



Plant Protection Products – Regulation 1107/2009 – general update

Advisory group on the food chain and
animal and plant health plenary
7 May 2019

Food Safety



- updates on GD (*follow up last WG meeting of the Advisory Group with focus on PPP - 21 Sept 2018*)
- Implementation: new ED criteria, Co-formulants, Risk Mitigation, update of data requirements
- Specific Protection Goals
- REFIT

Food Safety

Guidance Documents & implementation



Recently adopted GD

endorsed PAFF @ March 2019:

- Draft Commission Notice – **Technical Guidelines on Data Protection** according to Regulation (EC) No 1107/2009 (SANTE/10407/2018 Rev.4)
 - under adoption & publication
- **EFSA's Administrative guidance on submission of dossiers and assessment reports**
 - Combined Template to be used for Assessment Reports according to Regulation (EC) No 1107/2009 and Proposals for Harmonised Classification and Labelling according to Regulation (EC) No 1272/2008SANCO/12592/2012.
 - GD on the renewal of approval of active substances to be assessed in compliance with Regulation (EU) No 844/2012 (the Renewal Regulation). SANCO/2012/11251
 - GD on preparing lists of test and study reports according to article 60 of Regulation (EC) No 1107/2009. SANCO/12580/2012
 - GD for applicants on preparing dossiers for the approval of a chemical new active substance and for the renewal of approval of a chemical active substance according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013. SANCO/10181/2013– - including updated Document N3



GD under development

- Renewal of authorisations (Art. 43)
- Zonal assessments, mutual recognition
- Metabolites produced by micro-organisms
- Antimicrobial resistance
- Low-risk criteria
- Dermal absorption
- Data matching checks
- Seed treatments



EFSA Bee Guidance

- EFSA published in 2013 the Guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees).
- Commission proposes a stepwise implementation: acute and chronic risk to honeybees first.
- Discussion with MS during the last years, restarted in May 2018.
- Mandate sent to EFSA in March 2019 to review bee GD
- Feedback mechanism expected for amendment to the uniform principles (*bees only*)
- Once uniform principles are amended, Commission Notice can be adopted






Implementation Reg 1107/2009

- ED Criteria
 - implementation since November 2018
- Co-formulants
- Data requirements
- Risk Mitigation




Specific Protection Goals






Background



no unacceptable effects on the environment (PPP regulation)

what, when and how long to protect (specific protection goals)




Final slide




Objective

define specific protection goals





guidelines for environmental risk assessment for pesticides

Final slide




STATE OF PLAY

- Action plan presented to Member States in 2018
- Time to move on...
- ... also needed because
 - EFSA is working on update GD B&M
 - EFSA is mandated to review bee GD

Steps in the process... (project overview)



EFSA Opinion 2010 (stakeholder + risk manager workshops)

