk of the use of the product, other ways to restrict pesticides of concern need to be sought.

b) Approvals are not limited in time

In case there are no provisions regarding a review of approvals at a certain time point, other ways to restrict approved pesticides which may have a negative impact on human health or the environment need to be explored. One option is to update your current law and introduce such provision, to enable a review that includes the possibility to ask the applicant for updated information or use already existing information from other sources.

2) Chemicals including pesticides can be banned or the use restricted.

In case there are provisions in a law in your country, it doesn´t necessarily have to be a specific pesticide law, regarding banning or restriction of chemicals with reference to their intrinsic properties or the risk they may pose, you should explore whether these provisions can be used also for pesticides. Such provisions can exist both in combination with an approval system, according to pt. 3 below, and without.

In case there is a possibility to ban or restrict hazardous pesticides, the recommendations in this guidance document can be used to support identification and prioritisation of the most problematic pesticides in your country with a view to possible restricting or banning an active substance, a co-formulant or a pesticide product. Obligations may also be set out by certain conventions with the intention to protect human health and the environment from chemicals. To be able to execute such ban, national legislation and regulations in conformity with the convention are required.

3) The legislation stipulates a combination of a requirement for a pre-market approval and a possibility to restrict or ban certain chemicals (combination of 1 and 2). In case there are several possibilities to phase out or to prevent that hazardous pesticide products enter the market, the most cost-effective way to do this should be identified. If you have an approval system in place in your country, with approvals limited in time in accordance with 1a above, a decision not to re-approve the product could be one option to restrict the use. Another choice is to ban the substance itself, which means that all products containing that specific substance should be removed from the market. Depending on the way you choose, this guidance can be used differently.

4) Pesticides are regulated by licensing.

Certain countries may have legislation which includes provisions on licensing of pesticides and other toxic substances or approvals of labels. In case the application for a license contains information demonstrating that the pesticide product is highly hazardous, it should be explored whether this information can serve as a basis for not

granting a license in accordance with the legislation. If there is a possibility not to grant a license with reference to the toxicity of the pesticide and if additional information extracted from risk assessments conducted by other authorities can be used to support this conclusion, the recommendations in this guidance document are applicable. The possibility to replace part of the licensing system with a more extensive approval system for pesticides may also be considered.

5) **There are no provisions regarding pre-market approvals or on bans or restrictions of hazardous chemicals in the legislation.**

In case no law regulating pesticides exists in your country, identification of highly hazardous pesticides may still be useful and help to raise awareness about the need for legislation that allows measures to be taken. It can also be used for action plans and communication with stakeholders.

In case there is a lack of provisions to restrict the use of pesticides you may want to consider to either include this in an existing law or develop new legislation. The recommendations in chapter 2.2 serve as a guidance for developing a national framework for registering pesticides. This is a coherent and logical way of handling pesticide approvals that has been followed by authorities in various countries for many years. Provisions that enables a regulatory body to be able to execute a ban or restrict a chemical, including a pesticide, when associated with unacceptable risks to human health or to the environment may also be considered.

7 Sustainable pest control

The EU has established rules for the sustainable use of pesticides to reduce the risks and impacts of pesticide use on people's health and the environment (Directive 2009/128/EC)[45]. At present, the Directive only applies to pesticides that are plant protection products.

7.1 Plant Protection Products

The framework directive on the sustainable use of pesticides in the EU states that the following actions should be taken regarding the use of plant protection products in the Member States:

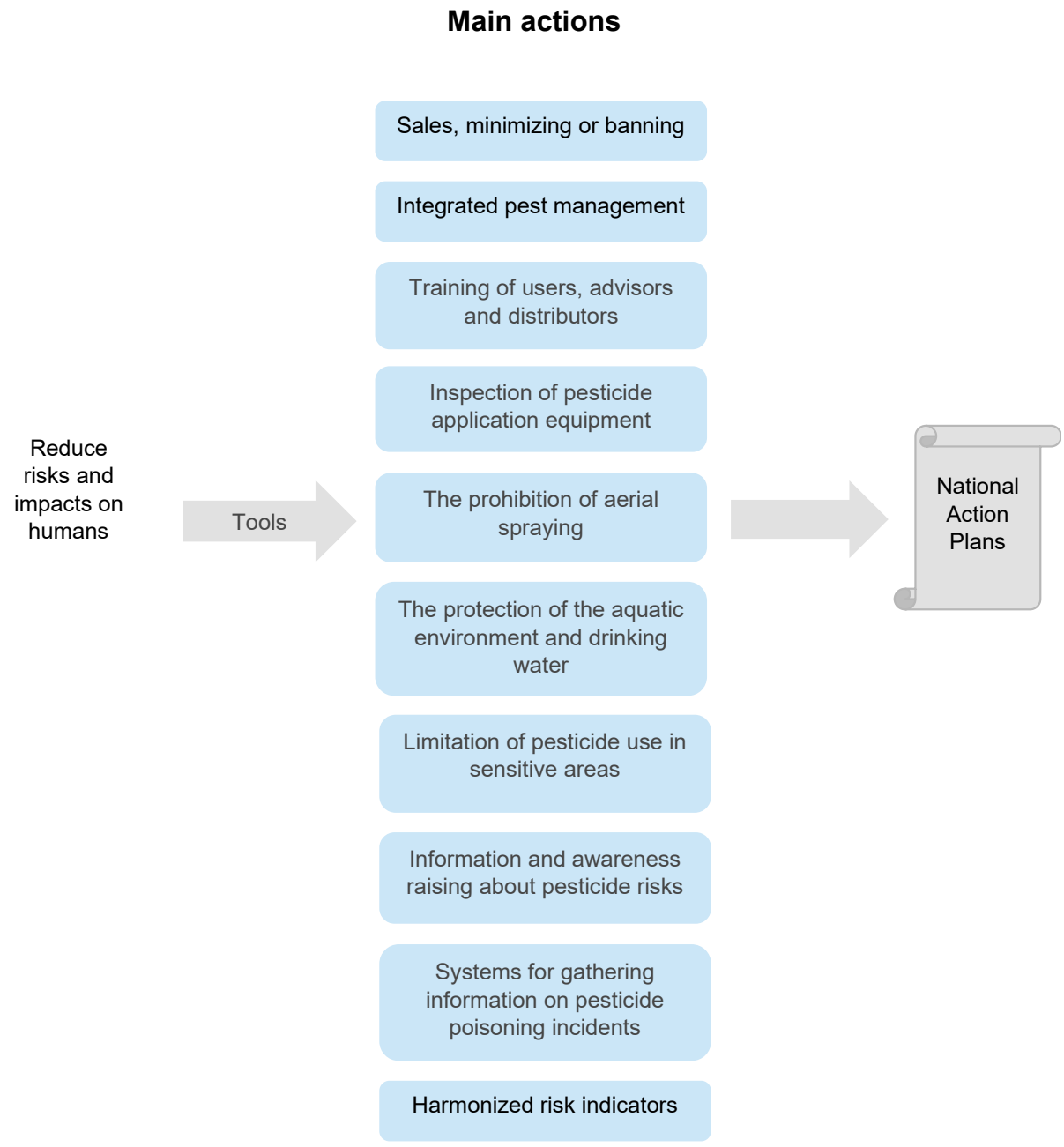
- **National Action Plans** – EU countries shall adopt plans and set objectives and timetables to reduce the risks and negative impacts of pesticide use.
- **Training** – Professional pesticide users, distributors, and advisors shall get proper training.
- EU countries shall establish **competent authorities** and **certification systems**.
- **Information and awareness raising** – Member States shall take measures to inform the general public and shall put in place systems to gather information on acute poisoning incidents and chronic poisoning developments.
- **Aerial spraying** – Aerial spraying is prohibited. EU countries may allow it under strict conditions after having informed the general public.
- **Minimising or banning** – EU countries shall minimise or ban the use of pesticides in critical areas for environmental and health reasons.

[45] EUR-Lex (2009). *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.* Retrieved 18 December, 2019 from: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32009L0128

- **Inspection of equipment in use** – All pesticide application equipment has had to be inspected annually since 2016 in order to ensure the proper and efficient use of any plant protection product.
- **Integrated pest management** – Since 1 January 2014, professional users have had to apply the general principles of integrated pest management, including the promotion of low pesticide-input management and non-chemical methods.

A number of main actions have been identified that the EU Member States have developed into national actions plans, see Figure 5.

Figure 5. Main actions within the EU to achieve the sustainable use of pesticides



7.2 Biocidal Products

Although biocides are not currently covered by the EU framework directive on sustainable use of pesticides, many of the possible actions remain relevant also for biocides. Further tools or actions that might be used to stimulate innovation and the development of new products with a better safety profile include the following:

- Exclusion, substitution, and comparative assessment.
- Labelling schemes including information on hazards and proper use instructions.
- Best available techniques regarding industrial emissions.

Sustainable pest control by the use of biocidal products seeks to reduce the risks and impacts of the use of biocidal products on human health, animal health, and the environment. It also includes the promotion of integrated pest management and alternative approaches or techniques such as non-chemical alternatives to biocidal products. Sustainable use strategies for biocides shall also ensure that sufficient biocidal products remain available on the market to ensure the protection of human and animal health and the environment.

