15 September 2017

Practical guidance on hazard assessment, risk assessment and risk management of pesticides

Introduction

Här skrivs ett förord in.

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Summary

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Sammanfattningen bör inte överstiga en sida.

1 Aim and scope

The aim of this guidance document 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 in their achievements to reduce the risks and impacts of pesticide use on people's health and the environment. The document is intended to add practical information from a country perspective to the global "Code of conduct on pesticide management[1] "developed by Food and Agriculture Organization (FAO) and to the Toolkit described in chapter 4. The guidance is generally built on practice gained during the work with the pesticide review programs within the European Union (EU), from 1996 and onwards. The guidance is referring to data and reports based on the outcome and results from the review programs for Plant Protection Products[2] (PPP) and Biocidal Products[3] (BP) and should preferably be read in conjunction with the documents on how to access information[4]. Biocidal products are defined as pesticides which are used to protect humans, animals, materials or articles against harmful organisms like pests or bacteria, like rodenticides, insect repellents or wood preservatives. This guidance document has primarily been compiled for evaluators and decision makers working with registration processes worldwide.

Although the aim of the guidance document is to facilitate the work of evaluators and decision makers on how to access peer reviewed data on pesticides, this document does not propose a decision making framework for pesticide registration. Existing data on pesticides can however be used for various purposes such as for risk mitigation activities or for identification of pesticides which may be the most harmful.

The initial part of the document aims to describe very briefly the work by FAO and the World Health Organization (WHO) on pesticide management globally, whereas the next part will provide the reader with a number of checklists with the intention to serve as a guide on how data can be used for national or regional risk management or risk assessment activities. The last part of the document gives a brief description of the FAO Toolkit and of the registration processes laid down in the legislation of the EU and how pesticide data is developed and handled. A few examples are also given in terms of actions taken to reduce the risk and impact of pesticide use on people's health and the environment as far as possible.

2 Introduction

2.1 FAO/WHO "Code of conduct on pesticide management"

Significant work is currently ongoing within the FAO/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 new 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

1 http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Code/CODE_2014Sep_ENG.pdf

2 https://ec.europa.eu/food/plant/pesticides_en

3 http://ec.europa.eu/health/biocides/policy_en

4 http://www.kemi.se/global/guidance-documents/guidance-document-eu-pesticide-registration-process.pdf

http://www.kemi.se/global/guidance-documents/guidance-document-eu-biocides-registration-process.pdf

of reference in relation to sound life cycle management practices, in particular for government authorities and the pesticide industry. Some corner stones in the Code are the following:

- 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;
- 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; pesticides that are of low risk to human and animal health and the environment, that as far as possible or desirable, are target specific, and that degrade into innocuous constituent parts or metabolites after use."

2.2 Highly Hazardous Pesticides

Highly Hazardous Pesticides are defined by the FAO/WHO International Code of Conduct on Pesticide Management [2013] 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 Organization (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.

The FAO/WHO Joint Meeting on Pesticide Management [2008] recommended that 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; or

Criterion 2: Pesticide active ingredients and their formulations that meet the criteria of carcinogenicity Categories 1A and 1B of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS); or

Criterion 3: Pesticide active ingredients and their formulations that meet the criteria of mutagenicity Categories 1A and 1B of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS); or

Criterion 4: Pesticide active ingredients and their formulations that meet the criteria of reproductive toxicity Categories 1A and 1B of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS); or

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; or

Criterion 7: Pesticides listed under the Montreal Protocol; or

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 Highly Hazardous Pesticides:

> "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."

The use of highly hazardous pesticides is still considered to be of serious concern in many parts of the world. The pesticides may have acute and/or chronic toxic effects and may pose a risk to humans, especially children, and to the environment.

2.3 Use of available information

The registration process as described in the FAO Guidelines for Registration of Pesticides from 2010[5] includes the following major steps for the first-time and re-registration of pesticides:

1. Preparation and submission of the dossier by the applicant;
2. Initial administrative actions by the responsible authority;
3. Completeness check;
4. Technical and scientific evaluation;
5. Preparation of summaries and conclusions;
6. Risk management and registration decision;
7. Publication and dissemination of registration decision and label extension.

This is a coherent and logical way of handling pesticide registrations which has been followed by many authorities in various countries for a long time. Extensive work has been carried out of producing data and reports over the years, information which may be valid for risk management purposes and found by accessing the websites of different authorities within the EU, the US-EPA etc. It is therefore sensible that authorities, who are planning and prioritising their work on re-evaluation of registrations and identification of highly hazardous pesticides, use available information as a starting point. This guidance document suggests that authorities start by using available data to manage and mitigate the risk caused by pesticides and when relevant, use this as a basis for registration and risk management decisions. As a next step more specific risk assessments may be performed, based on already available information, for those pesticides for which no alternatives are available.

Reviewed data and risk assessments made in accordance with established guidance and legal frameworks may serve as a good starting point for countries with an aim to improve the

[5] http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Code/Registration_2010.pdf

control of the trade and use of pesticides and which do not yet have a robust regulatory system in place.

This guidance document suggests, as a first step, that reviewed data and assessments for primarily **highly hazardous pesticides**, generated within different authorization schemes, be used as a trigger for pesticide risk management actions in the country in question. When deemed necessary, e.g. when a product which may cause risk to humans or the environment must be kept on the market due to an extensive need where no alternative pest control methods are available, a second step would be to perform a risk assessment taking local conditions into consideration. The risk arising from the use of the pesticide has to be mitigated as far as possible, see fig.1 below.

