

Approval of Pesticides

Lilian Törnqvist, September 2014

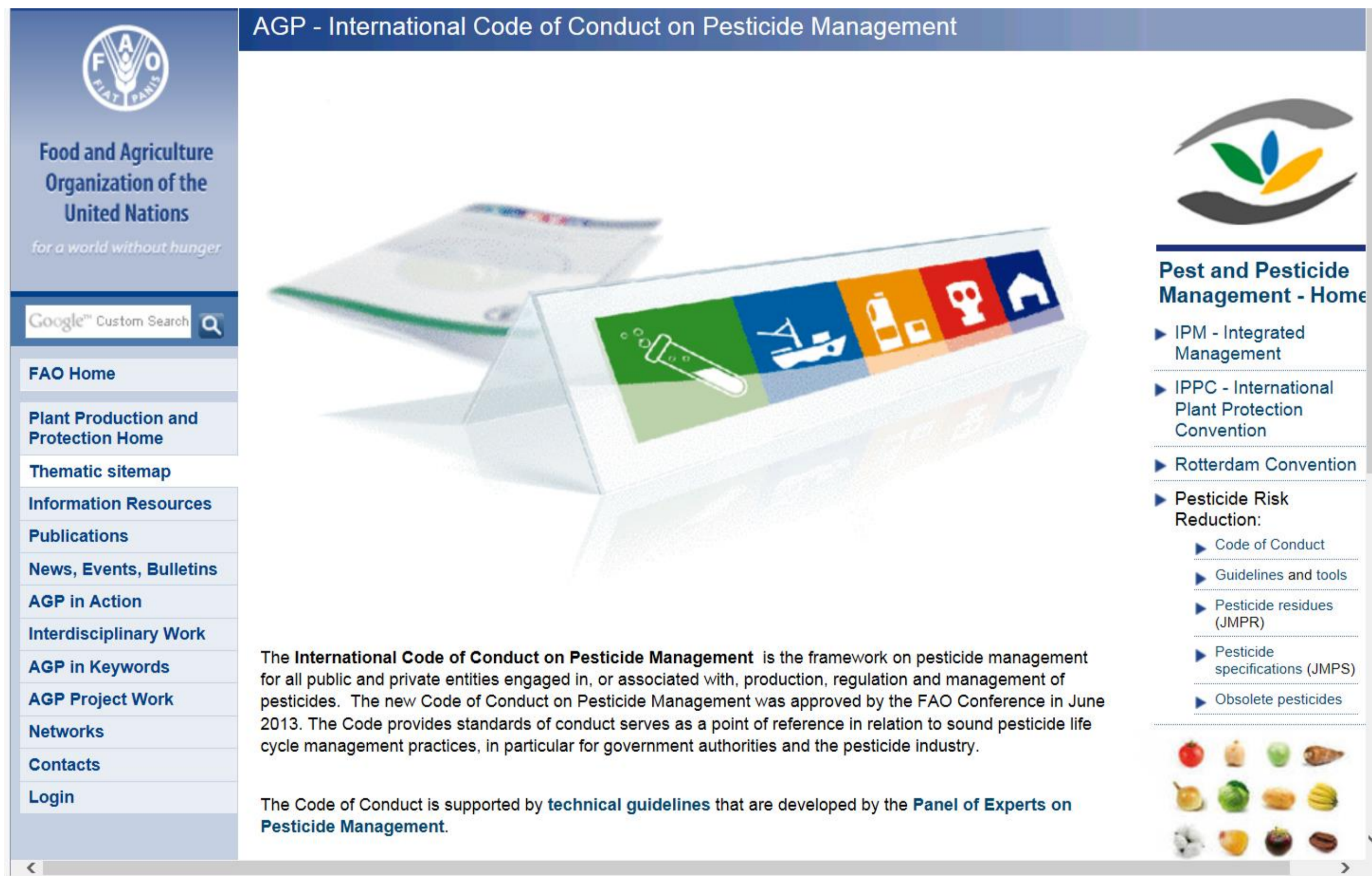
Content

- Why risk assessments and risk management on pesticides?
- FAO: Code of conduct
- Criteria: FAO: Highly Hazardous Pesticides
- History on authorisation of pesticides in Sweden
- Pesticide regulation today
- Decisions
- Share of work burden
- Sustainable use of pesticides
- Discussion

