Planbureau voor de Leefomgeving

Risk assessment of pesticides:

The role of scientists and policy makers

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Outline

- Risk management versus risk assessment

- Defining protection goals
- Guidance development
- Authorization of active substances

- Separation of tasks – does it (still) work in practice?

- Concluding remarks

Risk management versus risk assessment

- **Risk assessors** provide independent scientific advice on risks of pesticides to human health and the environment
  - e.g. EFSA, scientists working for national authorities

- **Risk managers** use this advice as a basis for making decisions on e.g. the approval of active substances
  - e.g. the European commission (EC), national governments, the European Parliament and National Parliaments

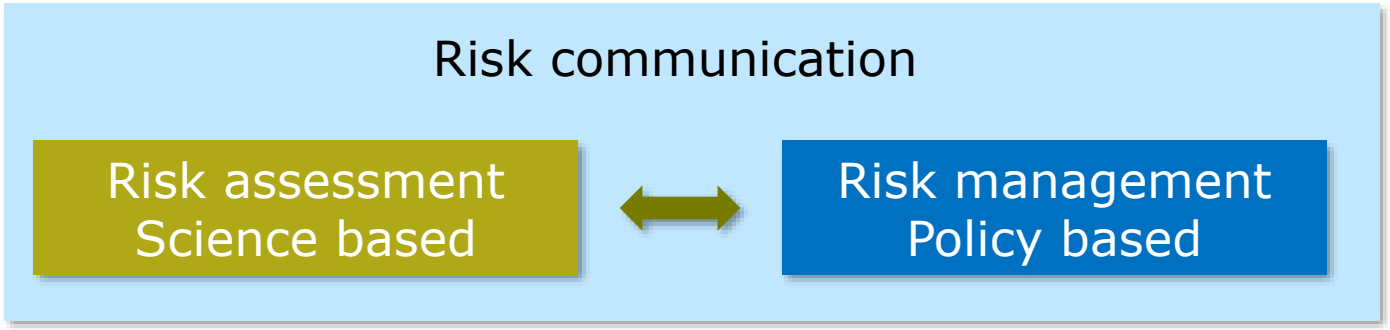
Risk assessment
Science based

Risk management
Policy based

Separation of tasks

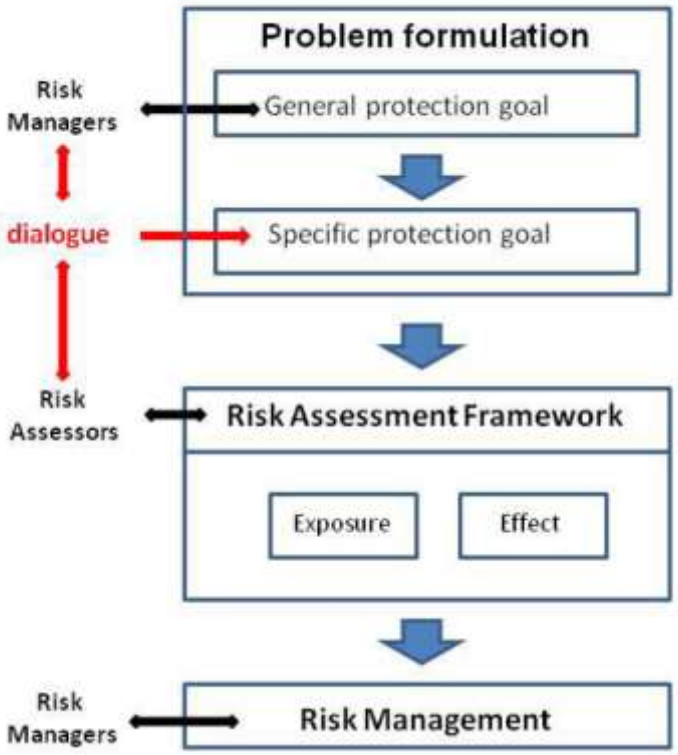
- In Europe, the tasks of risk managers and risk assessors are strictly **separated**
  - This is implemented in the General Food Law Regulation of 2002 following food scandals like the BSE-crisis

- This, however, only works when there is sufficient **communication** between risk managers and risk assessors



Steps in risk analysis

1. Problem definition: define protection goals
2. Set-up a risk assessment framework including development of guidance documents
3. Apply framework to individual substances
4. Decision on approval of substances



EFSA PPR Panel 2010

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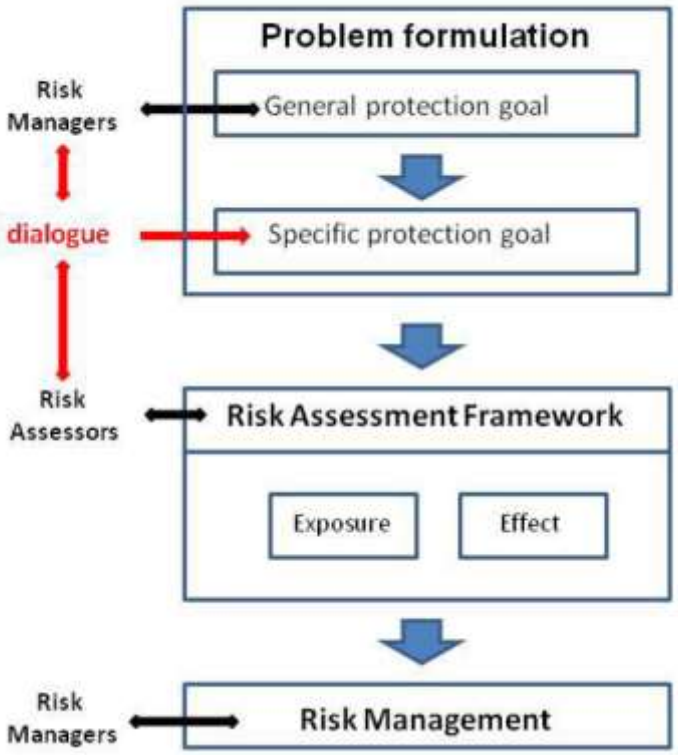