EFSA GD 2016


Action Plan PAFF July 2018

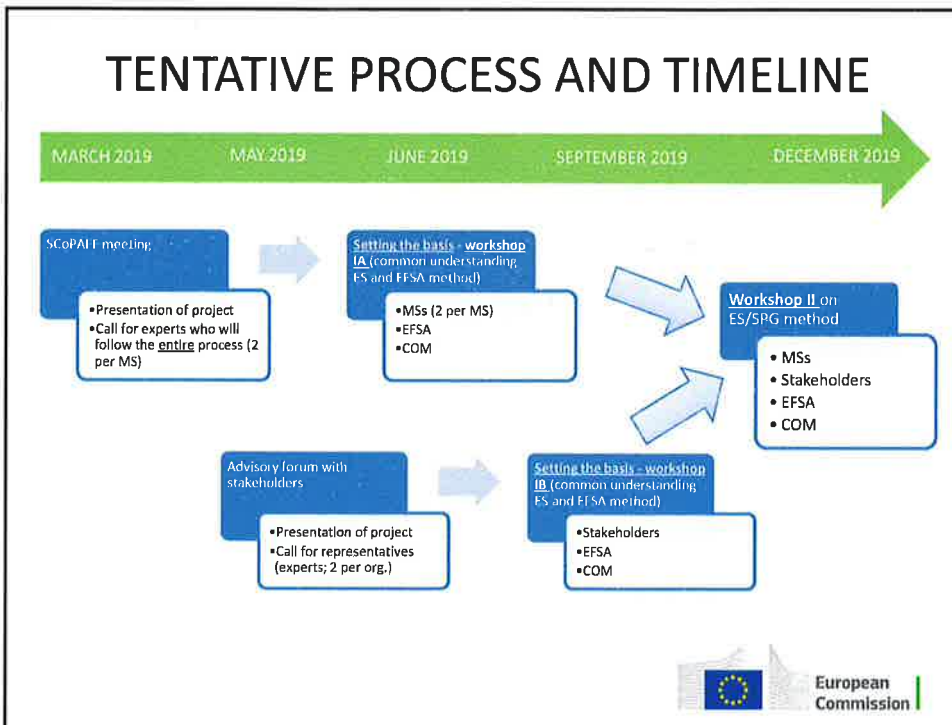
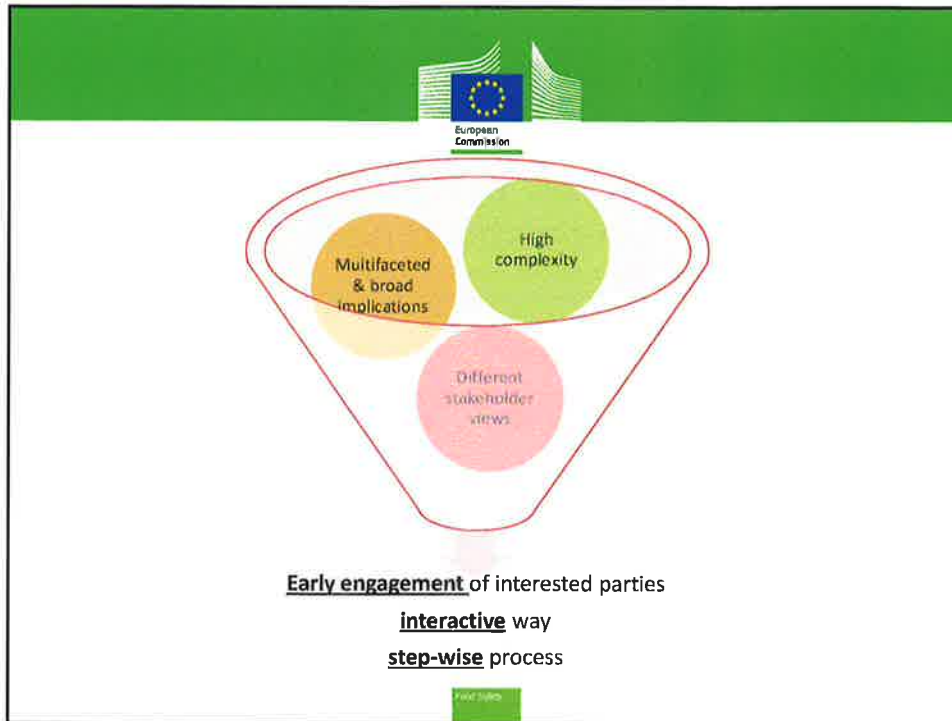
Setting the basis: common understanding on ES and EFSA's 2010 & 2016 method
Workshops IA and IB


Workshop II on ES / SPG

Defining SPG

Update GD (EFSA) & uniform principles (COM)








Setting the basis workshop (common understanding)

- Objectives**
 - Achieve a common understanding on ecosystem services
 - Achieve a common understanding of the method proposed by EFSA (2010 & 2016)
 - what are the important questions to be addressed
- Themes**
 - Ecosystem services
 - EFSA 2010 & 2016 ES/SPG method
- Format**
 - General presentations
 - Interactive session (breakout sessions)
- Tentative date**
 - End of September
 - One day



