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Update on Regulation (EC) No 1107/2009

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Health and Consumers

Active substances

first approval

- New Active substances (Reg. 188/2011)
  - 10 substances still in the peer-review
  - 8 conclusions expected by February 2014
  - No overlap with other review programs (list 4, AIR2)

- New Active substances (Reg. 1107/2009)
  - 21 dossiers declared admissible since June 2012
  - Delays in admissibility check and dossier sanitization

Active substances

Renewal of approval

- From 7 (AIR 1) to 150 (Air 3) a.s.
- AIR 2:
  - RAR-commenting ongoing
  - Emerging concern about delays in submissions to EFSA
- AIR 3:
  - Divided into 4 batches
  - Dossier submission after 1 Jan. 2016 -> new data requirements apply
  - Extension of approvals as and if appropriate

Implementing measures

New data requirements

- Published on 3 April 2013 (Reg.s (EC) No 283/2013 and 284/2013)
- Accompanied by 2 Communications on test methods and guidelines
- Application dates:
  - Approvals or amendments of approval where dossier is submitted after 31 December 2015;
  - AIR3 substances where supplementary dossier is submitted after 31 December 2015;
  - For all remaining substances: applications concerning the authorisation of plant protection products submitted after 31 December 2013 (voluntary) or 31 December 2015 (obligatory) require a dossier according the new data requirements
  - A Guidance Document on transitional measures is under preparation ☺

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Implementing measures

Basic Substances

- Working document on approval of basic substances (SANCO/10363/2012)
- Ongoing discussions about the concept
- 15 substances currently in the system
- Pilot project (5 substances) close to finalisation
- New applications are announced

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Implementing measures

Endocrine Disruptors

- First draft identification scheme presented in Feb 2013
- Comments and reports from MS, stakeholders, EFSA, JRC,...
- Given the complexity of the issue, an Impact Assessment became necessary
- Roadmap and TOR under preparation
- Commission proposal for scientific criteria will take into account outcome of the Impact Assessment

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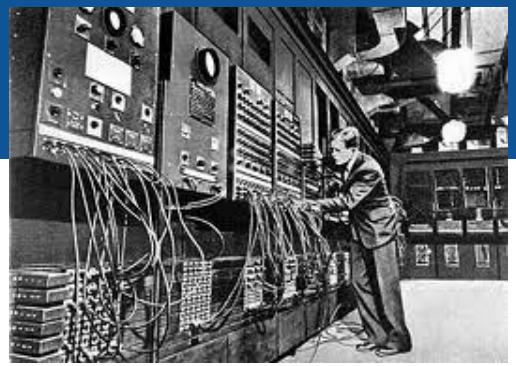
Implementing measures

Candidates for Substitution

- Commission to present by 13 December 2013 a list of approved substances fulfilling the criteria of a candidate for substitution
- A report was presented to the SCFCAH in October 2013
- Next step: Stakeholder consultation (November 2013)
- Initial list will cover substances approved before 1 January 2012
- Thresholds used for the list will be basis for future decisions
- Guidance document on comparative assessment not finalized yet



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Implementing measures

Authorisation Database

- EU-wide database for product authorisations (also including e.g. minor uses, parallel trade,...)
- In future, all new applications will go through the database
- Two main functionalities:
  - Partially public information portal (Art. 57), allows queries
  - Exchange of information and documents between applicants and MS during the assessment (Art. 36, 52)
- Modular approach: zonal module to be kicked off in early 2014, others to follow later

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Keeping us busy in 2014

… and beyond

- Application of approval criteria:
  - Endocrine disruption
  - Negligible exposure
  - Art. 4(7)
- Authorisation/applications database
- AIR 2
- Confirmatory data
- Guidance documents
- Art. 21
- Bees

Thank you very much for your attention!

Health and Consumers