

Regulatory and Monitoring Approaches

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Workshop on micropollutants, metabolites and mixtures (3Ms) in drinking water and its sources

18-19 June 2012 – KWR Research Institute, Nieuwegein, Netherlands

CONTENT :

-General Context : regulatory Frameworks / Requirements...

-Environmental “fate and behaviour” (data package available on active substance / metabolites...)

-Environmental Exposure scenarios (Pesticides / biocides ...).

-Monitoring (objectives, issues, feedbacks, improvements...)

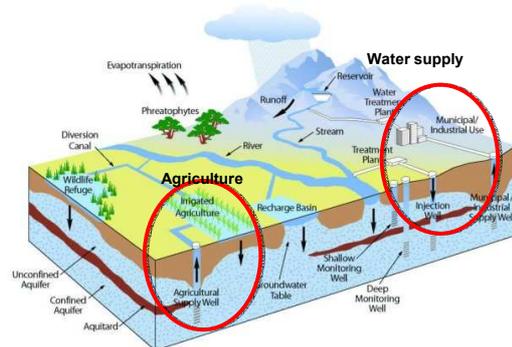
-Lessons we learned / discrepancies / positive points / improvements done and needed...

Pesticides / Biocides / Reach ...

General Context : Frameworks / Requirements...

Similarities and “discrepancies” live together in perfect harmony ?

Regulatory and Monitoring Approaches



Regulatory Frameworks

From the “oldest” to the “youngest” regulations

PPP-1991 COUNCIL DIRECTIVE 91/414/EEC + updates (REGULATION (EC) No 1107/2009)

Biocide-1998 Directive 98/8/EC

REACH -2007

From “1000” to “100.000” compounds

...

Regulatory enforcement :

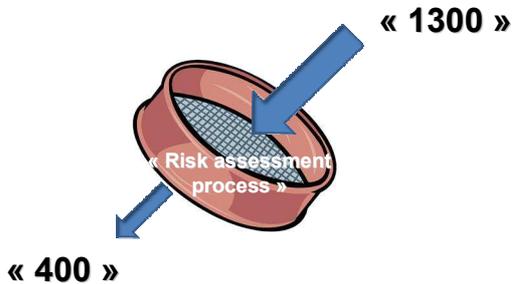
« Pesticides 1991-2012 »

Approved	407
Not approved	772
Pending	71
Other:	20 (safener/synergist)
Total:	1270

Sources : http://ec.europa.eu/sanco_pesticides/public/index.cfm

Category AC - Acaricide AT - Attractant BA - Bactericide EL - Elicitor FU - Fungicide HB - Herbicide IN - Insecticide MO - Molluscicide NE - Nematicide OT - Other treatment PA - Plant activator PG - Plant growth regulator Pruning RE - Repellent RO - Rodenticide ST - Soil treatment Safener Synergist VI - Virus inoculation DE - Desiccant

Regulatory enforcement for "Pesticide": Outcome



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And with time the grid is getting enhanced ...

(EC) No 1107/2009 ; (eg:soil)

- Persistent Organic Pollutant (POP)
Persistence DT50soil >6 months
+ ...
- Persistent, Bioaccumulable et Toxic (PBT)
Persistence DT50soil >120 days
+...
- very Persistent, very Bioaccumulable (vPvB)
Persistence DT50soil >180 jours
+...

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Feedbacks :

The borders between different regulations may be ...permeable...

(POP); (PBT); (vPvB) classification ; substitution principle come from other regulations

➔ Copper(Cu) is present in all regulations

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Feedbacks :

Some « good feedbacks » from the regularity enforcement (pesticides) :

- The grid is getting enhanced
- From a "toxico-pragmatic" risk assessment to a wider RA : Efate / Ecotox / Residues ...