Reasons for approval of pesticides

1. Designed to kill living organisms = **Toxic**
2. Are handled by people by mixing/loading and application → health problems
3. Are deliberately applied to foodstuff and the environment (usually not relevant for non-agro-pesticides) → food and environmental problems

FAO: Code of conduct on pesticide management



The screenshot shows the FAO website page for the International Code of Conduct on Pesticide Management. The page features the FAO logo and name on the left, a search bar, and a navigation menu. The main content area includes a 3D graphic of a book with icons representing various aspects of pesticide management. The text describes the Code of Conduct as a framework for pesticide management, approved by the FAO Conference in June 2013. A sidebar on the right lists related topics such as IPM, IPPC, and Pesticide Risk Reduction. The bottom of the page shows a grid of various fruits and vegetables.

AGP - International Code of Conduct on Pesticide Management

Food and Agriculture Organization of the United Nations
for a world without hunger

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Plant Production and Protection Home

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AGP in Action

Interdisciplinary Work

AGP in Keywords

AGP Project Work

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Pest and Pesticide Management - Home

- ▶ IPM - Integrated Management
- ▶ IPPC - International Plant Protection Convention
- ▶ Rotterdam Convention
- ▶ Pesticide Risk Reduction:
 - ▶ Code of Conduct
 - ▶ Guidelines and tools
 - ▶ Pesticide residues (JMPR)
 - ▶ Pesticide specifications (JMPS)
 - ▶ Obsolete pesticides

The **International Code of Conduct on Pesticide Management** is the framework on pesticide management for all public and private entities engaged in, or associated with, production, regulation and management of pesticides. The new Code of Conduct on Pesticide Management was approved by the FAO Conference in June 2013. The Code provides standards of conduct serves as a point of reference in relation to sound pesticide life cycle management practices, in particular for government authorities and the pesticide industry.

The Code of Conduct is supported by **technical guidelines** that are developed by the **Panel of Experts on Pesticide Management**.

FAO: Code of conduct on pesticide management

new Code updated June 2013

- Article 6.1: Governments should;
 - Establish pesticide registration schemes and infrastructures under which each pesticide product is registered before it can be made available for use;
 - Conduct risk evaluations and make risk management decisions based on all relevant available data and information, as part of the pesticide registration process.

FAO/WHO highly hazardous chemicals:

- Article 7.5: 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 practices are insufficient to ensure that the product can be handled without unacceptable risk to humans and the environment.

JMPM:

- As a first step in the development of a risk reduction programme, the [FAO/WHO Joint Meeting on Pesticide Management \(JMPM\)](#) was requested to provide a working definition for highly hazardous pesticides.

Working definition:

- Classes 1a or 1b of the WHO classification
- Carcinogenicity Cat. 1A or 1B GHS
- Mutagenicity Cat. 1A or 1B
- Reproductive toxicity Cat. 1A or 1B
- Annexes A or B or paragraph 1 of Annex D in the Stockholm convention
- Montreal protocol
- High incidence of severe or irreversible adverse effects

WHO classification of pesticides by hazard 2009



The screenshot shows the WHO website interface. At the top, there are language options: عربي, 中文, English, Français, Русский, and Español. The WHO logo is prominently displayed. Below the logo, there are social media icons for RSS, YouTube, Twitter, Facebook, and Google+. A navigation bar includes links for Health topics, Data, Media centre, Publications, Countries, Programmes (highlighted), and About WHO, along with a search box. The main heading is "International Programme on Chemical Safety".