Next Steps

- Commission will send an invitation letter to the relevant stakeholders



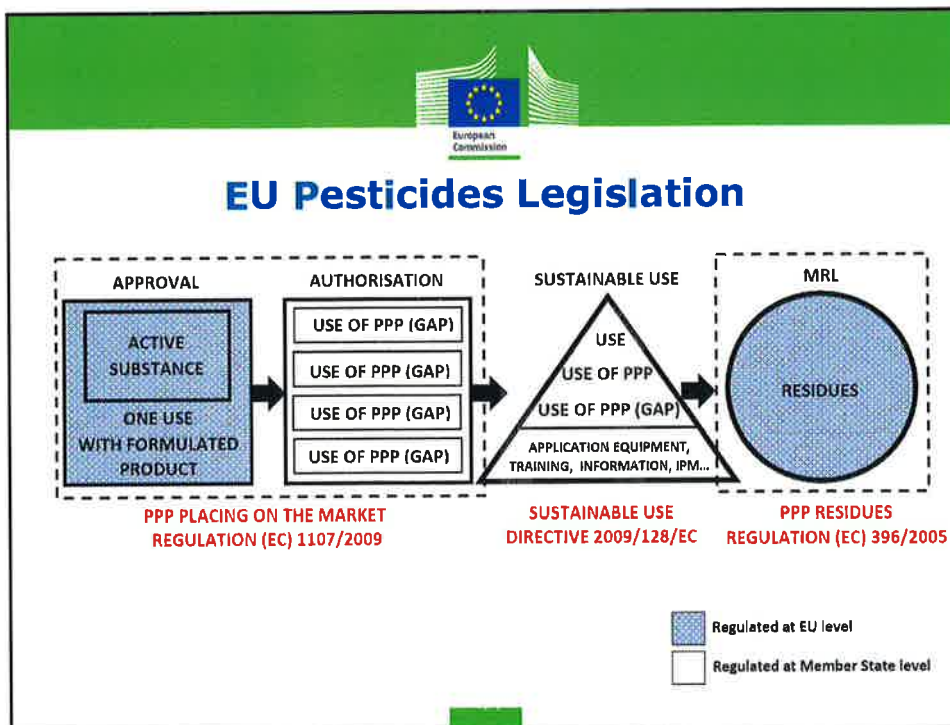
REFIT



REFIT - Evaluation of EU pesticide legislation

- **Objective:** to assess if the needs of citizens, businesses and public institutions are met in an efficient manner, legislation should be fit for purpose
 - **Ex-post evaluation** - BACKWARD LOOKING!
 - **Reporting obligations to Council and Parliament:**
 - i) Articles 62(5) and 82 of Reg. (EC) No 1107/2009
 - ii) Article 47 of Reg. (EC) No 396/2005
- **Commission Report and accompanying Staff Working Document expected in June 2019**



