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...TODAY

The new Biocides Regulation proposal and the key issues for pest control in Europe

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Agenda

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- **The Regulatory Environment in Europe**
- **Focus on Biocides**
  - New Regulation
  - Cut-offs and comparative assessment
  - Advocacy activities
- **Sustainable Use**
- **Working together: CEPA, Cefic and ECPA**
- **Closing remarks**

The Regulatory Environment in Europe

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- Plant Protection Products – **authorisation**
  - **Directive 91/414/EEC** for placing on the market; active ingredients are included into Annex I list and then products containing those actives are approved via evaluation of Annex III dossiers.
  - **Regulation 1107/2009** recently published, will take effect from July 2011 and replace 91/414
- Plant Protection Products – **use**
  - **Directive 2009/128** published recently concerns the use phase of plant protection products and requires Member States to develop National Action Plans to reduce risks associated with the use of approved products
- Biocidal Products – **authorisation**
  - **Directive 98/8/EC** to establish a harmonised regulatory framework for biocidal product authorisations. 23 product types of biocide are identified of which PTs 14 (rodenticides) and 18 (insecticides) are most important for pest control. As for 91/414, an active substance must be included into Annex I and then associated products may be authorised.
  - **Draft Regulation** to replace 98/8 was adopted by Commission in June 09 and is now undergoing review and amendments in Parliament.
- Co-formulants – **registration and use**
  - **Regulation 1907/2006, REACH** (**R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals) concerns placing on the market of chemicals. Particular interest for pest control products is co-formulants.

New PPP Regulation 1107/2009

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- Similar principles to 91/414 – ai inclusion, then product authorisation
- Parallel trade is more focussed on identicality than « substantially similar »
- Mandatory vertebrate data sharing
- Mandatory mutual recognition within zones (3 climatic zones established)
- Introduction of exclusion (« cut-off ») criteria based upon inherent hazard of the active substance including **endocrine disruption**
  - ***Pending the adoption of these criteria, substances that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogenic category 2 and toxic for reproduction category 2, shall be considered to have endocrine-disrupting properties. In addition, substances such as those that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 2 and which have toxic effects on the endocrine organs, may be considered to have such endocrine disrupting properties.***

Focus on Biocides

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- New Regulation
- Exclusion criteria – « Cut-offs »
- Comparative assessment
- Advocacy activities

New Biocides Regulation Draft

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- Adopted (draft text released) June 09:

  - Simplified procedures, especially central authorisation
  - Criteria for exclusion ("cut offs") from Annex I (DG SANCO, PPPR)
  - Substitution and comparative assessment
  - Low risk products, procedures and criteria (failure of Annex IA)
  - Treated articles and materials (loophole)
  - Global "step 1" Jan 1st 2014
  - New Parliament assembled September.
    - First reading expected June 2010.

- Entry into Force aim: January 2013
- Lead Committees Environment (Rapporteur MEP Klass) and IMCO (Internal Market; Rapporteur MEP Sartori) with comments from ITRE (Industry, Trade, Research; Rapporteur MEP Karim)

Community authorisation: simplified procedures

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- "One zone" allows for an optimal level of harmonisation? Community authorisation?
- Restricted to low risk products and new actives (initially? Options to extend to all PTs?)
- Possible for some PTs used identically across whole EU.
- Product authorisation in one MS followed by MR in subsequent MS either in parallel or in series.
- ECHA is the supporting agency (as for REACH) but does not actually do any evaluations (management role?) which differs from the way EFSA acts for PPPs

Exclusion Criteria

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- Generally referred to as « cut offs », these were heavily debated during the revision of the Plant Protection Products Directive, 91/414/EC
- So, expect the same battle; unlikely to have fewer cut offs, expect to see extra ones being tried (those that « failed » for PPPs will come back!!)
- So ….. What are they???
- First, let's look at what was finally decided for Plant Protection …

Exclusion «Cut-off » criteria.

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An a.i fulfilling a cut-off criteria should not be approved.

