



Planbureau voor de Leefomgeving



Regaining trust by using post-registration monitoring

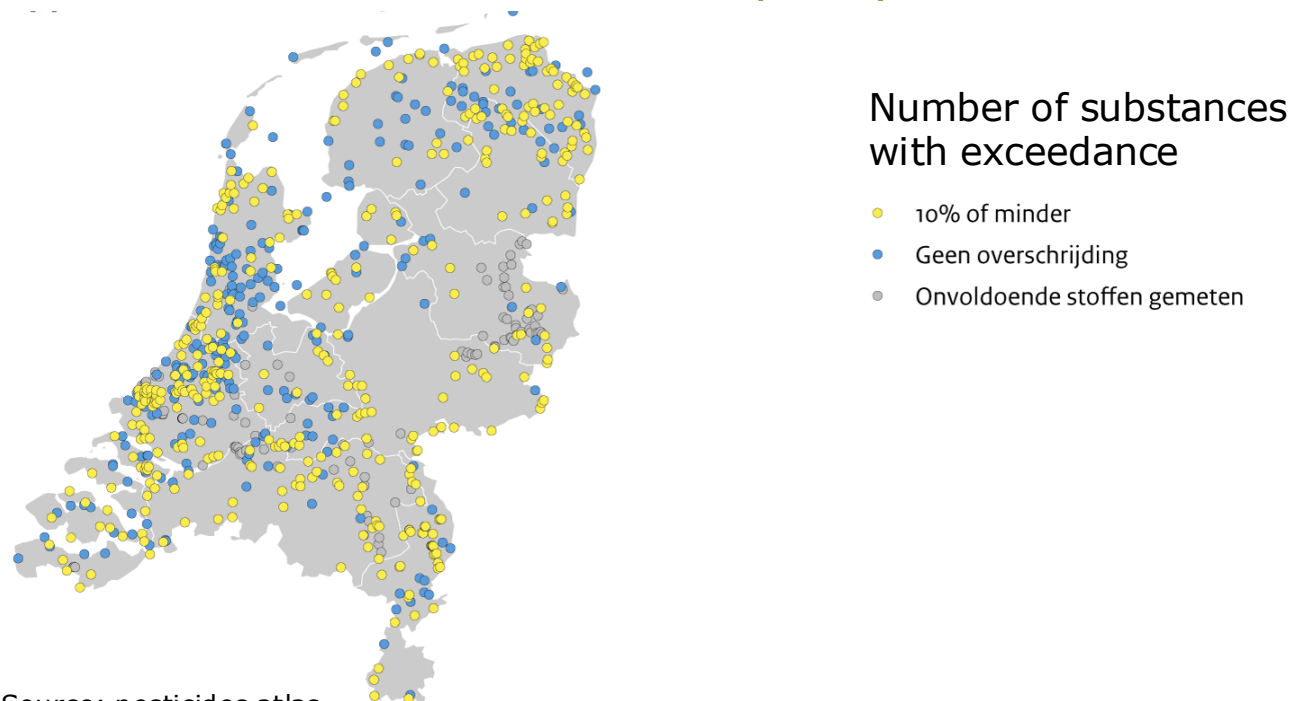
Aaldrik Tiktak & Mascha Rubach

Cremona, 4 September 2026

Societal concerns about pesticide use

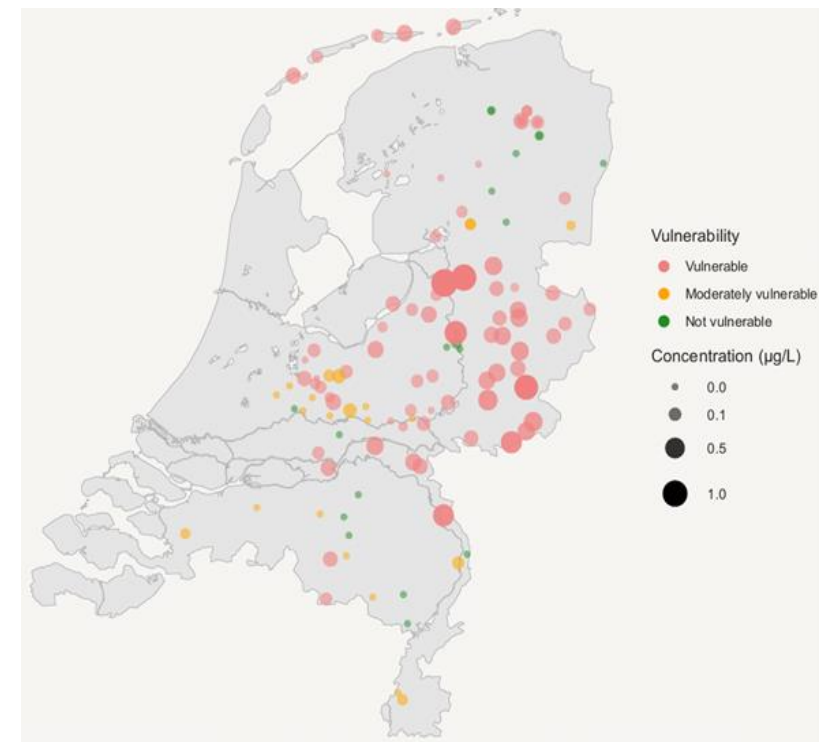
- Pesticides are often detected in (ground)water and in nature reserves

Exceedance of environmental quality standards, 2024



Source: pesticides atlas

TFA in groundwater, 2023



Source: KWR

Societal concerns about pesticide use

- Pesticides are often detected in (ground)water and in nature reserves
- Adverse effects are frequently reported in the **scientific literature** and/or claimed; e.g., insect decline, effects on humans (cancer, Parkinson's disease, ..)
- Ngo's provide evidence and call for stricter legislation and often achieve success in **lawsuits**

Societal concerns about pesticide use

- Pesticides are often not in nature

Toelating pesticiden onder druk door uitspraak rechter

Een uitspraak van de rechter zet de toelating van pesticiden op de tocht. Bij de beoordeling moet naar alle relevante kennis worden gekeken, ook als de werkzame stof al eerder is toegelaten, oordeelt de rechtbank. Tot dusver gebeurt dit niet.

