Challenges and opportunities with the EU Sustainable Use Directive for blight control

Review Crop Protection Legislation 1107/2009

Euroblight Workshop – Aarhus, May 2017

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ECPA ECCA Conference – Brussels, March 2017

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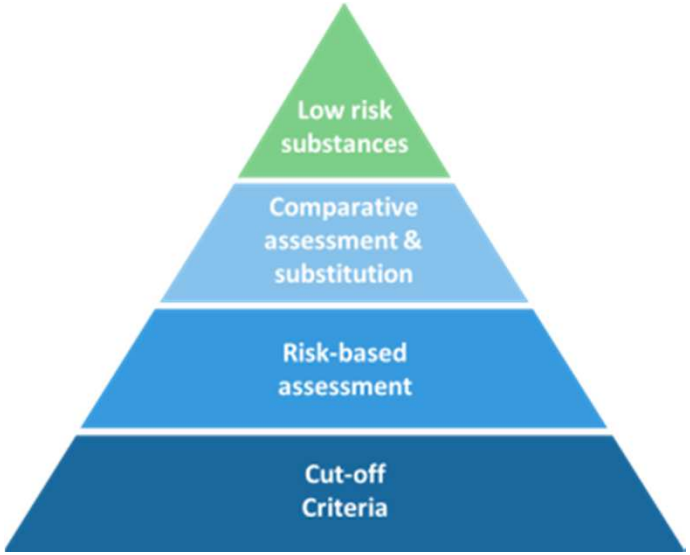
- history
- EU Sustainable Use Directive and PPP Regulation
- challenges and opportunities

History

- Plant Protection Products Legislation **1107/2009** effective since 2011
- 2015 **ECPA forward looking statements** (*ref* Euroblight Workshop Brasov)
  - start of Comparative Assessment
  - progress on framework legislation for Endocrine Disruptors
  - challenges for capacity in Member States
- 2015 **ECPA recommendations** for improvement (*ref* Euroblight Workshop Brasov)
  - make the zonal process work efficiently
  - ensure fast introduction of new active substances
  - establish a zonal helpdesk
  - implement scientific guidance efficiently



Sustainable Use Directive 2009/128

- Targeting the **actual use** of Plant Protection Products
- Aims at achieving **sustainable use of pesticides**
  - by reducing risk and impact of pesticide use on human health and environment
  - by promoting the use of integrated pest management

Promoting Integrated Pest Management

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http://www.endure-network.eu/da/endure/endure_ipm_training_guide

Integrated Blight Control

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- Integrated blight control requires a fungicide toolbox filled adequately with effective fungicides

Euroblight April 17	early blight	late blight
active substances	12 (9)	20
modes of action	7 (4)	15
coformulations	6	22

- Mutations in early blight populations to key MoA
- Canopy growth phase….

  most critical for late blight control and for (re-)authorisation of PPP

Sustainable use and PPP regulation

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Challenges

- Active substance renewal and re-authorisation of products
- Approval of new active substances
- Zonal process
- Genotoxicity
- Cut-off criteria consequences

Opportunities

- Review of PPP legislation
- Stakeholder engagement

Challenges | active substance renewal

- Annex I Renewal (AIR) of active substances is phased by 4 rounds of active substance groups
  - **AIR rounds 1,2 and 3** are still ongoing…
    - capacity constraints at country level: serious delays vs original timelines
  - **AIR round 4** with expiration of Annex I listing after January 2019 has started
    - application / submission dates fixed but RMS not yet identified for all substances
    - lack of regulatory capacity at country level
- Timeline for re-authorization of products is not manageable
- Challenging process without additional resources and duplication of work on formulation level
- Data requirements are detailed in Regulations 283/2013 for active substances and 284/2013 for products but not in 1107/2009
- New data requirements (1107/2009) apply for substances in AIR 3 and AIR 4 and are likely to result in loss of registered active substances or serious restrictions for products when re-authorised
- **EFSA conclusions for 30 pending active substances: 'first' non-approval proposed for 60%**

Process for approval of a new active substance

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submission by applicant → assessment rapporteur member state (RMS) and co-RMS → draft assessment report (DAR) → commenting concerned member states → review European Food Safety Authority (EFSA) → EC writes proposal based on DAR and EFSA report → voting on proposal by member states in SCOPAFF → approval active substance*