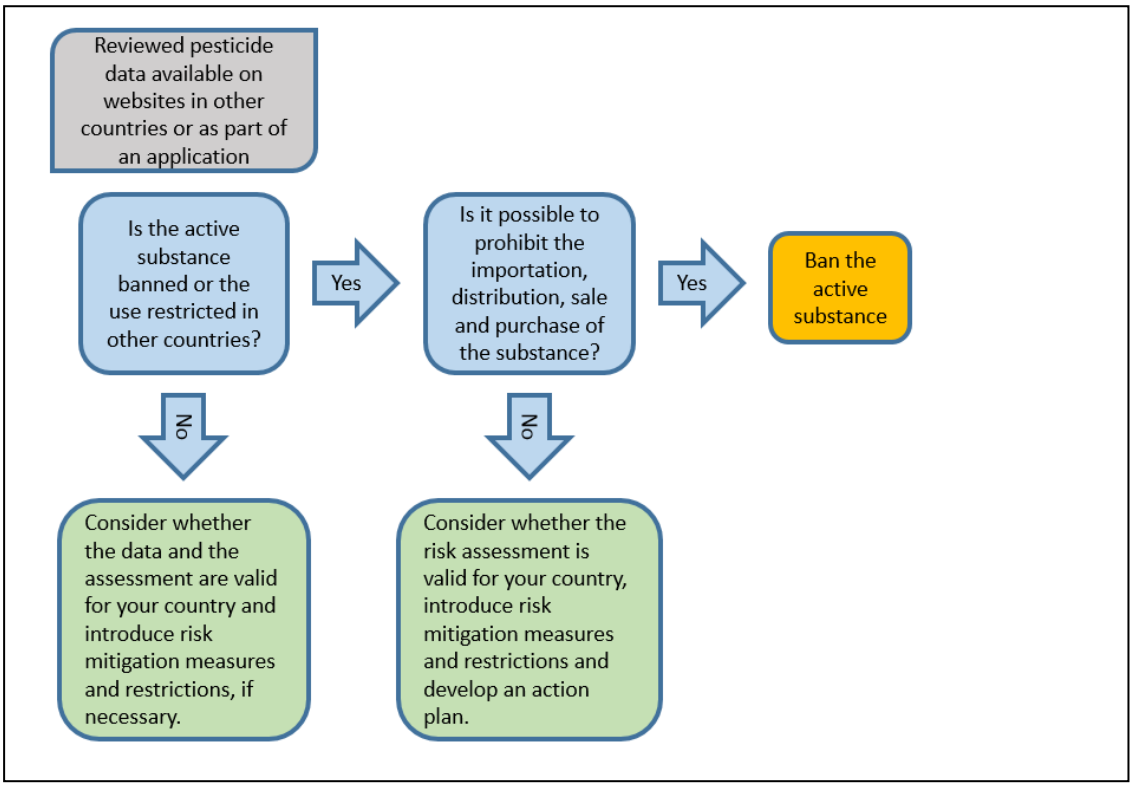

Figure 1. Overall scheme of the use of data on pesticides

2.4 Information generated within the EU 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 procedures may be required. For a more extensive description of the procedures, see chapter 5. The EU director general (DG) Sante is responsible for 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 component. The active component against pests/plant diseases is called “active substance”. Each active substance is evaluated for safety before it reaches the market in a product. Substances must be proven safe for people's health, including their residues in food, and to cause no unacceptable effects on animal health and the environment. The assessment of the active substance is made within the EU in cooperation between the Member States (MS), while the product assessment is performed within the country in which the product is going to be sold and used. Two EU

agencies, the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA) in terms of the Biocidal Products Committee (BPC) play a key role, together with the authorities within the Member States to review the application for the active substance approval and put forward a proposal for decision to the European Commission (COM) to decide upon. The Commission takes the decision with support of a committee consisting of representatives from the Member States. An evaluating authority (RMS) is appointed for the work on the assessment of an application for approval of the active substance. This work is organized in programs and the responsibility for the assessments is divided between the different Member States.

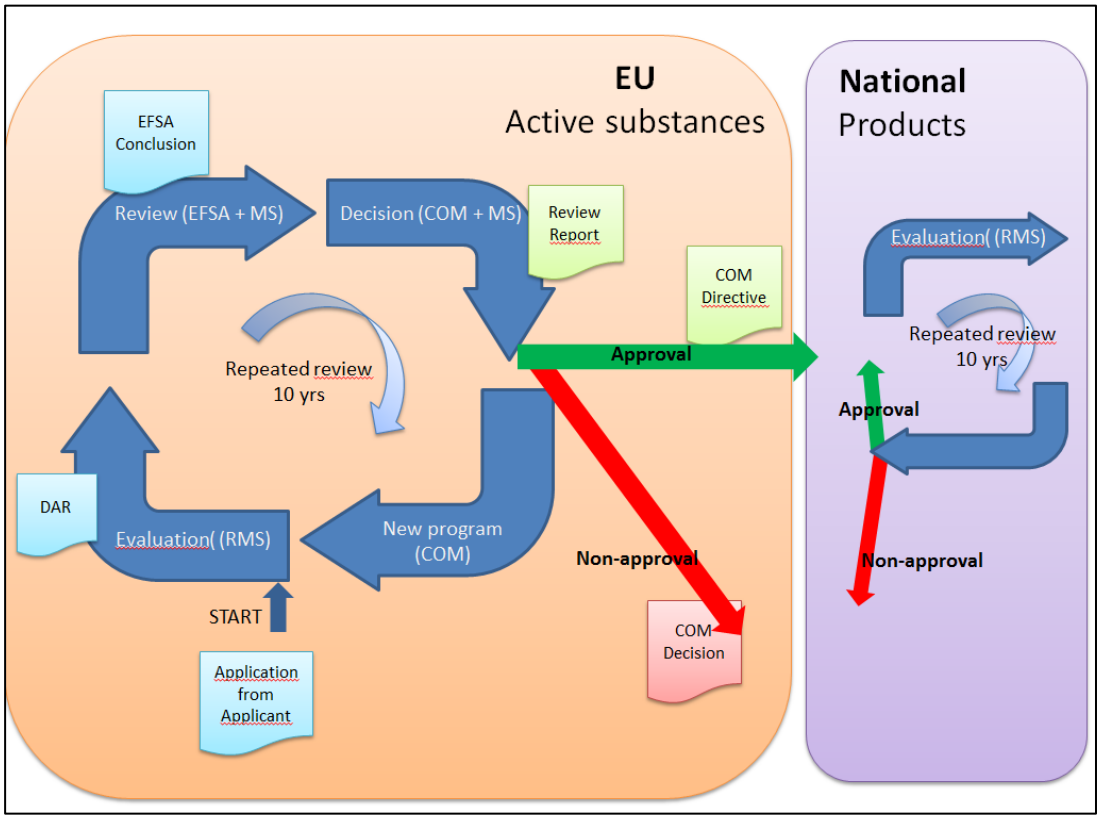

Figure 2. The procedure for approval of active substances within the European Union and the authorization of plant protection products in the Member States

