European Commission

XVIIIth CEUREG Forum
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Update on Regulation (EC) No 1107/2009

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

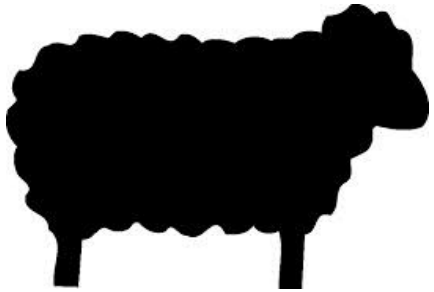
Health and Consumers

A new Commission

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

- From DG SANCO to DG ?????

Contents



Regulation (EC) 1107/2009

"Article-by-Article"

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Article 2: Scope

Plant Protection Products

Fertilisers

Plant Biostimulants

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Plant biostimulants: Temporary definition

"A plant biostimulant is any substance or microorganism, in the form in which it is supplied to the user, applied to plants, seeds or the root environment with the intention to stimulate natural processes of plants benefiting nutrient use efficiency and/or tolerance to abiotic stress, and/or crop quality, regardless of its nutrients content, or any combination of such substances and/or microorganisms intended for this use."

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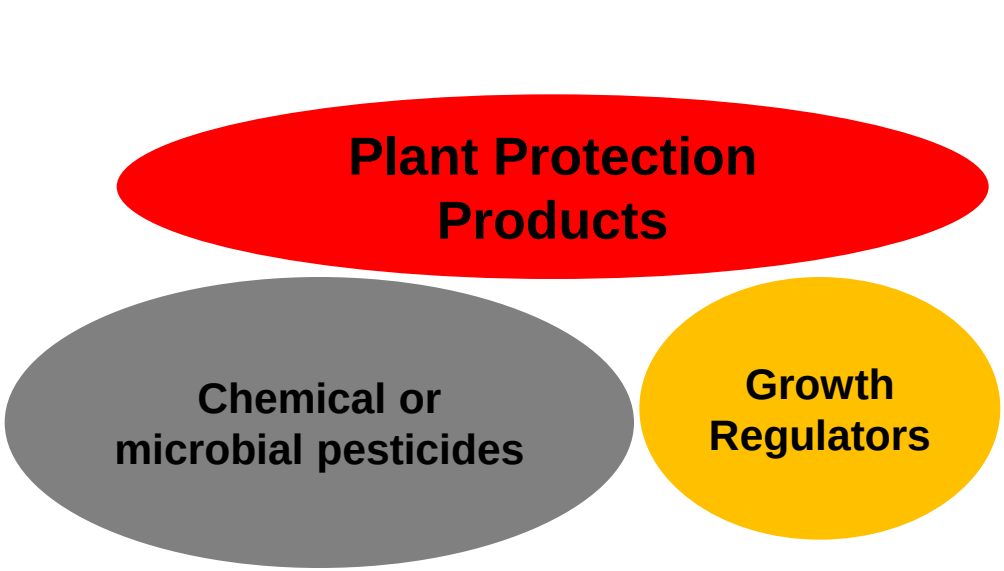
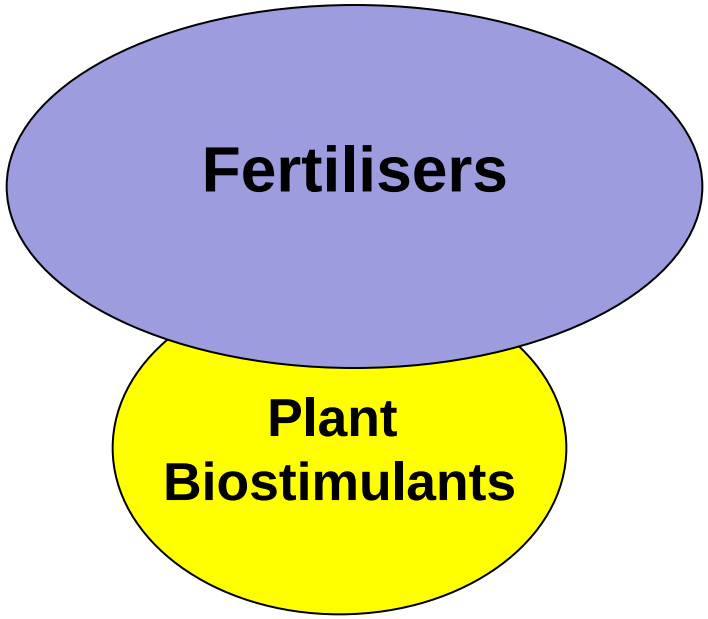
Legally consistent definitions, based on clearly identified functions/claims





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Article 4: Approval Criteria – 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.