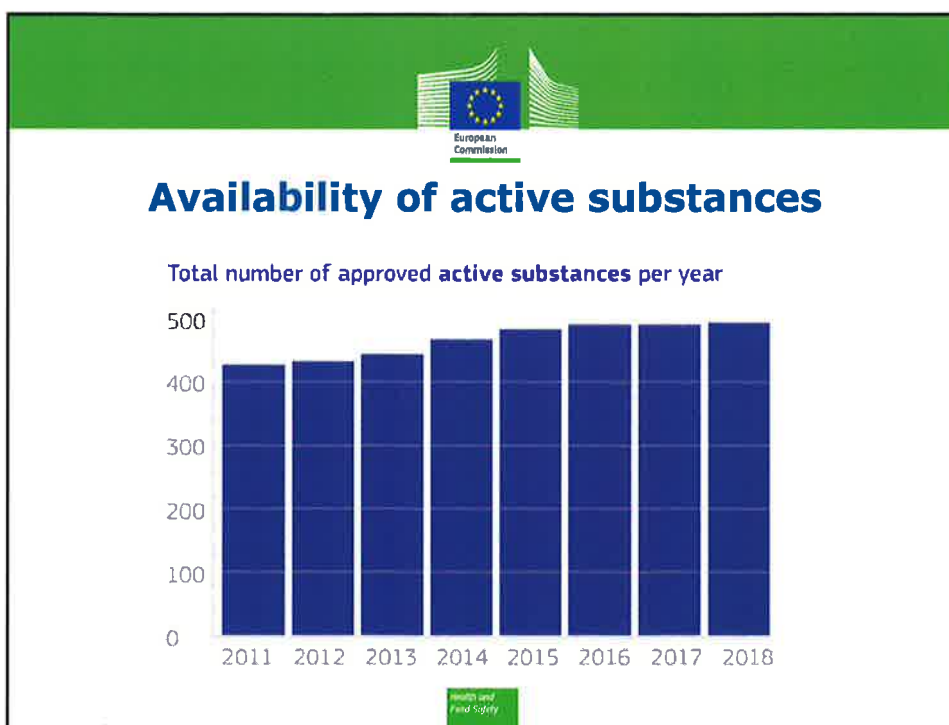
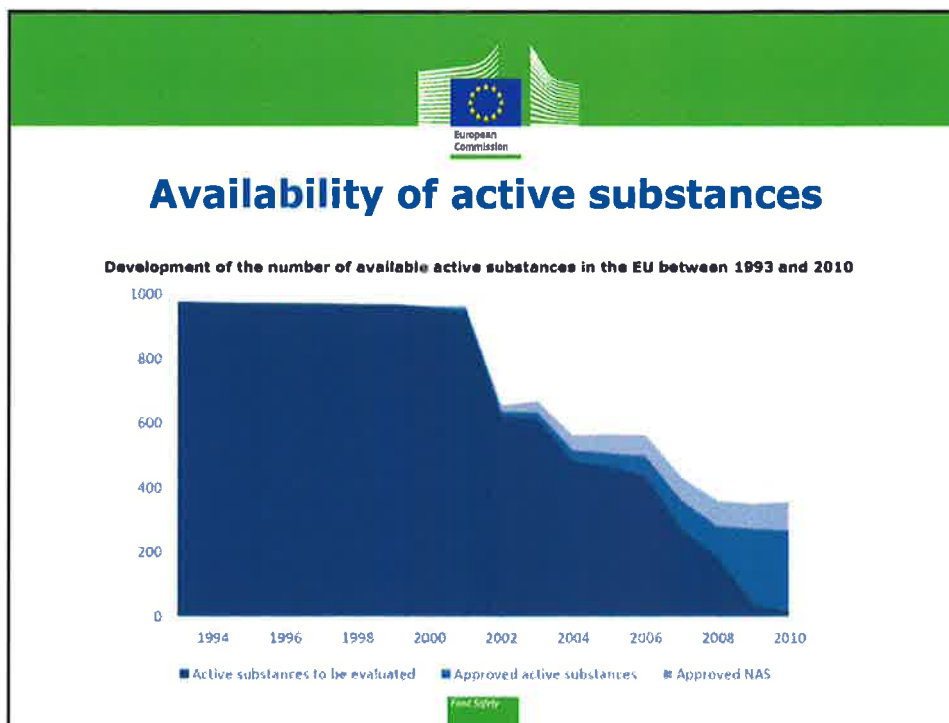


