General update on pesticide legislation

Information session on the EFSA Guidance on predicting environmental concentrations in soil
Parma 4.5/6/2019

European Commission,
DG SANTE - Unit E-4

Content

Update on legislation:

- *Active Substance evaluations*
- *REFIT*
- *General Food Law*

Update on specific implementation issues:

- *Endocrine Disruptors*
- *Guidance Documents*
- *Defining Specific Protection Goals for ERA*
- *Risk indicators according to SUD*

Active substances evaluation

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Evaluation work for active substances

- Review programme active substances + NAS (including re-submission of ‘old’ ones)
- Quality of dossiers triggers quality of the assessment
- EFSA conclusions = the basis of our decision making

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Evaluation work for active substances (2)

- Evolving environment
  - **New criteria, data requirements and uniform principles (regulatory)**
  - **New guidance documents (to be endorsed by PAFF)**
  - **Court Cases, Ombudsman provides interpretations and defines our boundaries**
  - **Influence of stakeholders : Co-legislators >>NGO >>> industry**
- **Risk management options may be considered during the regulatory decision making at PAFF (based on evidence)**

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Figures - May 2019

Number of approved active substances	487
Number of not approved active substances	822
Evaluation dossiers in the pipeline	±34
Number of substances qualified for substitution (art 24)	67
Number of low-risk substances	13
Number of approved basic substances	20

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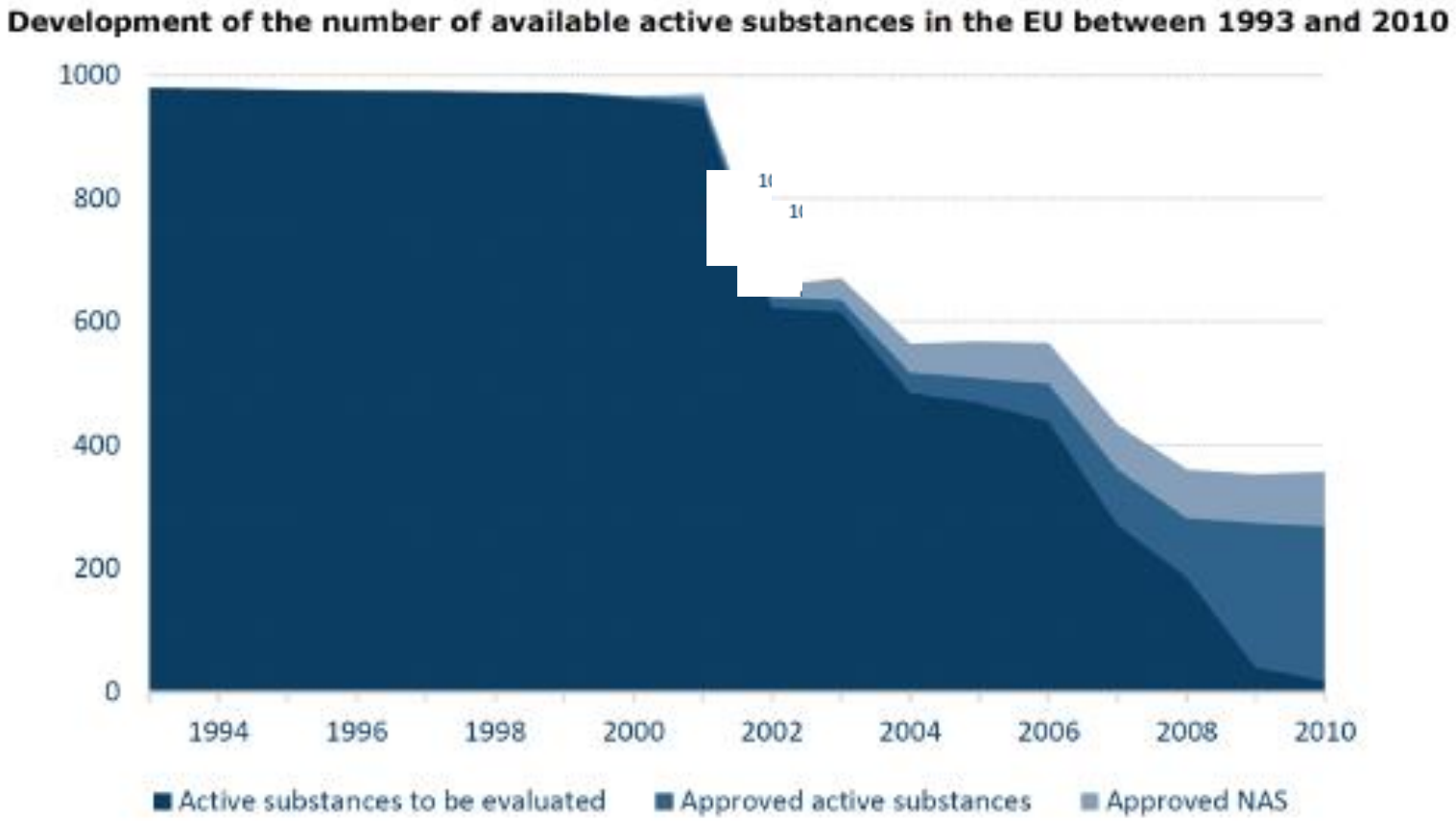
Availability of active substances