The EU Regulation on Biocidal Products stipulates that the following elements need to be considered:

- The promotion of best practices as a means of reducing the use of biocidal products to a minimum.
- The most effective approaches for monitoring the use of biocidal products.
- The development and application of integrated pest management principles with regard to the use of biocidal products.
- The risks posed by the use of biocidal products in specific areas such as schools, workplaces, kindergartens etc., and whether additional measures are needed to address those risks.
- The role of improved performance of the equipment used for applying biocidal products.

7.3 Examples from Sweden on how to achieve sustainable pest control with support from Plant Protection Centres

The aim of the Plant Protection Centres is to make plant protection in agriculture and horticulture both efficient and environment friendly. The Centres are located in five different places in Sweden. The following sections contain information, extracted from the webpage of the Swedish Board of Agriculture[46], about the activities conducted by the Centres.

7.3.1 Pest and disease prognosis

The presence of pests, and thus the need for pesticides, varies from year to year as well as geographically the same year. Adapting the use of pesticides according to actual need is beneficial for the environment and for the individual farmers' financial situation and for their exposure to pesticides. It is also one of the key aspects of integrated pest management.

[46] Swedish Board of Agriculture. (2018). Retrieved 18 November, 2019 from: http://www.jordbruksverket.se/swedishboardofagriculture/engelskasidor/crops/plantprotection/plantprotectioncentres.4.6621c2fb1231eb917e680003284.html

The prognosis and early warning service is an important aid for those farmers who wish to use pesticides only when needed. For certain pests, prognoses are made in advance and state the expected development. Such prognoses are made on a regular basis.

7.3.2 Early warning of pests and diseases

For most pests, there are not yet any methods for prognosis. For such pests, information on the current incidence (early warning) is given based on regular field observations and assessments of pests and diseases. During the growing season, observations are made in approximately 1,100 fields per week. After processing and analysing these observational data, a weekly summary is sent out to subscribers (mainly farmers and advisors). Appropriate measures are discussed in the weekly telephone conferences led by the Plant Protection Centres for each region. Participating in those conferences are local advisors as well as market representatives.

7.3.3 Identifying the symptoms or causes of disease

In order to avoid the unnecessary use of pesticides by using the wrong or ineffective substances on a suspected pest, the right diagnosis must first be made. It often takes special skills and equipment to determine the cause of symptoms and diseases. Every year, the Plant Protection Centres receive a large number of samples from the advisory service and market agents.

7.3.4 Information

There is a great need for information concerning the use of pesticides and the risks associated with their use. The Plant Protection Centres take an active part in a large number of courses, field excursions, and telephone meetings as well as in national and international conferences.

The Centres also provide advisory and study material and take part in studies on environmental, weed, and plant protection issues. Furthermore, most of the information from Plant Protection Centres is made available through digital channels, for instance through apps or from the website of the Board of Agriculture.

7.4 Examples from Sweden on how to achieve sustainable pest control through training

If you are going to use plant protection products for professional use in Sweden, you need to be approved and hold a certificate. To receive an approval you must attend a training course given by the county administrative board or the Swedish Board of Agriculture. There are courses on outdoor use, greenhouse use, seed treatment, and treatment of plants in forest plantations.

The training courses vary in length for the different certificates. The outdoor and greenhouse use courses are four days, the seed treatment course is two days, and the plants in forest plantations course is one day. Attendance is mandatory, and at the end of the course you have to pass a written test in order to be approved and receive a certificate. You need to be 18 years of age or older in order to be certified.

Certificates are valid for five years. If you would like to renew your certificate, this has to be done before the end of the five-year period by attending a one-day course.

The Board of Agriculture maintains a record of all certified users with information on what courses they have taken and which certificates they hold. The information is kept for control purposes.

Annex 1

Examples from Sweden on application of the substitution principle

A number of examples are listed below with the purpose of demonstrating how comparative assessment and the substitution principle can be applied in practice.

Example 1 – A group of chemically related substances

There is an application for approval of a selective herbicide intended to be used for pre- and post-emergence weed control in spring and winter cereals. The product contains an active substance A belonging to a group of chemically related substances included in herbicide products approved for use in cereals. The four substances in question have similar properties with regard to weed control, thus being replaceable with each other. However, assessment of the environmental properties of the substances also taking into account the main metabolites revealed that substance A differs significantly from the others because it is considered to be far more mobile and to degrade more slowly in soil. Substance A is – in contrast to the other substances – associated with risk for ground water contamination.

Decision: Product containing substance A is not approved.

Example 2 – Two different active substances

There are a few products with different active substances approved for total weed control in non-crop areas and in willow plantations. Two of the products contain an active substance B, for which several concerns were raised during the first review of old substances. Substance B and its main metabolite show very slow degradation in soil. The metabolite is also very mobile and frequently detected in ground water monitoring. Furthermore, substance B is very volatile and has been identified to cause very specific toxic effects in the olfactory nasal mucosa in experimental animals, giving rise to concerns for operator safety. There is another substance available on the market for the same use that is also sufficiently effective but is considered to present significantly less risk in all aspects compared with substance B.