EFSA PPR Panel 2010

General Protection Goals

- Protection goals are very generally described in EU-legislation: **General Protection Goals**
  - Regulation (EC) No 1107/2009:
    "…no harmful effects on human health, directly or through drinking water…"
    "…no unacceptable effects on the environment…"

- In the case of groundwater the **Uniform Principles** (2011) apply:
  - "…concentration in groundwater shall not exceed 0.1 µg/l…"
  - Too vague for regulatory practice

Specific Protection Goals

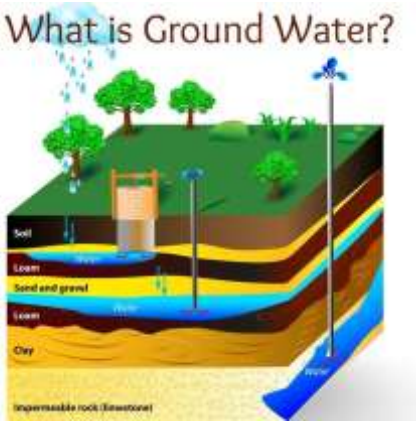
- For regulatory practice, a more detailed description of protection goals is needed
  - EFSA PPR Panel (2010): "…risk assessors need to know **what** to protect, **where** to protect it and over what **time period**…"
  - These are called **Specific Protection Goals (SPGs)**

- SPGs increase consistency, reproducibility and transparency of the risk assessment

- Without SPGs, an objective scientific risk assessment scheme cannot be made!

SPG definition: Example for groundwater

- In the case of groundwater, the Uniform Principles do not define groundwater in further detail and concentrations vary in space and time.
- So the following questions need to be answered:
  - **What** to protect
    e.g. the uppermost groundwater, groundwater deeper than 1 m, deep groundwater
  - **Where** to protect it
    e.g. groundwater below agricultural fields, only in drinking water abstraction areas
  - Over what **time period**
    e.g. always, 90-percent of time



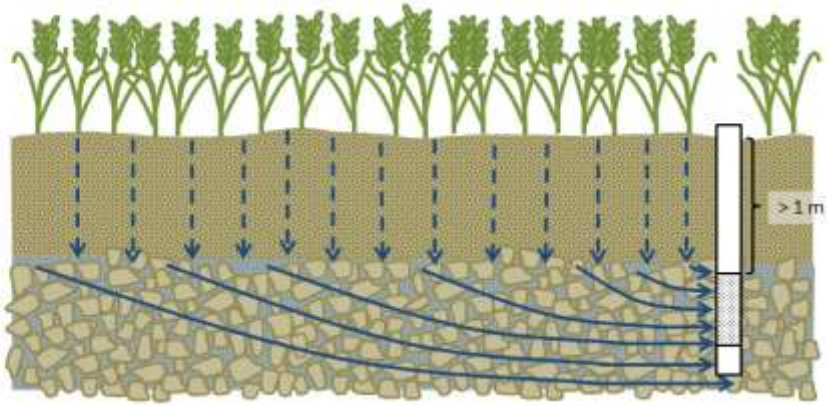
Provide options

- Risk managers don't specify protection goals in scientific language; they think in intentions
  - "… adequate protection of groundwater …"
  - "… realistic worst-cases …"

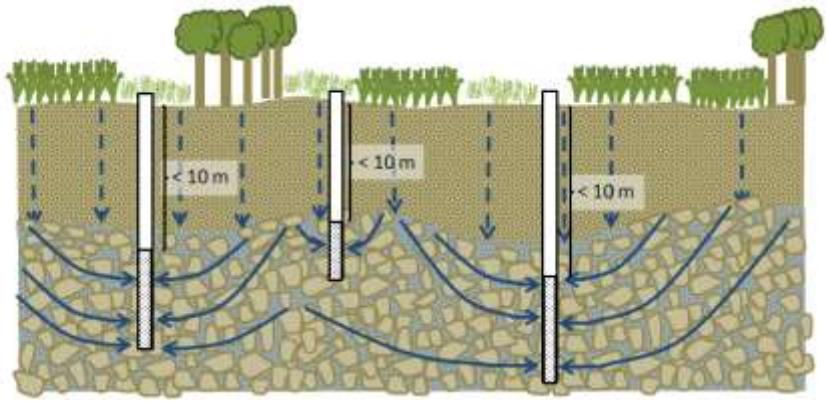
- To make the translation between this scientific language and these intentions, provide risk managers with **options** including examples and **consequences** for product registration

Options: Example for groundwater

Most stringent



- Shallow groundwater below **each individual** field may never exceed 0.1 µg/l
- > 90% of herbicides are expected to fail



Least stringent

- Concentration in groundwater abstraction wells may not exceed 0.1 µg/l
- Concentration will be lower because of dilution and degradation
- Possible to register products that degrade in the saturated zone

SETAC-EMAG report, 2018

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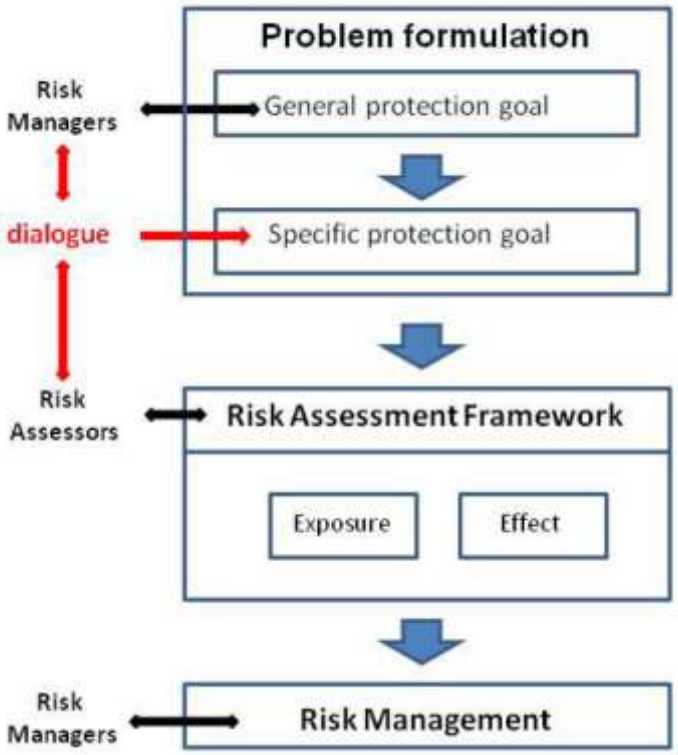