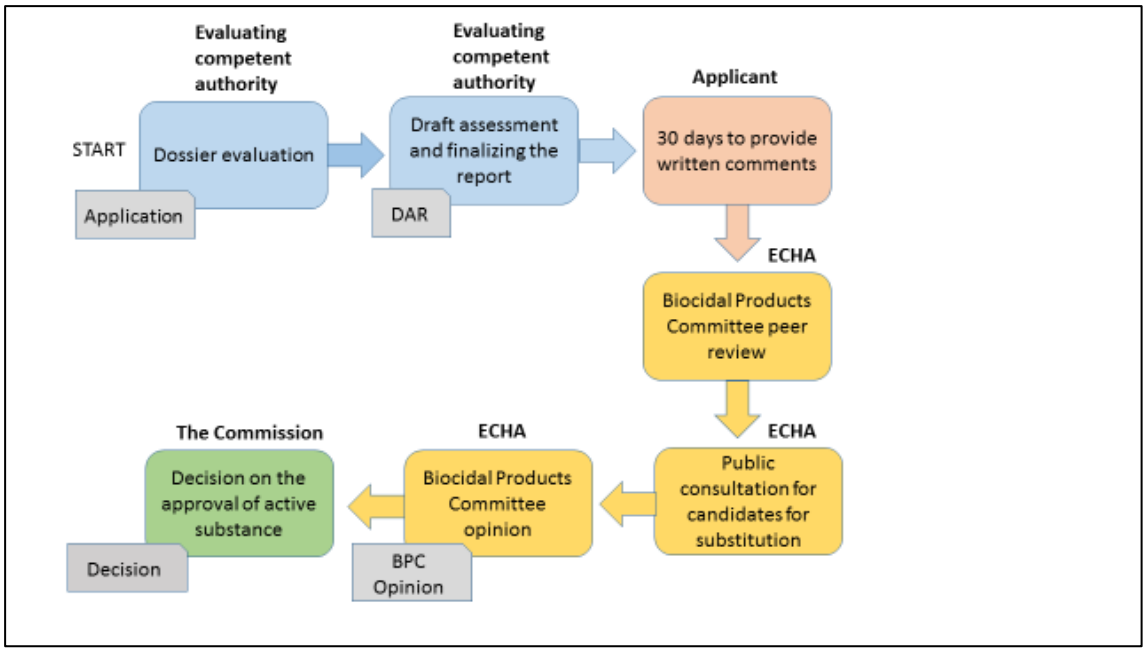

Figure 3. The procedure for approval of active substances within the European Union and the authorization of biocidal products in the Member States

The different documents which play a key role for the development of the decision for approval or non-approval of an active substance are found in table 1. It describes the scope, content and owner of the information generated during the EU review process for active substances in plant protection or biocidal products. Note that the matter of proprietary rights has not been considered in this context.

Table 1. Different types of documents generated within the EU programs for pesticides

Type of document	Owner	Content/scope
Application	Industry	The formal application and data/studies to support the conclusion that the product can be used without causing any risk to humans, animals and the environment
Draft assessment report (DAR)	RMS	An evaluation, not peer-reviewed, presented as: 1) A hazard assessment of the active substance, areas evaluated : - 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" which should be used when carrying out risk assessments for products at Member State level.
BPC Opinion	ECHA	The opinion serves as the basis for the decision on approval which is adopted by the European Commission and reflects the BPC agreements. It is based on the (draft) assessment report submitted by the RMS and relevant comments provided by other member states and the applicant.
Review report (PPP)	COM	A summary of the evaluation process as background to the Decision/Directive. Contains • 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[6] the Review report also includes the "List of Endpoints".
Directive /Implementing Regulation	COM	Legal document for approved active substances. Contains e.g. required purity • Specific provisions • Confirmatory data
Decision	COM	Legal document for non-approved active substances. Contains details about withdrawal and periods of grace of products from the EU-market

On the DG Sante website a database[7] of approved and non-approved active substances in plant protection products can be found. The database contains, among other things, information on approval status, residues, some toxicological information and information on

[7] http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN

classification and labelling of the active substance. Similar information on active substances[8] in biocides can be found on the ECHA website.

3 Recommended methods for national/regional risk assessment of pesticides

Since this guidance is referring to data and reports based on the outcome and results from the EU review programmes for Plant Protection Products (PPP) and Biocidal Products (BP), it should preferably be read in conjunction with the documents on how to access EU information[9]. A number of general checklists are provided below which refer to methods recommended for national and regional risk management and risk assessments. The initial checklist refers to the recommendations regarding Highly Hazardous Pesticides found in the FAO/WHO Code of Conduct on Pesticide management. The FAO/WHO has also developed the guidelines on Highly Hazardous Pesticides in which the designing of an action plan is recommended. More detailed advice and tools related to HHP criteria are found in the toolkit on the FAO website.

3.1 Checklist for substances fulfilling HHP criteria

The aim of the checklist below is to guide assessors to find reviewed data which can be of help when identifying highly hazardous pesticides in a country.

Issue	Action	Comments
1) Identify the products registered on the market.	List the current products registered in the country by using the excel template available in the toolkit.	List also when possible the use and crops for which the products are registered in the table. This information is useful when searching for alternatives.
2) Identify which registered pesticides are considered to be HHPs	Check criteria 1-7 against information available on the internet and from other sources, e.g. the European databases on PPP and BP for identifying active substances classified for CMR, cat. 1a and 1b and acute toxicity that correspond to criteria 1- 4. Substances fulfilling criteria 5-7 are found on the Rotterdam and Stockholm convention websites. Check also the EU Regulation concerning the export and import of hazardous chemicals[10].	