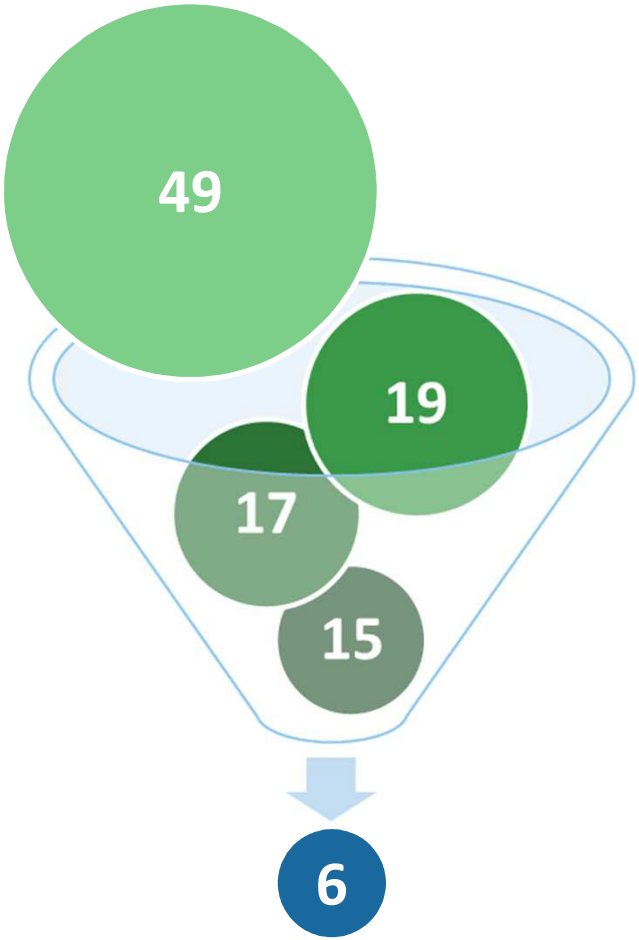



average approval timeline: 46 months

* Once the active substance is approved, the MRL needs to be approved with Entry Into Force 7 months after MRL setting; the timeline of 46 months represents the average timeline for active substance approval and MRL setting

Challenges | new active substances

- Almost 6 years after Entry Into Force of PPP Regulation 1107/2009:
  - 49 new active substances submitted since June 2011
  - 19 have approval vote
  - 17 also have MRL vote
  - 15 have MRL regulations, which apply
  - 6 active substances approved by February 2017,
    of which 2 relevant for potatoes:
    - benzovindiflupyr
    - oxathiapiprolin
- 12 active substances relevant to potatoes approved in the US in the same period

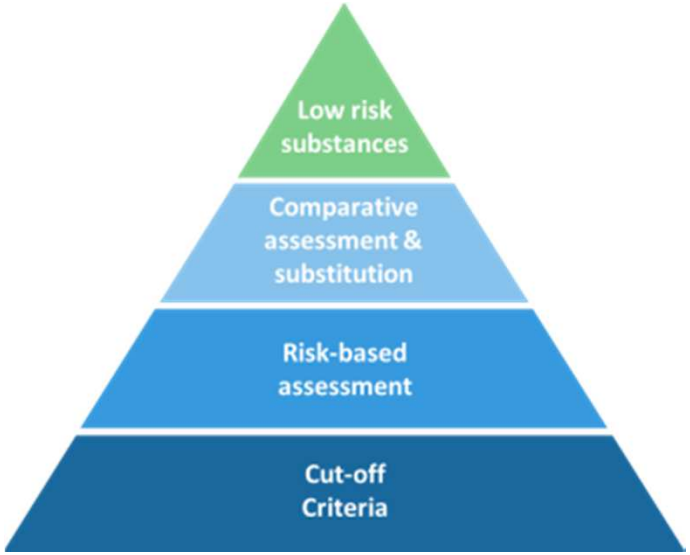


Challenges | evaluation of genotoxicity

- Major issue affecting up to 20 substances
- **3 Substances already non approved**
- Lack of endpoint setting after peer review
- Insufficient consideration: weight of evidence approach
- No clear guidance on which studies to conduct: conflicting information since 2011
- Animal welfare concerns (e.g. additional studies requested)

Challenges | consequences of cut-off criteria

- Defining **Negligible Exposure**
  - clear need for Guidance to be finalised
- Derogation for **Phytosanitary need** (application of Article 4.7)
  - methodology pending, harmonisation is key
  - clear guidance needed from DG SANTE on the evaluations made by MS to ensure consistency
  - MS need to be fully involved in the evaluation
  - consideration of efficacy and resistance management



Opportunities | review of PPP legislation

- Commission report in 2018/19
- DG SANTE 'roadmap'– with public consultation November 2016
- Consultant review to start 2Q 2017?, completion 2018?
- Important consideration: MS Audits from Directorate F

- ECPA view
  - support joint review of **both Regulations**
    - evaluate the implementation of the current legislation
    - review options for future improvements

  - proposal for efficiency improvement by introduction of **data call-in system** in EU

Opportunities | stakeholder engagement

- Interaction with all stakeholders together is key for an efficient functioning of the legislation
- ECPA have regular bilateral meetings with DG SANTE, EFSA, MS
- However, no platform where all parties can review process and work together on solutions
- For Biocides and Medicines greater collaboration exists with all stakeholders

- Concerns with the **EFSA peer review**
  - lack of dialogue and predictability
  - repetition of review of RMS
  - EFSA report lacking options for risk managers
  - view of MSs not taken into account
  - no participation yet for industry

- **Opportunities for dialogue**
  - ECPA welcome the proposals to review stakeholder participation in peer review
  - have early dialogue with EFSA and with other MSs
  - clarify uncertainties in EFSA conclusion

Summary and conclusions

- Integrated blight control possible today
  - promotion of integrated pest management in accordance with the Sustainable use directive
  - effective toolbox available

    … yet at risk because of though regulatory challenges for existing and new substances

- To maintain an effective fungicide toolbox – ECPA sees a need for
  - authorisation of innovative products and re-authorisation of existing products

    … procedures to support innovation and ensure products remain/ become available for farmers
  - review of PPP Legislation

    … data call-in process ensuring efficient use of resources
  - engagement of stakeholders

    … stakeholder participation important for an efficient and scientifically based process