Large screening ➔ "Enhanced" screening

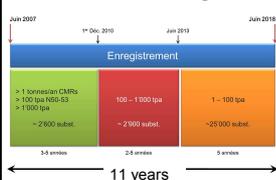


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Regulations might be fitted to the "task"

Primary prioritization in order to protect "workers" / "operators" from direct exposure

REACH Timing



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Regulations provide the legal duty / and protection goals

➔ Guidance documents provide the methodology for an up-to-date risk assessment

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Regulation and guidance docs

- Pesticides:
 - New Regulation (EC) No 1107/2009
 - SANCO guidance documents
 - European Food Safety Agency guidance documents
 - OECD Guidelines ...etc...
- Biocides:
 - Directive 98/8/EC
 - Proposal for a Regulation concerning the placing on the market and use of biocidal products (COM(2009)267)
 - TGD (Technical guidance Document)
 - ESD (Emission Scenario Documents)

Different regulations; different data requirements

- Pesticides:
 - Full data package mandatory (for all active substances; nearly)
- Biocides:
 - Data package according to Product Type
- Reach:
 - Risk assessment is not a routine
- ...

The Exposure scenarios

- Exposure assessment
 - One efficient way to anticipate further possible contamination of the environment (e.g. surface water / groundwater) is to predict the fate of the compounds

Data package / protection goal



The way of exposure defines exposed compartments and protection goal

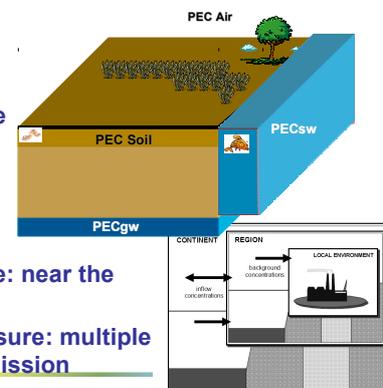


Uses / Product Types / Chemicals



Different Uses / Exposures

- Pesticides:
 - local exposure
- Biocides:
 - local exposure: near the source
 - regional exposure: multiple sources of emission



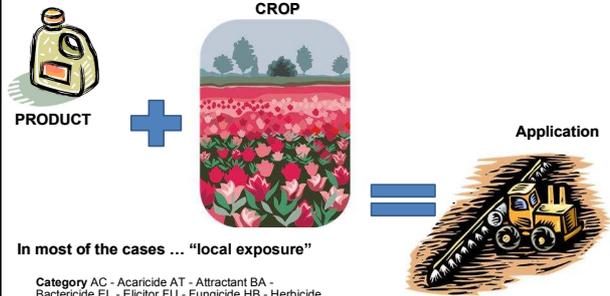
Pesticides



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Pesticides : Exposition



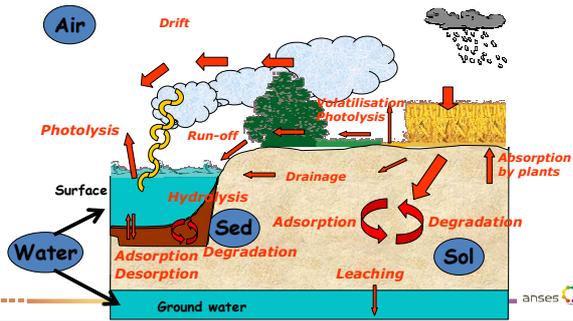
In most of the cases ... "local exposure"

Category AC - Acaricide AT - Attractant BA - Bactericide EL - Elicitor FU - Fungicide HB - Herbicide IN - Insecticide MO - Molluscicide NE - Nematicide OT - Other treatment PA - Plant activator PG - Plant growth regulator Pruning RE - Repellent RO - Rodenticide SI - Soil treatment Safener Synergist VI - Virus inoculation DE - Desiccant

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Pesticides

Advantage : deep knowledge of the process; large data package



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Pesticides

Advantage : deep knowledge of the process, large data package

Limitations :