[8] https://echa.europa.eu/information-on-chemicals/biocidal-active-substances

[9] http://www.kemi.se/global/guidance-documents/guidance-document-eu-pesticide-registration-process.pdf
http://www.kemi.se/global/guidance-documents/guidance-document-eu-biocides-registration-process.pdf

[10] 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

Issue	Action	Comments
	Criterion 8 has to be checked nationally by consulting national poison control centres, hospitals, reports from institutions and universities and/or by performing risk assessments of the actual use. This is especially relevant for highly acute toxic substances.	
3) Take stock of the current uses of the HHPs and the reasons for their use;	Collect information by consultations and interviews with other stakeholders such as user organizations.	
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 substitution for PPP[11] and BP[12]. Collect information by consultations, interviews and by sharing information with other relevant countries.	
5) Alternative products or methods are available.	If phase out action of the use is decided, phase out periods may be necessary/required.	
6) No alternative products or methods are available.	Determine the risks of the use of the products, taking into account the actual conditions of use.	See the checklists below on risk assessment.
7) Select and implement mitigating measures based on the risk assessment	Restrict the use 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 under section 6.1, also see checklists below on health and environmental risk assessment and management.
8) 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.

[11] Guidance document on Comparative Assessment and Substitution of Plant Protection Products in accordance with Regulation (EC) No 1107/2009; The EPPO standard PP 1/271 Guidance on comparative assessment covers assessment of efficacy (effectiveness, crop safety, risk for resistance),practicability, economical disadvantages, alternative measures, and effects on minor uses

[12] https://circabc.europa.eu/sd/a/d309607f-f75b-46e7-acc4-1653cadcaf7e/CA-March14-Doc.5.4%20-%20Final%20-%20comparative_assmt_consolidated_version.doc

Issue	Action	Comments
9) Introduce less hazardous alternatives	Introduce the less hazardous alternatives and phase out the HHPs	Allow for relevant time periods to ensure the effectiveness of the less hazardous alternatives

3.2 General registration process: Checklist for intrinsic properties and approval of active substances

The checklist below suggests an approach to be taken based on the intrinsic properties of the active substance and whether the substance is approved within the EU or not. Any pesticide product for which an application for authorisation has been submitted in a country needs to be evaluated for its composition and physical-chemical characteristics in order to ensure that it meets the specification for content of active ingredients and co-formulants, and that no unacceptable impurities are present.

Active substances			
Issues and sources		**Conclusion and action**	
Issue	**Sources to be checked**	**Outcome**	**Actions**
Is the active substance fulfilling any of the HHP criteria?	Apply the criteria for HHP	Yes	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 and an end date established. An action plan should be designed which includes stakeholder involvement and a communication strategy.
		No	Continue the work according to the check list below.
Is the active substance approved in EU and/or in other countries?	Check the EU databases for plant protection products and biocides; Check the review reports and EFSA conclusions; Check the ECHA website for the assessment report for the active substance and the BPC opinion; Check other databases if no information is available from the EU system.	Yes	Use data and information as far as possible, see further checklists below.

Active substances			
Issues and sources		**Conclusion and action**	
Issue	**Sources to be checked**	**Outcome**	**Actions**
		No	Use data and information as far as possible. Check the background for the non-approval, i.e. - whether there was no application for approval or, - the active substance was not approved based on the outcome of the risk assessment. Consider withdrawal or restriction of the use of the active substance if the reasons in EU for non-approval are relevant also in your country. Information on non-approvals in other countries may also be relevant.
Is the source of the active substance assessed in EU?	Check the EFSA conclusions; Check the ECHA website for the assessment report for the active substance and the BPC opinion	Yes	Use data and information as far as possible. The assessed dossier in EU covers the impurities.
		No	Check whether the active substance has been assessed by the Experts of the FAO/WHO Joint Meeting on Pesticide Specifications.
Are unacceptable impurities present?	Check the EFSA conclusions; Check the ECHA website for the assessment report for the active substance and the BPC opinion	Yes	Use the FAO guidance document on compliance check. Bridging studies might be necessary for risk/ hazard assessment.
		No	

3.3 General registration process: Assessment of risk to human health

Pesticides should only be registered/authorized 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 AOEL/AEL (Acceptable (Operator) Exposure level). 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 data bases. The AOEL/AEL is based on data for different endpoints (mainly from animal studies) which is submitted by industry. The AOEL/AEL is derived by dividing an adequate No-Observed-Adverse-Effect-Level (NOAEL) in an animal study with an assessment factor, usually 100. For certain types of application of the pesticide the exposure can be calculated by the use of models. For further information, please see the introductory guidance on hazard and risk assessment[13].

Plant protection products

On the EFSA website, 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 as well as an excel calculator for the exposure calculation. The exposure scenarios in the calculator are descriptions of the situations where the exposure to the pesticides may occur and typically include:

- The type of application equipment used
- Pesticide formulation
- Application rate
- Work rate
- Level of personal protection

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

Human health effects on 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 which has been (potentially) 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 relating 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 spray cloud (via dermal or inhalation routes) or indirectly through contact with pesticide

[13] Hazard assessment and risk assessment – an introductory guidance

deposits (dermal). Operator exposure likely to occur under the proposed conditions of use should not have an adverse effect on persons using the pesticide.

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 workers re-enter treated areas after application of a PPP (e.g. for crop inspection or harvesting activities). In addition, worker exposure can arise from other activities such as packaging, sorting and bundling. 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*. General guidance on how to perform risk assessments at different resource levels is given in the FAO toolkit.

Biocidal products

On the ECHA website guidance on biocides legislation can be found, 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 human health. The Guidance on Exposure Assessment[14] should be read together with the Biocides Human Health Exposure Methodology Document[15]. Many of the principles described for plant protection products above, apply also for biocides.

3.4 Check list for human health

The checklist below suggests an approach that can be taken for pesticides for which a similar use has been assessed within EU.