"All relevant information must be considered"

round)water in

Tijdelijk verbod op gebruik gewasbeschermingsmiddelen bij lelieteelt

rted a
on

"The precautionary principle must be applied"

's-Hertogenbosch | 22 juli 2025
Een lelieteler uit Maasbree mag tot en met 2028 geen lelies telen vlak naast een woonwijk met behulp van gewasbeschermingsmiddelen. Dat besliste het gerechtshof 's-Hertogenbosch vandaag in hoger beroep. Volgens het hof heeft de lelieteler een bijzondere zorgplicht ten aanzien van de omwonenden, die inhoudt dat hij in hun nabijheid geen lelies bespuit met de gewasbeschermingsmiddelen die hij wil gebruiken. De rechtbank Limburg verbood het gebruik van gewasbeschermingsmiddelen door de lelieteler eerder voor onbepaalde tijd.

The main question

- › Products are applied according to authorisation criteria based on best available scientific knowledge
- › However, empirical field observations and **post-registration monitoring data**, often financed by public funds or citizen initiatives, remain largely neglected
- › So, the main question is: ***Do the current pesticide approval and authorisation procedures have sufficient capacity for learning from post-registration monitoring data?***

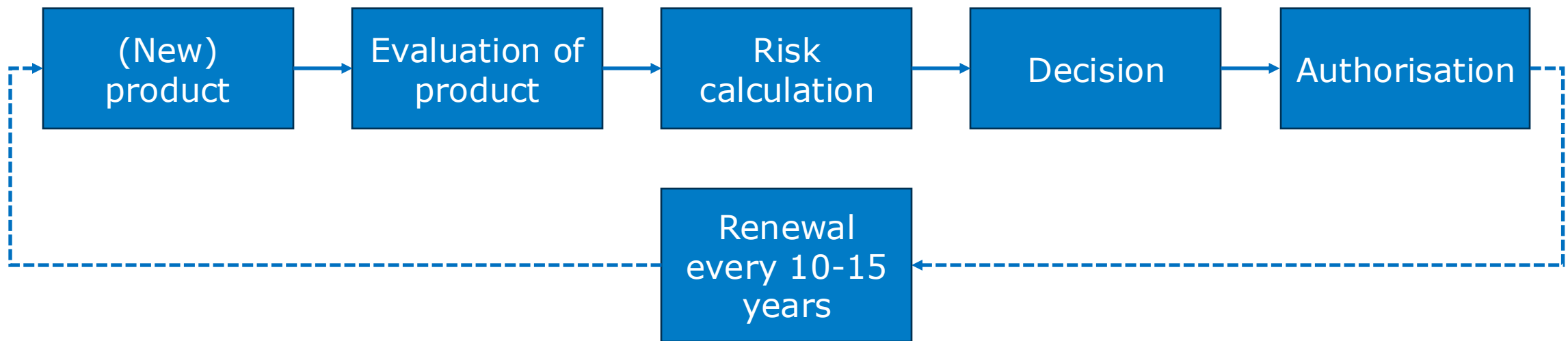


This presentation

1. The **current** pesticide approval and authorisation procedures
2. What can we learn from **post-registration monitoring**?
3. Towards **adaptive** approval and authorisation procedures

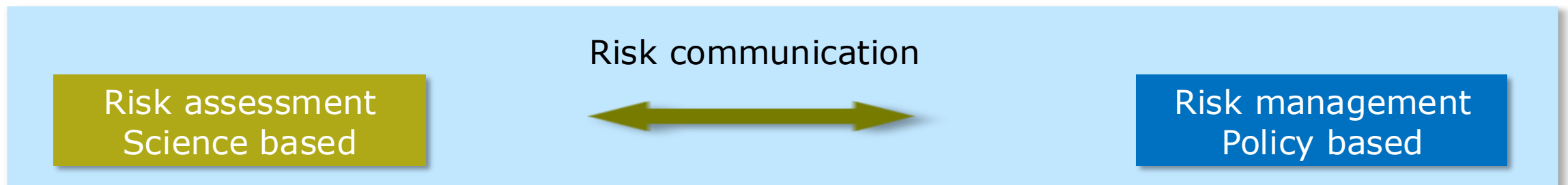
Now: renewal every 10-15 years

- › New products are **systematically evaluated** using experimental data and modelling
- › Renewal of authorisation every 10-15 years, depending on the substance, but **delays occur frequently**



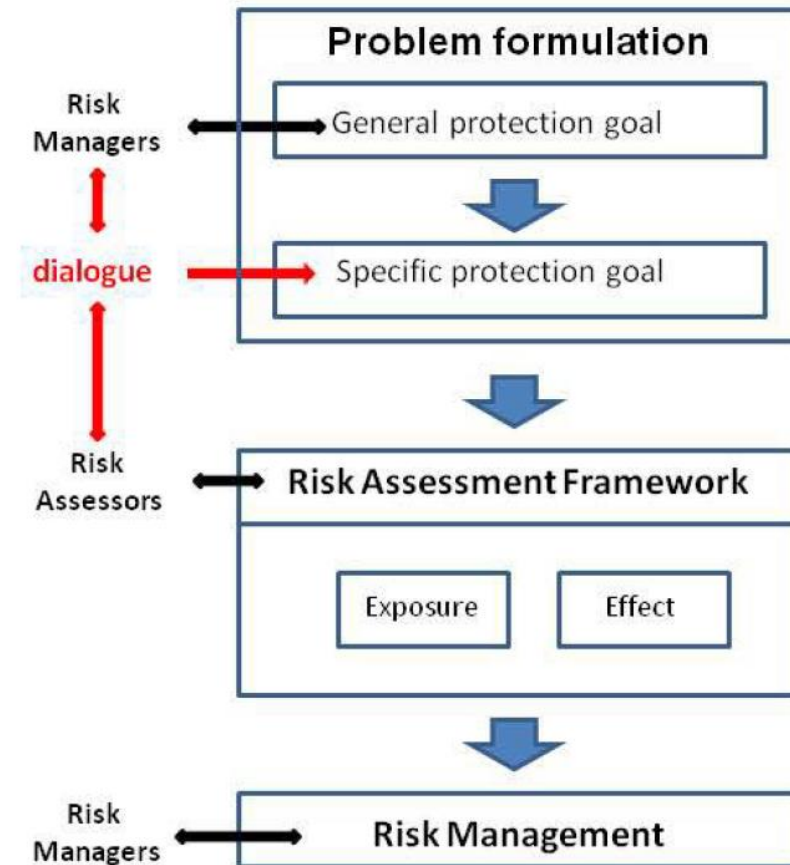
Risk management versus risk assessment

- › **Risk assessors** provide independent scientific advice on risks of pesticides to human health and the environment
- › **Risk managers** use this advice as a basis for making decisions on protection goals and or the approval of active substances
- › In Europe, these tasks are strictly **separated**
- › **Communication** between risk managers and risk assessors is essential



How is prospective risk assessment done?

