



EU & US Regulatory Harmonisation Efforts on biocontrol agents: Learning by doing

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The EU authorisation system for substances and products

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EU authorisation for substances

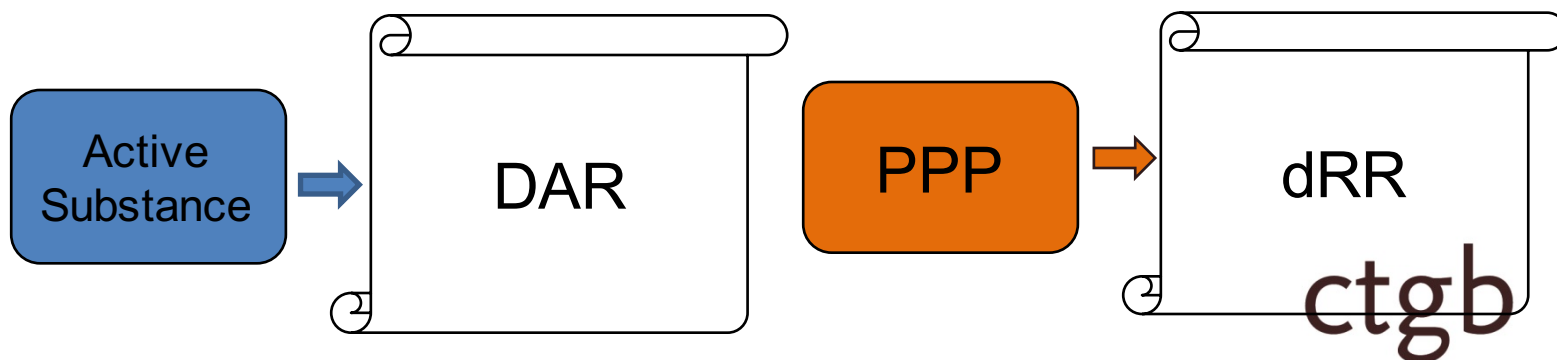
Legal framework

- **Regulation 1107/2009** (rules and procedures regarding placing on the market of PPP)
- **Sustainable Use Directive (SUD)**
2009/128/EC (a framework to achieve a sustainable use of pesticides by reducing the risks and impacts of pesticide use and promoting the use of IPM)

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EU authorisation for substances

- The European Commission is responsible for coordination of evaluation of active substances and their approval/non-approval
- Substances must be proven safe for people's health, including their residues in food, animal health and the environment.



EU authorisation for substances

Procedure

1. Application to an EU country called Rapporteur Member State (**RMS**);
2. RMS verifies if the application is admissible;
3. RMS prepares a draft assessment report (DAR);
4. **EFSA** organises peer review and issues its conclusions;
5. **Standing Committee** for Plants, Animals, Food and Feed votes on approval or non-approval;
6. Adoption by the **Commission**;
7. Publication of a Regulation in the EU Official Journal.