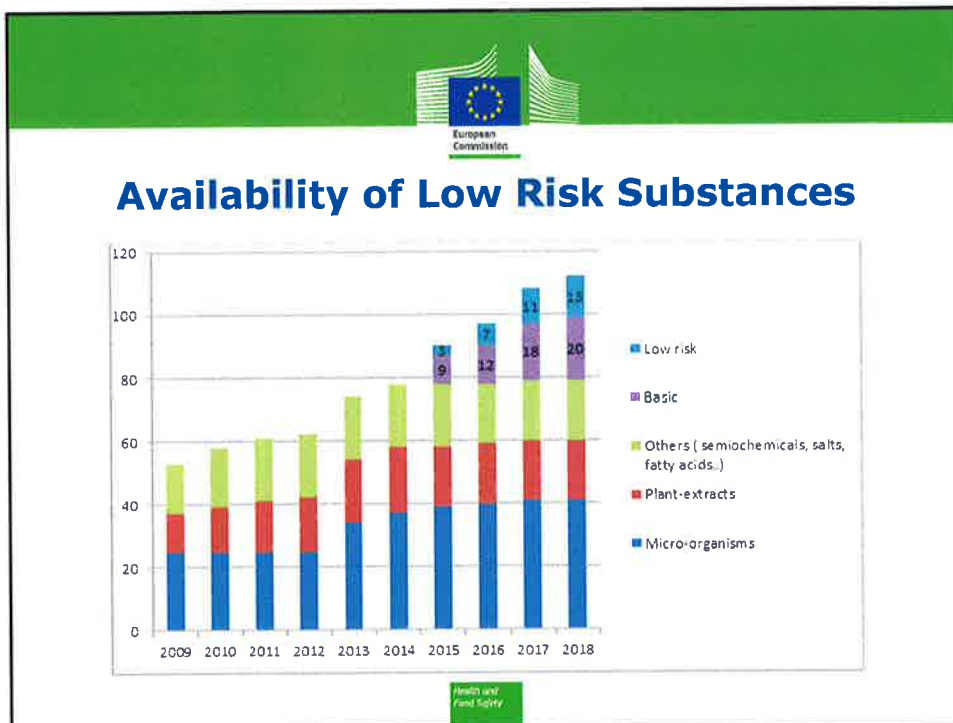
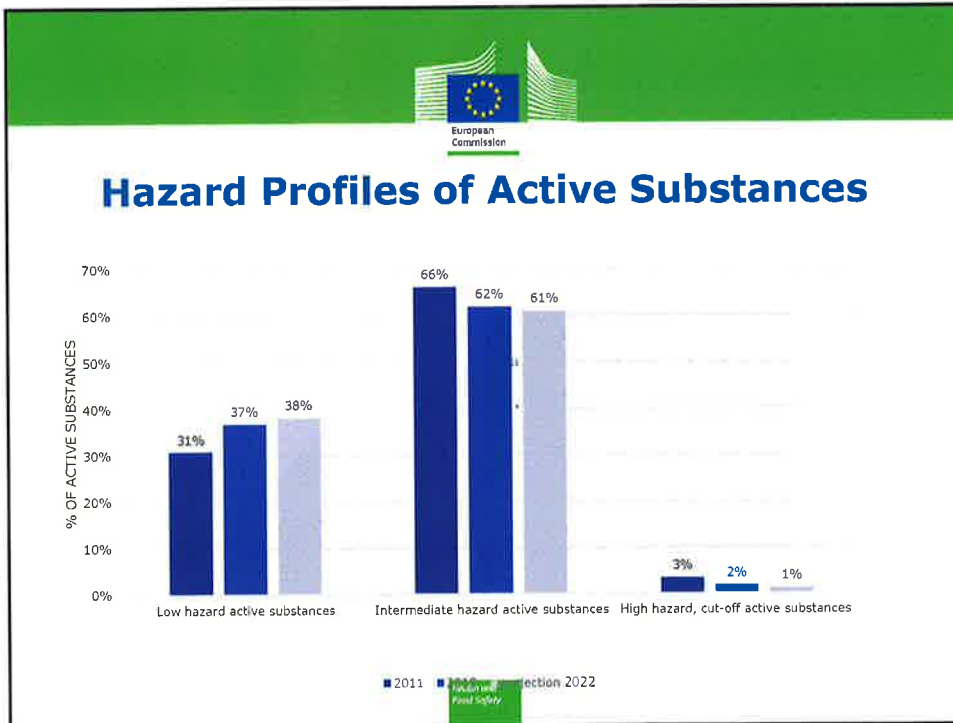