-active substance by active substance

-Preparation by preparation

-use by use

- cumulative exposure "under construction" : in space /time/toxicity

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Biocide uses: 23 Product types

MAIN GROUP 1: Disinfectants and general biocidal products

PT 1: Human hygiene biocidal products
PT 2: Private area and public health area disinfectants and other biocidal products
PT 3: Veterinary hygiene biocidal products
PT 4: Food and feed area disinfectants
PT 5: Drinking water disinfectants

MAIN GROUP 2: Preservatives

PT 6: In-can preservatives
PT 7: Film preservatives
PT 8: Wood preservatives
PT 9: Fibre, leather, rubber and polymerised materials preservatives
PT 10: Masonry preservatives
PT 11: Preservatives for liquid-cooling and processing systems
PT 12: Slimecidic
PT 13: Metalworking-fluid preservatives

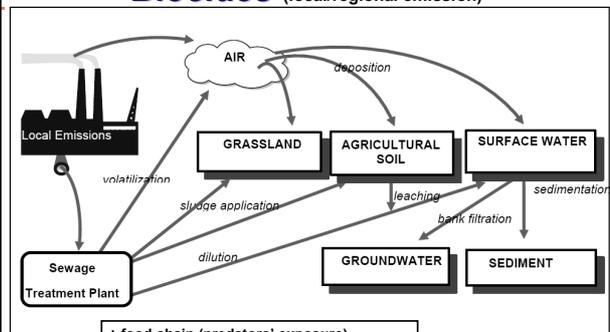
MAIN GROUP 3: Pest control

PT 14: Rodenticides
PT 15: Avicides
PT 16: Molluscicides
PT 17: Piscicides
PT 18: Insecticides, acaricides and products to control other arthropods
PT 19: Repellents and attractants

MAIN GROUP 4: Other biocidal products

PT 20: Preservatives for food or feedstocks
PT 21: Antifouling products
PT 22: Embalming and taxidermist fluids
PT 23: Control of other vertebrates

Biocides (local/regional emission)

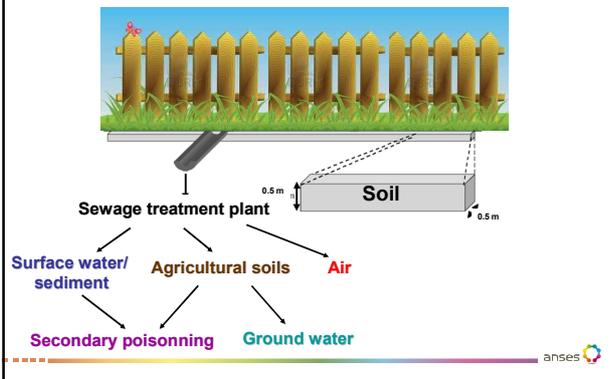


+ food chain (predators' exposure)
+ food chain and environment (human beings indirect exposure)

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ESD: e.g. PT8 (wood preservative)

Emission Scenario Documents



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E.g. Product type 21: Antifouling products



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BIOCIDES

Advantage : Emission Scenarios developed to address regional emission

Limitation : Limited Data package; no environmental risk assessment per default

-Product type by product type

-Cumulative exposure “under construction”:
in space / time / toxicity

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REACH

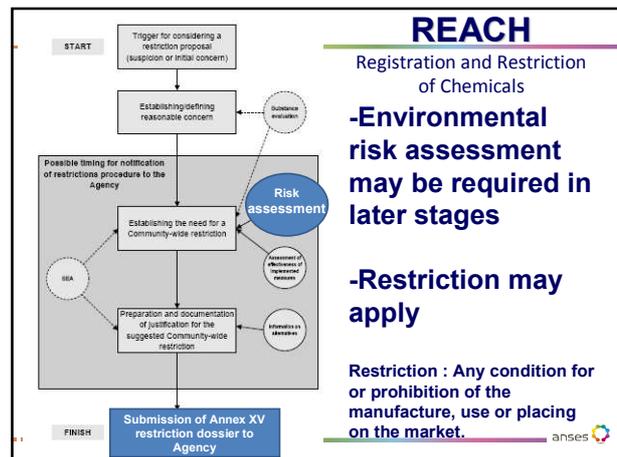
Registration and Restriction of Chemicals

-Environmental risk assessment may be required in later stages

-Restriction may apply

Restriction : Any condition for or prohibition of the manufacture, use or placing on the market.

