Sarajevo 20-22 September 2016

Ecotoxicological Risk Assessment in pesticide registration

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International Centre for Pesticide Safety

Summary

- EU PPP regulation - history
- Risk, hazard and risk assessment
- Ecotoxicological Risk Assessment (ERA)
  - principles
  - examples

EU regulation

COUNCIL DIRECTIVE

of 21 December 1978

prohibiting the placing on the market and use of plant protection products containing certain active substances

(79/117/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas plant production has a very important place in the European Economic Community;

products, restrictions or prohibitions of use covering also their marketing;

Whereas these provisions differ in the various Member States and result in obstacles to trade which directly affect the establishment and functioning of the common market;

Whereas it is therefore desirable to eliminate these obstacles by aligning the relevant provisions laid down in the Member States by law, regulation or administrative provision;

Whereas it therefore seems justified, as a basic principle, to introduce prohibitions of the use of all plant protection products containing active substances which, even when properly used for the

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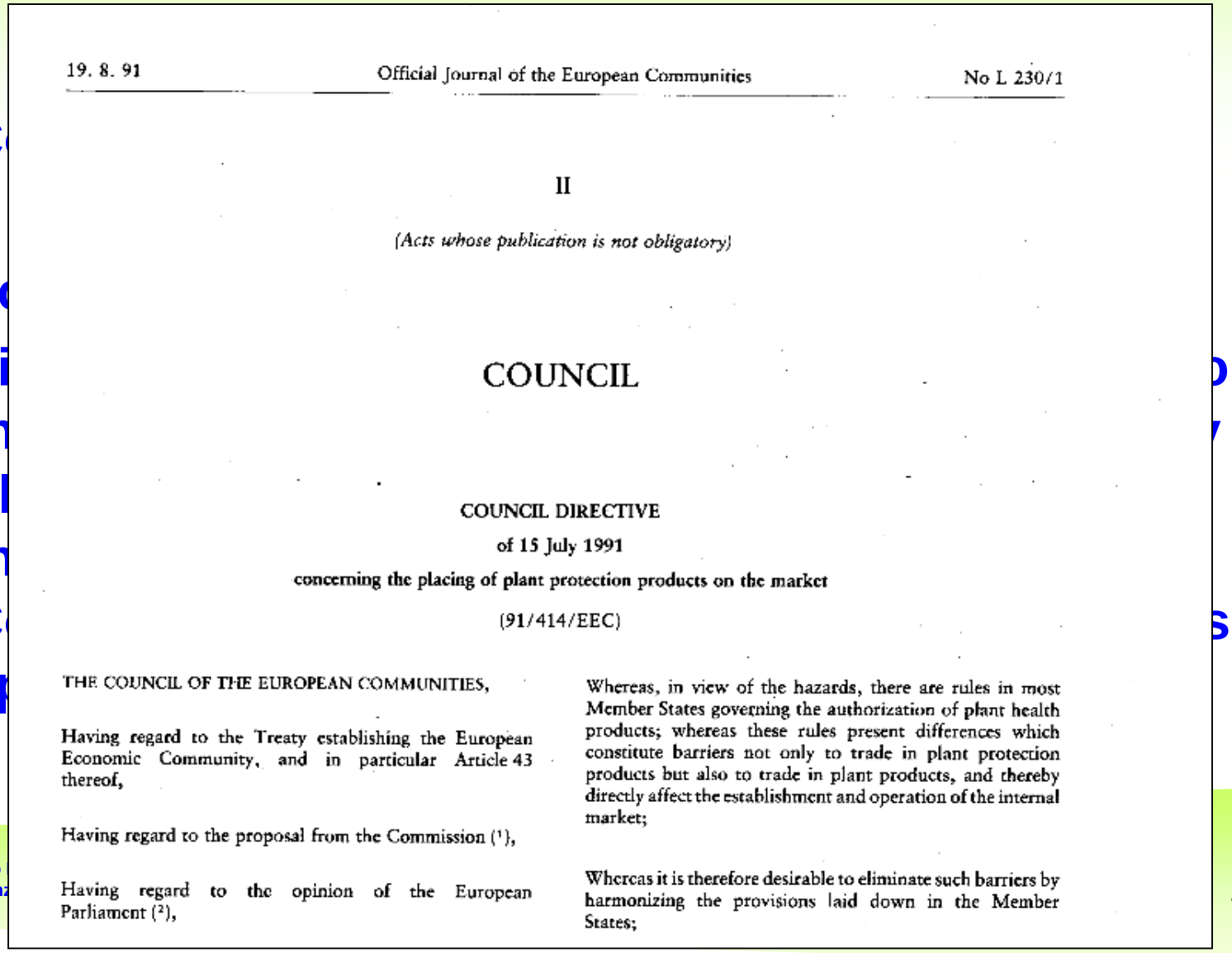