Decision: The two products containing substance B are not re-approved.

Example 3 – A chemical versus a non-chemical method

A product is approved for use as a soil disinfectant, and the main use is for the control of potato cyst nematodes. The active substance included shows high mobility, and long-term studies also indicate carcinogenic properties. The use is associated with risk for ground water contamination, which has been confirmed in monitoring. Progress in regional advisory programmes has at the same time made it possible to reduce the dependence upon soil disinfectants by promoting other plant protection practices such as crop rotation, use of resistant crop varieties, and by avoiding cultivation of susceptible crops in infected areas. Adopting these strategies can in the short term involve economic or practical disadvantages for the farmers. However, crop rotation does have a beneficial influence on the control of other plant diseases and is a long-term strategy in line with the development of sustainable agriculture.

Decision: The soil disinfectant is not re-approved.

Example 4 – Substitution in parts of the use area

An herbicide product is approved for use in cereals and some vegetable crops. It contains an active substance C showing high persistence in soil and high bioaccumulating potential. It is also volatile and highly toxic to different groups of aquatic organisms. There are several alternative products (including five different active substances) available on the market that are considered to be equally or more efficacious for use in cereals. However, no equally efficacious alternatives are available for use on onions, carrots, and beans.

Decision: The use area for the product containing substance C is restricted to onions, carrots, and beans. If better chemical or non-chemical alternatives become available for the remaining uses, re-approval will not be granted.

Example 5 – Different formulations

In a review of existing herbicides, it is concluded that four out of a total of six sugar beet herbicides containing the same active substance are based on an organic solvent D. The remaining two are instead based on an oil-miscible flowable concentrate (OF) containing vegetable oil. Solvent D is known to be a severe irritant to the skin, eyes, nose, and throat of exposed workers. The OF formulations show significantly better properties with regard to worker health but are identical with regard to efficacy compared with the solvent D-based formulations.

Decision: The four solvent D-based products are not re-approved. Re-approvals are only granted for the two OF formulations.

Example 6 – Step-wise approach in phase out plans

A group of chemically related substances (E) used in potatoes are subjected to phase out activities due to risks of chronic health effects associated with repeated exposure to farmers and the probable leakage of a mobile metabolite of health concern into the groundwater. These particular fungicides have dominated the use in potatoes for a very long time in the struggle against late blight. They are efficacious, show no risk for the development of resistance, and represent relatively low costs in plant protection management. Due to these circumstances, an immediate ban has not been possible to put into effect without far-reaching negative consequences on potato production. Out of eight products containing substance E, five are mono-component formulations and the other three are mixed formulations containing substance E in combination with substances having other modes of action. A comparative assessment reveals that the risks associated with the mixed formulations are almost solely based on their content of substance E. The use of the mixed formulations involves considerably lower amounts of substance E applied per treatment and also a reduced number of treatments due to longer treatment intervals, which means a reduced number of occasions where workers are exposed to substance E. There are also reports indicating that the use of mixed formulations (mixtures of contact and systemic fungicides) is the best chemical strategy available for control of the new mating type of *Phytophthora infestans.* Possibilities for the continued efficient control of late blight are therefore not considered to be affected if only mixed formulations containing substance E are approved.

Decision: The applications for re-approval of the five mono-component formulations containing substance E are withdrawn. Re-approvals for a limited period are only granted for the three mixed formulations in line with the on-going phase out plan.

Example 7 – Reconsideration after practical use of the substitute

There is an application for approval of a fungicide product intended for use in cereals. The product contains an active substance F that is chemically related to another substance already approved for the same use. Substance F shows significantly better environmental properties compared to the existing substance, particularly regarding persistence and bioaccumulation. However, because the new substance is a severe irritant, only a gel formulation in water-soluble plastic bags is considered to be acceptable. The comparative assessment leads to an approval of the gel formulation of substance F with the intention to substitute the existing chemically related substance at its next periodical review. The gel formulation of substance F has been shown to be sufficiently effective in earlier trials, but after being used in practice some technical problems become apparent.

Decision: The application for renewal of the existing chemically related substance is not rejected. The gel formulation of substance F is voluntarily withdrawn by the registration holder.

KEMI
Swedish Chemicals Agency

Swedish Chemicals Agency
Box 2, SE-172 13 Sundbyberg
+46 8 519 41 100

Visitors' and delivery address:
Esplanaden 3A, Sundbyberg

kemi@kemi.se
www.kemikalieinspektionen.se

Sweden
Sverige