



XIVth CEUREG Forum

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Implementation of Regulation (EC) No 1107/2009 - State of affairs -

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Regulation (EC) No 1107/2009

- Published 24 November 2009
- Entry into force 14 December 2009
- Applicable as from 14 June 2011
- Amendments with impact on follow-up activities:
 - Report on minor use fund
 - Report on pesticide passport
 - Provisions on parallel trade
 - More flexibility for MS in mutual recognition
- Reflects overall concept of COM proposal from July 2006
- Provides directly for a considerable number of implementation tasks for COM

Implementing measures with deadlines (1)

Reference Reg. 1107/2009	Date	Measure
Art 8(3)	Best \leq 14 June 2011	Format of the dossier and Summary dossier to be submitted by industry. Advisory procedure.
Art 11(4)	Best \leq 14 June 2011	Format of the draft assessment report of the rapporteur Member States on an active substance and of the assessment report on a plant protection product. Advisory procedure.
Art 13(4)	\leq 14 June 2011	Maintain a list of approved active substances electronically available to the public.



Implementing measures with deadlines (2)

Reference Reg. 1107/2009	Date	Measure
Art 84	14 June 2011	Transformation of Annexes I-VI to Directive 91/414 into Regulations
Art 51(6a)	14 December 2011	Report to European Parliament and Council on the establishment of a European fund for minor uses , accompanied, if appropriate, by a legislative proposal.
Art 67(1)	14 December 2012	Report to European Parliament and Council on the costs and benefits of the traceability of the information concerning the PPP applications on agricultural products (if necessary, with legislative proposals, pesticide passport).
Art 80(7)	14 December 2013	List of Candidates for substitution included in Annex I of directive 91/414/EEC (criteria point 4 Annex II)
Annex 2 3.6.5	14 December 2013	Specific scientific criteria for the determination of endocrine disrupting properties.

Implementing measures with deadlines (3)

Reference Reg. 1107/2009	Date	Measure
Art 26	14 December 2014	Regulation establishing a work programme for gradual review of synergists and safeners on the market +relevant data requirements.
Art 82	14 December 2014	Review clause Report to European Parliament and Council on the application by MS of the provisions referred to in Art 36(3) and art 50(2), the division of the community in three zones and on the criteria for the approval substances, safeners and synergists as set in Annex II. Impact on the diversification and competitiveness of agriculture in human health and environment. (if necessary, with legislative proposals)
Art 30(3)	14 December 2015	Expiry of application of derogation providing for provisional authorisations . Extension possible by Comitology with scrutiny.
Art 62(3a)	14 December 2016	Report + legislative proposal to European Parliament and Council on the effects of the provisions concerning data protection of tests and studies involving vertebrate animals. (if necessary, with legislative proposals)
Art 27(5), Art 81(2)	N.D. (≤14 June 2015)	Detailed rules for the implementation of the provisions for co-formulants .

Implementing measures without deadlines (1)



Reference	Date	Measure
Reg. 1107/2009		
Art 22(3)	N.D.	Criteria for approving an active substance as low-risk active substance.
Art 21(1), Art 18	N.D.	Renewal of approval. Work programme for renewal of approvals. (Not Compulsory)
Art 29(4)	N.D.	Harmonise methods for analysis of active substances, safeners and synergists and, where appropriate, any toxicologically, ecotoxicologically or environmentally relevant impurities and co-formulants (Not Compulsory)
Art 58	N.D.	Detailed rules for the national authorization of adjuvants (data requirements, notification, evaluation, assessment and decision making criteria).
Art 68	N.D.	Regulation setting out provisions for controls carried out by the Member States.
Art 75(5)	N.D.	The Commission shall publish and keep updated on its website a list of the competent authorities of the Member States

Implementing measures without deadlines (2)

Reference Reg. 1107/2009	Date	Measure
Art 38(5)	N.D.	Detailed rules on the assessment of equivalence of different sources of active substances. (Not Compulsory)
Art 39(4)	N.D.	Detailed rules on reporting and exchange of information on applications for authorisation. (Not Compulsory)
Art 43(4)	N.D.	Guidelines on compliance checks for plant plant protection products after renewal of approval of a substance. (Not Compulsory)
Art 52	N.D.	Further details and specific requirements for parallel trade in case of application where an authorisation has already been granted or for products for personal use only.
Art 54(5)	N.D.	Detailed rules on research and development , in particular the maximum quantities of plant protection products that may be released during experiments or tests and the minimum data to be submitted. (Not Compulsory)
Art 39(4)	N.D.	Detailed rules for Reporting and exchange of information on applications for authorisation to facilitate work-sharing . (Not Compulsory)



'Sustainable use Directive': Implementing measures with deadlines,

Reference Dir. 2009/128	Date	Measure
Art. 7(3)	14 December 2012	Develop together with Member States a strategic guidance document on monitoring and surveying of impacts of pesticide use on human health and the environment.
Art. 4(3)	14 December 2014	Report on the information communicated by the Member States in relation to the National Action Plans .
Art. 4(3)	14 December 2018	Report on the experience gained by Member States on the implementation of national targets established in their National Action Plans in order to achieve the objectives of the Directive. (if necessary, with appropriate legislative proposals).

