EU Framework - Pesticides

Sectoral Dialogues regarding the Control and Regulation of Pesticides and Biocides

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Key Directives

- Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market (PPPR);
- Directive 2009/128/EC establishing a framework for Community action to achieve a sustainable use of pesticides;
- Regulation (EC) No 1185/2009 concerning statistics on pesticides;
- Directive 2009/127/EC on machinery for pesticide application.

Outline

- Definition of pesticides;
- Approval process;
- Authorisation procedure;
- Substitution principle;
- Mutual recognition and parallel trade;
- Regulation of neonicotinoids;
- Sustainable use of pesticides;
- Integrated pest management principles.

Plant protection products

- *'plant protection product' = "products, […], consisting of or containing active substances, safeners or synergists, and intended for one of the following uses:*

  a) protecting plants or plant products against all harmful or preventing the action of such organisms;

  b) influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient;

  c) preserving plant products;

  d) destroying undesired plants or parts of plants;

  e)checking or preventing undesired growth of plants.

Key actors

European Commission

EUROPEAN COMMISSION

efsa

European Food Safety Authority

Committed to ensuring that Europe's food is safe

National competent authorities:

Austria	Belgium	Bulgaria	Cyprus	Czech Republic
Denmark	Estonia	Finland	France	Germany
Greece	Hungary	Iceland	Ireland	Italy
Latvia	Liechtenstein	Lithuania	Luxembourg	Malta
Netherlands	Norway	Poland	Portugal	Romania
Slovakia	Slovenia	Spain	Sweden	United Kingdom

Member State Zones

Zone A North	Zone B Centre	Zone C South
• Denmark • Estonia • Latvia • Lithuania • Finland • Sweden	• Belgium • Czech Republic • Germany • Ireland • Luxembourg • Hungary • Netherlands • Austria • Poland • Romania • Slovenia • Slovakia • United Kingdom	• Bulgaria • Greece • Spain • France • Italy • Cyprus • Malta • Portugal

Active substance approval

RMS

- Application to Rapporteur Member State (RMS)
- Initial scientific and technical evaluation of dossier by RMS
- Completeness check by RMS
- Request for additional information

RMS

- Dossier evaluation (12 months)
- Request for additional information (6 months)
- Draft assessment report & conclusions of evaluation

EFSA

- Sends DAR to applicant, MSs and makes it available to public
- Receipt of comments (60 days) & expert meetings, if applicable
- Request for additional information (90 days)
- Consideration of comments & draft EFSA conclusions
- EFSA conclusion on approval of active substance

COM

- Review report (6 months) and draft Regulation
- Comments from application
- Implementing Regulation approving active substance, or
- Implementing decision that an active substance is not approved.

Dossier

a) information on representative uses;

b) summaries and results of tests and studies for each data requirement for the active substance

c) summaries and results of tests and studies for each data requirement for the plant protection product

d) justification of the steps taken to avoid animal testing and duplication of tests and studies on vertebrate animals;

e) checklist demonstrating that the dossier is complete for the uses applied for;

f) the reasons why the test and study reports submitted are necessary for application;

g) where relevant, a copy of an application for a maximum residue level;

h) an assessment of all information submitted.

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Exclusion criteria

Substance can not be classified as one of the following:

-mutagen category 1A or 1B,

-carcinogen category 1A or 1B,

-toxic for reproduction category 1A or 1B,

-persistent organic pollutant (POP),

-persistent bioaccumulative and toxic (PBT) substance, or

-very persistent and very bioaccumulative substance (vPvB), or

-having endocrine disrupting properties.

- Hazard based criteria therefore use as ‘cut-off’ criteria.
- Limited exceptions to this where exposure will be negligible.
- Emergency approval

Approval criteria

- Product must be sufficiently effective;
- **Product must have no immediate or delayed harmful effect on human or animal health, directly or indirectly**;
- Product must have no unacceptable effect on plants or plant products;
- Product must not cause unnecessary suffering and pain to vertebrates;
- Product must have no unacceptable effects on the environment, taking into account its fate and distribution in the environment, its impact on non-target species, and its impact on biodiversity and the ecosystem.

Substitution

An active substance shall be approved as a candidate for substitution where any of the following conditions are met:

-its ADI, ARfD or AOEL is significantly lower than those of the majority of the approved active substances within groups of substances/use categories,

-it meets two of the criteria to be considered as a PBT substance,

-there are reasons for concern linked to the nature of the critical effects which, in combination with the use/exposure patterns, amount to situations of use that could still cause concern,

-it contains a significant proportion of non-active isomers,

-it is or is to be classified as carcinogen category 1A or 1B or as toxic for reproduction category 1A or 1B, if the substance is not already excluded under the cut-off criteria,

-it is considered to have endocrine disrupting properties that may cause adverse effects in humans if the substance is not already excluded under the cut-off criteria.

Authorisation of PPP

MS

- Application to Member State
- Completeness check by zonal RMS (6 weeks)
- Request for additional information
- Validation or rejection of application
- Evaluation of application (12 – 18 months)
- Request for additional information (6 months)
- Initial assessment of application (8 months)
- Receipt of comments from other zonal Member States (6 weeks)
- Grant or refusal of application for authorisation
- Emergency authorisation

Mutual recognition

- Harmonisation between MSs;
- Application can be made for same PPP, same use and under comparable agricultural uses in another Member States, where:

  - the authorisation was granted by a Member State in same zone;

  - the authorisation was granted by a Member State in a different zone provided that the authorisation has not already been used for mutual recognition in another Member State within that zone;

  - the authorisation was granted by a Member State for use in greenhouses, or as post-harvest treatment, or for treatment of empty rooms or containers used for storing plant or plant products, or for seed treatment, in any zone.