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PEC calculations more details ...

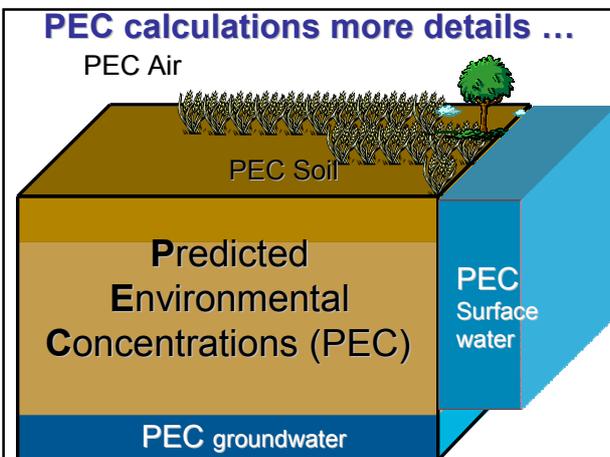
PEC Air

PEC Soil

Predicted Environmental Concentrations (PEC)

PEC Surface water

PEC groundwater



PEC calculations: more details ...

- Pesticides:
 - Focus sw
 - Focus soil

-PEC ground water

- Biocides:
 - Environmental Scenario Emission (ESD) defined for each use
 - EUSES

-PEC gw for risk refinement (except when $K_{oc} > 500$ and $DT50 < 21d$)

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Mandatory studies (Degradation)

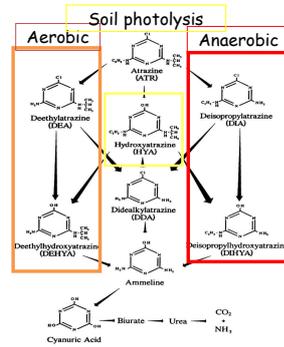
Studies for PPP : AS & metabolite(s):

- **Aerobic Degradation** (OECD 307)
- **Anaerobic Degradation** (OECD 307)
- **Soil Photolysis**
- **+ field studies**



Mandatory studies (Degradation)

Route of degradation (fake)



Metabolites:

- minor
- minor non-transient
- major

Metabolites

minor, minor non-transient, major ...

- Metabolites, which account for **more than 10 %** of the amount of active substance added in soil at any time during the studies; or
- which account for **more than 5 %** of the amount of active substance added in soil in at least **two sequential measurements** during the studies; or
- for which at the end of soil degradation studies the **maximum of formation is not yet reached**.

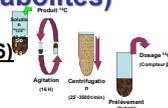
Moreover, all metabolites found in **lysimeter** studies at annual average concentrations exceeding 0.1 µg/l in the leachate should be identified and subject to further assessment.

Mandatory studies (Mobility)

Soil Mobility :

(Studies for PPP : AS et metabolites)

-Adsorption/desorption (OECD 106)



- Soil column



- Lysimetre



Studies for "other" chemicals

-These Material and Methods (OECD) guideline may be used to assess the fate and behaviour and characterize other compounds

➡ Pharmaceuticals (Kow not useful for mobility potential...)

➡ Nanomaterials (Kah et al, 2012, under press)

...

Endpoints for which purpose ?