EFSA PPR Panel 2010

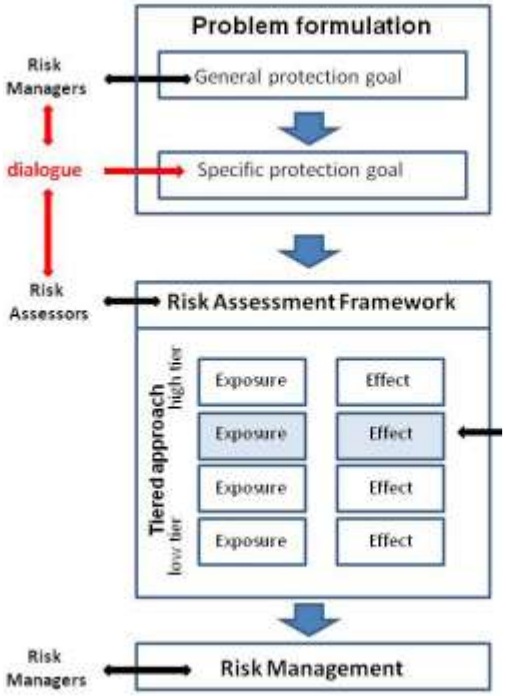
Guidance development – the generalised process

- Guidance is usually developed by a **working group** consisting of risk assessors and scientists
- Two inputs are used:
  - A scientific opinion describing the state-of-the-art in the respective field
  - The agreed SPGs
- The working group produces a draft GD that is usually sent out for **public consultation**
  - An impact assessment is also being carried out
- The working group revises the draft GD
- The revised GD is **noted by the EC**.
- From now on the applicant must use the GD

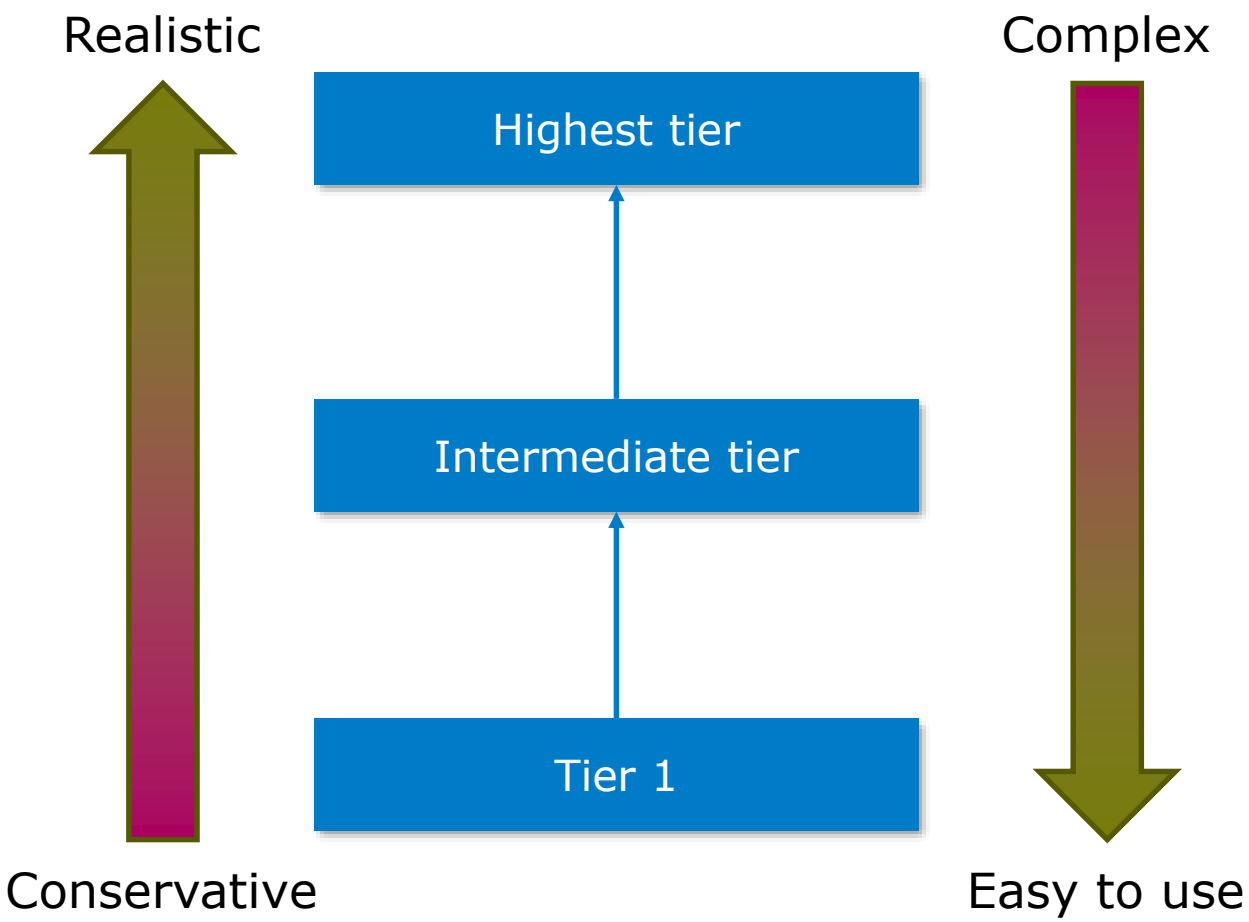
Development of a risk assessment framework