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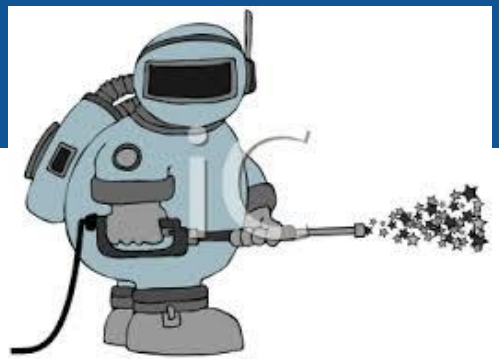
Approval criteria for Endocrine Disruptors are NOT purely hazard-based

- 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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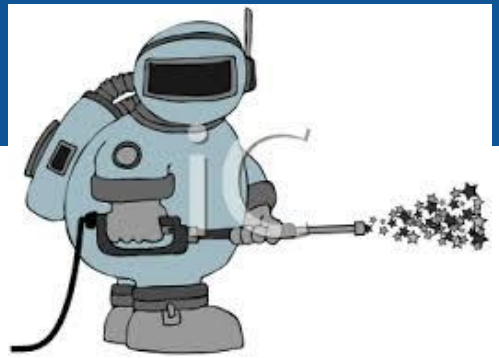
Negligible exposure

- 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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Bees

Health and Consumers

Criteria for approval of pesticides

Relates to point 3.8.3 of Annex II to Reg. 1107/2009

Approval only when the use confirms:

- Negligible exposure to honeybees or
- No unacceptable acute or chronic effects on colony survival and development
- Taking into account effects on larvae and behaviour

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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

EFSA GD on Bees: separate RA schemes

Contact & oral

- *sprays*
- *solids (seed treatments, granules)*

✓**Honey bee**

✓**Bumble bee**

✓**Solitary bee**

✓Additional separate schemes for water consumption and for the metabolites

Difference from the previous Guidance

The previous risk assessment scheme (EPPO) only considered the risk from acute oral and acute contact toxicity.

There was no consideration of:

1. Chronic risk to adults;
2. Risk to larvae, (unless specific mode of action);
3. Risk from guttation water or metabolites;
4. Accumulative effects.

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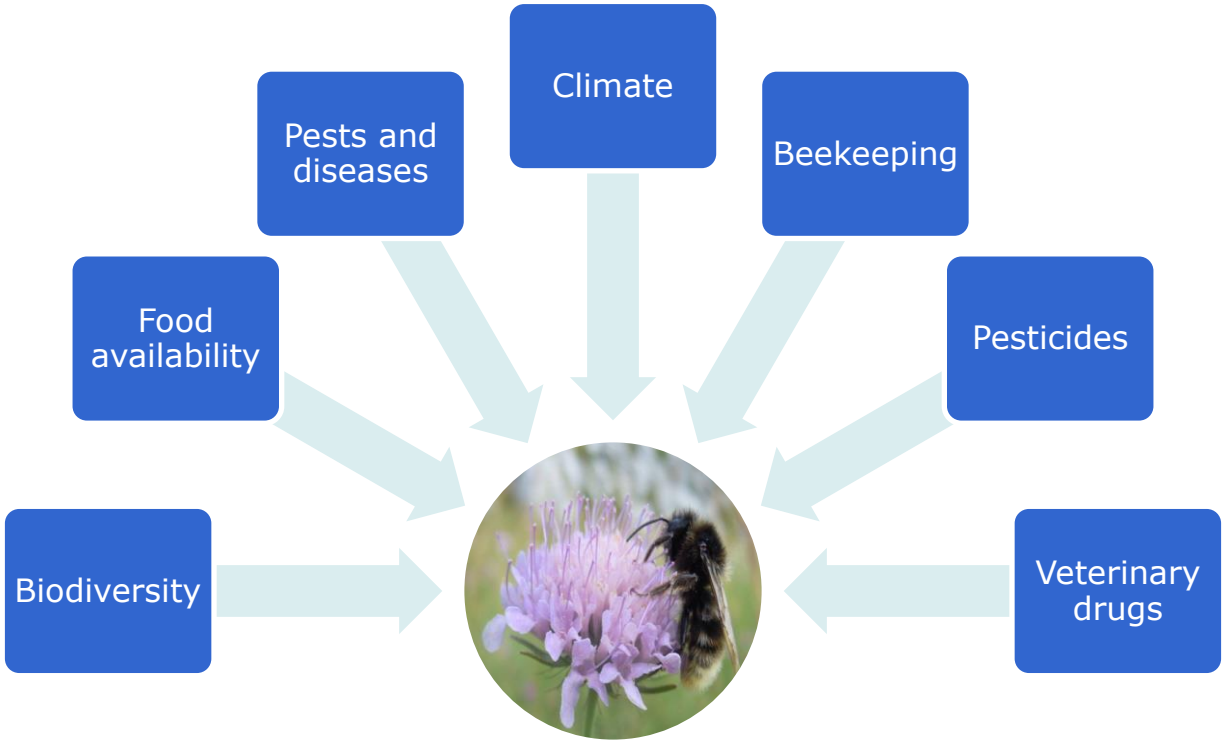
Bee health – a multifactorial issue