'Sustainable use Directive': Implementing measures without deadlines

Reference Dir. 2009/128	Date	Measure
Art. 4(4)	N.D.	Publish information submitted by Member States on National Action Plans
Art.15(1)	N.D.	Establish harmonised risk indicators (Annex IV to the Directive)
Art. 15(4)	N.D.	Calculate risk indicators at Community level in order to estimate trends in risks from pesticide use and to assess progress in achieving Community policies on reduction of impact from pesticide use.
Art. 16	N.D.	Regularly submit to the European Parliament and to the Council a progress report on the implementation of the Directive.
Art. 18	N.D.	Put forward as a priority for discussion the exchange of information and best practice in the field of sustainable use of pesticides and integrated pest management.
Art. 20	N.D.	Establish standards for compliance of application equipment in use with health/safety/environment requirements set in Annex II to the Directive



Don't panic!

Zonal evaluation and mutual recognition

- Workshops on EU- and on zonal level
- e.g.: Vilnius (Nov. 2009), Braunschweig (Jan. 2010), Paris (Apr. 2010)
- Envisaged outcome: (procedural) guidance documents, Standing Groups
- Precursors of Zonal Steering Committees exist
- Draft GDs under preparation:
 - Zonal evaluation and mutual recognition
 - Renewal of authorisations
 - Risk envelope
 - Remit of the Zonal/Interzonal Steering Committees
- First meeting of the Interzonal Steering Committee on 9/10 December 2010

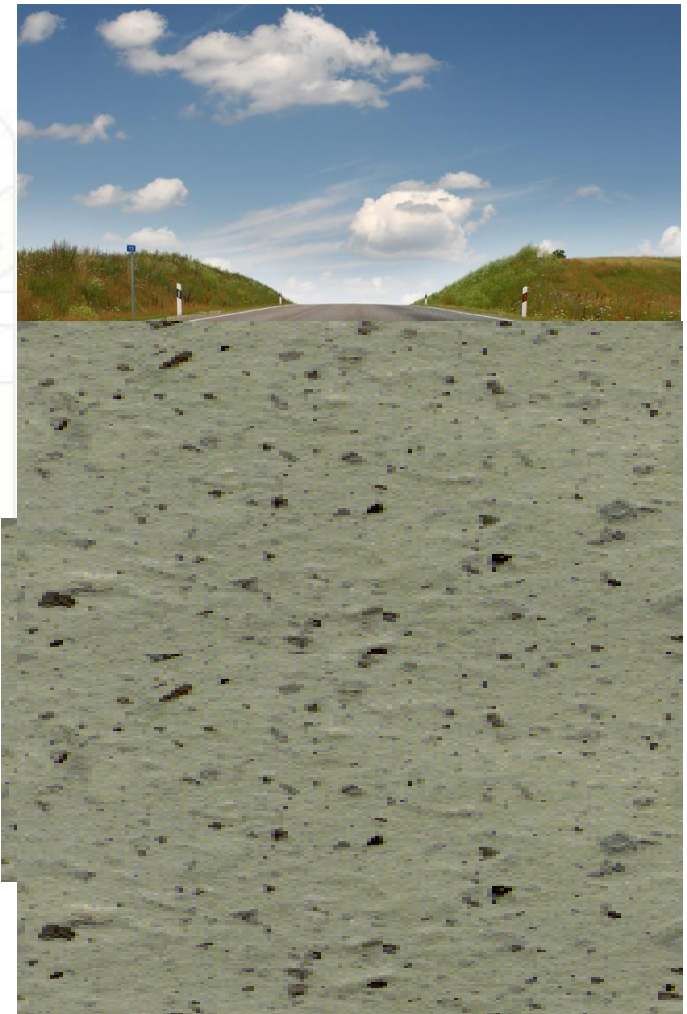
Classification and labelling

- Art. 80(6): Transitional phase for products labelled according to Dir. 91/414
- Reg.s 1107/2009 and 1272/2008 largely discussed in EP and Council in parallel
- Open questions make further fine tuning between COM, MS, ECHA and EFSA necessary
- To this end, PSC initiated a workshop on classification for March 2011
- Amendment of Reg. 1107/2009 will become necessary with view to 1 June 2015

On the way to Regulation 1107/2009...

... some leftover from Directive 91/414/EEC is still to be removed:

- 77 decisions under “resubmission” procedure
- 61 “green track” substances
- >64 “new” substances



Thank you for your attention!

**As we all know: the sun is
rising in the East...**

For more information...

... please consult our website:

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