EU CHANGES IN REGULATIONS

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The EU Legislation Maze

1970
1980
1990
2000
2005
2008
2010?

67/548 Classif. & Labelling

Drinking Water Directive

EC 91/414

OSPAR Convention

Water Framework Directive

REACH

6th Environmental Action Plan

6th Framework Programme for R&T Development

EQS Directive

Groundwater Directive

Marine Directive

91/414 Revision

SoilsThematic

Thematic Strategy on Sus. Use of Pesticides

Soils Framework Directive

Sustainable Use Directive

Introduction

Two new pieces of EU legislation were recently agreed in Parliament:

- **The new regulation replacing Directive 91/414**:
  - updates the pesticide legislation to reflect the considerable scientific and political changes since 1991, and
  - sets out a series of further measures designed to ensure a continued high level of protection to humans and the environment.
- **The Framework Directive on the Sustainable Use of Pesticides:**
  - regulates the application of crop protection products by setting out a legally binding set of use practices across the EU
  - Instructs Member States to develop National Action Plans (NAPs) that will reduce risks from product use

Revision of 91/414 and Sustainable Use Directive

Cut-off criteria continue the current direction of EU regulation

- CMR 1 & 2
- POPs
- PBTs
- VpVb's
- **Endocrine Disruptors**
- Honeybees

Comparative assessment at Member State level has to consider both benefit and risk

- Many candidates for substitution
- Countries will have flexibility to decide

Other changes under the new regulation are neutral or may even be beneficial

- Zonal authorisation and Mutual recognition
- **Parallel trade rules clarified**
- Clearer review timelines for new ai's
- Additional data protection for minor uses
- Safeners and synergists

Sustainable Use Directive mandates good practice at user level and helps to reduce risk

- Focus on risk reduction
- Use reduction for substances of concern
- Monitoring could increase regulatory pressure
- **Improvements in terms of training, inspection, storage and use**

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Cut-off Criteria Definition

No approval for substances that are:

- Carcinogenic, Mutagenic or Toxic for Reproduction category 1 & 2 (**CMR 1 & 2**)
- Persistent Organic Pollutants (**POPs**)
- Persistent , Bioaccumulating and Toxic substances (**PBTs**)
- Very persistent, very bioaccumulating substances (**vPvB**)
- Endocrine Disruptors:
  - scientific criteria to be defined within 4 years
  - Interim definition; C3+R3 *shall…*, R3 plus effects in ED organs *may*….
- Unacceptable for **Honeybees** when assessed to international guidelines

Candidates for Substitution : Definition

- **An Active Substance is a candidate for substitution when:**
  - Toxicology endpoints (ADI, ARfD or AOEL) are significantly lower than majority of approved substances within groups of substances or use categories
  - It meets 2 out of 3 PBT criteria
  - Critical effects (e.g. neurotoxic or immunotoxic effects) in combination with use/exposure patterns, e.g. high potential risk to groundwater, give cause for concern
  - It contains significant proportion of non-active isomer
- **Candidates for substitution will only be approved for 7 years**
- **A list of candidates for substitution will be established within 48 Months of the date of application of the new regulation (end 2014)**

Comparative Assessment

- **Member States will apply CA to <u>products</u> containing candidates for substitution and will not authorise *in a given crop* if:**
  - other products or control methods already exist that are “significantly safer”
  - substitution presents significant economic or practical disadvantages
  - the chemical diversity remains adequate to minimise resistance in the target organism
  - consequences for minor uses are taken into account
- **Taking account of mixtures, a very large percentage of all products will be subject to comparative assessment**
- **Member States will have considerable freedom to decide which products to authorise**

Timelines

	Authorisation Regulation	Sustainable Use Directive
13 January 2009	Text adopted by the EU Parliament	Text adopted by the EU Parliament
March 2009	Approval of same text by Council	Approval of same text by Council
April 2009	Publication in the Official Journal of the EU and Entry into force	
October 2010	Regulation becomes legally binding in all countries	
2011		Transposition into national law
2014		Report to Parliament on content of National Action Plans (NAPs)
2017		Deadline for revised NAPs

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Likely Application Scenarios

Criteria	Who will apply the criteria?	When will action be taken?	Timing	Probability
Cut-offs	EU	Once criteria are fully defined	2013/2014	High
		At time of Annex I expiry	2011-2018	Medium
	Member States	Products banned immediately	2009	Possible for new products
		Products banned once regulation applies	End 2010	Likely for new products
Comparative Assessment	Member States	Before the candidate for substitution list is available	End 2010	Low for existing products Medium for new products
		After publication of the substitution list	2012-14	High

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