Directorate-General for Health & Consumers

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First experiences from the application of Regulation (EC) No 1107/2009

Wolfgang Reinert
Unit E.3 – Chemicals, Contaminants and Pesticides

What changed on 14 June? – "Big standards"

- Criteria for approval
- Zonal system
- Data protection and data sharing
- Deadlines
- Diversification of approval types
  - Basic (facilitated use, no authorisation), unlimited
  - Low risk (economic incentives), for 15 years
  - "normal", for 10 years
  - Candidate for substitution, for 7 years
  - Art. 4(7), for 5 years
- Comparative assessment
- Safeners, synergists and co-formulants added to the scope

What else changed on 14 June? - examples

- IPM
- Parallel trade
- Minor uses
- Extended approval criteria (efficacy, biodiversity,…)
- NPAs
- Advertising
- Record-keeping
- Information duty for users
- Monitoring and controls
- Confirmatory data
- Emergency measures
- Fees and charges

Some things never change -Transitional provisions 1

- For active substances, Directive 91/414 shall continue to apply with respect to procedures and conditions of approval to:
  - substances under AIR 1 (Reg. 737/2007)
  - substances resubmitted under Reg. 33/2008
  - New active substances for which completeness of the dossier is established before 14 June 2011 (cf. Reg. 188/2011)

- Data sharing (except for vertebrate studies) and data protection:
  - 5 years for existing active substances
  - 10 years for new active substances
  - 5 years for renewal of approval, if initial approval expired by *24 November 2011*
  - Annex II and III of Dir. 91/414 remain valid

Some things never change -Transitional provisions 2

- Regarding products:
  - Applications for authorisations pending on 14 June and
  - Authorisations to be amended or withdrawn following inclusion/approval on 14 June
  shall be decided on the basis of national law in place before that date

- Provisional authorisations (NPAs)
  - Particular case
  - No explicit reference under the transitional measures
  - NPAs seem to be rather as a part of the inclusion/approval procedure
  - Therefore, art. 8(1) of Directive 91/414 can be applied after 14 June to active substance to which completeness of the dossier was established before that date

Implementing tasks

- Transformation of the annexes to Directive 91/414 (14 June 20011)
- Maintain a list of approved active substances electronically available to the public (14 June 2011)
- Report to European Parliament and Council on the establishment of a European fund for minor uses, accompanied, if appropriate, by a legislative proposal (14 December 2011)
- Report to European Parliament and Council on the costs and benefits of the traceability of the information concerning the PPP applications on agricultural products (14 December 2012)
- List of candidates for substitution from currently approved substances (14 December 2013)
- Specific scientific criteria for the determination of ED properties (14 December 2013)
- Report to the European Parliament and the Council on the functioning of the key elements of Regulation 1107/2009 (Art. 82) (14 December 2014)
- Work programme and data requirements for safeners and synergists (14 December 2014)

Guidance Documents (recently finalised)

- Peer reviewed open literature (EFSA)
- Zonal assessment and mutual recognition
- Renewal of authorisations
- Risk envelope approach
- Revised GD on equivalence (SANCO/10597/2003) (Lead: DE+EL)
- Revised GD on residue analytical methods post registration (SANCO/825/00)
- Submission and assessment of confirmatory data after approval (SANCO/5634/2009 Rev. 4.3)
- Authorisation of PPP following inclusion of an existing active substance in Annex I of Council Directive 91/414/EEC ("Re-Reg. GD" Sanco/10796/2003 – rev 12.2)
- Format of the Reregistration report

Guidance Documents (under drafting)

- Emergency authorisations (Art. 53, ex-8(4))
- Changing the chemical composition of authorised PPP (Lead: DE)
- Implementation rules for including unacceptable co-formulants into Annex III to Regulation 1107/2009 (Lead: DE/ES)
- Risk Assessment for PPP used in Protected Crops (Lead: NL)
- Efficacy assessment during phase of active substance assessment
- Evaluation of isomers (initiated in PSC, lead: AT/BE/ES)
- Exposure operators-workers-residents-bystanders
- Tiered groundwater assessment decision scheme (Lead: UK)
- Risk assessment to bees (EFSA)
- Use of treated seed (Lead: NL/FR/DE)
- Parallel trade
- Dossier submission under article 4(7)

Expert groups and others

- Workshops on:
  - Harmonisation and new procedures in regard to product chemistry of AS and PPP
  - Harmonised classification and labelling of active substances in PPP
  - Seeds
- Renewal of approval (AIR3)
- Parallel trade
- Authorisation database
- Drift and drift reducing methodologies
- Revised data requirements on active substances (end of 2011)
- Format of dossier and DAR
- Zonal Steering Committees and InterZonal Steering Committee

New active substances

- 71 new active substances still to be decided under the rules of Directive 91/414
- Regulation (EU) No 188/2011 establishes procedures for the review
- 6 conclusions are likely to be submitted in 2011
- Commenting on the (updated) DAR has been opened for 13 substances
- For three substances, dossiers have been declared admissible under Regulation 1107/2009

Emerging questions (1)

- Does Mutual recognition also apply to substances approved under Directive 91/414/EEC?
- All substances on Annex I to Directive 91/414/EEC are considered to be approved under Regulation (EC) No 1107/2009 (Art. 78(3));
- Mutual recognition applies to substances approved under Regulation 1107/2009 (Art. 40 in conjunction with Art. 29(1a);
- See also the GD on mutual recognition (SANCO/1369/2010 rev.5), chapter 3.1;
- All MS took note of the GD in the Standing Committee on the Food Chain and Animal Health, only DE took a reservation on the application of this provision.
- It is difficult to see how this provision could be interpreted differently and EU-MS could keep products on the market authorised under Directive 91/414.
- Rather technical than legal problem; therefore, emphasis should be put on finding a solution for the deadline for recognition (120 days) together with industry.

Emerging questions (2)

- Back-to-back registrations; amendment of an existing registration or new registration?
- Assumption: "back-to-back" = different applicants, product identical
- Regulation 1107/2009 does not distinguish between "regular" and "back-to-back" authorisations
- The application for authorisation and for amendment of an authorisation follow the same rules (Art. 33)
- Applicant / authorisation holder has a prominent role in the process (cf. Art. 33, 45, 73)
- Regulation 1107/2009 implicitly assumes that there is only 1 product name and 1 holder per authorisation (Art. 57.1)
- Rather technical than legal problem; therefore emphasis should be put on efficient communication in order to avoid repetition of work

Emerging questions (3)

- Minor uses for products which are not re-registered?
- The provisions on authorisation of PPP in Regulation 1107/2009 assume that such authorisation has been granted in accordance with the Uniform Principles
- This is not the case for products which are not re-registered yet
- It is questionnable, in how far obligations from Regulation 1107/2009 would be effective in this case
- Before MS take a final decision, it is advisable to check the national legislation in place before 14 June 2011

Our website, with a new look...

...but for the time being still at the same place:

http://ec.europa.eu/food/plant/protection/evaluation/index_en.htm

Thank you for your attention!