- Once the protection goals are agreed upon by risk managers, a **guidance document** can be developed by risk assessors/scientists

- Guidance documents generally follow a **tiered approach**.
  - Start with a simple conservative assessment and do only additional work if necessary.
  - Cost-effective for both industry and regulatory agencies

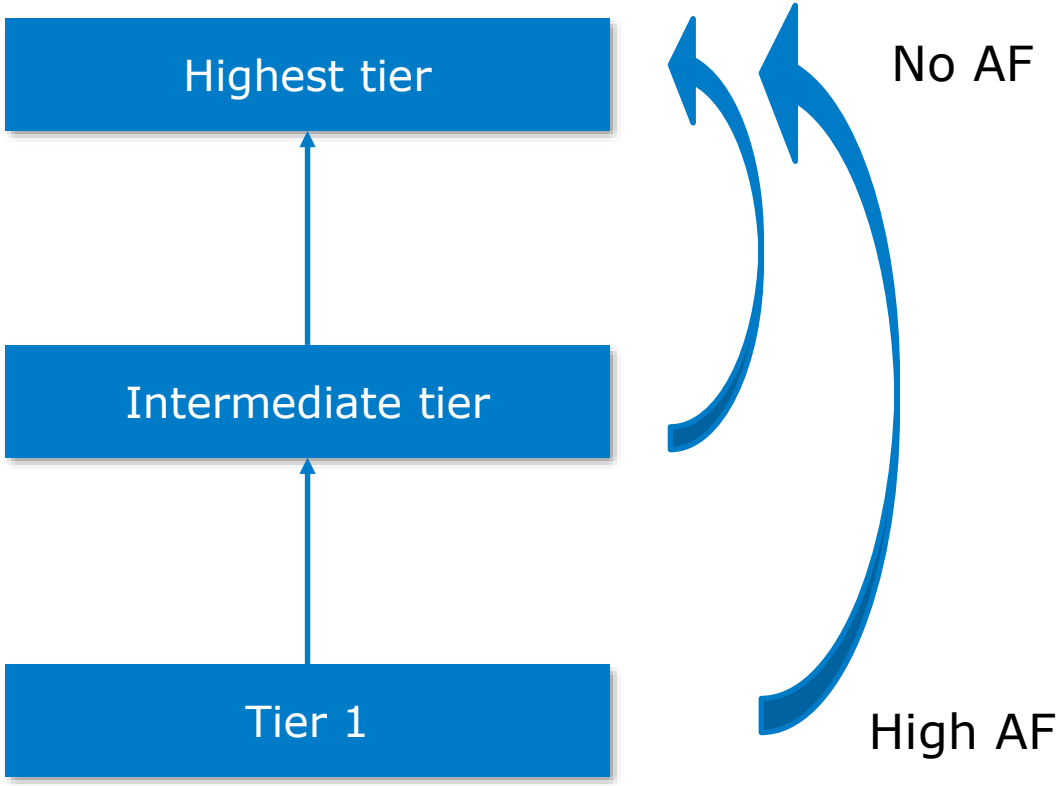


The principle of tiered approaches

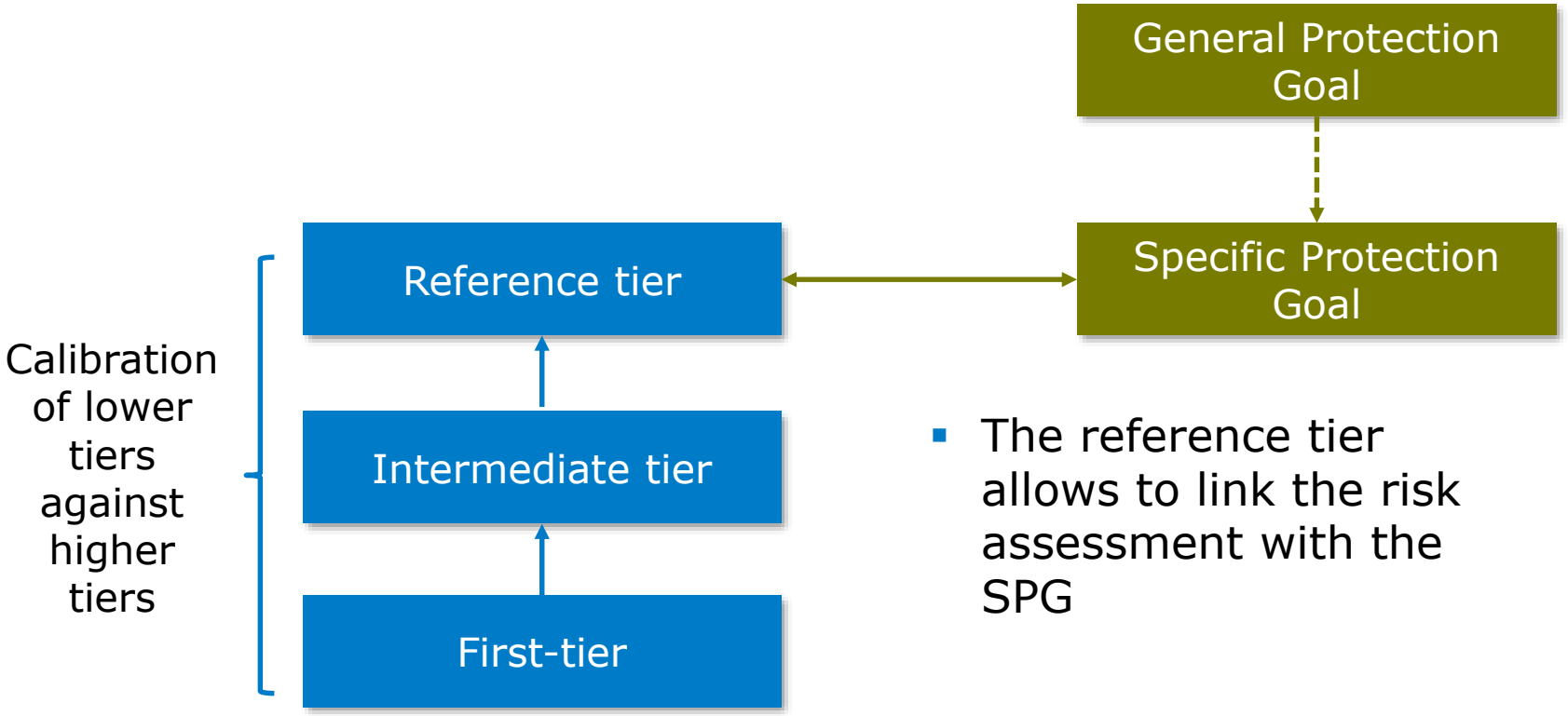


Assessment factors (AF)