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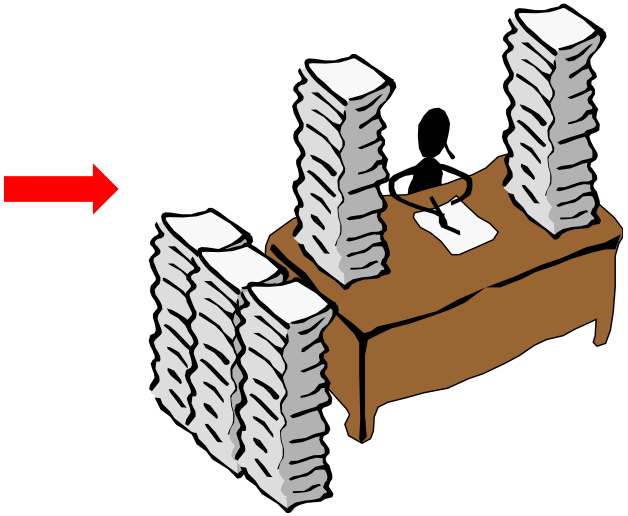
Article 7-13: Approval Procedure



Approval Procedure

first approval

- New Active substances (Reg. 188/2011)
  - 1 active substance still in the peer-review
  - all EFSA conclusions are available

- New Active substances (Reg. 1107/2009)
  - around 30 dossiers declared admissible since June 2012
  - Delays in admissibility check and dossier sanitization
  - First decision expected December 2014

Art. 14 – 20: Renewal Programme

- From 7 (AIR 1) to 150 (Air 3) a.s.

- AIR 2 (29 substances):
  - First decision expected December 2014
  - Expiry of approval: 31 December 2015 -
  - Emerging concern about delays

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"AIR-3"

- Legal framework for AIR-3:
  - Regulation with the general procedure (Reg. (EU) No 844/2012);
  - List of RMS & Co-RMS (Reg. (EU) No 686/2012);
  - Guidance Document has been noted (SANCO/2012/11251 rev. 1.2).
- Extensions only possible if an application has been submitted.
- Strict timelines (29.5 months from dossier submission till decision).

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New Data Requirements

- Apply from 1 January 2014.
- Active Substance:
  - for all applications submitted under Regulation 844/2012 ("AIR-3" and beyond);
- Products:
  - Not to AIR-1 and AIR-2 as long as applications for re-authorisation are submitted before 31 December 2015;
  - Applicable to all re-authorisations AIR-3.
- Guidance Document on transitional measures (in preparation).

Art. 43: Renewal of Authorisation

…3 months after renewal of approval of active substance!

Renewal of Authorisation

- Application (dRR) 3 months after Commission decision to renew the approval of the active substance to each zone.
- Compliance check (Step I) and Assessment (Step II) by zRMS to be completed in 6 months.
- Decision on renewal of product authorisation by all concerned Member States in the zone after a further 3 months.
- No application then product authorisation withdrawn.
- Application must not contain new uses (for the zone).