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



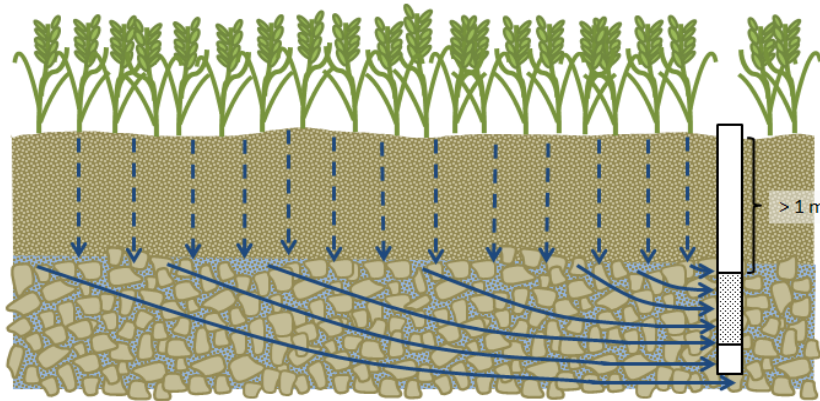
EFSA PPR Panel 2010

Step 1: definition of protection goals

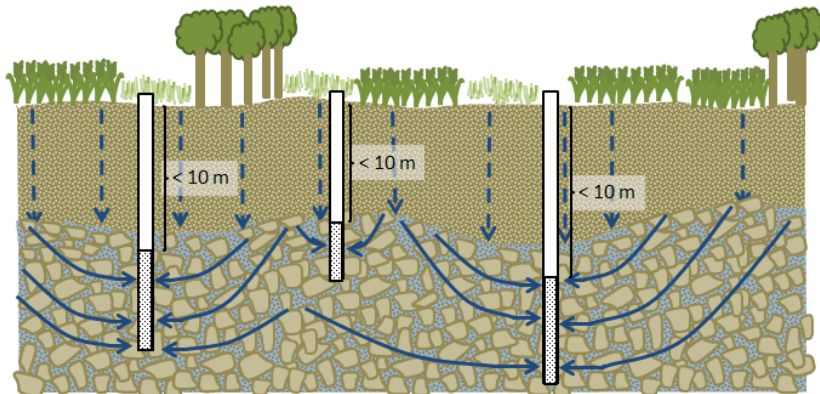
- Protection goals are generally described in EU-legislation
 - “... no harmful effects on human health”
 - “... no acceptable effects on the environment...”
- For regulatory practice, a more detailed description is needed:
 - “risk assessors need to know **what** to protect, **where** to protect it and over what **time period**”
- Without this, an objective scientific risk assessment scheme (guidance document) cannot be made

Communication about protection goals difficult

Shallow
groundwater:
stringent



Deep
groundwater:
less stringent



SETAC-EMAG report, 2018

- The protection goal determines how strict the assessment will be
- This has consequences for the products that can be registered, so this is a risk management decision
- However, risk managers find it difficult to oversee the consequences
- There are different political views between EU-countries
- Risk managers did not decide so far
→ **delay in guidance development**

Protection goals can differ between regulations

- > Standards of the WFD are stricter
- > WFD-guidance allows only negligible effects on aquatic organisms
- > Harmonisation of specific protection goals needed