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Applications for new active substances

Year	2011	2012	2013	2014	2015	2016	2017	2018
New active substance applications	4	8	12	6	15	10	4	10

Information from the summary reports from the Standing Committee on Plants, Animals, Food and Feed.

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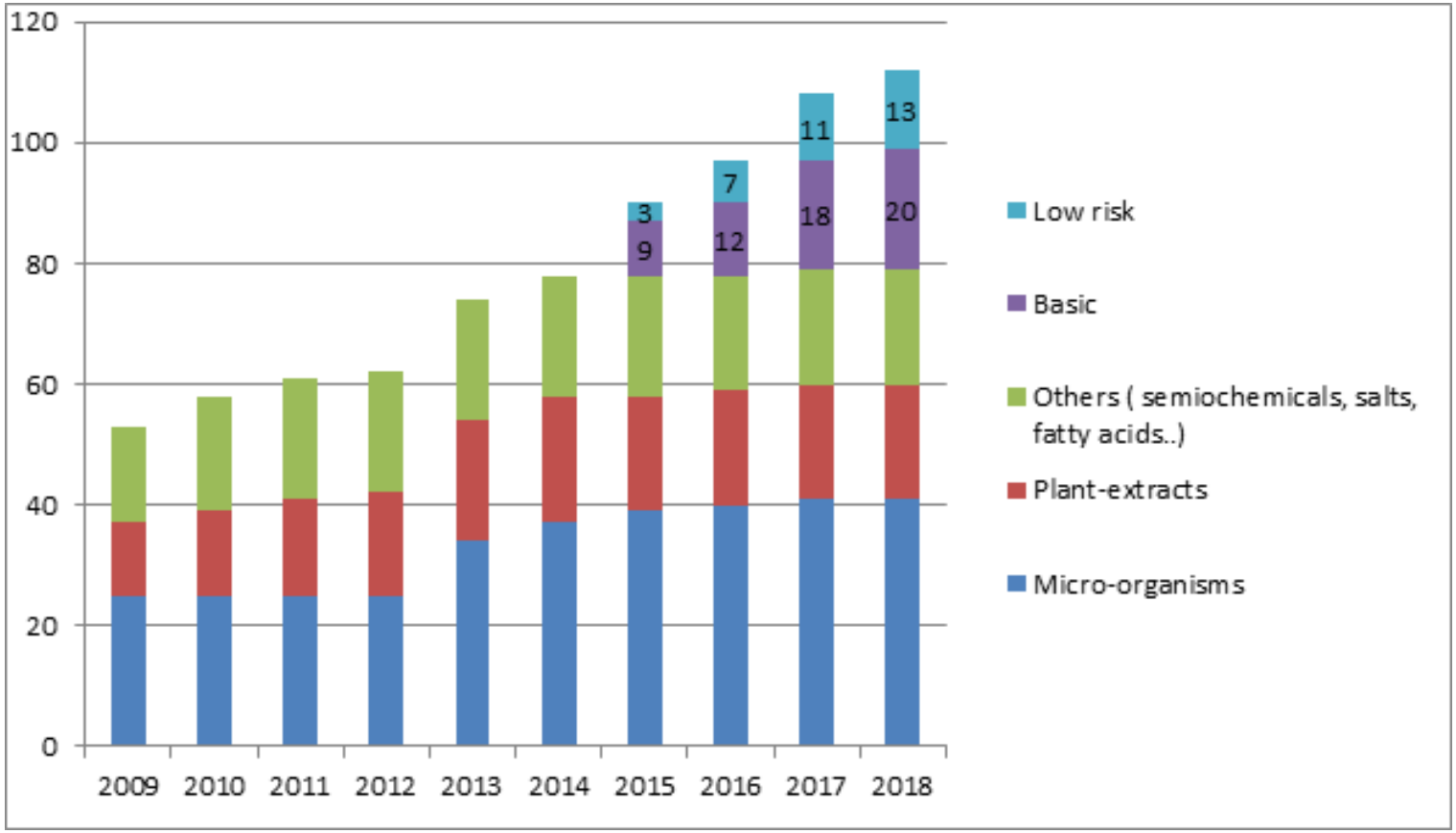
Availability of Low Risk Substances