They come in addition to, but do not replace risk-based criteria.

	Human health	Environment
Unconditional	Mutagen cat. 1 and 2	POP : Persistent Organic Pollutant PBT : Persistent Bioaccumulative and Toxic vPvB : Very Persistent and very Bioaccumulative.
Conditional	Carcinogen 1 unless * Repro. Tox. Cat. 1 unless * Repro. Tox. Cat. 2 unless ** Carcinogen cat. 2 unless ** ED : Endocrine Disruptor unless **	ED: Endocrine Disruptor to non target organisms unless **

* : Exposure negligible.

** : Exposure negligible or addresses ‘serious danger to plant health’

Exclusion, plus « substitution » …

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- An active substance may not be excluded, but if it meets certain other criteria (also hazard-based), then it may become a « candidate for substitution »

- We already know that the AVK rodenticides that are included under BPD are labelled as candidates for substitution under the existing rules, hence the inclusion is for 5 years, only …….

The proposed Biocides regulation

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- What does it propose for exclusion criteria?
- What are the implications?

Article 5 Cut-offs - derogations

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(Current report from rapporteur MEP Klass (Environment Committee))

- ***Notwithstanding Article 4(1),*** active substances ***referred to in paragraph 2 may*** be included in Annex I ***if*** at least one of the ***following*** conditions is met:

- (a) the **exposure** of humans or the environment to that active substance in a biocidal product, under normal conditions of use, is **negligible**, in particular where the product is used in closed systems or strictly controlled conditions;

- (b) it is shown that the active substance is **necessary** to control a serious danger to public health or to the environment;

- (c) it is shown that not including the active substance in Annex I would cause **disproportionate negative impacts** when compared with the risk to human health or the environment arising from the use of the substance and that there are **no suitable alternative substances or technologies.**

- ***Point (c) shall not apply to active substances for product types 4 and 14 to 19.***

Impact Assessment for BPR

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- At Barcelona BPD Conference 09 asked COM/MSs if Impact Assessment was planned. Answer « not a resource priority ».
- Bayer ES decided to conduct own assessment of the impact on biocidal actives of the « exclusion criteria » and « substitution provisions » in the proposed 1st draft Biocidal Products Regulation.
- Approach used published human health and environmental hazard endpoints from active substances already reviewed under 98/8/EC (CARs and DCARs)
- Subjective assessment as in some areas hazard criteria not defined
- Focus on most complete data sets available:
  - PT08 – wood preservatives;
  - PT14 – rodenticides
  - PT18 – insecticides, acaricides and products to control other arthropods.

Impact Assessment

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Active substances:	**PT08 Wood preservatives**	**PT14 Rodenticides**	**PT18 Insecticides**
Not approved according to the proposed exclusion criteria	31 % (11 out of 35)	64 % (9 out of 14) all anticoagulants	8 % (2 out of 24)
Combined: 30% potentially excluded i.e. 22 out of 73 a.s's **» Addition of PBT to exclusion criteria adds another a.s from both PT08 & PT18**			
Possible candidates for substitution	46 % (16 out of 35)	79 % (11 out of 14)	38 % (9 out of 24)
Combined: 49% potential candidates for substitution, i.e. 36 out of 73 a.s's.			

Impact Assessment

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- Anticoagulants represent the majority of the rodenticide market today (>90%), their exclusion would have serious public health consequences.
- Reductions in availability of different actives could significantly increase the risk of resistance developing in the future for certain uses within PTs.
- This « worse case » assesment highlighted the requirement to include « risk – benefit public health exceptions» to the exclusion criteria

Advocacy: CEFIC Documents (external examples)

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- Biocides: Protecting our health and our environment
- Press release: Cefic position paper on the Commission proposal for a regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products (2009/0076 (COD))
- Issues sheets provided to European Council Working Group members prior to each meeting, chapter by chapter through the proposed text.
- 81 amendments provided to MEPs Klass and Sartori (European Parliament rapporteurs for environment and internal market committees, respectively).
  - Klass included more than 75% of Cefic amendments in her report to the Environment Committee
  - A total of more than 500 amendments were tabled!!

