9th ABIM Meeting, Basel, Switzerland

Regulatory Issues in Europe
including low risk substances and endocrine disruptor developments

Michael Flüh and Jeroen Meeussen

European Commission
DG SANCO (Health and Consumers Directorate-General)
Unit Chemicals, contaminants, pesticides

Health and Consumers

A new Commission

- From **Health and Consumer Protection** to **Health and Food Safety**.
- From Borg to Andriukaitis.

- From DG SANCO to DG ?????

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Contents

- Endocrine Disruptors
- Low risk substances
- Basic substances
- Minor Uses
- Other issues related to Reg. 1107/2009

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Endocrine disruptors

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Endocrine Disruptors

- Relates to points 3.6.5 & 3.8.2 of Annex II to Reg. 1107/2009
  - COM is asked to develop scientific criteria for ED by Dec. 2013
  - Until these criteria are set, interim criteria are in place.
- Given the complexity of the issue
  - expected significant socio-economic impacts
  - diverging views among scientists (and science evolving)

  an Impact Assessment has been started.

Endocrine Disruptors Impact Assessment (I)

- Roadmap published in June 2014

  http://ec.europa.eu/smart-regulation/impact/planned_ia/docs/2014_env_009_endocrine_disruptors_en.pdf

  - outlines various options for the criteria
  - outlines expected impacts and the way to asses them
  - includes background information

- Public consultation launched in September 2014 (up to Jan. '15)

  http://ec.europa.eu/yourvoice/consultations/index_en.htm

  - contributions from all stakeholders/consumers welcome

Endocrine Disruptors Impact Assessment (II)

- At least two studies needed:
  - 1st study will identify substances under options for criteria outlined in the Roadmap.
  - 2nd study will assess socio-economic and environmental impacts associated with the various options.

- Commission proposal for criteria will take into account outcome of the Impact Assessment

Endocrine Disruptors Interim Criteria

- Pending the establishment of the new criteria, strict interim criteria based on harmonized classification according to Reg. 1272/2008 are in place:
  - Classified or to be classified as R2 + C2
  - Classified or to be classified as R2 + endocrine mode of action

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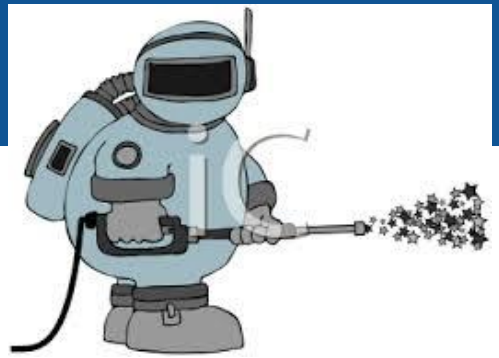
Approval criteria for Endocrine Disruptors are NOT purely hazard-based

- Approval criteria in Reg. 1107/2009 are commonly referred to as "cut-off criteria", but…
  - only some approval criteria (mutagens, POPs, PBTs and vPvB substances) are purely hazard-based;
  - other approval criteria (carcinogens, toxic for reproduction and endocrine disruptors) have a strong hazard-component, but they can be authorised if under **realistic conditions of use** the exposure is **negligible**.



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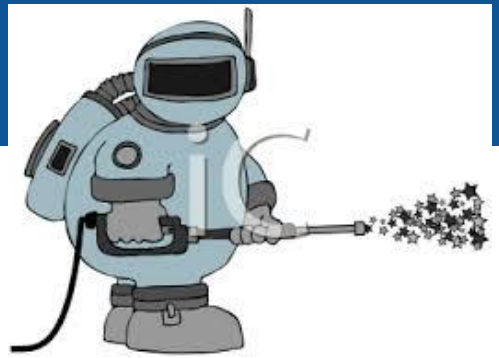
Negligible exposure

- Negligible exposure under realistic proposed conditions of use relates to Annex II to Reg. 1107/2009:
  - points 3.6.3/3.6.4/3.6.5 refer to human exposure (carc. And reprotox cat. 1A and 1B; endocrine disruption);
  - point 3.8.2 refers to ecotoxicology;
  - point 3.8.3 refers to honeybees.

- For point 3.8.3 reference is made to the *'Guidance Document on the risk assessment of plant protection products on bees*'.



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Negligible exposure

- Dietary exposure: legislation is precise (reference to default value of Reg. 396/2005)
- Non-dietary exposure and environment: legislation leaves margin of interpretation
- Guidance document under preparation (*Guidance on Decision Making under points 3.6.3 to 3.6.5, and 3.8.2 of Annex II of regulation (EC) No 1107/2009*):
  - Discussion ongoing between COM, MS and EFSA;
  - stakeholder consultation foreseen.

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Low Risk Substances

Low risk substances and products

Regulation (EC) No 1107/2009

- favours the inclusion of low risk substances in PPP and
- facilitates their placing on the market

Incentives and facilitated market access

- Approval up to 15 years
- Data protection up to 13 years
- Low risk PPP:Member States to decide in 120 days
- Separate listing
- Allowed to be mentioned in advertising

Low Risk Criteria – Annex II, point 5 (1)

An active substance shall **not** be considered of low risk where it is or has to be classified in accordance with Regulation (EC) No 1272/2008 as at least one of the following:

— carcinogenic,

— mutagenic,

— toxic to reproduction,

— sensitising chemicals,

— very toxic or toxic,

— explosive,

— corrosive.