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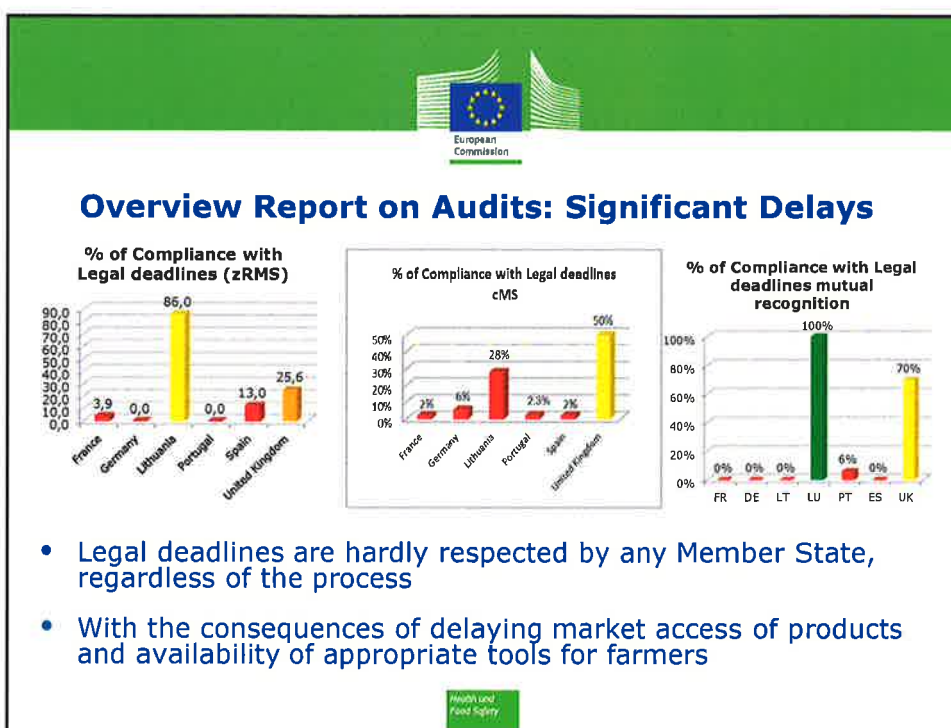
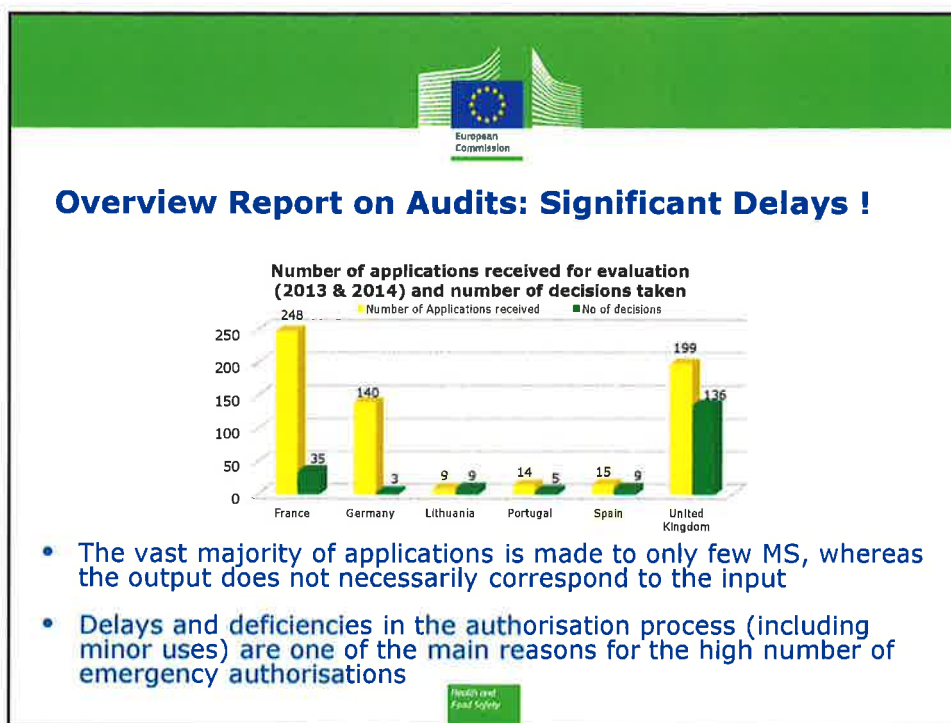
REFIT – Evaluation Steps

- Refit **Roadmap** published on 17 November 2016: purpose, content and scope of the evaluation + main evaluation criteria
- Evaluation study carried out by **external contractor** from July 2017 until June 2018
- **Workshops on specific topics** with a limited group of Member States and stakeholders in 9/2017 + 5/2018
- **Consultations:** general public, Member States, stakeholders and SMEs
- Other information sources: reports from the Commission on **audits** in Member States, 2 reports and studies from the European Parliament, Scientific advice mechanism, ...
- Commission website on the evaluation:
http://ec.europa.eu/food/plant/pesticides/refit_en


Health and Food Safety









Amendment of GFL on Transparency

- Improve and clarify **the rules on transparency** (in particular as regards scientific studies supporting risk assessment).
- Increased **reliability, objectivity and independence of studies used by EFSA** in its risk assessment (mainly **authorisation dossiers**).

In particular the **reply to the ECI highlighted** the need to:

- involve more public authorities in the process of deciding which studies need to be conducted;
- enhance auditing of compliance with GLP principles;
- publication of full study reports to increase transparency while respecting confidential business information;
- exceptionally commission ad-hoc studies in specific cases.

Health and
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Thank you for your attention!

For further information:

https://ec.europa.eu/food/plant/pesticides_en
https://ec.europa.eu/food/plant/pesticides/refit_en

https://ec.europa.eu/food/plant/pesticides/approval_active_substances/approval_renewal/neonicotinoids_en

https://ec.europa.eu/food/plant/pesticides/sustainable_use_pesticides_en

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