IPCS Home

- Health impacts of chemicals
- Tools for assessing chemical risks
- Poisons information, prevention and management
- Chemical incidents and emergencies
- Capacity building

The WHO Recommended Classification of Pesticides by Hazard

ISBN: 978 92 4 154796 3



This document sets out a classification system to distinguish between the more and the less hazardous forms of selected pesticides based on acute risk to human health (that is the risk of single or multiple exposures over a relatively short period of time). It takes into consideration the toxicity of the technical active substance and also describes methods for the classification of formulations.

The document lists common technical grade pesticides and recommended classifications together with a listing of active ingredients believed to be obsolete or discontinued for use as pesticides, pesticides subject to the prior informed consent procedure (Rotterdam Convention), limitations to trade because of the Stockholm convention (POPs), and gaseous or volatile fumigants not classified under these recommendations.

Share Print

- Full text pdf, 2.23Mb
- To order a copy online
- To order a copy by fax or e-mail pdf, 547kb

Risk reduction

- Effective risk reduction from HHPs is mainly carried out at the national level, and national governments thus have the prime responsibility in this respect. Therefore, the JMPM recommended that FAO, in collaboration with WHO, invite national governments to ensure that at least the following risk reduction measures for HHPs are taken into account:

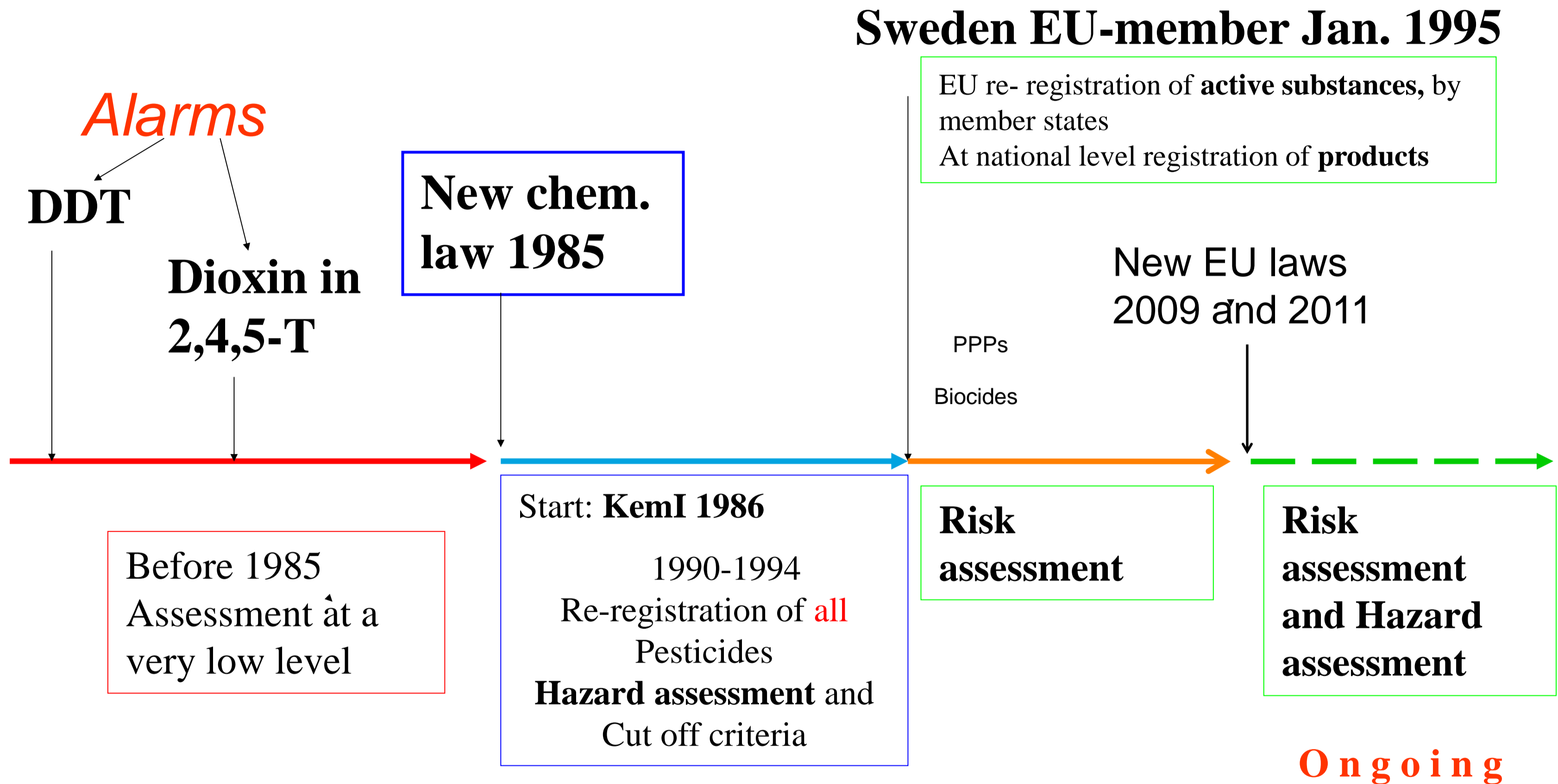
Risk reduction cont.(2)