Datapoints with exceedance of authorisation criteria

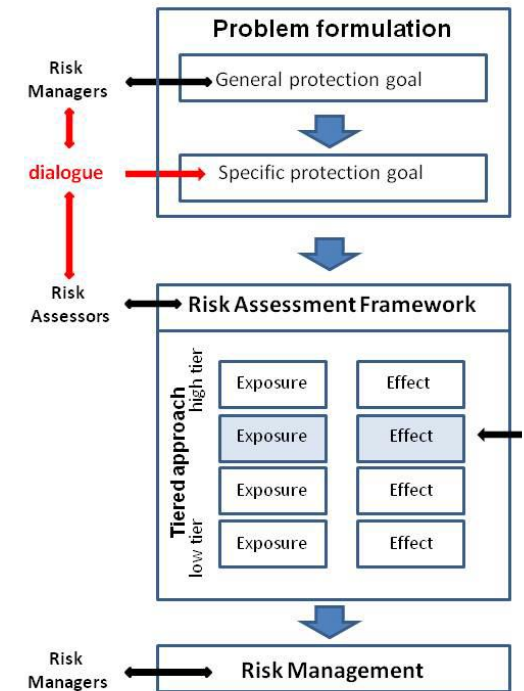


Datapoints with exceedance of environmental quality standards of the WFD

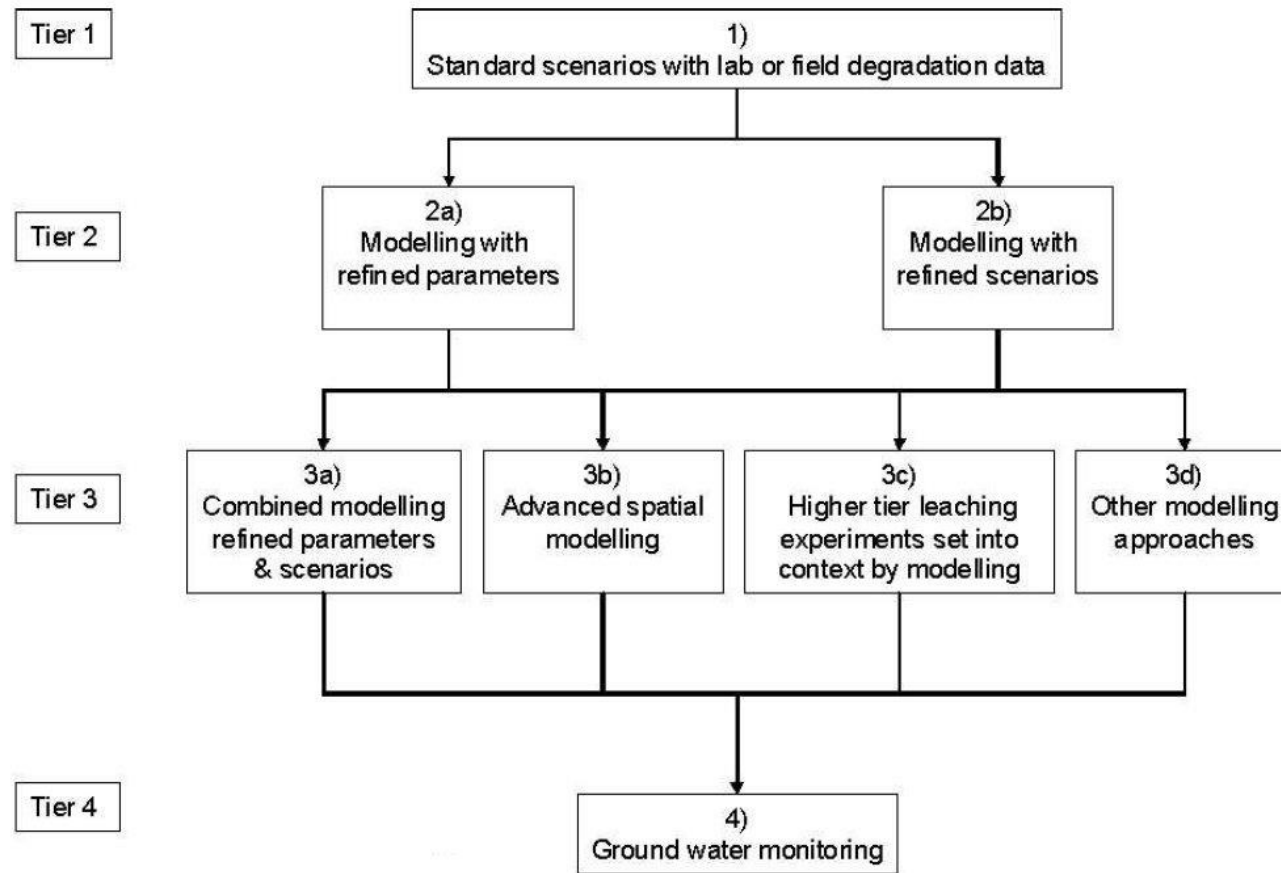


Step 2: guidance development

- Guidance is usually developed by a **working group** consisting of risk assessors and scientists
- It must be used once **noted** by the EC
- Guidance documents generally follow a **tiered approach**
 - Start with a simple conservative assessment based on laboratory experiments and/or modelling
 - Perform additional work only if necessary
 - Cost-effective for both industry, and regulators



Example: FOCUS Groundwater



- > Development started around 2000, introduction around 2010
- > Lower tiers based on **modelling**
- > **Groundwater monitoring** at Tier-4 used to demonstrate a safe use (see yesterday's presentation on SDLM)

No fundamental developments since 2010

- › No fundamental new developments since 2010: optimisation of current procedure by adding more realisms to lower tiers
 - E.g., incorporation of aged sorption, field-degradation studies, etc.
- › Guidance is becoming **increasingly complex**, and workload increases for both regulators, and industry
- › Progress slow: **lack of political interest** from EC
 - No decision on protection goals
 - No mandate for developing guidance for groundwater monitoring
 - No mandate to keep the assessment scientifically up to date (e.g., to include preferential flow)

Public monitoring data can close the cycle ...

- Provide information on the current state and trends of groundwater bodies
- Usually, a **vast amount of data** that is available
- EFSA: include public monitoring data in the risk assessment as supportive information (**weight-of-evidence** approach)
- If large scale exceedances of the regulatory limit occur, applicants must provide **additional information** on the safe use of a product

STATEMENT



ADOPTED: 27 March 2023

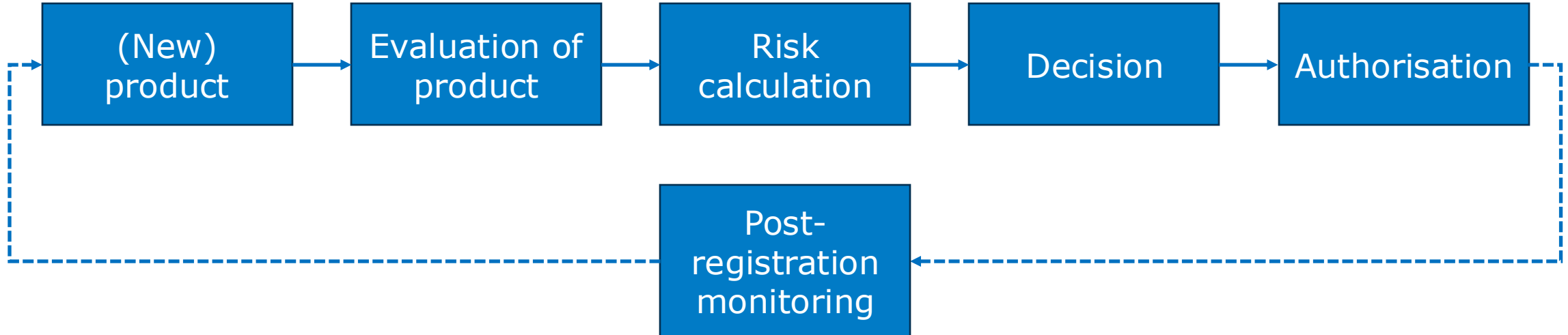
doi: 10.2903/j.efsa.2023.7990

Statement of the Scientific Panel on Plant Protection Products and their Residues (PPR Panel) on the design and conduct of groundwater monitoring studies supporting groundwater exposure assessments of pesticides

EFSA Panel on Plant Protection Products and their Residues (PPR),
Antonio Hernandez-Jerez, Paulien Adriaanse, Annette Aldrich, Philippe Berny, Tamara Coja,
Sabine Duquesne, Andreas Focks, Marina Marinovich, Maurice Millet, Olavi Pelkonen,
Silvia Pieper, Christopher Topping, Anneli Widenfalk, Martin Wilks, Gerrit Wolterink,
Roy Kasteel, Konstantin Kuppe and Aaldrik Tiktak