Risk assessment Human Health				
Issues and sources			Conclusion and action	
Issue	**Sources to be checked**	**Outcome**	**Plant protection products**	**Biocidal products**
Is the use of your product covered by the EU assessment?	For the PPP check the GAP (Good Agriculture Practice) in the dossier for the product in question. Check the summary of represented uses evaluated in the EU assessment;	Yes	Use data and information in the EFSA conclusions as far as possible. In the conclusions a summary on the assessment of human health can be found, describing how the overall conclusions has been reached. Check the addendum on the	Use data and information in the assessment report as far as possible. In the summary of the risk assessment a description of the health risks can be found. Check the addendum on the impact on human and animal health for a summary of the toxicokinetics, the toxicity, medical data, established

[14] https://echa.europa.eu/home
[15] https://echa.europa.eu/home

Risk assessment Human Health				
Issues and sources			**Conclusion and action**	
Issue	**Sources to be checked**	**Outcome**	**Plant protection products**	**Biocidal products**
	For BP check the ECHA website whether the active substance is approved and for which uses.		impact on human and animal health for a 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 has been submitted in the dossier for your product or if the product is the same as in the EU assessment.	limit values, dermal exposure and exposure scenarios. Default values on dermal absorption may have to be used, unless data has been submitted in the dossier for your product or if the product is the same as in the EU assessment.
		No	Use toxicity data and established limit values if considered relevant. Default values on dermal absorption should be used, unless data has been submitted in the dossier for your product. The EFSA exposure model for calculating the exposure of operators, workers, resident and bystanders may be considered for the exposure assessment.	Use toxicity data and established limit values if considered relevant. Default values on dermal absorption should be used, unless data has been submitted in the dossier for your product. The guidance on biocides human health exposure methodology may be consulted for the exposure assessment.
Are the risk management methods relevant for the country/region?		Yes	Authorize with appropriate risk management requirements.	
		No	Consider other options such as alternative risk management requirements or restrictions in use. In cases where the risk cannot be mitigated appropriately a phase out of the use of the product may have to be considered.	

Interpretation of the outcome

If anticipated that the Acceptable Operator Exposure Level (AOEL) for the pesticide is basically the same globally, it may 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.

Table 2 extracted from the FAO toolkit shows the various possible outcomes of the bridging exercise.

Table 2 bridging approach between existing data and the situation under review

Risk in existing assessment considered acceptable?	**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	Extrapolation not possible: carry out a local assessment	Risk for the situation under review acceptable	Risk for the situation under review acceptable
No	Risk for the situation under review not acceptable	Risk for the situation under review not acceptable	Extrapolation not possible: carry out a local assessment

3.5 General registration process: Assessment of residues from use of pesticide products

In addition to the above mentioned an assessment of the traces pesticides leave in treated crops/products ("residues") is also 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 on the Commission website.

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

- The toxicological reference values; Acceptable daily intake (ADI) and Acute Reference Dose (ARfD)
- Residue estimates such as MRL
- Food intake estimates (based on a typical national diet)

To assess whether the residue level expected to occur in commodities does not lead to unacceptable consumer risk, available residue data are combined with cultural dietary information to estimate potential residue intake by consumers, which is compared to toxicological reference values. Acceptable residue levels are also of great importance in order to ensure safe trade of commodities between countries.

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

3.6 Check list for residues

Assessment of residues			
			Conclusion and action
Issue	**Sources to be checked**	**Outcome**	**Plant protection products**
Is the GAP (Good Agriculture Practice) of your product covered by the EU assessment?	Check the EFSA conclusions.	**Yes**	Use data and information as far as possible.
		No	Use the codex alimentarius and methods to perform national risk assessments.
Are the risk management methods are relevant for the country/region.	Check the EFSA conclusions.	**Yes**	Authorize with appropriate risk management.
		No	Authorize and/or restrict with appropriate risk management.

3.7 General registration process: Assessment of risk to the environment

Plant protection products

Pesticides should only be registered/authorized 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
- effects on terrestrial non-target higher plants
- earthworms

If risks are still of concern higher tier studies, such as field studies, should be required/performed.

Furthermore, an assessment is always made in order to conclude whether the active substance fulfils the decision-making criteria as being persistent, bioaccumulative or toxic (PBT), very persistent/very bioaccumulative (vPvB) or a persistent organic pollutant (POP). These criteria are agreed by the EU member states.

For exposure assessments the example models from the European Union or the "Primet"[16] or other relevant models could be used. Estimation of environmental exposure could be expressed as PEC – Predicted Environmental Concentration, which is the estimation of the concentrations/doses which organisms in environmental compartments are, or may be exposed to. There are different calculation models available to calculate/estimate PEC values. In the European Union calculation models exist for:

- Soil
- Groundwater
- Surface water
- 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 characterization is done by comparing the toxicity effect concentrations with the estimated concentration in the environment. TER (Toxicity Exposure Ratio) values used for plant protection products are "political values" used for decision-making and are agreed by member states in Regulation EU1107/2011. The TER-values are therefore not strictly scientifically based.

Biocidal products

On the ECHA website, guidance on biocides legislation can be found, 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 for plant protection products above, apply also for biocides.

3.8 Check list for the environment

[16] Primet…

Risk assessment Environment			
			Conclusion and action
Issue	**Sources to be checked**	**Outcome**	**Plant protection products and Biocidal products**
Does the active substance fulfil the PBT criteria for PPP or BP?	Check the European databases on PPP and BP for identifying active substances assessed as fulfilling the criteria. The PBT assessments are available in the DAR respectively the FAR.	Yes	Conclude whether these decision-making criteria are relevant for the country.
		No or if the criteria do not (exempel?) apply	Continue with the environmental risk assessment.
Is the use of your product covered by the EU assessment?	For the PPP check the GAP (Good Agriculture Practice) in the dossier in question (PPP). Check the summary of represented uses evaluated in the EU assessment. For BP check at the ECHA website whether the active substance is approved and for which uses.	Yes	PPP: Use data and information in the EFSA conclusions as far as possible. In the conclusions a summary on the assessment of the environment can be found, describing 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 behavior data, toxicity data for aquatic and terrestrial organisms and established "limit values" (Toxicity Exposure Ratio, TER) if considered relevant. Biocides: Use data and information in the assessment report as far as possible. In the summary of the risk assessment a description of the environment can be found. Use "limit values" (Predicted No Effect Concentration, PNEC) if considered relevant.
		No	Use fate and behavior data, toxicity data for aquatic and terrestrial organisms and established limit values if considered relevant. Perform a national risk assessment using relevant "limit values" in the EFSA conclusions respectively the ECHA assessment report, as far as possible. A description of the environment can be found in the summary of the respectively risk assessments. Use "limit values" (Predicted No Effect Concentration, PNEC) or TER values established if considered relevant.