- Identify HHPs with help of the criteria explained above;
- Review the need for the use of HHPs, while simultaneously reviewing use conditions, mitigation measures and comparative risk assessment;
- Where a specific need is identified for a HHP and no viable alternatives are available, governments should be advised to take all the necessary precautions, mitigation measures and apply restrictions, that may include the use only under certain conditions or by specifically certified users, severe restrictions, or a possible phase-out;

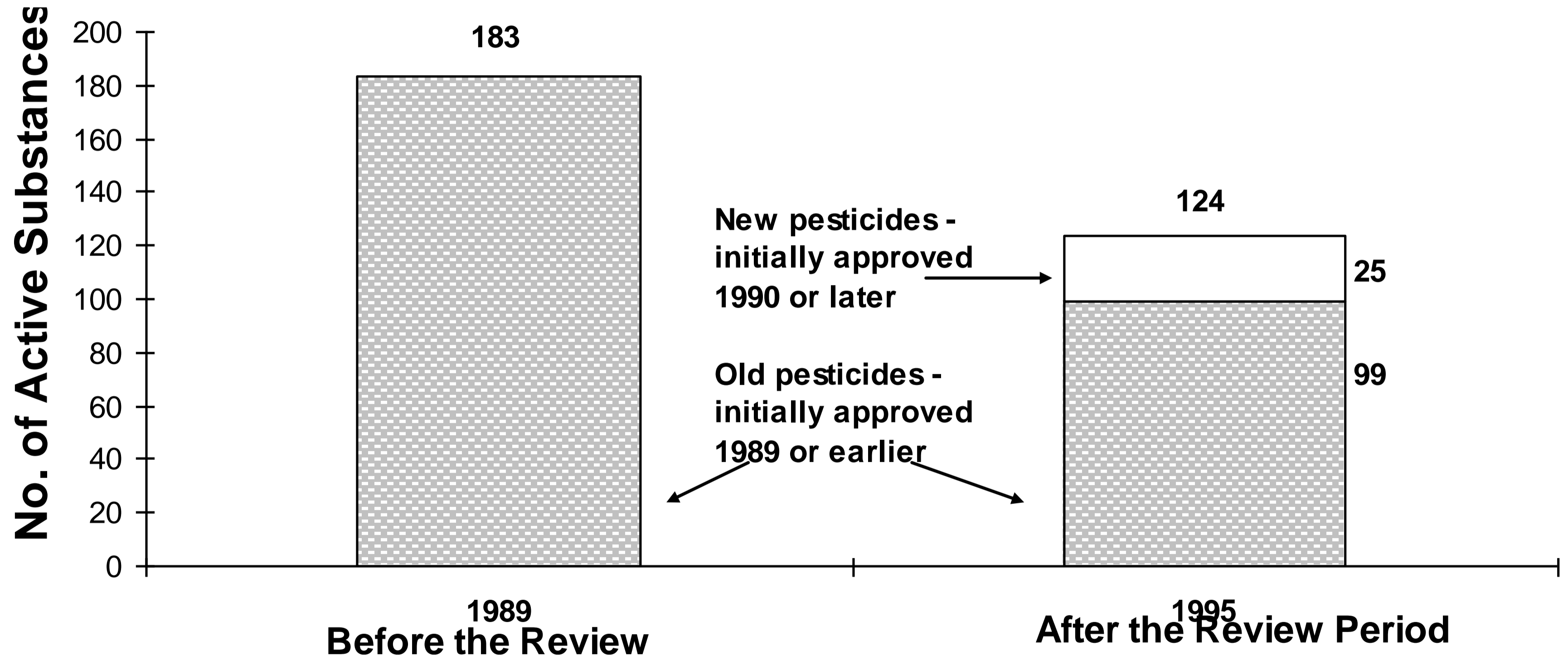
Risk reduction (3)