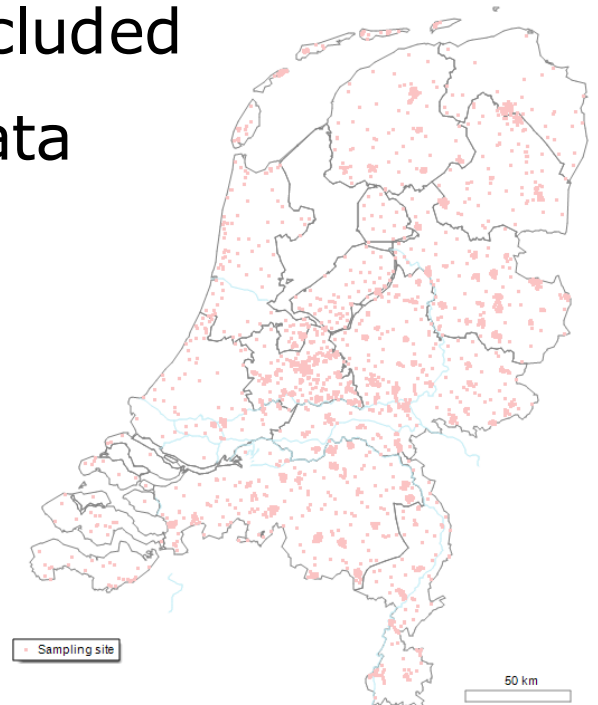
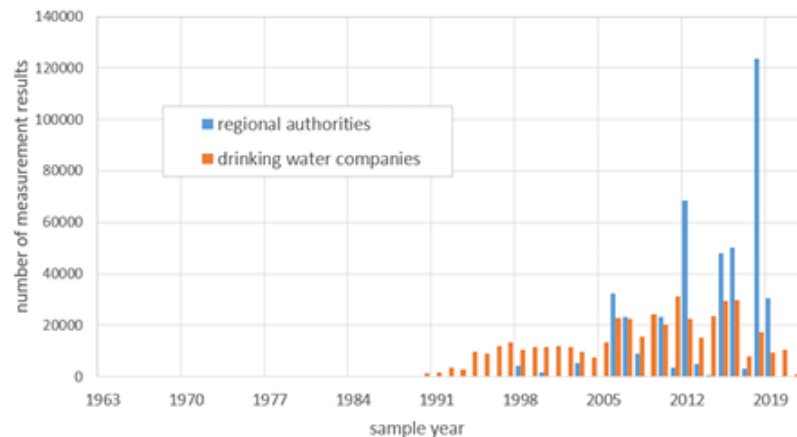
... but they are seldomly used

- › There are no **harmonised protocols** for data sharing and metadata standards, which leaves the datasets fragmented
- › For that reason, the Dutch Groundwater Atlas was created



The Dutch Groundwater Atlas for pesticides

- › Makes data from regional authorities and drinking water companies available in a **user-friendly manner**
- › Total number of 1780 sampling sites with over 400 000 observations
- › Only data that meet predefined quality standards included
- › **Metadata** included to ensure that the monitoring data can support the authorisation procedure

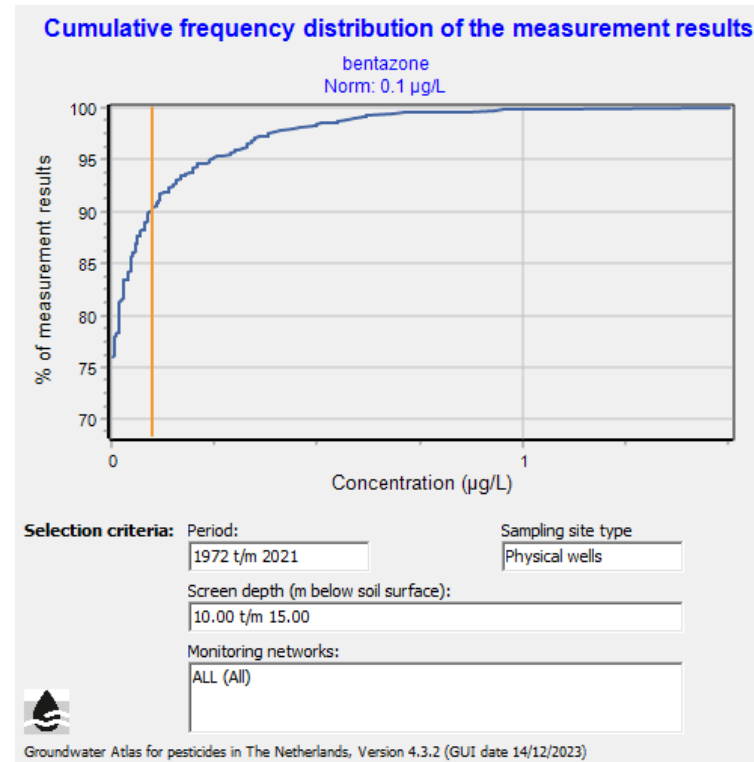


Report for the authorisation procedure

- A default **report** is created for use in the authorisation procedure
 - Evaluation depth: 10-15 meter
 - Begin period and end period based on registration dossier
 - Number of measurement values
 - Maximum and P90 of measurement values
 - Land-use for the sampling period with measurement values
- If exceedance of the target concentration is reported, applicant must provide additional evidence that use is safe (in line with EFSA GW-statement)

