Health and Safety Executive

The New Regulation – a regulatory view

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Outline

- Background
- Key changes
  - Hazard criteria
  - Derogation
  - Substitution
  - Comparative assessment
  - Zonal authorisations
- Challenges and next steps

Background

- Replacement for Directive 91/414
- Commission report to Council and Parliament on first 10 years
- Responses included hazard criteria
- Voted by Parliament 13 January 2009
- Council to endorse autumn 2009
- UK not in favour
- Effective 18 months after publication – spring 2011

Key changes

- Hazard criteria
  - Human
  - Environmental
- Derogation
- Substitution
- Comparative assessment
- Zonal authorisations

Hazard criteria – human health

No harmful effects on human health

- No category 1 or 2 mutagens
- No category 1 or 2 carcinogens
- No category 1 or 2 reproductive toxins
- Not considered to have endocrine disrupting properties
  - negligible exposure?

Hazard criteria – human health

Challenges?

- Definition of ‘endocrine disrupting properties’
  - Working ongoing with ECETOC
- Negligible exposure?

Hazard criteria – environmental

- Not a persistent organic pollutant (POP)
- Not a PBT
- Not a vPvB
- ‘not considered to have endocrine disrupting properties that may cause adverse effects on non-target organisms’

Hazard criteria – environmental

Challenges ?

- Definitions/clarification?
- Studies?

Derogation

- Where ... an active substance is necessary to control a serious danger to plant health which cannot be contained by other available means, such active substance may be approved for a time limited period not exceeding five years even if it does not satisfy the [hazard] criteria

- The Commission has indicated that it would expect this provision to be used only exceptionally.

Candidates for Substitution

Any of the following are met

- Toxicological endpoints (e.g. ARfD, AOEL) significantly lower than those of most approved substances

- Two of the persistent, bioaccumulative and toxic substance criteria

Candidates for Substitution

- Concerns about critical effects (developmental neurotoxic effects) in use (even with mitigation)
- Significant proportion of non-active isomers
- Category 1 or 2 carcinogens, or reproductive toxins or endocrine disrupters which are not excluded by the hazard criteria

Candidates for Substitution

- Commission shall establish a list of Candidate for Substitution (CfS) within 4 yrs – i.e. approx late 2013

- Comparative assessment (CA) is conducted when evaluating application for a PPP containing a CfS

- CA will occur at latest at renewal or amendment of the authorization

Comparative assessment

- Determine whether the alternative is as effective

- Uses are only substituted if:

  – Risk of resistance is minimal
  – Significantly safer to human health or environment
  – No significant economic or practical disadvantage

Comparative assessment

- For the environment, if relevant, a factor of at least 10 for the toxicity/exposure ratio (TER) of different plant protection products is considered a significant difference in risk.

- Major quantifiable impairment of working practices or business activity leading to inability to maintain sufficient control of the target organism, for example, where no technical facilities (e.g. application equipment) for the use of the alternative are available or economically feasible.

Candidates for Substitution

- MS shall not authorise or will restrict the use of candidates for substitution *where acceptable safer alternatives* (including non chemical methods) available.

Candidates for Substitution – challenges

Definitions/clarification of:

- No significant economic or practical disadvantage
- Where resistance risk minimised
- Where consequences for minor uses considered

Working up a mechanism of how this can be done

Zonal authorizations

- **North** – Denmark, Estonia, Latvia, Lithuania, Finland and Sweden

- **Central** – Belgium, Czech Republic, Germany, Ireland, Luxembourg, Hungary, Netherlands, Austria, Poland, Slovenia, Slovakia, United Kingdom

- **South** – Bulgaria, Greece, Spain, France, Italy, Cyprus, Malta, Portugal

Zonal authorizations

- Where the concerns of a Member State related to human or animal health or the environment cannot be controlled by the establishment of national risk mitigation measures...a Member State may refuse authorization...due to its specific environmental or agricultural circumstances

- MS needs to inform the applicant and the Commission of its decision as well as its technical/scientific justification

Zonal authorizations - challenges

- Develop process
- Clarity in what individual MS do
- Different protection goals?
- Scale of use?

Other issues

- Biodiversity
  - Variability among living organisms from all sources, including terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this variability may include diversity within species, between species and of ecosystems
- How is it assessed?

Conclusion

- Many new areas/concepts
- Lack of clarity/definitions
- Could make the process of assessing compounds difficult

Next steps

Implementation programme

- CRD has initiated eleven projects covering key areas including – active substance and product approval, zonal authorization, comparative assessment and substitution, and data requirements and uniform principles

- All aimed at trying to smooth the passage of the New Regulation