- Possibility to limit market access based on local conditions.

Parallel trade permit

- Available where PPP identical to product already authorised in the territory of a MS
- 'Identical' means they are:
  - manufactured by the same company or an associated undertaking in accordance with same manufacturing process;
  - identical in specification and content in respect of the active substances and the type of formulation;
  - the same in respect of the non-active substances present; and
  - either the same or equivalent in the co-formulants present and the packaging size, material or form, in terms of the potential adverse impact on the safety of the product with regard to human health, animal health or the environment.

Neonicotinoids

- Clothianidin, thiamethoxam, fipronil & imidacloprid were approved under Annex I of Directive 91/414/EEC & subsequently PPPR;
- Specific provisions for use as seed treatment, introduced in 2010;
- Increasing scrutiny of neonicotinoids in recent years due to environmental impacts, in particular adverse ecological effects, including honey-bee colony collapse disorder (CCD) and loss of birds due to reduction in insect populations;
- Precautionary principle - calls made for bans on neonicotinoids;
- Certain countries restricted or banned the use of neonicotinoids.

Neonicotinoids

- Commission review of the risk assessment for all neonicotinoids;
- Review under Article 21 of the PPPR;
- Scientific & technical review by EFSA;
- Commission Implementing Regulation (EU) No 485/2013:
  - Restricts the use of clothianidin, imidacloprid and thiametoxam for seed treatment, soil application (granules) and foliar treatment on bee attractive plants and cereals.
  - Remaining authorised uses are available only to professionals.
  - Exceptions will be limited to the possibility to treat bee-attractive crops in greenhouses, and in open-air fields only after flowering.
  - Seeds of specific crops treated with PPP containing either of the three active substances were prohibited from use or placing on the market with the exception of seeds used in greenhouses.
  - Restrictions apply for 2 years from 1 December 2013.
- Commission Implementing Regulation (EU) No 781/2013 for fipronil.

Regulation of the Use Phase

Directive 2009/128/EC on the Sustainable Use of Pesticides;

Aims to establish "… a framework to achieve a sustainable use of pesticides by reducing the risks and impacts of pesticide use on human health and the environment and promoting the use of Integrated Pest Management and of alternative approaches or techniques such as non-chemical alternatives to pesticides".

-National Action Plans

-Training and certification;

-Requirements for sales of pesticides;

-Information and awareness-raising;

-Inspection of equipment in use;

-Aerial spraying;

-Specific measures to protect the aquatic environment and drinking water;

-Reduction of pesticide use or risks in specific areas (e.g. public parks, schools etc.)

-Annex III - General principles for integrated pest management (IPM).

Aerial spraying

- Prohibited across EU;

- Derogations available:
  - where no viable alternatives, or clear advantages over land-based application of pesticides;
  - Pesticides used must be explicitly approved for aerial spraying;
  - the operator carrying out the aerial spraying must be certified for that application;
  - the enterprise responsible for providing aerial spray applications must be certified by the MS;
  - If the area to be sprayed is in close proximity to areas open to the public, specific risk management measures to ensure that there are no adverse effects on the health of bystanders shall be included in the approval. The area to be sprayed shall not be in close proximity to residential areas;
  - aircraft must be equipped with the best available technology to reduce spray drift.

- UK example where aerial application of herbicides in upland areas for bracken control and fungicides for potato blight.

Water environment

- Member States to take appropriate measures to protect the aquatic environment and drinking water supplies from impact of pesticides.

- Existing measures under EU Water Framework Directive.

- Member States may also:
  - give preference to pesticides that are not classified as dangerous for the aquatic environment nor containing priority hazardous substances;
  - give preference to the most efficient application techniques;
  - use mitigation measures to minimise the risk of off-site pollution - can include the establishment of **appropriately-sized buffer zones**;
  - reduce as far as possible or eliminate applications on or along roads, railway lines, very permeable surfaces or other infrastructure close to surface water or groundwater or on sealed surfaces with a high risk of run-off into surface water or sewage systems.

- UK example of use of agricultural subsidies requirements – pesticides not to be applied within 2m of a watercourse or field ditch.

IPM

1. Agricultural practices

4. Sustainable biological, physical and other non-chemical methods must be preferred to chemical methods if they provide satisfactory pest control.

5. The pesticides applied shall be as specific as possible for the target and shall have the least side effects on human health, non-target organisms and the environment.

6. The professional user should keep the use of pesticides and other forms of intervention to levels that are necessary, e.g. by reduced doses, reduced application frequency or partial applications, considering that the level of risk in vegetation is acceptable and they do not increase the risk for development of resistance in populations of harmful organisms.

- Regulation 2009/127/EC with regard to machinery for pesticide application

7. Where the risk of resistance against a plant protection measure is known and where the level of harmful organisms requires repeated application of pesticides to the crops, available anti-resistance strategies should be applied to maintain the effectiveness of the products. This may include the use of multiple pesticides with different modes of action.

IPM - Monitoring

2. Harmful organisms must be monitored by adequate methods and tools, where available.

3. Based on the results of the monitoring the professional user has to decide whether and when to apply plant protection measures.

8. Based on the records on the use of pesticides and on the monitoring of harmful organisms the professional user should check the success of the applied plant protection measures.

- Regulation (EC) No 1185/2009 concerning statistics on pesticides

Questions?

Thank you

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