



ABIM Annual Biocontrol Industry Meeting
Basel October 2017

REFIT pesticides legislation: Regulations 1107/2009 and 396/2005

Patrizia Pitton
DG SANTE Unit E4 Pesticides and Biocides
European Commission



What is a Refit evaluation?

- *Regulatory Fitness and Performance : under the Better Regulation scheme COM committed to **ensure EU legislation is effective and efficient** in achieving its public policy objectives at minimum cost*
- *Objectives of REFIT : collate evidence and rely on sensible monitoring arrangements – compare performance against what was expected to happen – 5 main criteria **effectiveness - efficiency - relevance – coherence - EU added value***
- *Steered by an ISG and supported by a consultation strategy (public consultation)*



REFIT - Evaluation of EU pesticide legislation

- **Objective:** *to perform an evidence based assessment of the implementation of both the legislation on plant protection products and pesticides residues with focus on efficiency so pinpoint simplification potentials*
 - **Ex-post evaluation** - BACKWARD LOOKING!
 - **Reporting obligations to Council and Parliament:**
 - i) Articles 62(5) and 82 of Reg (EC) No 1107/2009 (Mutual recognition and zonal system – Impacts of approval criteria-sharing of tests involving vertebrates)
 - ii) Article 47 of Reg (EC) No 396/2005
- ***Commission Staff Working Document and Report: first half of 2019***



Main issues under evaluation

- mutual recognition and functioning of the zonal system,
- comparative assessment of plant protection products containing candidates for substitution,
- the application of the criteria for approval, including “cut-off” criteria,
- the effects of the provisions concerning data protection of studies involving vertebrate animals,
- procedures for setting, modifying, deleting and reviewing MRLs and adaptation to technical and scientific progress,
- links, synergies, gaps and potential contradictions between Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005.



Other relevant issues...

- Approval and renewal procedure (including application of the “cut-off” criteria),
- Placing on the market of treated seeds,
- Emergency authorisations,
- Approval of basic substances,
- Approval of low risk substances,
- Minor uses,
- Labelling of plant protection products,
- Definition of plant protection products,
- How the goal of competitiveness of the European agriculture and improvement of agricultural production is taken into account in this legislative framework,
- Transparency and confidentiality,
- Role of scientific peer-reviewed open literature in the assessment of active substances.



REFIT – State of play

- *Refit **Roadmap** published on 17 November 2016: purpose, content and scope of the evaluation plus main evaluation criteria*
- ***Feedback** received was reflected in the **Terms of Reference***
- *Evaluation study carried out by **external contractor** from July 2017 until June 2018*
- ***First workshop** held in September 2017*



REFIT – Next steps

- *Launch of surveys planned beginning November 2017*
 - i) Open public consultation*
 - ii) Stakeholders survey*
 - iii) Member States Competent Authorities survey*
 - iv) Small and Medium Enterprises (SME) survey*
- *Future consultations (after surveys):*
 - Focus groups, in-depth interviews, Workshop (2)*
- *Commission website on the evaluation:*

http://ec.europa.eu/food/plant/pesticides/refit_en



Consultation time

- *Open public consultation per 12 weeks (around 15' minutes to fill questionnaire) in all languages*
- *Online surveys MS authorities (6 weeks) and stakeholders (6 weeks)*
- *SME survey will be distributed to the SME panel of the Enterprise Europe Network (8 weeks) in all languages*



HEALTH

FOOD

ANIMALS

PLANTS

AMR

PESTICIDES

EU Pesticides database

Sustainable use of pesticides

Approval of active substances

Authorisation of Plant Protection Products

Maximum Residue Levels

REFIT Evaluation

ALL TOPICS

REFIT - Evaluation of the EU legislation on plant protection products and pesticides residues

Plant protection products (PPPs) and their residues are regulated in the EU by Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005. As announced in the **2016 Commission Work Programme**  of 27 October 2015, the Commission is now carrying out a REFIT evaluation of the EU pesticide legislation in order to assess if the regulations meet the needs of citizens, businesses and public institutions in an efficient manner.

Plant protection products (PPPs) are used to protect plants against pests or diseases. The Commission approves active substances, i.e., the agent used to achieve the protective effect, for the use in PPPs. In order to protect consumers, the Commission also sets maximum residue levels (MRLs) for pesticides, i.e. the highest levels of pesticide residues that are legally tolerated in or on food or feed, including imported products. The evaluation aims to perform an evidence-based assessment of the implementation of the PPP and MRL regulations and address synergies, gaps, inefficiencies and administrative burdens.

Evaluations and Fitness Checks are tools that are used to implement the **Regulatory Fitness and Performance programme (REFIT)**. REFIT is a rolling programme to keep the entire stock of EU legislation under review and ensure that it is 'fit for purpose'; that regulatory burdens are minimised and that all simplification options are identified and applied.

The evaluation process is constituted of different steps, of which the initial ones are outlined below. The evaluation is foreseen to be finalised in the second half of 2018.

The Roadmap

The Commission published on 17 November 2016, **a Roadmap**  on the REFIT

 Share

QUICK LINKS



GMO register



EU Pesticides database



Procedure to apply for authorisation of a PPP



Plant variety database



Community Plant Variety Office (CPVO)



Health and food audits and analysis



European Food Safety Authority (EFSA)



E-news



Press Releases



Infographics and factsheets



THANK YOU FOR YOUR ATTENTION!

For up-to-date information DG SANTE website:
https://ec.europa.eu/food/plant/pesticides_en