4 Global agreements – a decision support system (toolkit)

4.1 FAO Pesticide registration toolkit

The website "FAO Pesticide registration toolkit" may serve as a decision support system for registrars in different countries. The system is based on the Code of conduct on pesticide management while more details can be found in the FAO/WHO Guidelines for the registration of pesticides. Under the Registration Tools menu on the site you will find technical advice on various processes and methods for pesticide registration, such as data requirements, assessment methods for parts of the registration dossier, decision making steps, etc. These are general procedures, applicable to all pesticides. 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 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 to the environment.

The pesticide registration strategy described in the toolkit is the recommended overall system that a registration authority applies to evaluate and authorize pesticides. The registration strategy chosen will depend much on national legislation, the resources that are available in the country for pesticide registration (i.e. the number of staff, their knowledge and experience) and the level of funding. For more information regarding funding, see the KemI Guidance document on Sustainable Financing of institutional capacity for Chemicals Management[17].

The main strategies proposed are registration by analogy, registration by equivalence and registration based on a complete evaluation.

5 Description of procedures at the European Union and national level

5.1 Risk management

5.1.1 Exclusion and substitution criteria for PPP and BP

The Plant Protection Product Regulation (PPPR) introduces formal exclusion criteria which apply to the evaluation of active substances. These criteria are very similar to the FAO/WHO criteria for identifying Highly Hazardous Pesticides, see below.

The exclusion criteria[18] relates to the intrinsic hazardous properties according to CLP and include:

- Carcinogens Cat. 1A or 1B
- Mutagens Cat. 1A or 1B

[17] XXX

[18] In principle, active substances meeting the exclusion criteria will not be approved. However, there are derogations, in particular when the active substance may be needed where no alternatives are available. In this case, approval of an active substance is time-limited for a maximum of five years.

- Toxic for reproduction Cat. 1A or 1B
- Endocrine disrupting properties
- Persistent, bioaccumulative and toxic (PBT)
- Very persistent and very bioaccumulative (vPvB)
- Fulfilling POP criteria[19]

The same criteria apply for active substances in biocidal products according to the Biocidal Products Regulation (BPR). 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 proved 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[20]. The active substance will then be regarded as a so called candidate for substitution.

5.1.2 The substitution principle and comparative assessment

The application of the substitution principle and a comparative assessment is an additional 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 which meet at least one of the exclusion criteria but there are also a number of additional criteria which are listed in the EU regulations. Additional provisions may be cases where non-chemical control or prevention methods or other available substitutes exist which can be applied instead, something which is highly recommended. Examples of such methods could be the use of special warehouses to avoid chemical post-harvest treatment or heat treatment of bed bugs.

A comparative assessment of products shall be made before authorizing a product which contains a candidate for substitution. The purpose is to either 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 replacing the product with a non-chemical control or prevention method.

5.1.3 Risk management 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 being communicated both as part of the specific provisions of the authorization of the product, in case there is a registration scheme in place, and included in the guidance of 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.

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

[19] For biocides, the BPR stipulates that the criteria is included in the definition of a substance of concern.
[20] For an active substance which does not meet the exclusion criteria or is a candidate for substitution the time for approval shall not exceed 10 years.

than what is required in order for the pesticide to still be efficacious. For operators who are usually both mixing and loading and applying the plant protection product, risk reduction measures, such as use of products which do not require mixing (like the use of seeds pre-treated with seed dressing or ready-to-use packages) and appropriate personal protection equipment (like gloves, respiratory mask and coveralls) will contribute to a reduced exposure. However, an assessment whether the measures are feasible and affordable in the country or the region needs to be made. For workers the time before re-entry into a sprayed area is an important factor which will affect the level of exposure but also the access to adequate personal protective equipment.

Regarding bystanders, it may be a matter of information when to avoid an area being sprayed or entering 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 get into contact with food or cooking facilities or making sure that the person handling exposed clothes or containers protect him or herself. The lowering of dose rates and number of applications will also reduce the amount of residues and thereby result in a lower exposure of consumers.

Biocidal products

The same general principles apply also 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 without protective equipment or that the equipment used mainly concerns items like gloves and other personnel protective equipment. However, industrial use of biocidal products or 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 ensure that it 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, determination of weather conditions and level of infestation. This demonstrates the relevance and importance of making proper and specific use instructions available for the users of biocidal products.

5.1.4 Risk management environment

Plant protection products

Generally the exposure of the environment could be reduced by lower dose rates, reduction in number of applications, or application only by seed dressing methods. Risks to groundwater could be lowered by different risk reduction methods such as no application in areas used for abstraction of drinking water, application every third year (linked to rotation of certain crops), lowering dose rates, restrictions to special seasons like autumn or spring spraying. Spray-free zones to protect surface water and terrestrial ecosystems and no spraying in flowering crops, or at times when bees are not active, are examples of reducing risks to bees.

Biocidal products

Some of the risk mitigation measures applied to minimize the direct exposure to humans may also be applicable in order to minimize exposure to the environment. Others may be more specific such as disposal of dead rodents exterminated by a rodenticide in order to minimize 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 to 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.

5.2 Risk assessment

5.2.1 Process for Plant Protection Products

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 EU-level and the authorization of the products is made on national level. The procedure is laid down in the legislation for plant protection products as well as in different types of guidance documents and is illustrated in Fig. 2. The different background documents which are generated by this process and serve as a basis for the management of the pesticides within EU are found in table 1.

Approval of active substances

A plant protection product usually contains more than one component. The active component against pests/plant diseases is called “active substance”. The Commission evaluates every active substance for safety before it reaches the market in a product. This evaluation consists of an assessment of the risk to people, animals and to the environment and includes an assessment of the residues in food. The procedure for approval of active substances is as follows:

1. Application to an EU country called *Rapporteur Member State (RMS)*;
2. RMS prepares a draft assessment report;
3. EFSA (The European Food Safety Authority) organizes the peer review and issues its conclusions which are referred to in this document. The conclusions contain a summary of the intended uses and the risk assessment for human and animal health and environment
4. The Standing Committee on Plants, Animals, Food and Feed consisting of the member states votes on approval or non-approval of the active substance
5. Adoption by the EU Commission and publication of a Regulation in the EU Official Journal.

Authorization of a plant protection product (PPP)

PPPs contain at least one approved active substance; these may include chemicals, micro-organisms, pheromones and botanical extracts. Before any PPP can be placed on the market

or used, it must be authorized in the Member State(s) concerned. Regulation (EC) No 1107/2009 lays down the rules and procedures for authorization of PPPs.