Where we are now….
Additional amendments to Klass report

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- Remove the « exclusion » of PTs 4, 14-19 from the derogation based on lack of scientific, ecological or health reason.
  - In Council, many MS see this as unfounded and arbitrary
  - In ITRE report, the reference to these PTs is removed due to no scientific justification
  - Also removed in IMCO report
  - Klass was under pressure from German Government to include ***more*** PTs in this group!
  - Vote in the Envi committee due 23 June; Plenary in September (?)

Safer alternatives ?????

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- There is a belief that Industry will develop new, less hazardous active substances
- For Agrochemiocals, there is some basis for this since new active substances arrive all the time, 5 – 10 per year.
- Agrochemical markets can support the 80 – 100 moi€ investment per new active!!!
- Since the BPD came into force in May 2000, less than one really «new ai per year has been submitted for biocidal use across all 23 product types
- With approx 250 actives « surviving » from the 1000 or so present in 2000, a further major loss will have enormous implications
- Rodenticides is a particular case in point – where will less hazardous ***and effective*** alternatives come from????

Advocacy – rodenticides

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- The European Crop Protection Association, ECPA has formed an *ad hoc* Biocides team
- Cefic has a working group for rodenticides
- BASF-Sorex has been especially active in developing position papers that can be used by CEPA members, locally, to raise awareness among MEPs
- (Note that Sorex had already lobbied, successfully, to defend the inclusion of difenacoum when comitology changed and the Environment Committee was considering non-inclusion due, largely, to the equivalent of exclusion criteria).
- These documents are accompanied by a list of the MEPs who sit on the relevant committees ….. especially the Environment Committee.

What can CEPA do?

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- Use the documents and contact list as a means to explain what would happen if AVK rodenticides were banned
- Politicians are not scientists – they respond to public perception and the input from local businesses
- Public health and hygiene are critical issues in European politics.
- The risks posed by rodents outweigh the risks associated with responsible use of rodenticides

- Demonstrating professionalism and a continuing commitment to responsible/sustainable use
- Inform the politicians – tell them what you do, why, how ….. and what would happen if you did not!!
- Tell them again !!!!!!!!!

Other activities …

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- Rejection of ED interim proposal (will be tough but maybe of little practical significance if an agreed definition arrives before 2013)
- Update Impact Assessment as public data expands.
- Sustainable Use of Biocidal Products proposal.
  - Remember how important the Roma protocol was to avoid the inclusion of biocides within the scope of the new Directive for Plant Protection Products!!!
  - But the issue has not gone away …… nor should it!!

The Use phase

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- **A few words on sustainable use**
- **Directive 2009/128**
  - Currently, scope includes pesticides that are considered as plant protection products
  - Biocides are included as a second group of « pesticides » but are currently outside the scope of this Directive

The main themes

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- Information and awareness raising
- Training and sales requirements
- Protection of aquatic environment
- Reduction of use/risk in specific areas
- Handling, storage and disposal
- Inspection of equipment
- Aerial spraying
- IPM

NATIONAL ACTION PLANS

What lies ahead …

- Responsible use: training to professionals; point of sale information; adverse incident reporting; recycling
- Authority National Action plans
- Incentives for technologies that prevent mis-use, reduce accidents and risk (accelerated reviews, longer approvals)
- Obligation on authorities to act against illegal products and illegal uses
- Best practise information on all labels & in advertising, responsible uses in sensitive areas.

- Input to Hydrotox-Milieu -RPA Impact assessment (individual companies and associations such as CEFIC) inclusing proposal to focus on individual PTs.

Closing Remarks

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- As living standards improve, both politicians and public expect a « safer » environment to live in
- It's easy to scare and focus on hazard
- We take a clean and healthy environment for granted in developed countries
- Regulations are driven by political agendas
- We cannot win by science alone

- We need to be more pro-active in promoting the benefits of what we do!!

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Thank you

Bayer Environmental Science