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Renewal of Authorisation

- At the point of submission of the AIR active substance dossier product re-authorisation has to be planned.
- Risk assessments need to be written before the active ingredient endpoints are finalised.
- Choice of zonal rapporteurs.
- Capacity issues.
- Products containing mixtures of active substances will trigger multiple Article 43 submissions and reviews.

Renewal of Authorisation

Article 43(6): 'reasons beyond the control of the authorisation holder.'

- If it is not possible for the applicant to provide studies in time due to a new endpoint requirement.
- Applicant has to justify the lack of data.
- Member States may find it appropriate to apply Article 43(6) and delay re-authorisation of the product.
- Member States have the responsibility to ensure the appropriate protection standards are respected.

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Art. 22: 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"

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

3 Subgroups to discuss:

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

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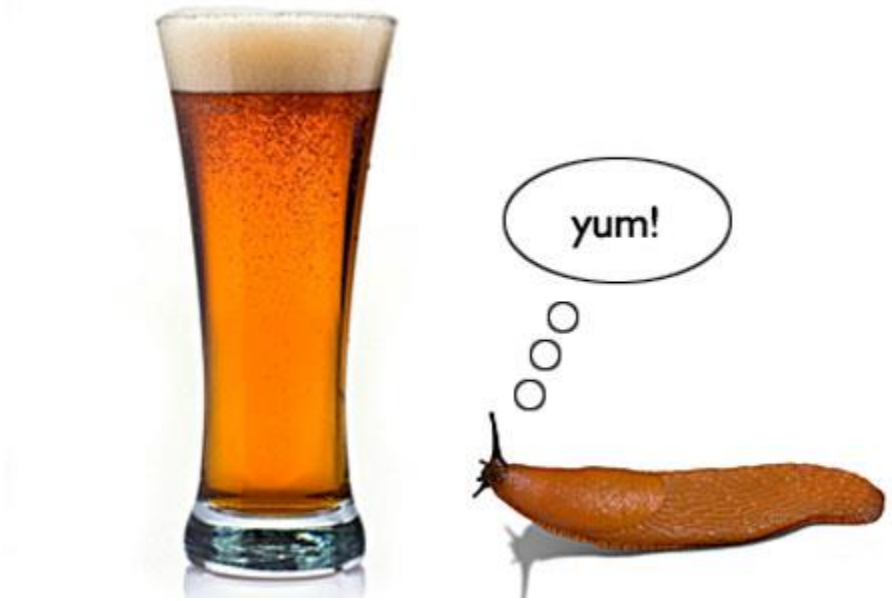
Art. 23: Basic Substances



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.

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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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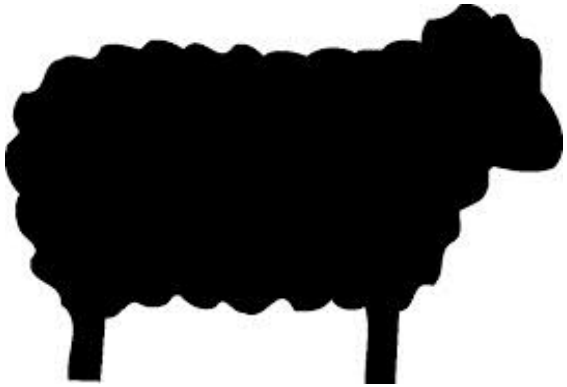
Art. 24 and Art. 80(7): Candidates for Substitution



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Candidates for Substitution

- Commission to present by 14 December 2013 a list of approved substances fulfilling the criteria of a candidate for substitution.
- A report was presented to the SCFCAH in July 2013.
- Stakeholder consultation (November 2013).
- Initial list covers substances approved before 1 January 2013.
- List is based on existing peer-reviewed data (relied upon for approval of the active substance).
- Thresholds used for the list will be basis for future decisions.

Condition 1

1. Its ADI, ARfD or AOEL is significantly lower than those of the majority of the approved active substances within groups of substances/use categories;

- An absolute threshold is preferred.
- On the basis of an absolute threshold a number of 20 active substances qualify for this condition.
- Provides greater predictability compared to a dynamic threshold.