There are different types of applications that can be submitted depending on the intended use of the PPP, the Member State(s) for which the PPP is required and the regulatory status of any existing authorizations. What´s common for these different types of applications is that they all contain a risk assessment which serves as the basis for the decision.

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

- Phytotoxicity and efficacy
- Absence of unacceptable effects on plants or plant products
- Impact on target vertebrates 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
- Influence on the environment
- Fate and distribution in the environment
- Impact on non-target species
- Analytical methods
- Physical and chemical properties

5.2.2 Process for Biocidal products

The process for placing of biocidal products on the market in the EU is very similar to the one for plant protection products i.e. it is divided into two steps, the assessment and approval of the active substance is made on EU-level and the authorization of the products is made on national level. The procedures for this process are laid down in the legislation for biocidal products as well as in different types of guidance documents. For a more detailed description of the different documents generated within the process, please see section 4.2.3.

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 EU country and is followed by a peer review involving all EU countries, coordinated by the European Chemicals Agency (ECHA). On the basis of the conclusions of this assessment, the Commission decides whether to approve or not, the use of the active substance in biocidal products after a vote in 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 at product authorization. The conditions of the approval are found in the implementing regulation of the active substance. The conclusions of the risk assessment are found in the assessment report.

Authorization of Biocidal products (BP)

The EU Regulation on biocidal products requires all biocidal products to be authorized by the appropriate authority before they are placed on the market. Authorities can only authorize 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 proven to be

effective for its intended use(s). Companies can choose between several alternative processes, depending on their product and the number of countries where they wish to sell it.

- A national authorization or a mutual recognition
- Union authorization
- Simplified authorization
- Same biocidal product authorization

The different types of authorizations all have in common that they are based on a risk assessment. 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 which data the companies need to provide to support the risk assessment.

The risk assessment shall determine:

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

5.3 Work-sharing

Due to the very extensive workload of authorities which are responsible for registration of pesticides before they can be sold and used, and in order to ensure harmonization between countries, the EU legislation promotes the possibility to place products on the market by mutual recognition. After approval of the active substance within EU, industry applies for product authorization in one Member State and may then, based on that first decision, apply for product authorization in other Member States within the Union. One prerequisite that needs to be fulfilled when this procedure is applied is that the conditions of use and the agricultural practice is 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 allows

for refusal or adjustment of terms and conditions of the authorization.

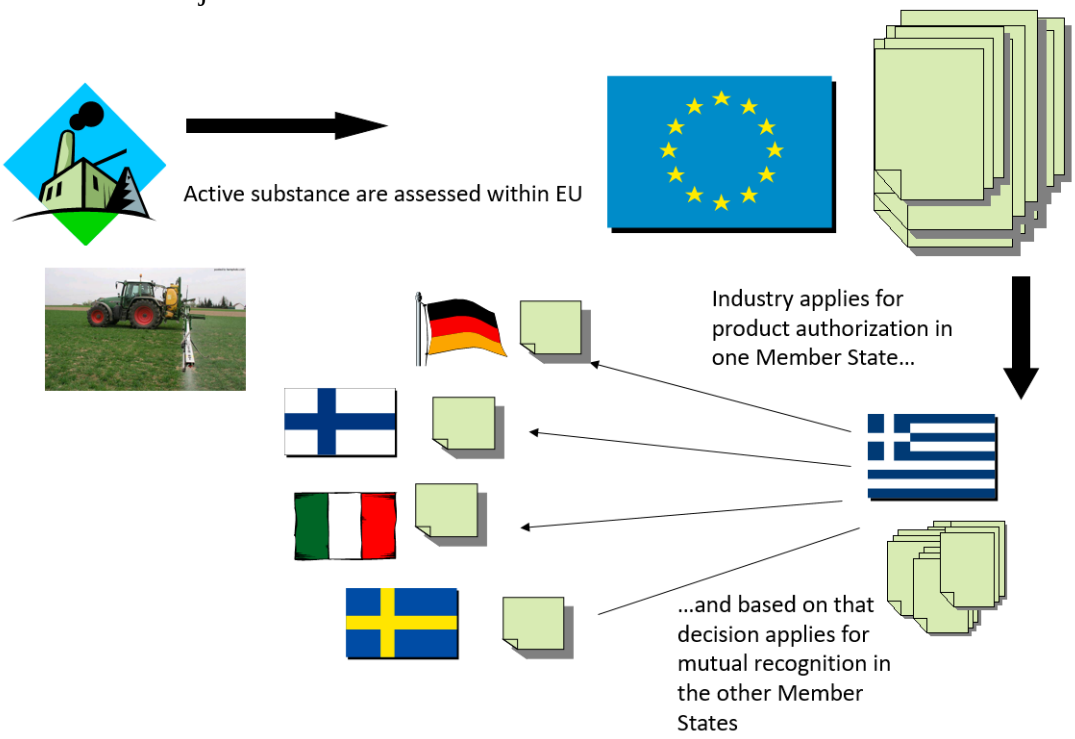

Figure 4. Work-sharing by mutual recognition

Other ways to decrease the workload is to establish simplified procedures for products which 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.

5.4 Export and import of hazardous chemicals

Substances listed in Part 1 and 2 of Annex I to the EU Regulation concerning export and import of hazardous chemicals[21] are subject to export notification procedures since the Rotterdam Convention allows Parties the right to take action that is more stringently protective of human health and the environment as long as the called action is consistent with the provisions of the Convention and is in accordance with international law. The substances listed in Part 1 and 2 are hazardous substances that are banned or severely restricted within the European Union.

6 Sustainable use of pesticides

6.1 Frame Directive on sustainable use in EU

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). At present, the Directive only applies to pesticides which are plant protection products.

[21] 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

The directive states that the following actions should be taken in the member states:

- **National Action Plans** - EU countries shall adopt plans, setting objectives and timetables to reduce risks and 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 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;
- **Minimizing or banning** - EU countries shall minimize or ban the use of pesticides in critical areas for environmental and health reasons;
- **Inspection of equipment in use** - All pesticides application equipment had to be inspected at least once by 2016 to grant a proper efficient use of any plant protection product;
- **Integrated pest management** - Promotion of low pesticide-input management including non-chemical methods. Professional users have to apply general principles of IPM from 1 January 2014.