Example graphs

- > Spatial distribution
- > Cumulative frequency distribution

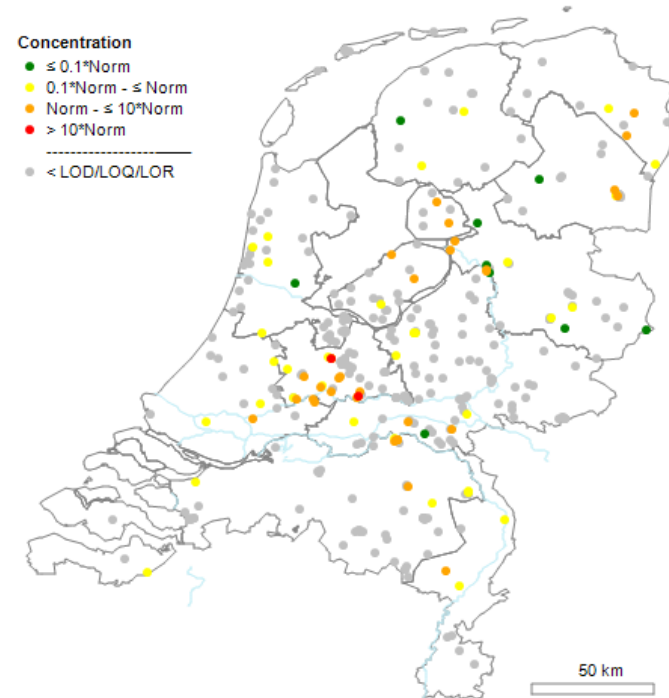


Maximum measurement value per sampling site

bentazone
Norm: 0.1 µg/L

Concentration

- $\leq 0.1 \times \text{Norm}$
- $0.1 \times \text{Norm} - \leq \text{Norm}$
- $\text{Norm} - \leq 10 \times \text{Norm}$
- $> 10 \times \text{Norm}$
- $< \text{LOD/LOQ/LOR}$



Selection criteria:

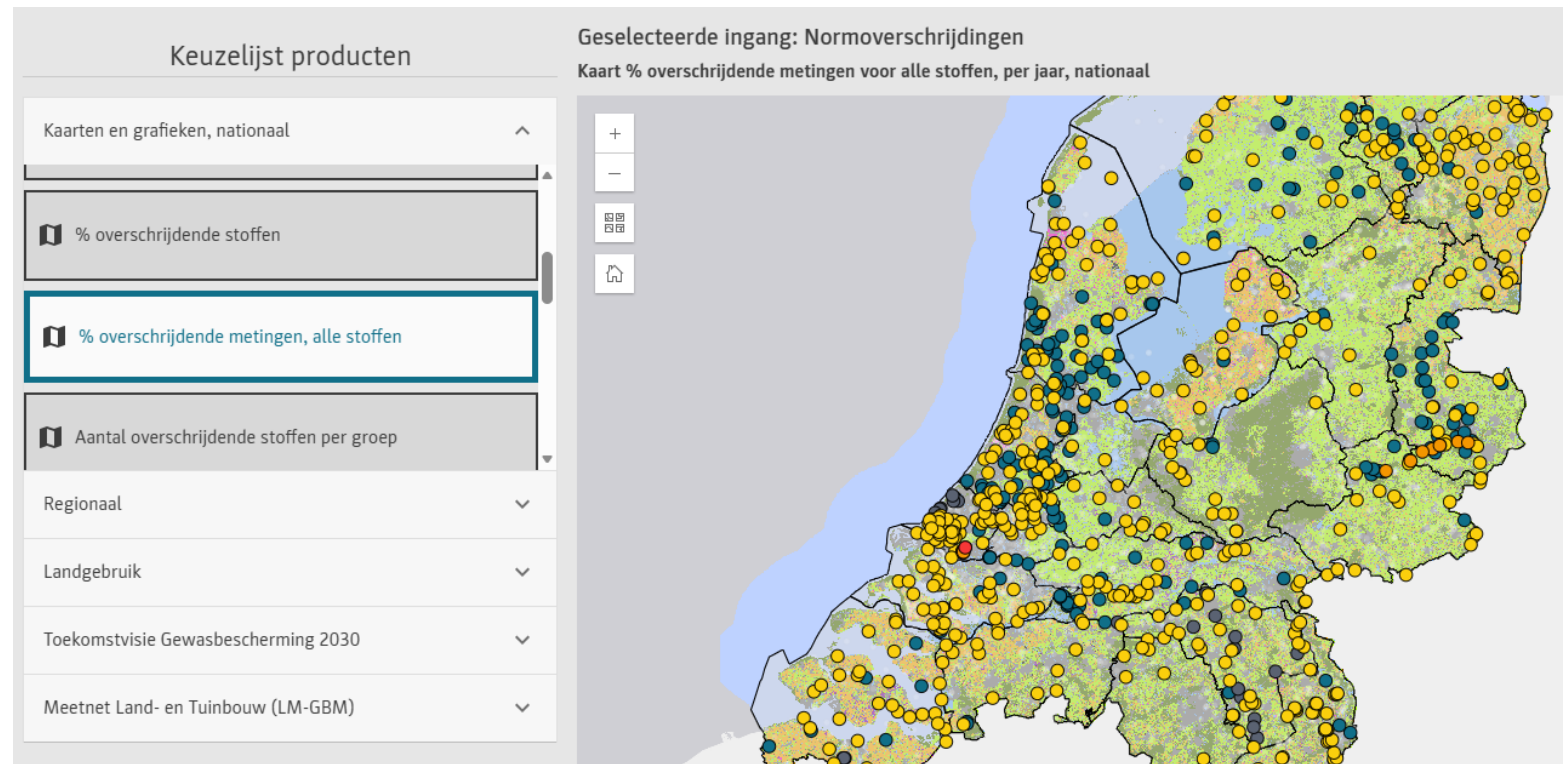
Period:	1972 t/m 2021	Sampling site type:	Physical wells
Screen depth (m below soil surface):	10.00 t/m 15.00		
Monitoring networks:	ALL (All)		



Groundwater Atlas for pesticides in The Netherlands, Version 4.3.2 (GUI date 14/12/2023)