19. 8. 91 Official Journal of the European Communities No L 230/1

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 15 July 1991

concerning the placing of plant protection products on the market

(91/414/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Parliament (2),

Whereas, in view of the hazards, there are rules in most Member States governing the authorization of plant health products; whereas these rules present differences which constitute barriers not only to trade in plant protection products but also to trade in plant products, and thereby directly affect the establishment and operation of the internal market;

Whereas it is therefore desirable to eliminate such barriers by harmonizing the provisions laid down in the Member States;

EU regulation

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ANNEX II

REQUIREMENTS FOR THE DOSSIER TO BE SUBMITTED FOR THE INCLUSION OF AN ACTIVE SUBSTANCE IN ANNEX I

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INTRODUCTION

The information required shall:

1.1. include a technical dossier supplying the information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may entail for humans, animals and the environment and containing at least the information and results of the studies referred to below;

▼M4

1.2. where relevant, be generated using test guidelines, according to the latest adopted version, referred to or described in this Annex; in the case of studies initiated before the entry into force of the modification of this Annex, the information shall be generated using suitable internationally or nationally validated test guidelines or, in the absence thereof, test guidelines accepted by the competent authority;

EU regulation

I

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

REGULATIONS

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 and repealing Council Directives 79/117/EEC and 91/414/EEC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37(2), Article 95 and Article 152(4)(b) thereof,

Having regard to the proposal from the Commission,

Parliament by its Resolution of 30 May 2002 ([5]) and the Council in its Conclusions of 12 December 2001 asked the Commission to review Directive 91/414/EEC and identified a number of issues for the Commission to address.

(3) In the light of the experience gained from the application of Directive 91/414/EEC and of recent scientific and technical developments, that Directive should be replaced.

EU regulation

- **Annex II, point 4: active substances candidate for substitution if:**
  -POP
  -PBT
  -vPvB
  -Category 1 & 2 CMR (*Carcinogenic-Mutagenic-Reprotoxic*)
  -Endocrine disruptor (ED)

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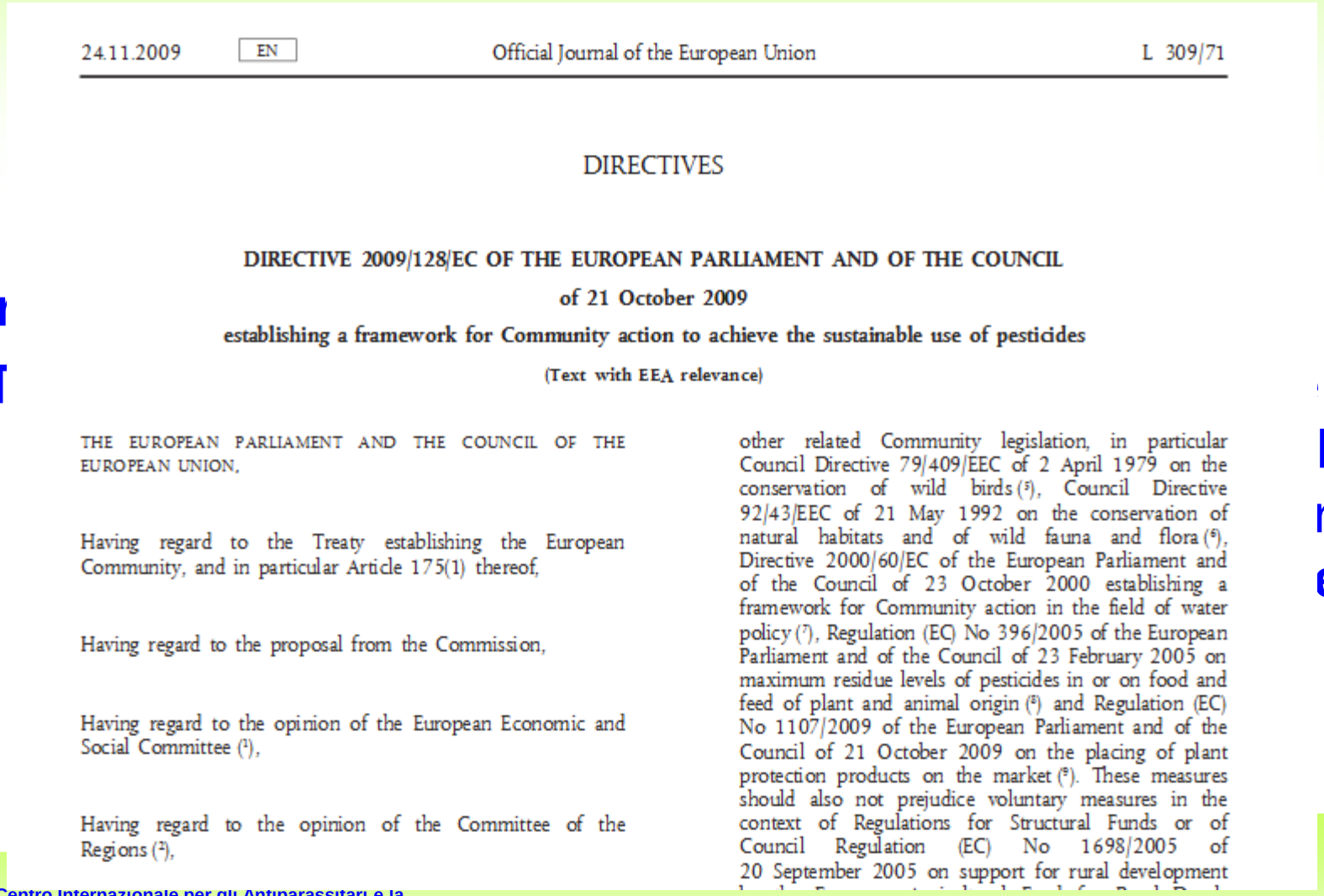