- The scheme only works if lower tiers are more conservative than higher tiers
- So lower tiers must be calibrated against higher tiers: **assessment factors** or safety factors
- These assessment factors are generally science based



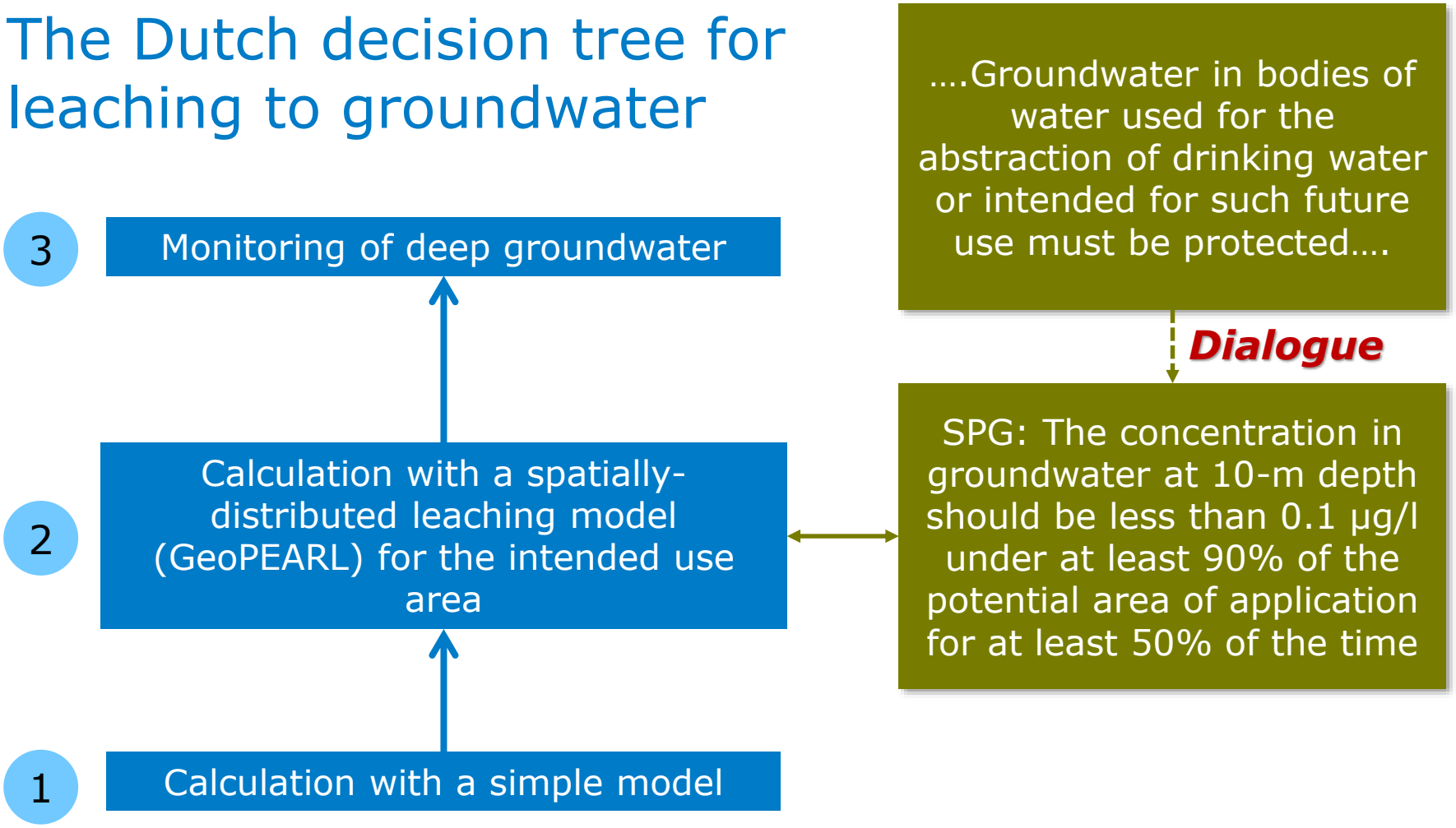
How to link the risk assessment with the specific protection goal?