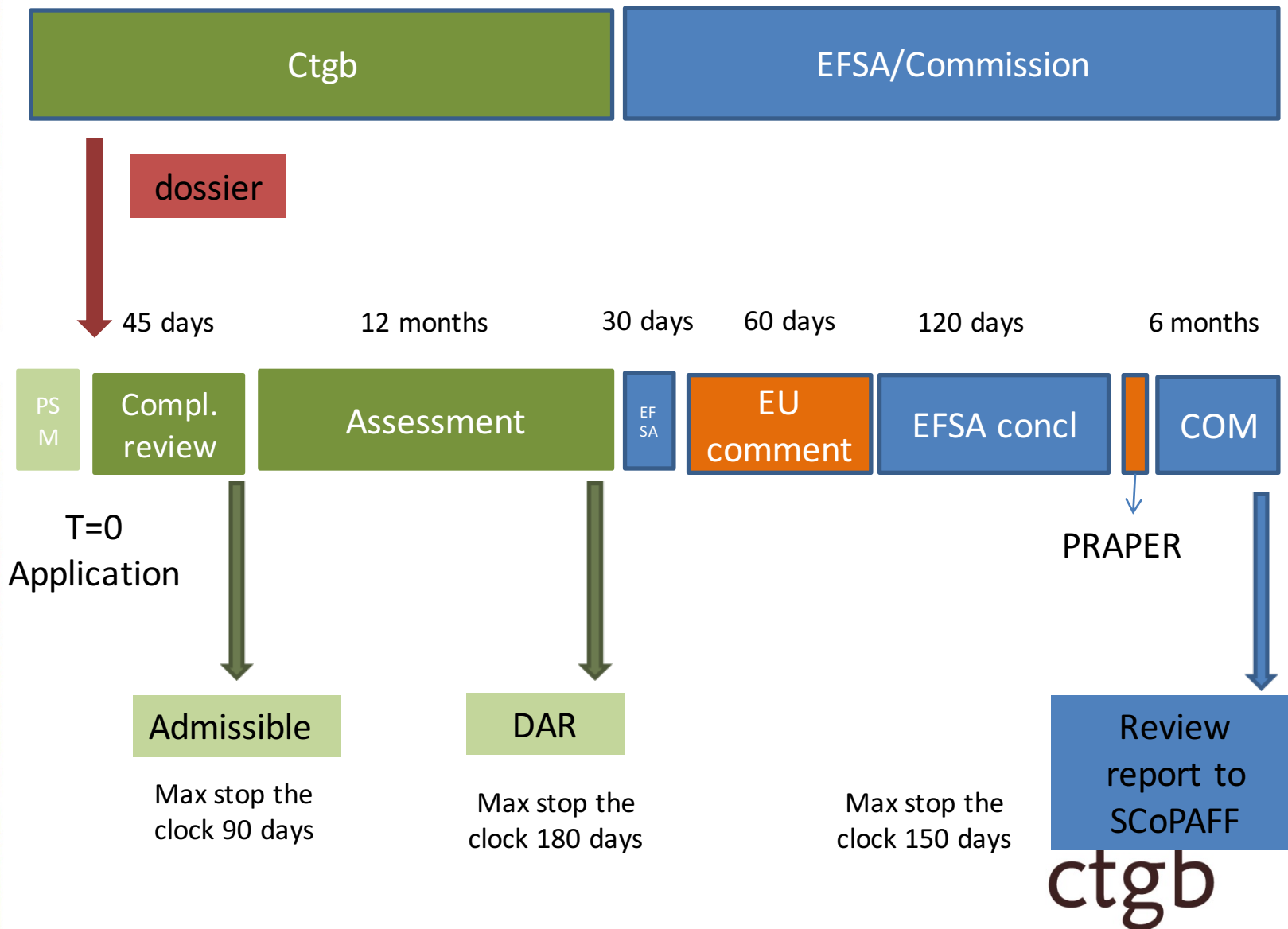
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EU authorisation for substances

- Total time for approval of an active substance is 30 months (ex stop the clock)
- Microorganisms have same timelines but different tariffs in NL

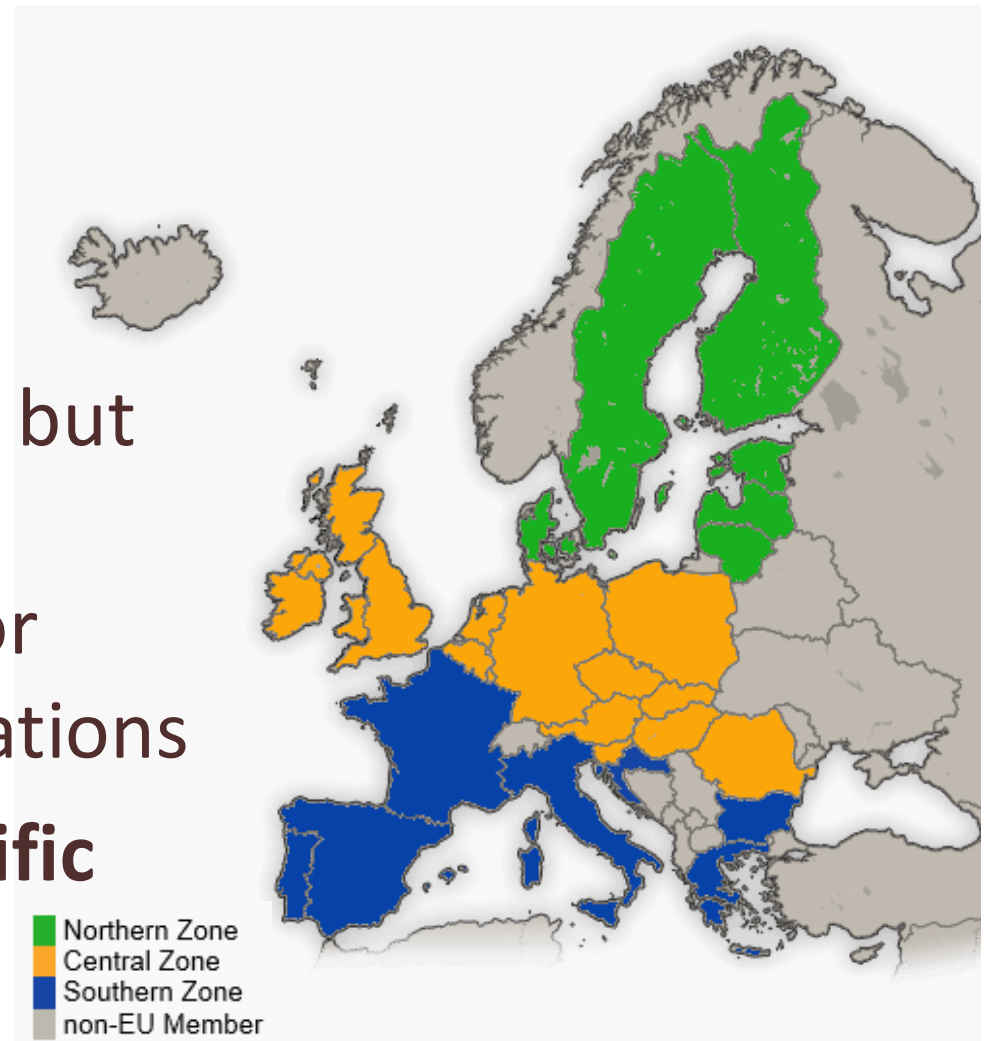
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EU authorisation for new substances