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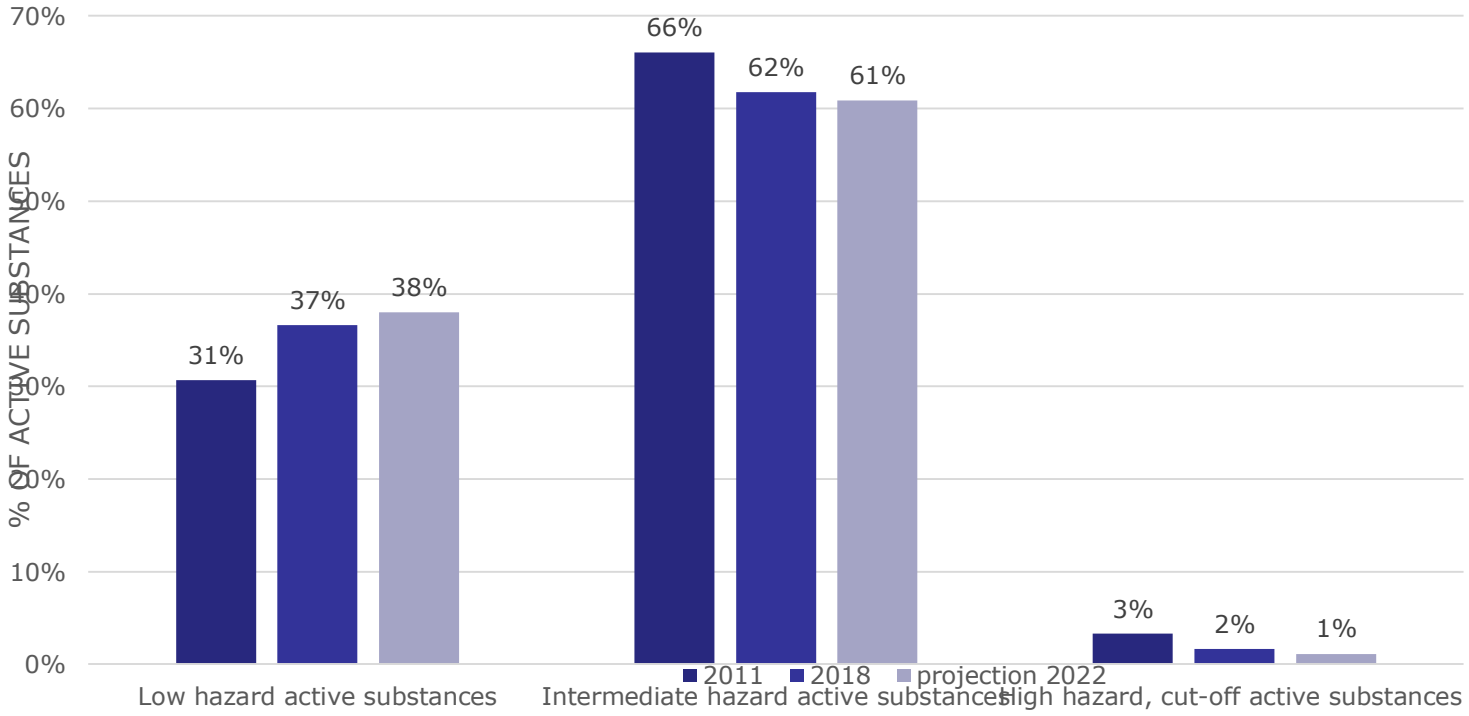
Hazard Profiles of Active Substances