Condition 2

2. It meets two of the criteria to be considered as a PBT substance;

   Based on an individual assessment of the:

   - Persistence, Bioaccumulation and Toxicity.

- Based on SANCO Working Document: « *Evidence needed to identify POP, PBT and vPvB properties for pesticides* »
- 52 active substances qualify for this condition.

Condition 3

3. There are reasons for concern linked to the nature of the *critical effects* (such as developmental neurotoxic or immunotoxic effects) which, *in combination with the use/exposure patterns*, amount to situations of use that could still cause concern, for example, high potential of risk to groundwater; *even with very restrictive risk management measures* (such as extensive personal protective equipment or very large buffer zones);

- None of the currently approved active substances clearly fulfils Condition 3.

Condition 4

4. It contains a significant proportion of non-active isomers;

- The racemic isomer mixtures of 2 substances may be considered as CFS.

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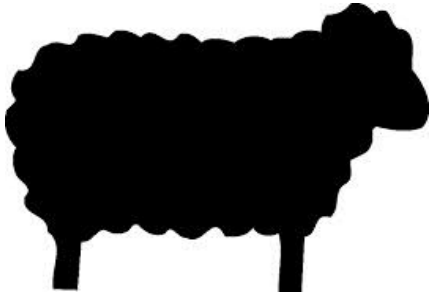
Condition 5, 6 and 7

CFS criterion	Number of a.s.
Condition 5	0
of which classified as Carc. 1A	0
of which classified as Carc. 1B	0
of which to be classified Carc. 1A	0
of which to be classified Carc. 1B	0
Condition 6	9
of which classified as Toxic for repr. 1A	2
of which classified as Toxic for repr. 1B	6
of which to be classified as Toxic for repr. 1A	0
of which to be classified as Toxic for repr. 1B	1
Condition 7	7
of which classified as Carc.2	22
of which classified as Toxic for repr. 2	17
of which to be classified as Carc.2	13
of which to be classified as Toxic for repr. 2	10
of which classified as Carc.2 and Toxic for repr. 2	6
of which to be classified as Carc.2 and Toxic for repr. 2	1

Candidates 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?
- Such a list will not affect current approval periods, nor on-going applications and re-authorisations.
- At the stage of renewal of the approval of the AS the status will be reconsidered.



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Art. 50: Comparative Assessment

Comparative Assessment: Key elements

- Reduce risks…

…while in the same time…

- Minimise agricultural disadvantages;
- Ensure effective resistance management;
- Take account of consequences for minor uses.
- GD will follow a stepwise approach (noted in Standing Committee, October 2014).

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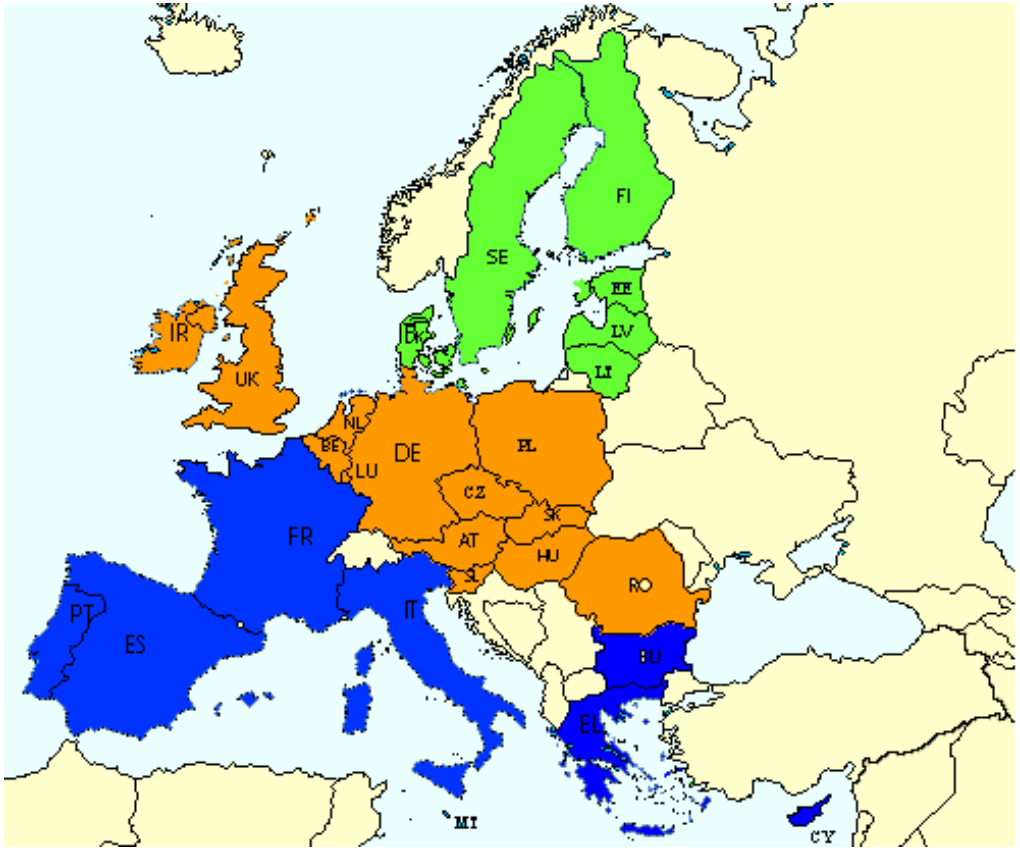
Art. 28-42: "Zonal System"