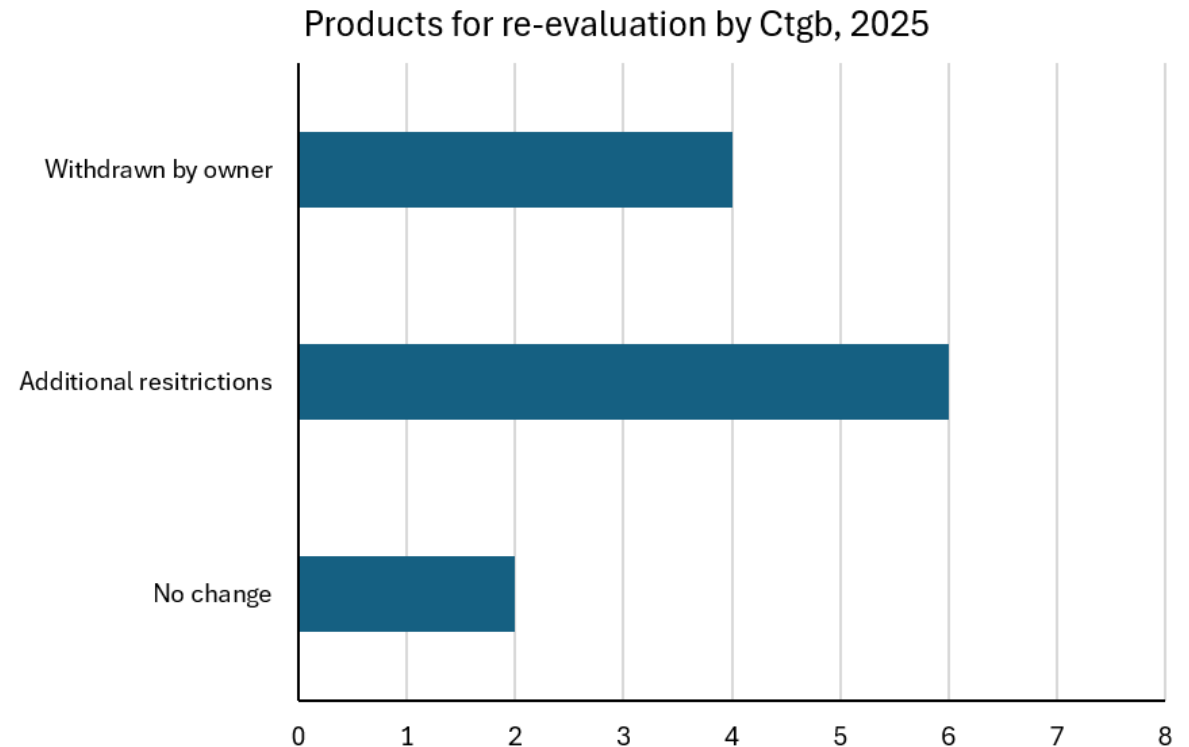
Post-registration monitoring is already applied for surface water in the Netherlands

- Possible because of years of systematic monitoring and the presence of an **open online database** (*The pesticide Atlas*)
- Contains 11 million records for the period 2003-2024



12 products re-evaluated in 2025

- Pesticides are re-evaluated when they exceed the regulatory acceptable concentration (RAC) for at least 3 years
- In 2025, 12 products with six active ingredients were re-evaluated
- Restrictions mainly because new toxicity data was available
- Procedure does not look at exceedance of WFD-standards



Re-evaluation done with existing models

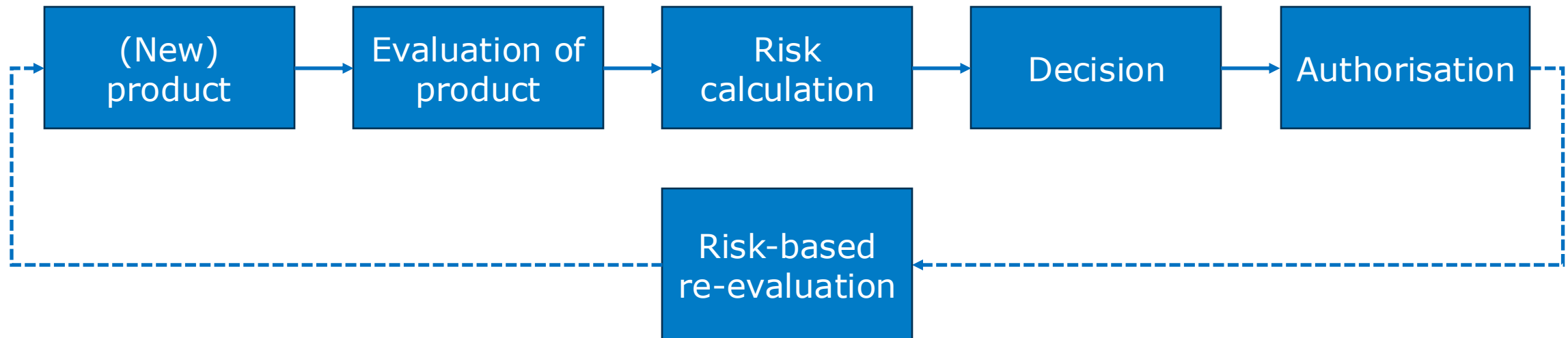
- › Re-evaluation is done with **the existing tools and models** and within the current legal framework
- › The question whether the **models are incorrect** is not evaluated
- › E.g., Dutch authorisation only considers spray drift, **run-off and drainage** are not included
- › A model including these two exposure routes was available since 2012, but risk managers did not give **political priority** to implementing this

Post-registration monitoring improves learning capacity

- › The use of post-registration monitoring data **closes the evaluation cycle** in the authorisation procedure
- › The availability of easily accessible **high-quality datasets** is necessary
- › Re-evaluation is done with existing tools and models. There must be the willingness to **also evaluate the tools and models** and improve them based on post-registration monitoring
- › However, there is **little political priority** to improve the tools and models

Omnibus proposal introduces new uncertainty

- › Periodic renewal replaced by “**risk-based re-evaluation**”
- › Unknown what and who **triggers a re-evaluation**
- › Re-evaluation must be agreed upon by more Member States; difficult to incorporate new **scientific knowledge**
- › There is a risk that the burden of proof is shifted towards others, who must prove that a product is **no longer safe**