REFIT

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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
- **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, pending political votation

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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 held 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*

General food law

European Commission

Fitness Check of General Food Law

- The system was found to work well
  - **No systemic failures identified**
  - **EFSA significantly improved the scientific basis of EU measures**
  - **International recognition of EU safety standards**
- Opportunities for improvement:
  - **Civil society perceived a certain lack of transparency and independence in the context of regulated products**
  - **Need to ensure the long-term sustainability of EFSA to maintain high level of scientific expertise**
  - **Risk communication was not always effective enough**

Health and Food Safety

European Commission

Four Pillars

Sustainability & governance of EFSA

Quality & reliability of studies

Improved risk communication

Transparency of EU risk assessment

Health and Food Safety

European Commission

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 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.

‘Transparency’ rules: Proposal and provisional agreement

Commission's legislative proposal on the transparency and sustainability of the EU risk assessment in the food chain

- Adopted by the College on 11 April 2018
- Targeted revision of the GFL and - as regards transparency – of eight other related sectorial legislative acts

- **Provisional agreement reached on 11 February 2019 – within 10 months**
- Voted Plenary April 2019
- The new rules expected to be published in the OJ over summer and enter into application in early 2021

It will improve:

- **Quality and reliability of studies**
- **Transparency of EU risk assessment**
- **Risk communication**
- **Sustainability and governance of EFSA**
  - Regular review of the GFL Regulation as such
  - Every 5 years, COM review of EFSA's performance

- *Publication in OJ over summer 2019*
- *Entry into force 20 days after publication*
- *Entry into application: 18 months later (early 2021?)*

In 18 months (2019-early 2021), preparatory work must be carried out both by EFSA and Com

Endocrine disruptors

New scientific criteria for EDs

applicable to new and on-going applications

- **Biocides:**
  applicable from 7 of June 2018
  Commission Delegated Regulation (EU) 2017/2100 of 4 Sept. 2017

- **Pesticides (plant protection products):**
  applicable from 10 November 2018
  Commission Regulation (EU) 2018/605 of 19 April 2018

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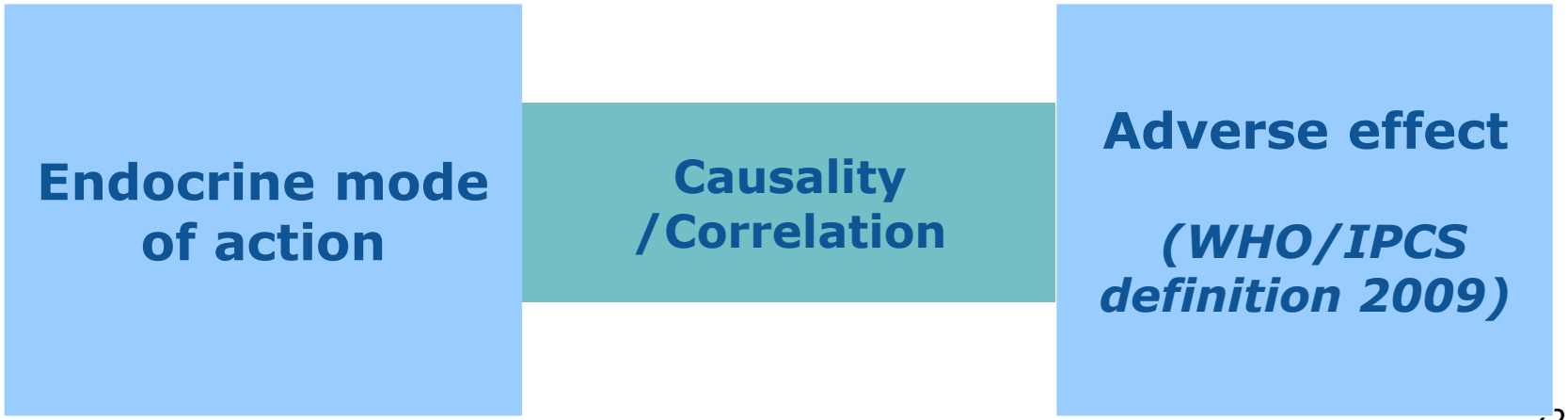
New scientific criteria for EDs