EU authorisation for products

- **Zonal** system (three zones)
- **Harmonised** Authorisation but each country responsible for own authorisations
- National **specific** issues



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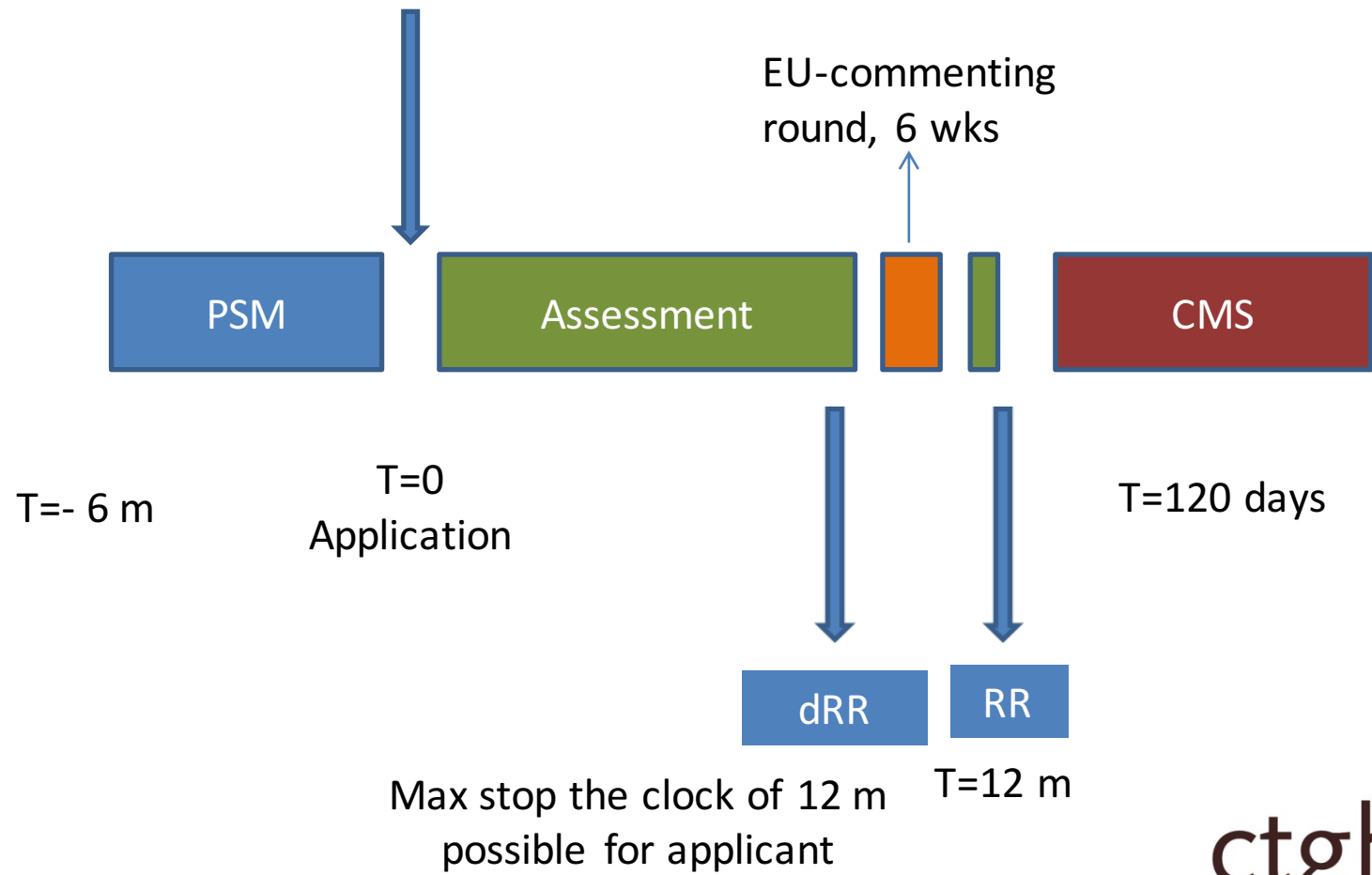
EU authorisation for products