➡ -These endpoints can feed very simple indicators to very sophisticated models

➡ -Tools for prioritization / selection of compounds to be found in the environment

Groundwater “a priori” risk assessment

ex. : GW risk assessment : FOCUS Scenarios

« Endpoints » from SA (DT50 /Koc...)+Models

=

“a priori” risk assessment

Agro-Pedo-Climatologic models for PECgw calculations (scenarios FOCUS:Forum for the Coordination of pesticide fate models and their Use)



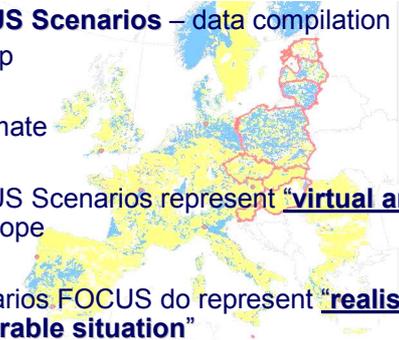
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FOCUS Scenarios

- **FOCUS Scenarios** – data compilation
 - Crop
 - Soil
 - Climate

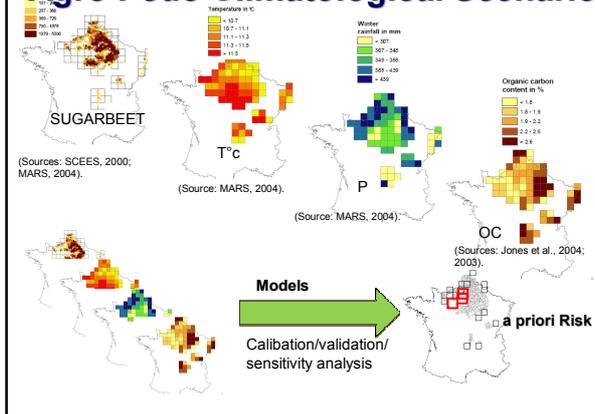
- FOCUS Scenarios represent “**virtual areas**” in Europe

- Scenarios FOCUS do represent “**realistic vulnerable situation**”



FOCUS:Forum for the Coordination of pesticide fate models and their Use)

Agro Pedo Climatological Scenario



Looking for the active substances we have learned about ... metabolites

- They must be integrated in the risk assessment
- Same triggers (as active substance) may be applied to some metabolites
- Some metabolites may be the key point for some approvals
- The “effort” made for metabolites water monitoring remain limited



Risk assessment for metabolites

Soil metabolite to account for : DG Health and Consumers :

Sanco/221/2000 –rev.10- final 25 February 2003
GUIDANCE DOCUMENT ON THE ASSESSMENT OF THE RELEVANCE OF METABOLITES IN GROUNDWATER OF SUBSTANCES REGULATED UNDER COUNCIL DIRECTIVE 91/414/EEC (to be updated)

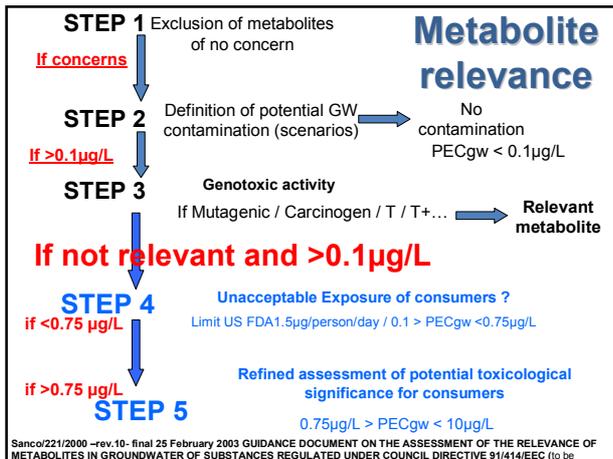
Metabolites:
 -minor
 -minor non-transient
 -major



Relevant metabolite

Relevant metabolite: a metabolite for which there is reason to assume that it has **comparable intrinsic properties as the active substance** in terms of its biological target activity, or that it has certain toxicological properties that are considered severe and unacceptable with regard to the decision-making criteria described in the text. Such a metabolite is therefore **treated like the parent active substance** in the assessment according to Annex VI, point C.2.5.1.2 of Directive 91/414/EEC., a non-inclusion 6 decision would be triggered at Community level. Where such a metabolite exceeds the maximum permissible concentration (0.1 µg/l) for groundwater the active substance or a **non authorisation** decision would be triggered at national level for specific uses of products containing that substance;





The borders between different regulations may be ...quite impermeable...