- replace the interim criteria which were not fit-for-purpose
- protect human health and the environment
- are harmonised for BP and PPP
- based on the 3 elements of the 2002 WHO/IPCS definition of an ED



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Implementation of the ED-criteria

A. ***A joint EFSA/ECHA GD - published in June 2018***

B. ***Review*** *of* ***data requirements*** *for PPP and BP*

C. ***Amendment*** *of Regulations and Procedural Guidance for PPP and BP to* ***specifically foresee implementation*** *of the criteria* ***for on-going evaluations*** *of applications*

Other "ED-news"

- *Science & Horizon 2020*
  - Horizon 2020 topic **'New testing and screening methods to identify endocrine disrupting chemicals'** has been evaluated.
  - 8 proposals started early 2018.

- *Commission Communication - Towards a comprehensive EU framework on endocrine disruptors (COM 2018 734, 7 Nov 2018)*

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Towards a comprehensive EU framework on endocrine disruptors

- ***Taking forward the EU's policy on ED****; significant progress achieved in the past 20 years but more is needed*
- ***Comprehensive****; launch of a cross-cutting Fitness Check on ED (and a public consultation)*
  - First time for cross-cutting look at the legislation on endocrine disruptors
  - will build on scientific evidence and data collected through finalised/on-ongoing evaluations (e.g. food contact materials, chemicals, etc.)

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Towards a comprehensive EU framework on endocrine disruptors

- ***most up-to-date science; commitment to invest in research:***
  - fill knowledge gaps for ED
  - Several relevant research strands under Horizon Europe
- ***Inclusive***
  - Annual Forum on ED with all interested stakeholders
  - Commitment to step up international work (OECD, international system for classification of chemicals)
  - Launch of a web portal on ED
  - Encourage MS to develop specific information and educational campaigns

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Guidance Documents & implementation

Recently adopted GD endorsed PAFF March 2019:

- *Draft Commission Notice – **Technical Guidelines on Data Protection** according to Regulation (EC) N. 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 1272/2008 ….SANCO/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**

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To be discussed at Paff July 2019

- *EFSA Guidance Document on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees)*
- *Working Document on emergency authorisations according to Article 53 (discussion)*
- *Data requirements and list of agreed test methods - Update of the Communications 2013/C 95/01 and 2013/C 95/02*
- *Guidance Documents for biopesticides and low risk pesticides – update on progress*
-

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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

Specific Protection Goals

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Background

no unacceptable effects
on the environment (PPP regulation)

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

guidelines for environmental risk assessment for pesticides

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Next Steps

- Workshop with MS, EFSA, COM 21 June
- Workshop with stakeholders Sept 2019

Risk indicators

European Commission

Sustainable Use Directive

Reduce risks and impacts on human health and the environment

Tools

1. Training
2. Sales
3. Awareness raising
4. Equipment
5. Aerial applications
6. Aquatic environment
7. Protected areas
8. Handling, storage, disposal
9. Integrated pest management
10. Harmonised indicators

NATIONAL ACTION PLANS

European Commission

RISK INDICATORS

HARMONISED RISK INDICATORS (HRI):

- *Commission Directive awaited (voted in January 2019, Scrutiny of EP and Council on-going, adoption & publication in May or June 2019)*

MEMBER STATES:

- *Shall calculate HRI using statistical data available at EU level;*
- *Shall identify trends in the use of some active substances;*
- *Shall identify priority items (active substances, crops, practices) to be used as examples for achieving SUD objectives*
- *May continue using any existing national indicators, in addition to HRIs.*

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/en

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