- The reference tier allows to link the risk assessment with the SPG

EFSA PPR Panel 2010

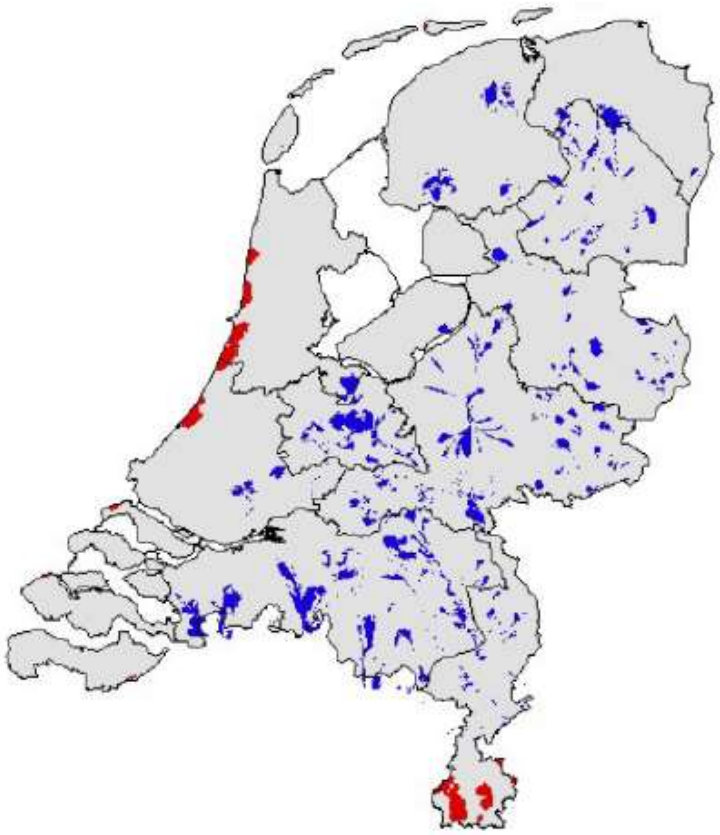
The Dutch decision tree for leaching to groundwater



Only drinking water abstraction areas?

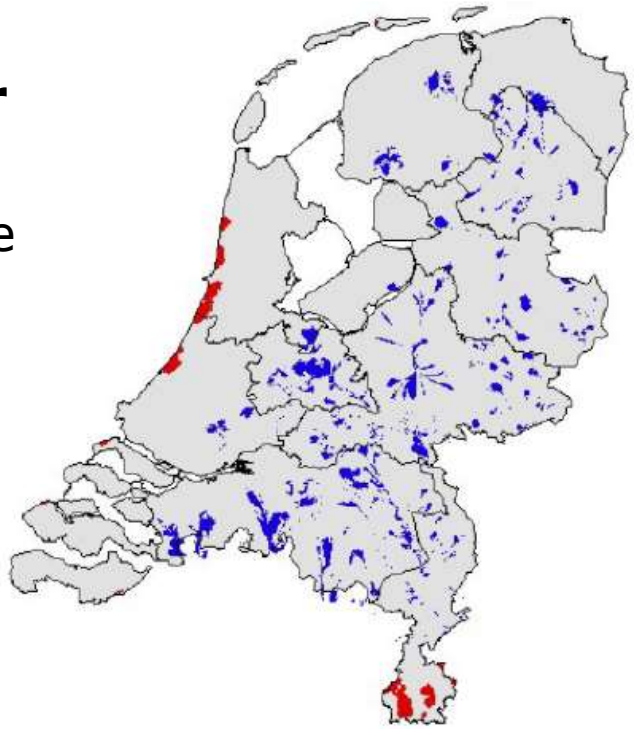
….Groundwater in bodies of water used for the abstraction of drinking water **or intended for such future use** must be protected….

- Analysis showed that drinking water abstraction areas are **more vulnerable to leaching** than the rest of the Netherlands
- So if drinking water abstraction areas were the standard, the authorisation for the Netherlands as a whole would be stricter



So the Dutch Government agreed upon two SPGs

- One for the **entire use area** of a pesticide
- One for the use area in **drinking water abstraction areas**
  - If the predicted concentration in the entire use area exceeds 0.01 μg/l, a product cannot be used in drinking water abstraction areas and this must be stated as a **restriction** on the label of a product



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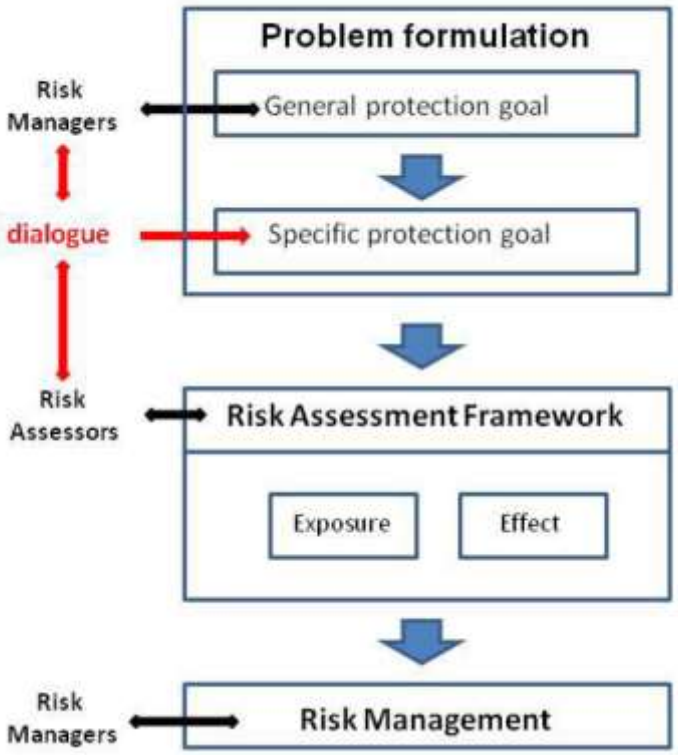
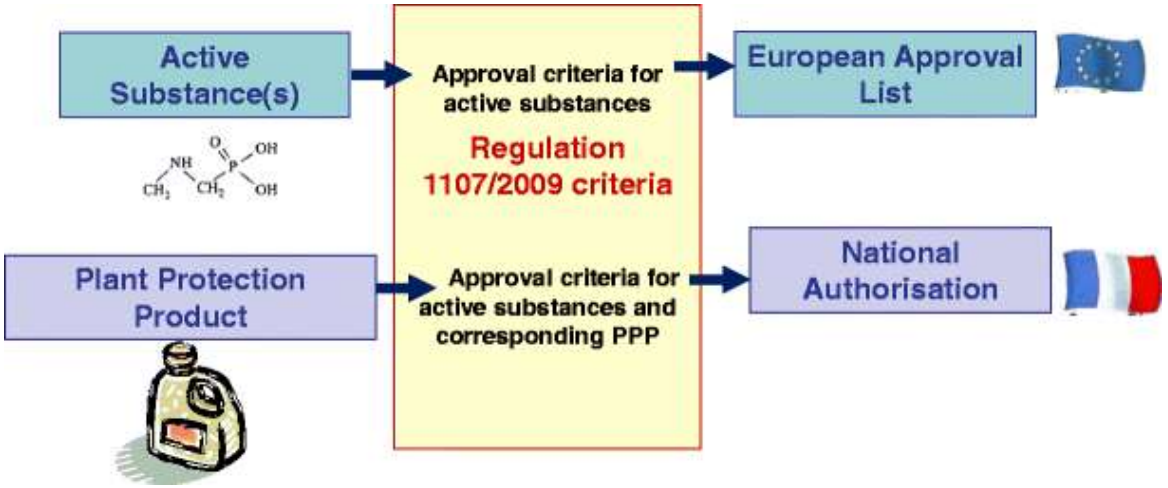