1. An **application** is made, zRMS carries out an assessment of the application;
2. Other Member States in the same zone **comment** on the zRMS's evaluation;
3. zRMS decides on whether to **grant or refuse** an authorisation;
4. Other Member States decide to grant or refuse an authorisation in **CMS** procedure ;
5. If later the applicant wishes to place the same product on the market in another Member State, an application is made for '**mutual recognition**'.

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EU authorisation for products

- Time line zonal application



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Biopesticides

.. are not a specified category in EU law

Biological pesticides: a mass produced agent manufactured from a living microorganism or natural product and sold for the control of plant pests (definition by Chandler and others 2011)

EU guidances for assessment of:

- Microorganisms
- Semiochemicals/pheromones
- Plant extracts/botanicals

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EU authorisation special substances

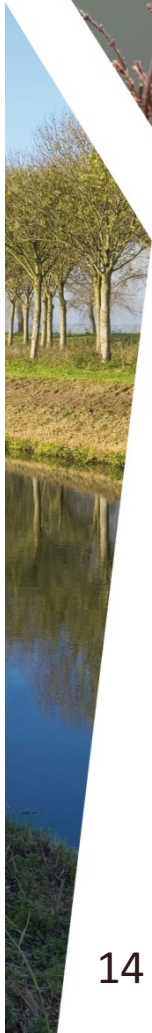
- **Basic substances**

active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest of applying for approval may be limited. Application to Commission.

- **Low risk substances**

at end of assessment, no classification,
special conditions: authorisation for 15 years and
120 days for zonal product application
Can be of chemical or biological origin.

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Introduction to Dutch agriculture

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Dutch agriculture

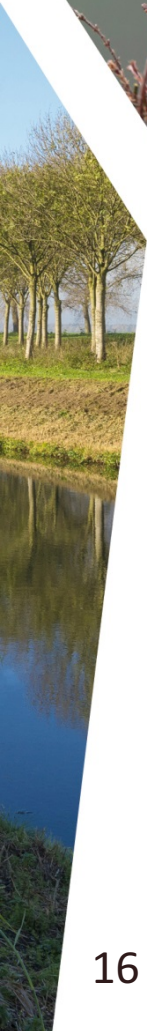
- Focus points: dairy and horticulture
- A highly innovative sector
- Exporting products as well as technology
- Development of “Precision Agriculture”
- Based on GPS-technology, IT and automated machinery

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Dutch agriculture

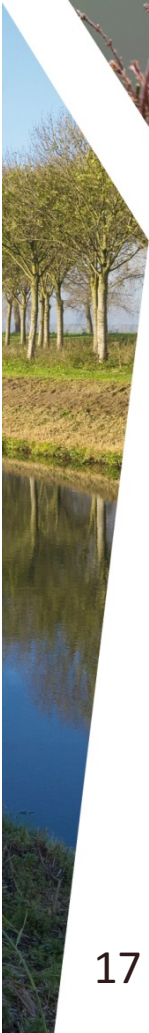
- Dutch horticulture has a long history in biocontrol and Integrated Pest Management (IPM)
- Greenhouses: controlled conditions and a perfect environment for IPM
- Still: it has its problems, mostly due to the very intensive use of land
- The region between Rotterdam and The Hague is called the “glass city”

