ABIM Annual Biocontrol Industry Meeting
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REFIT pesticides legislation:
Regulations 1107/2009 and 396/2005

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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,
**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 competiveness 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
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
THANK YOU FOR YOUR ATTENTION!

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