EFSA PPR Panel 2010

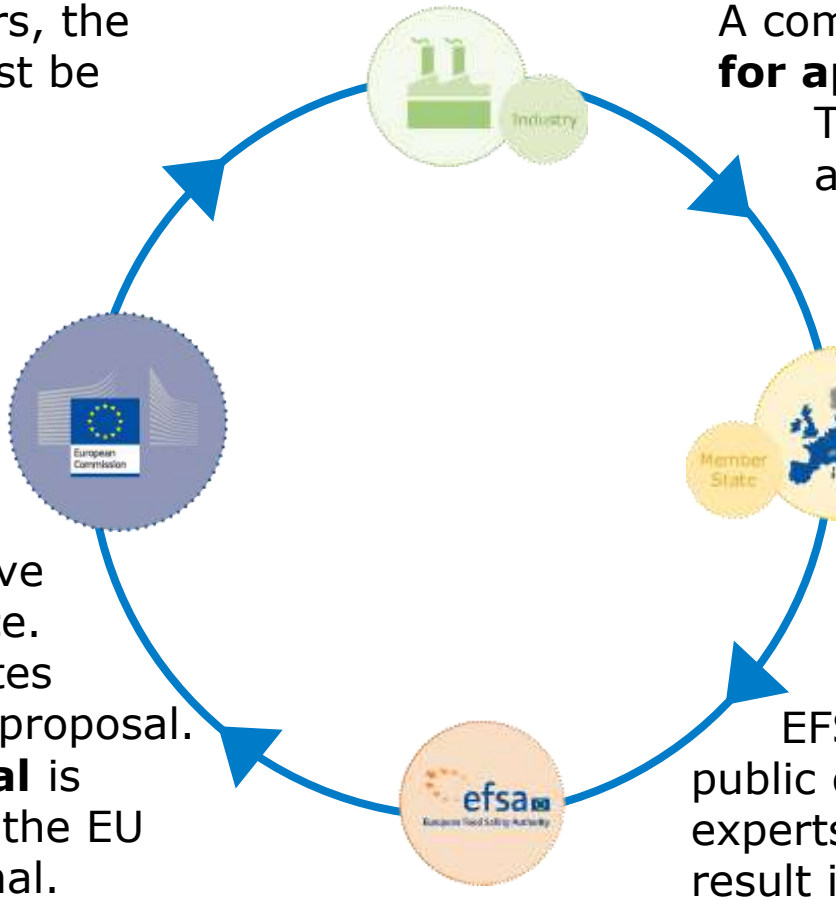
Product authorisation is a dual process

1. The **active ingredient** of a substance has to be approved. This is done at the European level
   - In theory, one "safe use" is enough for approval
2. **Products** containing the active ingredient must be authorised. This is done by the Member States
   - The actual use of a substance including dosage and formulation is evaluated



1. Approval of active substances in the EU

After 15 years, the approval must be **renewed**.



A company submits an **application for approval** to a Member State. The company should use the applicable guidance.

The Member State evaluates the application and writes a **Draft Assessment Report** (DAR).

EFSA peer reviews the DAR. A public consultation is organised and experts are invited if needed. The result is an **EFSA conclusion**.

The EC makes a proposal whether or not to approve the substance. Member States vote on this proposal. The **approval** is published in the EU Official Journal.

2. Authorisation of Plant Protection Products

- Once an active ingredient (AI) is approved, an applicant can request authorisation for a product containing this AI.
- Realistic conditions including the formulation and the actual uses are assessed
- Assessment is done by one Member State in a zone; the other Member States follow (**mutual recognition**)
- Also here, guidance documents play an important role

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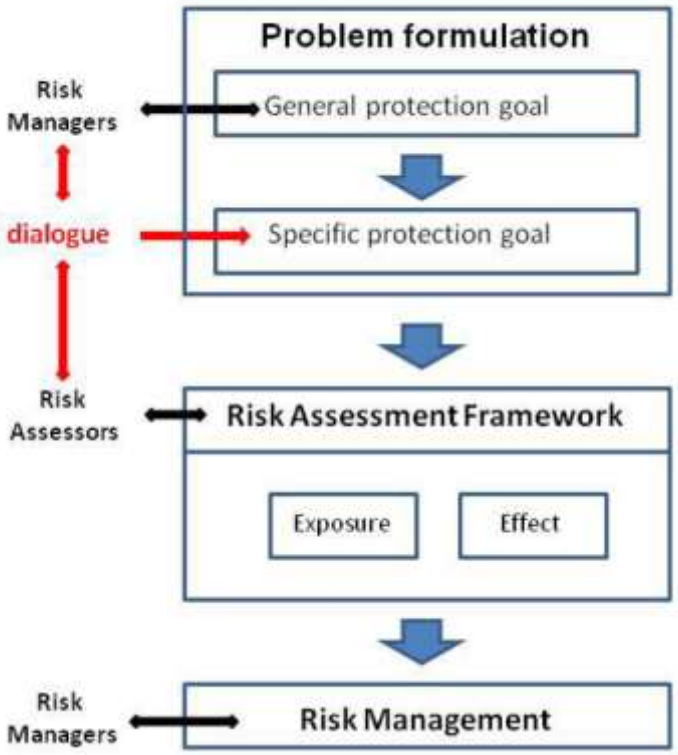