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Introduction to Ctgb

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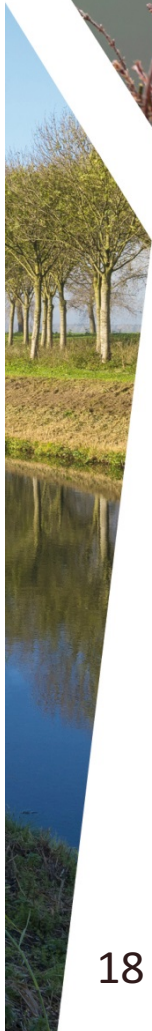


Ctgb: the Dutch Competent Authority

The Dutch Board for the Authorisation of Plant Protection Products and Biocides

- An independent body for assessment as well as authorisation
- The Board consists of 9 experts on all relevant fields
- All appointed by the minister
- Assisted by a secretariat of 125 fte, covering all aspects of assessments

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Dutch ambitions for sustainability

The Green deal initiative

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The need for change

- Agricultural production to match a growing world population
- Societal demands in an urbanised continent and urbanizing world
- Product stewardship
- The industry is innovating towards a greener portfolio

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Sustainable plant protection

- “Empowering your crops”
- Integrated Pest Management (IPM)
- Minimise interventions with (chemical) Plant Protection Products
- Development and registration of “green” Active Ingredients and Plant Protection products

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The “Green Deal”

Aims:

- To stimulate sustainable plant protection by collaboration between all stakeholders
- To resolve obstacles in the authorisation process
- To enable innovation of plant protection products

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Issues for industry and RA

For the industry:

- Development of new Active Ingredients and products
- Building a dossier and registration of the products

For the regulatory agencies:

- To assist the SME's
- To innovate along with industry instead of stifling innovation

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Green Deal

- 2 pilots with active substances
- 8 pilots with products
- Contribution to harmonisation
- Document and share the lessons learned

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Lessons learned 1

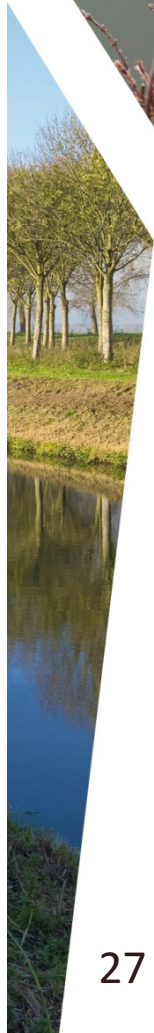
- A Pre Submission Meeting is important to clarify possibilities and difficulties
- Managing of expectations
- A specialised “greenTEAM” of assessors for intake and assessment
- Tailor made solutions for dossiers

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Lessons learned 2

- The current, “chemistry based”, requirements are not always helpful
- Sometimes the data requirements are not realistic
- There is a need to harmonise guidances within EU and worldwide

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A Dutch perspective Challenges for the Competent Authorities

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Challenges for the CAs

- To stimulate innovation while performing adequate risk assessments
- Focus on the real risks, e.g.
- Can we regard a botanical blend as one Active Ingredient if properly “fingerprinted”?
 - What can we learn from risk assessments of food and feed stuffs e.g. sugars, oils, probiotics?

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Some issues to be solved

- How to incorporate IPM in the authorisation process?
- How to describe efficacy on the label?
- What will be the need for “correction” or “knock out” chemicals in a biobased IPM-system?

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EU & US Regulatory Harmonisation Efforts on biocontrol agents

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EU & US regulatory harmonisation

Aim

- Learning from each others experience
- Exchange of views

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EU & US regulatory harmonisation

- Meeting of Director Ctgb and EPA officers in March
- Meeting with EPA and Ctgb experts in April

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EU & US regulatory harmonisation

- Learning by doing
- “Take a look in each others kitchen”
- Discuss assumptions and starting points
- Compare assessment methods
- Compare outcomes of assessments

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The image is a collage of four photographs. The top-left photo shows a small brown bird with its beak open. The top-right photo shows a child's face next to a plant with red roots. The bottom-left photo shows a field of dark soil next to a body of water. The bottom-right photo shows a row of trees next to a body of water. A large, semi-transparent brown rectangle is overlaid in the center, containing the text "Thank you for your attention".

Thank you for your attention

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