- Promote the use of alternative pest management strategies and, in case they are not available, promote research for development of alternative strategies;
- Promote the substitution principle for HHPs;
- Ensure the provision of sufficient advice and information to users.

Authorization of Pesticides over time (Sweden)



Review result in Sweden



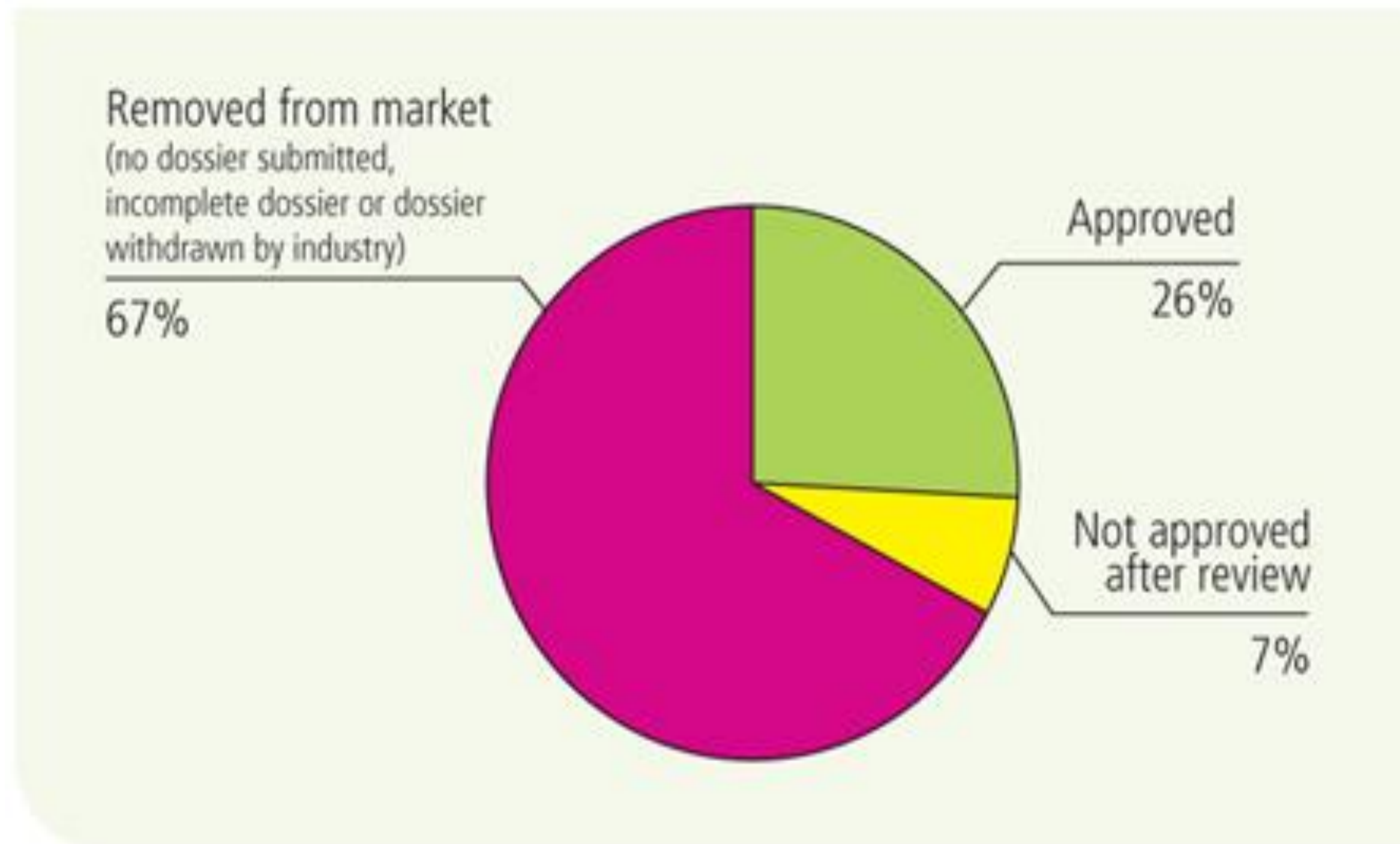
Plant protection Products in EU

- PPP-Directive 91/414/EEC – work started 1993-2011
 - Long time for the development of guidelines
 - Currently around 450 active substances on the market.

PPPs in EU 2009

- http://ec.europa.eu/sanco_pesticides/public/index.cfm

Existing substances





Decision –making criteria product level based on risk assessments “Uniform Principles” Annex VI

- General Principles
- Specific Principles
 - Human health:
 - Consumers: ADI (Acceptable Daily Intake), ARfD, (Acceptable reference Dose)
 - Operators, bystander, workers: AOEL (Acceptable Operator Effect Level)

Decision –making criteria product level based on risk assessments “Uniform Principles” Annex VI

No authorisation should be granted if:

- Persistence: DT 50 > 3 months; DT90 > 1 year
- Groundwater or surface water used for extraction of drinking water: 0,1 µg/l or 1/10 of the ADI (if lower)
- BCF > 1000 for readily degradable or > 100 for not readily degradable

Unless it is scientifically demonstrated that under field conditions.....

Decision –making criteria product level based on risk assessments “Uniform Principles” Annex VI

Impact on non-target species, no authorisation if TER:

- Birds/mammals: < 10 acute; <5 long- term; BCF>1 in fat tissue
- Fish/Daphnia: < 100 acute; < 10 long-term
- Algae: < 10 acute
- Earthworms: short-term < 10; long-term < 5
- Beneficial arthropods:>30% affected
- Bees: Hazard quotient >50

Unless it is scientific demonstrated that under field conditions.....

Plant protection Products in EU

- New regulation on PPP: Regulation 1107/2009; Applicable 14 June 2011
 - New cut off criteria: CMR category 1A and 1B, endocrine disruptors and very persistent and bio-accumulating substances not to be approved (\leftrightarrow "serious danger to plant health", 5 years extra, but not canc. or repro. cat 1A)
 - Substitution by comparative assessment of products
 - Zonal authorization
 - Safeners and synergists to be approved according to the same procedure as for active substances.
 - A work plan established by 14 December 2014.
 - Co-formulants: Negative list Annex III
 - Uniform Principles for authorisation of products the same as before.

New Regulation 1107/2009

”to ensure a high level of protection..”