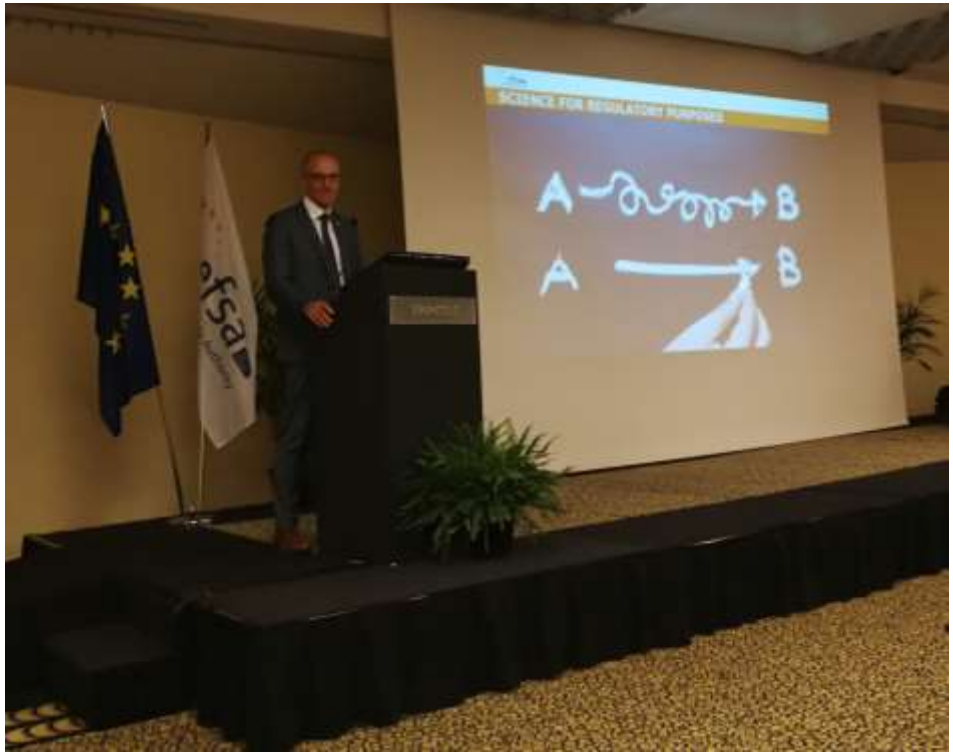
EFSA PPR Panel 2010

The comitology process

- EC must make a proposal on approval and usually follows EFSA's advice
- However, Member States must vote on this proposal in the PAFF committee (**comitology**). A qualified majority is needed
- There is concern about increasing "**politicisation**" of the approval and authorisation processes, particularly in this stage
- This is particularly the case under **scientific uncertainty**

Separation of tasks – does it work in practice?

- The decision making process is not always as straightforward
- Two cases:
  - Glyphosate
  - The neonicotinoids



The glyphosate case

- In 2015, a controversy started about the renewal of the approval of **glyphosate**
  - IARC classified glyphosate as "probably carcinogenic"
  - EFSA conclusion: "…unlikely to pose a carcinogenic hazard…", "…concerns about the co-formulant tallowamine…"
- Based on EFSA's conclusion, the EC proposed a standard renewal for 15 years
- However, the proposal failed to reach a qualified majority amongst Member States
- EC asked ECHA to also give its opinion
  - ECHA (and later FAO/WHO) confirmed EFSA's conclusion
- EC gave a renewal but only for 7 years

So what is the background?

- EFSA looked only at the pure active ingredient
  - But expressed its concern about the co-formulant tallowamine
  - This was, however, not a reason for the EC not to approve glyphosate because formulations are dealt with at the national level
- IARC used public studies in which also formulations are included, so they did not look at the pure ingredient
- Complexity of regulation (the dual authorisation process) and scientific uncertainty led to **confusion and controversy**
- Based on the precautionary principle, the EC finally decided to **withdraw the approval** of tallowamine containing glyphosate formulations at the European level, which is an usual step

Part of the discussion is about broader sustainability issues and not about glyphosate

- EU Parliament calls for a ban on glyphosate by 2020
- "… The call for a ban on glyphosate by the European Parliament is probably not about the safety of the substance but about modern agricultural practices and the role of multinational biotech firms in our food supply…"
  "… A broader societal discussion about these issues is essential, but it won't be achieved by picking on regulatory science. It is the role of politicians to represent the values, needs and expectations of their constituents through democratic processes …"

  (Bernhard Url, Nature 553, 381)

The precautionary principle – the neonicotinoids

- Concerns about bee decline and pollination started already in 2000.
- EC mandated EFSA in 2012 to review three substances
- EFSA 2013 "…concerns are risks to bees cannot be excluded…", "…there are relevant data gaps to ensure a proper risk assessment…"
- So the EC invoked the **precautionary principle** and proposed severe restrictions on outdoor uses of these three substances
- MS were highly divided, so the proposal did not reach majority.
  - Some MS followed the EC (precautionary principle), others pointed to the lack of alternatives and consequences of old substances
  - High pressure from lobby groups
- No clear guidelines how to deal with **scientific uncertainty** in the risk management phase

The lessons

- Organise **a broader societal discussion** about the role of modern agricultural practices in our food production system
- Develop regulatory and legal guidelines how to interact with society under **scientific uncertainty**
- Open up the data that are used for pesticide approval and authorisation – **transparency**
- **Simplify** the dual approval and authorisation process. EFSA input to the 2018 REFIT-programme:
  - "…extend the EU-level assessment of active substances to include Plant Protection Products and relevant co-formulants…"

Concluding remarks

- The EU-uses a model of strict **separation** of risk management and risk assessment
- This model is at stake due to increasing **politicisation** of the approval and authorisation process
- Steps should be taken to get back trust of society (**transparency and openness**)

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Thanks

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