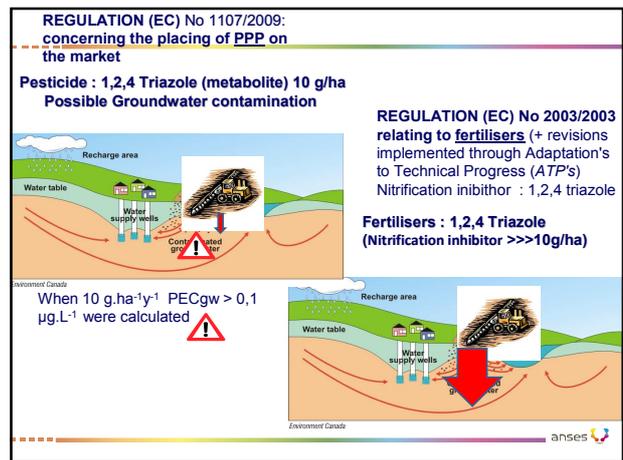
Same compound, same environmental fate and behavior, same toxicity ; ... but different regulation....

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Risk assessment / regulations

1,2,4 Triazole : Common metabolite to all Triazole compounds (fungicide)

- 1,2,4-triazole used as active substance (pharmaceutical, nitrification inhibitor...).
- **Specific toxicologic risk assessment** (US-EPA ; 2006 and EFSA, 2007). Based on (CE) n°1107/2009 and toxicological properties (repro tox cat.2 (H361d); Acute tox cat .4; (H302), potential effect on fertility...).
- Unique metabolite with EU common Endpoint for FRA



Residus definitions & monitoring

REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market

3. Criteria for the approval of active substances, safeners and synergists

3.9. Residue definition
 An active substance, safener or synergist shall only be approved if, where relevant, a residue definition can be established for the purposes of risk assessment and for enforcement purposes.

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Residus definitions & monitoring

3.5. Methods of analysis

3.5.2. The methods of residue analysis for the active substance and relevant metabolites in plant, animal and environmental matrices and drinking water, as appropriate, shall have been validated and shown to be sufficiently sensitive with respect to the levels of concern.

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VOLUME 1

**APPENDIX 3: Listing of end points
(EPCO Manual)**

Residues requiring further assessment
Monitoring data, if available (Annex IIA, point 7.4)

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil:	E-fate
	Surface Water:	
	Sediment:	
	Ground water: Air:	

Ecotoxicologically relevant compounds
(consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	
soil	Parent (state name), Metabolite 1 (state name)
water	Parent (state name)
sediment	Parent (state name), Metabolite 2 (state name)
groundwater	Parent (state name)

Ecotox

Residus definitions & monitoring

Unclassified
ENV/JM/MONO(2009)30
28-Jul-2009
English - Or: English

ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY

General Considerations

SERIES ON TESTING AND ASSESSMENT
No. 63 and
SERIES ON PESTICIDES
No. 31

GUIDANCE DOCUMENT ON THE DEFINITION OF RESIDUE
(AS REVISED IN 2009)