Example: pesticides in nature reserves

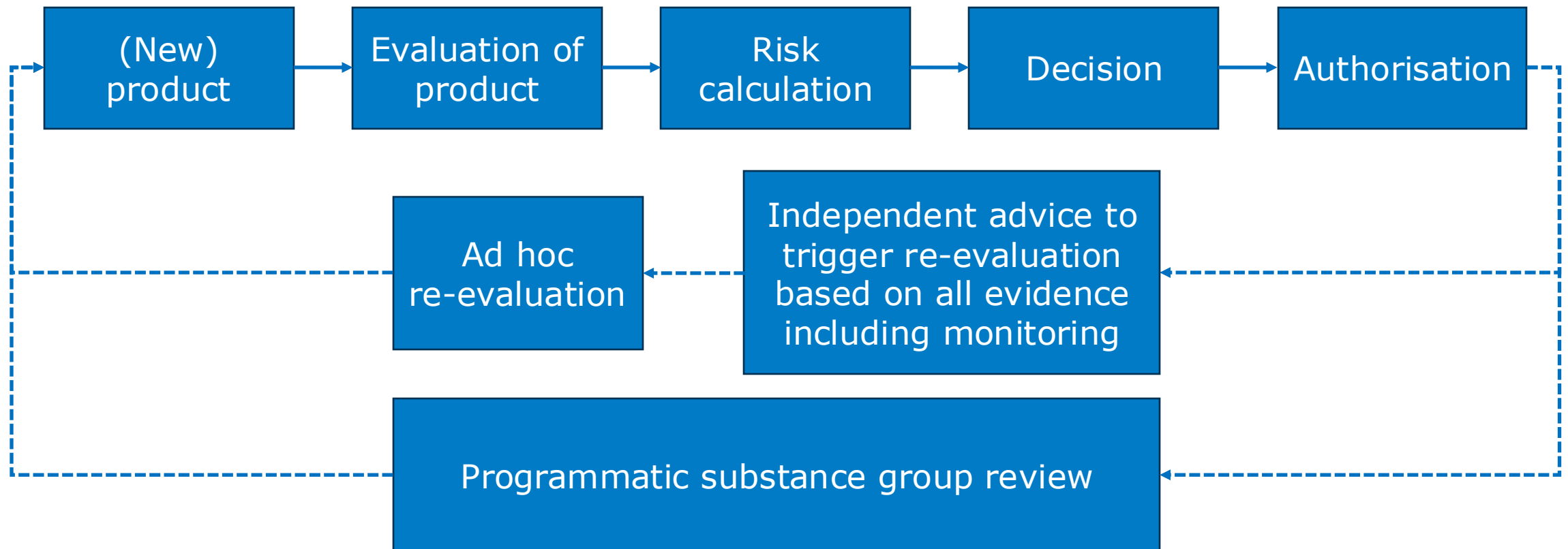
- › Ngo's already perform **measurement campaigns** where governments do not take appropriate action
- › Meten=weten proved that pesticides are detected far from arable fields
- › Current models probably underestimate **atmospheric deposition**
- › Triggered by court rulings, research is now underway to improve the models



Post-registration monitoring must be included

- › **Post-registration monitoring** must be advanced and included in approval and/or authorisation procedures
- › A standing working group consisting of scientists, risk-assessors and regulators must give independent and binding advice based on **all available scientific knowledge including new guidance**
- › **Conflicts of interest** must be avoided (declarations of interest needed)
- › Existing substances and products must be periodically reviewed using new methods
- › Workload can be reduced by performing programmatic **substance group reviews** based on their chemical similarity and mode of action

Ad hoc and programmatic review required





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Regaining trust by using post-registration monitoring data

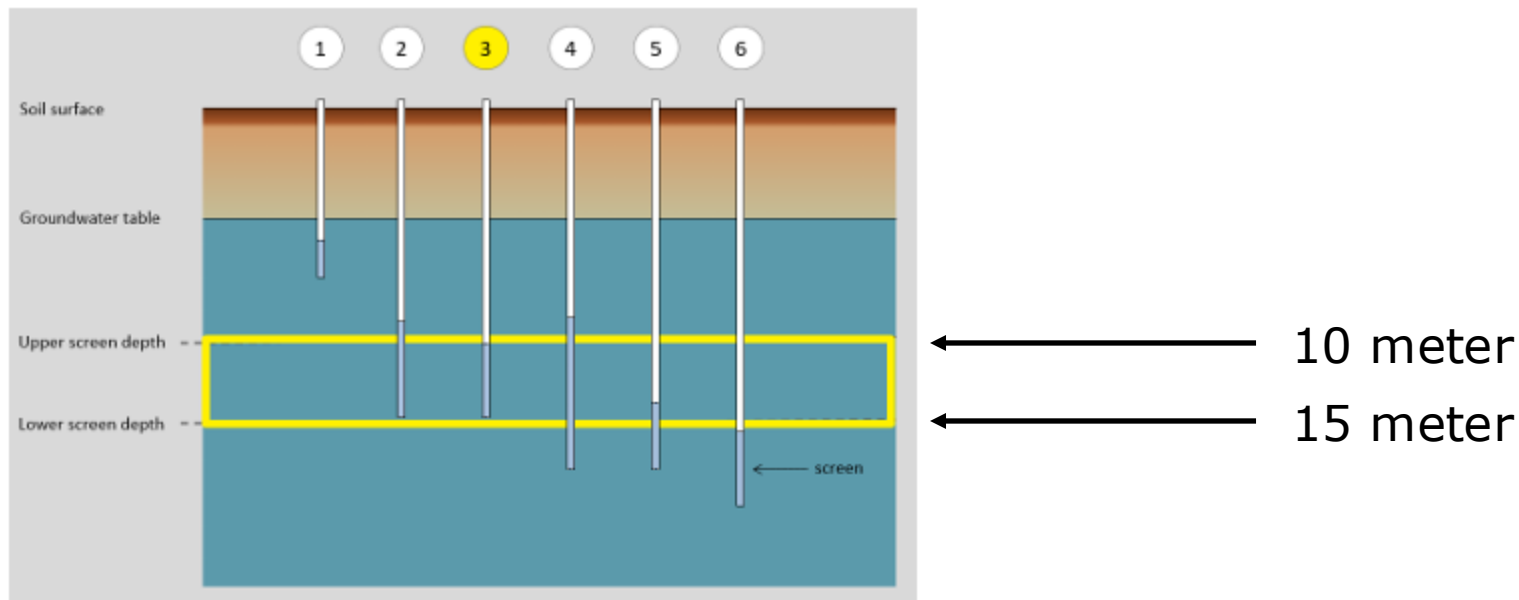
Questions and discussion

Aaldrik Tiktak & Mascha Rubach

Cremona, 4 September 2026

1: Selection based on sampling depth

- › Protection goal for the Dutch leaching assessment is 10 meter below soil surface
- › Maximum screen length is 5 meter
- › So, the procedure selects sampling points in the range 10-15 meter



2. Selection of samples with relevant land-use in area of influence

- › Area of influence calculated with the Dutch National Hydrological Model (LHM)
- › Results included in the metadata of the GWA
- › Samples without relevant land-use are removed from the selection