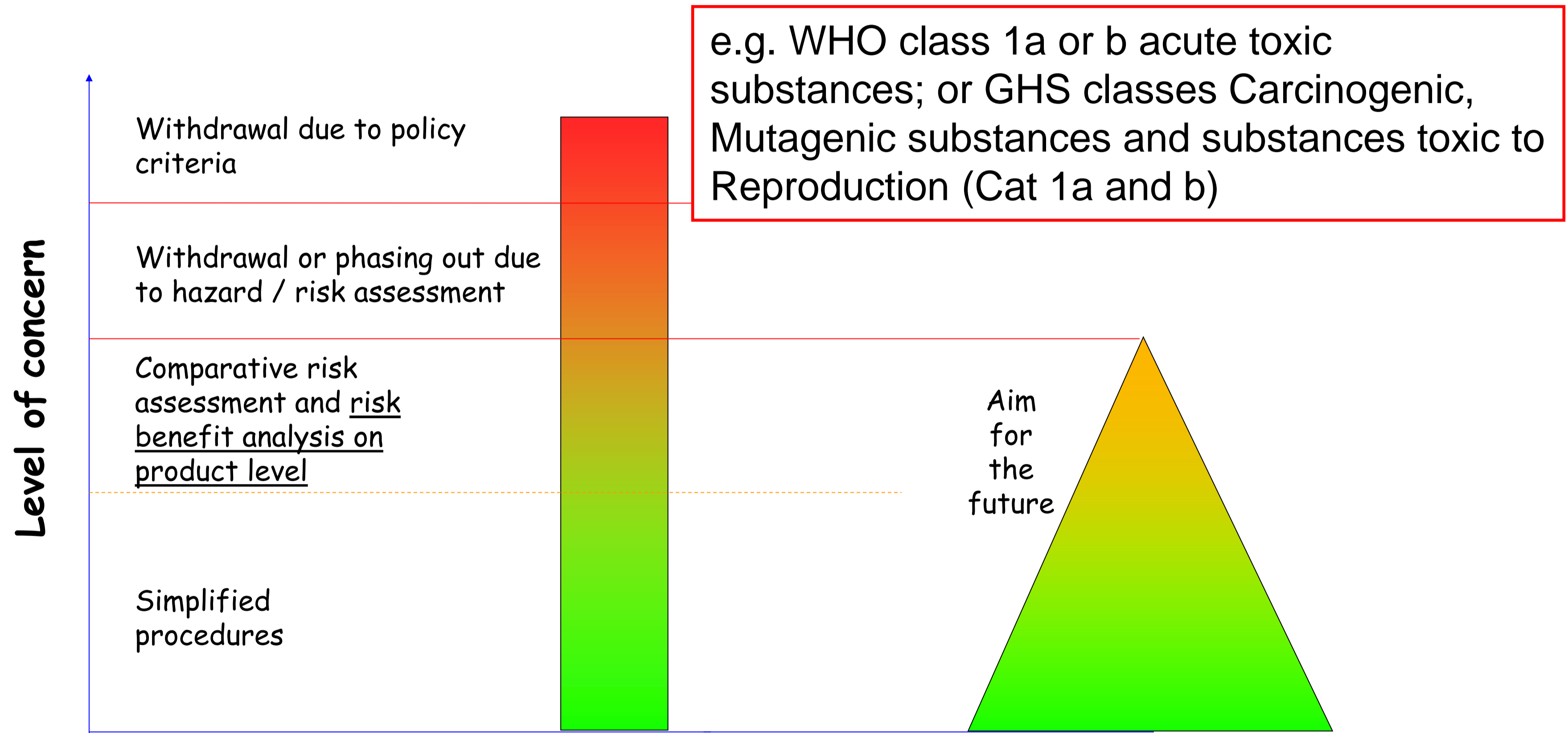
- Member States are placed in three zones
- The authorization process should be harmonized within the zones.
- Application in one Member State, the work to be carried out on behalf of the other MSs.
- Coordination work program within zones is ongoing
- New guidance docs produced for harmonized procedures

Biocides in EU

- The biocide directive 98/8/EC → Regulation 528/2012, in force: 1 September 2013.
22 product types
- Approx. 1020 identified existing active substances May 2000
- Approx 350 existing active substances "notified" (November 2012) 62 active substance are included in Annex I (many substances also included in the PPP-Regulation)

<http://www.echa.europa.eu/en/web/guest/regulations>

Use of comparative assessment and decision-making criteria



Substitution criteria

Substitution is only possible if

- an existing product or non-chemical method is significantly safer for human/animal health or the environment; **and**
- It presents no significant economic or practical disadvantages; **and**
- the chemical diversity are adequate to minimize the occurrence of resistance.