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More likely to be included	Less likely to be included
<ul style="list-style-type: none"> Parent compound is <u>highly toxic</u>. Metabolite/degradeate likely to be found in commodities that are human foods. Metabolite/degradeate levels in magnitude of residue studies exceeded those expected from metabolism studies. Metabolite/degradeate likely to cause toxicity through the same <u>mechanism of action</u> as the parent compound. Metabolite/degradeate is not formed through metabolism in rats. Parent compound was non-detectable, but metabolites were found in high levels in metabolism studies. <p>Considerations for drinking water:</p> <ul style="list-style-type: none"> Environmental degradeate is <u>persistent</u>. Environmental degradeate has <u>low soil binding potential</u>. Degradeate is detected in <u>water monitoring</u> studies. 	<ul style="list-style-type: none"> Parent compound has low toxicity relative to expected exposures. Metabolite/degradeate found in only one matrix at 10-20% of the total residue (unless that matrix is a major human food). Metabolite/degradeate present at very low residue levels (in mg/kg). Metabolite/degradeate structure is similar to innocuous chemicals. Metabolite/degradeate occurs predominantly in animal feeds rather than commodities that are human foods. Hydrophilic metabolites less toxic than the parent compound <p>Considerations for drinking water:</p> <ul style="list-style-type: none"> Environmental degradeate is short-lived. Environmental degradeate has high soil binding potential. Degradeate is not detected in terrestrial field dissipation studies.

Table 1: Considerations for Major (>10% of the TRR) Metabolites/Degradeates to be included in the Risk Assessment

Residus definitions & monitoring

More likely to be included	Less likely to be included
<ul style="list-style-type: none"> <u>Multi-residue methods</u> are able to recover and detect metabolite. Concentrations of metabolites in commodities are likely to be much greater than the parent compound. Metabolite likely to be found in commodities that are human foods. Parent is not expected to be found and is therefore not a suitable <u>marker compound</u>. Levels of metabolite adequate to serve as an indicator of misuse. Parent compound is highly toxic and metabolite/degradeate likely to cause toxicity through same mechanism of action. 	<ul style="list-style-type: none"> Metabolite cannot be determined by multi-residue methods, while parent can be recovered. Found in only one matrix at 10-20% of the total residue. Parent compound has very low toxicity (i.e., ADI or RID is very high). Metabolite does not warrant inclusion on toxicological grounds. Metabolite is naturally occurring Metabolite originates from other sources, e.g. other pesticides or industrial chemicals.

Table 2. Considerations for Major (>10% of the TRR) Metabolites to be included in the "MRL/Tolerance Expression"

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Monitoring : different objectives

Ground water monitoring

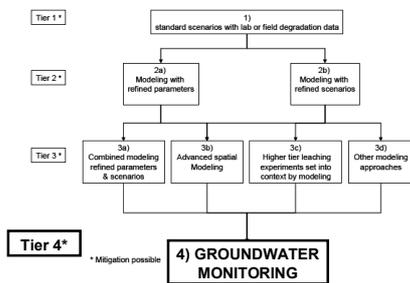
Water plant treatment efficiency monitoring

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Dedicated & national monitorings

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Dedicated monitorings



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Dedicated & national monitorings

- Facing « true life » (validation ?)
- illegal practices ?
- Different feedbacks where: Local actions may have significant impact; Isolated misused may ruin efforts etc...

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Pesticides MONITORING

- **Trends** have appeared but usually an in-depth analysis of data is still required.
- **Banned AS**, are still the most frequently found pesticides -together with their degradation products- in rivers and groundwater
- **Data collection** is growing; but : Efforts to increase **consistency** in the methodology points to establish **chronics** giving a description of the trends in water quality focusing on pesticides concentrations.

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Micropollutants Monitoring

- Effort should be made on several aspects:
- Consistency in **the analysis methods** + the quantification limits;
 - The molecules evolution associated with their **degradation products**
 - Efforts should also be made in view of **synchronizing** the information made available to the various public bodies.

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Micropollutants Monitoring

Lessons we have learned;

- We find the compounds/metabolites we look for (and the reverse is true)
- Banning an active substance and replace it by many other may “solve” 1 problem and create many others

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Thank you for your attention

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French Agency for Food, Environmental and Occupational Health & Safety
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