Low Risk Criteria - Annex II, point 5 (2)

It shall also **not** be considered as of low risk if:

— persistent (half-life in soil is more than 60 days),

— bioconcentration factor is higher than 100,

— it is deemed to be an endocrine disrupter, or

— it has neurotoxic or immunotoxic effects.

New criteria can be set ⇨ Annex II, point 5

EU-expert group on "low risk" (1)

Expert group of EU-Member States, Commission, Growers Organisations, NGOs and Industry.

Points to consider:

- Consistent with REACH and biocides?
- Adjust current 'negative' criteria?
- Formulate positive criteria?
- Develop further guidance?
- Are current incentives strong enough?

EU-expert group on "low risk" (2)

2 Meetings in 2013; 1 meeting scheduled for 2014

3 Subgroups to discuss:

- Possible decision schemes and/or criteria for low risk;
- Active Substances essential to Organic Farming;
- New incentives to Industry.

EU-expert group on "low risk" (3)

Points for discussion:

- Different criteria for AS and PPP,
- Develop guidance and
- Differentiate between groups of active substances (e.g. chemicals, micro-organisms, semiochemicals).
- Are substances essential for Organic Farming covered?
- New incentives related to fees, priority setting, accelerated process, no authorisation expiry date.

Aim: proposal by mid 2015.

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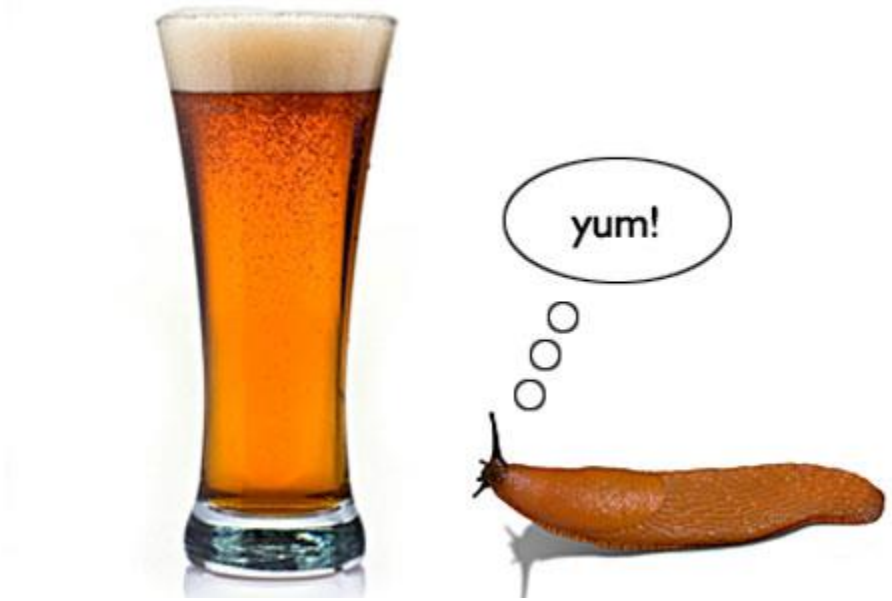
Basic Substances



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Criteria for identification of basic substances

Article 23(1)

- not a substance of concern;
- not inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects;
- not predominantly used for plant protection purposes but useful in plant protection directly or in a product consisting of the substance and a simple diluent;
- not placed on the market as Plant Protection Product.

Basic Substances and their products Derogations

Article 23 and 28

- A basic substance shall be approved for an unlimited period.
- No authorisation is needed for products containing exclusively one or more basic substances.

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Work in progress

- Working document on approval of basic substances (SANCO/10363/2012 – rev. 9)
- Ongoing discussions about the concept.
- 16 substances currently in the system.
- 3 substances have been approved (*Equisetum*, chitosan and sucrose).
- New applications are announced.

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Minor Uses

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Minor Uses

Article 51(9):

- "By 14 December 2011, the Commission shall present a report to the European Parliament and the Council on the establishment of a European fund for minor uses, accompanied, if appropriate, by a legislative proposal".
- Report was adopted on 18 February 2014.

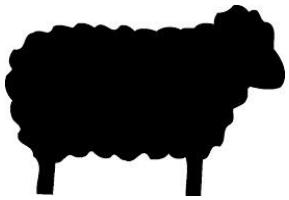
Report on Minor Uses

Key-messages:

- Commission will assist in the creation of an independent coordination facility ("Technical Secretariat") on minor uses which is co-funded by the Commission;
- Commission will support an ERANET on Integrated Pest Management with specific reference to minor uses.

Current status

- Strong support for the Report was expressed in AGRI-Council on 19 May 2014;
- A majority of MS supported the option where a coordination facility is co-funded by the Commission (€350,000/year);
- Adoption of the Financial Decision in October 2014;
- **If** proposal from interested party: November 2014;
- **Then** start of the technical secretariat first half 2015.