Substitution example

A chemical versus a non-chemical method

Examples:

Chemical methods	Non-chemical control and prevention methods
Post harvest disease control on fruit and ware table potatoes	Climatic control of storage diseases. ULO (Ultra Low Oxygen) and low temperature in warehouses.
Soil disinfection	Preventive methods such as crop rotation, use of resistant crop varieties and to avoid cultivation of susceptible crops in infected areas.
Aquatic weed control	Mechanical weed control and dredging in ditches and watercourses.

Substitution example product level

formulation	Formulation causing less risks
Powder	Suspension /liquid Wax block
Toxic solvent	Solvent less toxic
Need to mix with water/solvent	Ready to use /soluble small package
Etc.	

Application in Sweden

- Most pesticides in Sweden are not produced in Sweden
– Sweden is a gross-importer of pesticides
- The applicant should be the owner of the product dossier or have letter of access from the owner

Applicant

- The applicant shall supply KemI with the following:
 - Intended uses
 - Efficacy trials
 - Residue data **PPPs**
 - Quality of the active substance
 - Composition of the product
 - Full data package → **Risk assessment**
 - Label

Classification and labelling

- The applicant has to carry out classification and labelling of the product according to EU regulation (GHS). Kemi will check it and accept it or suggest changes
- The applicant shall include the **label** for the product at time of application.
 - It should be in **Swedish** and
 - has to be based on the **proposed authorized uses**

Annex IV and V

- labelling requirements
- Standard phrases
- Criteria for standard phrases

Zonal application Plant Protection Products

- Intended zones
- Source of the active substance
- General overview of products within the zone
- Summary of uses –critical GAP → risk envelope
 - Operators
 - Consumers
 - Environmental risk assessment
 - Ecological risk assessment

Decision (agro-pesticides)

- Different kinds of decisions:
 - Decision according to the intended uses (GAP), if no problems
 - Decisions with changes in the intended uses e.g. for PPPs fewer crops, change in doses, change in time of application, PHI (pre harvest interval);
 - No authorization

Decision cont.

- Length of approval PPP:
 - First inclusion 10 years
 - Basic substances unlimited period
 - Low risk substances 15 years
 - Candidates for substitution 7 years
 - Renewal of approval 15 years

Decision cont.

- Withdrawal of authorisation:
 - No more import
 - 6 months to sell out the stock at retailer level
 - Plus another year for the farmers to use the product
 - Highly hazardous immediate ban
 - to minimize stockpiles

”User classification” of products

- Besides the ”ordinary” EU classification and labelling pesticide products, Sweden has a special “user” classification, which are put in one of three user groups, to define needs of training.
 - **Class 3** products can be used by anyone, no need for education (low hazard / risk)
 - **Class 2** – only for users who have training
 - **Class 1** additional training and a permit is required

Directive 2009/128/EC

- National action plans (14 December 2012)
- Training, sales, information and awareness-raising
 - (14 December 2013 certification system)
 - 14 December 2015 sufficient educated staff, restrict sales for professional use, etc.
- Pesticide application equipment; inspections by 14 December 2016
- Aerial spraying –prohibited, but...
- Protection of aquatic environment and drinking water
- Reduction of amount use

Directive 2009/128/EC cont.

- Handling and storage
- Intergrated pest management
- Indicators, reporting and information exchange

Thank you for your attention!



List HHP related to GHS

- Cancer 1B
- Mutagen 1B
- Repro 1A
- Repro 1B
- Acute tox 1 (Extremely hazardous 1A)
- Acute tox 2 (Highly hazardous 1B)

Exercise

- Groups:
- Albania
- Bosnia Herzegovina
- Brazil
- Georgia
- Kosovo
- Macedonia
- Moldova
- Serbia
- Ukraine

Discussion related to FAO Code of conduct;

Use the GD document to get information

- Identify HHPs with help of the criteria;
- Select 3 important substances for your country;
- Review use conditions, mitigation measures in the report;
- Take all the necessary precautions, mitigation measures and apply restrictions relevant for your country, that may include the use only under certain conditions or by specifically certified users, severe restrictions, or a possible phase-out;