Zonal system – implementation (procedures)

- Zonal/interzonal Steering Committees are operational.
- SCs meet as foreseen by the GD (every 2nd month).
- Zonal guidance is gradually replacing national guidance.
- Three expert groups streamline the zonal system:
  - Interzonal Steering Committee (izSC) – organisational
  - Post Approval Issues (PAI) – technical
  - Standing Committee (PAFF) - supervision
- On efficacy, cooperation with EPPO established.

Zonal system – implementation (FEEDBACK)

- Recent analyses from industry and MS on the functioning → not yet working according to desire.
- Yet, no thorough analysis: figures presented too divergent.
- Complexity of the zonal vs. national authorisation:
  - Failure to comply with deadlines
  - Resource problems
  - Lack of streamlining in the procedure
- COM dedicated to the principle of mutual recognition and keen to enhance the functioning.

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Art. 34: Exemption from submission of studies

Guidance Document on Article 34 (in prep.)

- Article 34 provides the details for the exemption from the submission of data:
  - because certain data are out of protection or
  - because the applicant possesses a letter of access.
- Guidance Document is limited to applications for products:
  - which are entirely comparable, and
  - for which access to the protected data is shown or for which data are no longer protected, and
  - for which no technical assessment is needed.
- In all other cases a complete submission according to Article 33 is necessary.

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Art. 51: Minor Uses

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Art. 51: 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.

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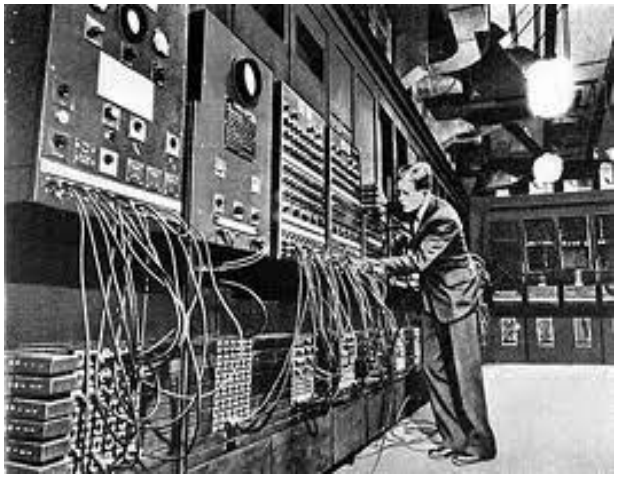
Art. 57: Autorisation Database



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Autorisation Database

- Modular: 1st Module (authorisation/ mutual recognition):
- What next?
  - Training ("Train the trainer" + conferences)
  - Incorporate existing entries from MS databases
  - Expand existing EPPO codes
  - Expand pre-submission module
  - Implement other modules (amendment of authorisation, minor uses…)
  - Publish catalogue of EU authorisations

Keeping us busy in 2015

… and beyond

- AIR programmes
- Product renewals
- Confirmatory data
- Guidance documents
- Safeners and synergists
- Art. 21
- Art. 82: Review Clause
- ……

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