A number of main actions have been identified which the EU member states develop into national actions plans, see fig. 4.

Figure 5 Main actions to achieve a sustainable use of pesticides

Although biocides are not currently covered by the EU frame Directive on sustainable use of pesticides many of the actions remain the same. Further tools or actions, which could be used to stimulate innovation and the development of new products with a better profile, are the following:

- Exclusion, substitution and comparative assessment
- Labelling schemes
- Best available techniques regarding industrial emissions

Sustainable use of biocidal products can be defined as the objective of reducing the risks and impacts of the use of biocidal products on human health, animal health and the environment and of promoting the use of integrated pest management and of 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 examined:

- 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.

6.2 Examples from Sweden on how to achieve a sustainable use of pesticides - Plant protection centers

6.2.1 Plant Protection Centers are performing regional activities under the Swedish Board of Agriculture

The aim of the Plant Protection Centers is to make plant protection in agri- and horticulture both efficient and environment friendly. The centers are located in five different places in Sweden. The objectives for the centers are the following:

- to achieve optimal integration of the cultivation system and technique with the factors of production while taking environmental concerns into account;
- to adapt the use of pesticides to need;
- to help avoid health and environmental hazards in pesticide use;
- and to obtain a more biodiverse fauna and flora.

6.2.3 Activities

Pest and disease prognoses

The presence of pests, and the need for pesticides vary much from year to year, and also from field to field in one year. To adapt the use of pesticides according to actual need is therefore very useful both for society's environmental concerns and for the individual farmer's financial situation.

The prognosis and early warning service is an important help for those farmers who wish to adapt their pesticide use to need. For certain pests, prognoses are made that in advance state an expected development. Such prognoses are made regularly for instance for bird cherry aphids, fruit flies and eyespot in cereals and sclerotinia disease in spring oilseeds. Prognoses are made also as regards horticulture, for instance for dart moths, carrot flies and apple scab.

Early warning of pests and diseases

For most pests, there is as yet no method of prognosis. For such pests, information on the current situation (early warning) is given based on regular field observations and assessments of pests and diseases. During the growing season, plant protection data is gathered from approximately 1100 fields per week. After processing and analysis of this data, appropriate measures are discussed in the weekly telephone conferences led by the Plant Protection Centres. Participating in those conferences are local advisors as well as market representatives.

Diagnoses

In order to correctly adapt pesticide use to need, the right diagnosis must first be made. It often takes special skills and equipment to determine the cause of damage. Every year, the Plant Protection Centres receive a large number of samples from the advisory service and market agents.

Information

There is a great need for information concerning the use of pesticides, and the risks associated with this use. The Plant Protection Centres take active part in a large number of courses, field excursions, telephone meetings, and 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 Plant Protection Centres' information is published on the Internet.

Development

The Swedish University of Agricultural Sciences (SLU) is responsible for e.g. research and development in the field of environmental and plant protection. This includes among other things development of methods of pest prognosis. The SLU works in close co-operation with the Plant Protection Centres, whose role is primarily to evaluate and spread the methods of prognosis.

Methods of prognosis currently being developed are for example a long term prognosis for aphids by the use of suction traps, risk assessment for winter wheat moulds and a dosage key for weed control.

6.3 Examples from Sweden on how to achieve a sustainable use of pesticides - training courses

Anyone wishing to use pesticides authorized in class 1L and 2L[22] must complete training in order to receive a usage permit. Usage permits for foreign authorizations are issued by the Board of Agriculture (Jordbruksverket) when individuals wish to become established in Sweden. Pesticides may be used outdoors, for seed treatment or in and around greenhouses.

The specific training in Sweden concerning pesticide use in gardening or out on the fields consists of initial (four days) and additional (one day) training. The four day course consists of three days general training. The participants will learn for instance about the Swedish Environmental Code and what personal protection they need when using pesticides. On the last day there are optional themes depending on the type of pesticide they use, for example in greenhouses or out on the fields. In the end there will be a test. The participants have to pass the test in order to be granted a certificate. Before anyone can use pesticides they need to;

- be 18 years or older;
- have the certificate showing that you have sufficient knowledge in the use of pesticides.

When they have completed the initial training and granted a certificate they have to update their certificate every fifth year by attending the one day additional course. The Swedish Board of Agriculture will register names and what training they have followed through once they have completed the course and passed the test. The record is used by the Swedish Agriculture Board and the county administrative boards and shows who is permitted to use pesticides in Sweden. The county administrative boards in Sweden arrange and administer the training courses.

6.4 Swedish examples on application of the substitution principle

In 1986 a program to reduce the risks of pesticides was launched in Sweden. The program comprised the following measures:

- Changeover to pesticides with less risks
- Regulations on the handling of pesticides
- Training and information dissemination concerning the safer handling of pesticides and control of pesticide residues in food and reduced consumption of pesticides

Among the measures to reduce use of pesticides the following actions were developed and are still applicable:

- Research and development
- Integrated crop protection
- Forecasting and warning of pests
- Advisory service towards reduced consumption of herbicides
- Pesticide fees

Below a number of examples are listed to show how comparative assessment and substitution can be applied in practice.

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- **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, since it is considered to be far more mobile and degraded more slowly in soil. Substance A is contrary 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 have been raised during the first review of old substances. Substance B and the 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 rice to concerns for operator safety. There is another substance available on the market for the same use, also sufficiently effective, but 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. Main use is for the control of potato cyst nematodes. The active substance included showed high mobility. 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 an achieving sustainable agriculture.

Decision: The soil disinfectant is not re-approved.

- **Example 4 - Substitution on 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, high bio accumulating potential, is volatile and highly toxic to different groups of aquatic organisms. There are several

alternative products (including five different actives) available on the market 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 to 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 considerable 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 (mixture between contact and systemic fungicides) is the best chemical strategy available for control of the new mating type of *Phytophthora infestans.* Possibilities for a 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 ongoing 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, which is chemically related to another substance already approved for the same use. Substance F show significantly better environmental properties compared to the existing substance, particularly regarding persistence and bioaccumulation. However, since 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 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 voluntary withdrawn by the registration holder.

END

7 Litteraturförteckning

Det finns inga källor i aktuellt dokument.