Other issues…

Candidates for substitution/comparative assessment:

- Commission to present by 14 December 2013 a list of approved substances fulfilling the criteria of a candidate for substitution
- Around 75 active substances (about 20% of the total number of approved active substances) will be a candidate for substitution.
- What will be the impact on availability of PPPs and workload?
- GD on comparative assessment has been noted in Standing Committee, October 2014.

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2013: EU measures to restrict the use of certain pesticides to protect bees

COMMISSION IMPLEMENTING REGULATION (EU) No 485/2013

of 24 May 2013

amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances

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COMMISSION IMPLEMENTING REGULATION (EU) No 781/2013

of 14 August 2013

amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substance fipronil, and prohibiting the use and sale of seeds treated with plant protection products containing this active substance

What happened since then?

- *Industry challenged the EU measures; 3 court cases on-going.*
- *The Ombudsman opened an investigation.*
- *New risk assessment proposed by EFSA: still debated with MS.*

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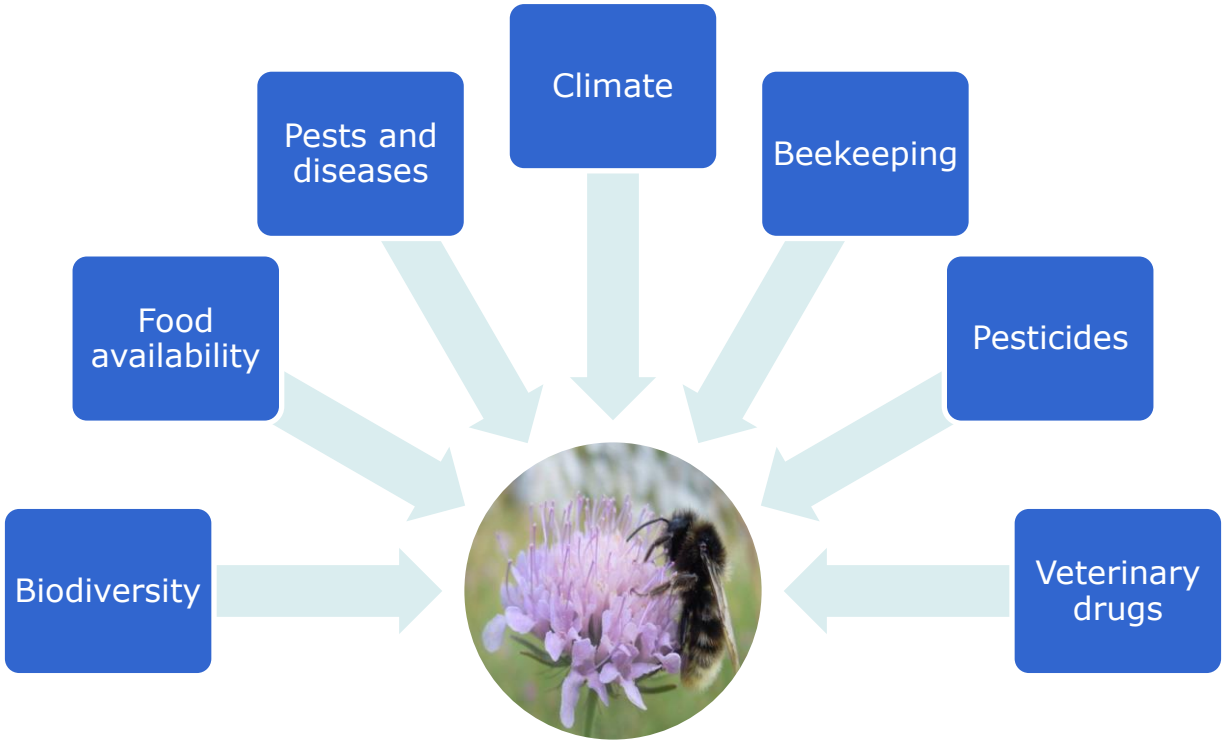
Bee health – a multifactorial issue



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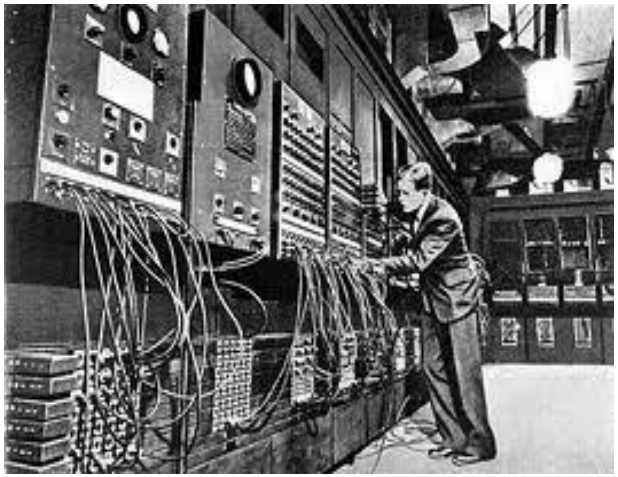
Autorisation Database



…presentation Wednesday morning 22 October 2014!

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