24.11.2009 EN Official Journal of the European Union L 309/71

DIRECTIVES

DIRECTIVE 2009/128/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 21 October 2009

establishing a framework for Community action to achieve the sustainable use of pesticides

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 175(1) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee (1),

Having regard to the opinion of the Committee of the Regions (2),

other related Community legislation, in particular Council Directive 79/409/EEC of 2 April 1979 on the conservation of wild birds (3), Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (4), Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (5), Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin (6) and Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 on the placing of plant protection products on the market (7). These measures should also not prejudice voluntary measures in the context of Regulations for Structural Funds or of Council Regulation (EC) No 1698/2005 of 20 September 2005 on support for rural development

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II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 540/2011

of 25 May 2011

implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 and repealing Council Directives 79/117/EEC and 91/414/EEC ([1]), and in particular Article 78(3) thereof,

After consulting the Standing Committee on the Food Chain and Animal Health,

containing the list of active substances included in Annex I to Directive 91/414/EEC at the moment of the adoption of this Regulatation,

(3) In this context it is to be borne in mind that, as a consequence of Article 83 of Regulation (EC) No 1107/2009 having repealed Directive 91/414/EEC, the Directives which included the active substances in Annex I to Directive 91/414/EEC have become obsolete to the extent that they amend that Directive. However, the autonomous provisions of these Directives continue to apply,

HAS ADOPTED THIS REGULATION:

Article 1

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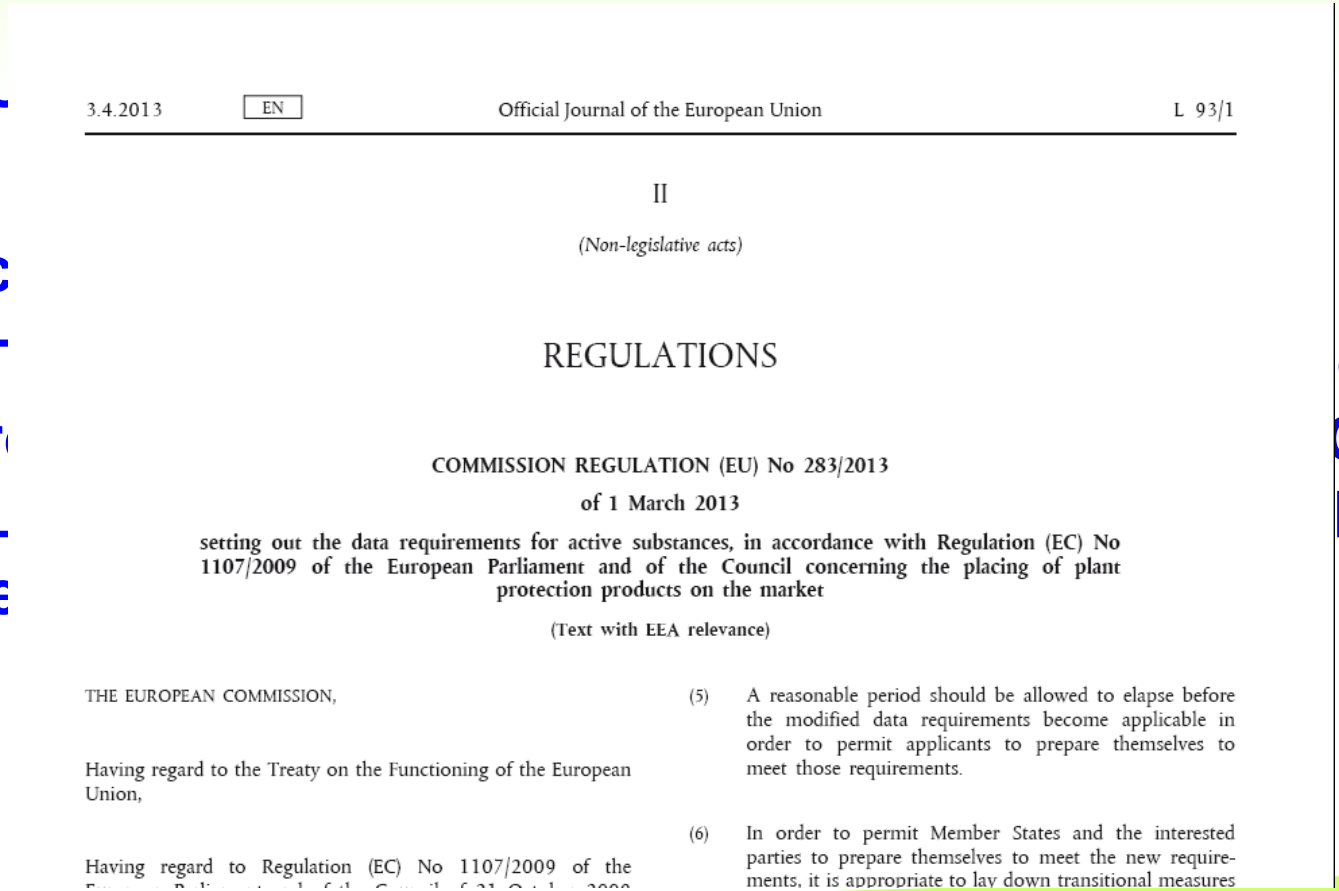

3.4.2013 EN Official Journal of the European Union L 93/1

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 283/2013

of 1 March 2013

setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the

(5) A reasonable period should be allowed to elapse before the modified data requirements become applicable in order to permit applicants to prepare themselves to meet those requirements.

(6) In order to permit Member States and the interested parties to prepare themselves to meet the new require-ments, it is appropriate to lay down transitional measures

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COMMISSION REGULATION (EU) No 284/2013

of 1 March 2013

setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 and repealing Council Directives 79/117/EEC and 91/414/EEC [1], and in particular Article 78(1)(b) thereof,

Whereas:

(1) In accordance with Article 8(4) of Regulation (EC) No 1107/2009, Commission Regulation (EU) No 545/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for plant protection products [2] was adopted. It contains the data requirements for the authorisation of plant protection products, as set out in Annex III to Council conditions of approval of active substances and for applications for authorisation, renewal of authorisation and amendment to authorisation of plant protection products.

(7) These transitional measures are without prejudice to Article 80 of Regulation (EC) No 1107/2009.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

Data requirements for plant protection products

The data requirements for plant protection products provided for in Article 8(1)(c) of Regulation (EC) No 1107/2009 shall be as set out in the Annex to this Regulation.

Active Substance authorisation process

Timeline	Evaluation step	Stakeholder
0	Application	Applicant
45 days	Completeness check	Rapporteur MS (RMS)
1 year	Draft Assessment Report (DAR)	RMS
30 days	Circulate DAR to other MS	EFSA
2 weeks	Ask for confidentiality request & publish	EFSA
60 days	Collate comments on DAR	EFSA
120 days	Adopt conclusion	EFSA
6 months	Review report & proposal for (non) inclusion	Commission
No timeline	Vote on (non) inclusion	Standing Committee SCFCAH
Total time (minimum): 2 years and 3 months		

PPP authorisation process

Timeline	Evaluation step	Stakeholder
0	Application to each MS where placing on market is intended	Applicant
1 year	Zonal assessment report Cooperation to share evaluation work	Zonal RMS Other MS from same zone
120 days	Authorisation decision based on zonal RMS	Other MS from same zone
120 days	Mutual recognition	Other MS from same zone or MS from different zone
3 mo after AS renewal	Application for PPP renewal	Applicant
1 year after AS renewal	Renewal of PPP authorisation	Each MS where PPP renewal is intended

Pesticide dossier sections

- Identity
- Physical and chemical properties
- Details of uses and further information
- Classification and labelling
- Methods of analysis
- Impact on human and animal health
- Residues
- Fate and behaviour in the environment
- Effects on non-target species
- Efficacy

Pesticide dossier

Hazard or Risk ?

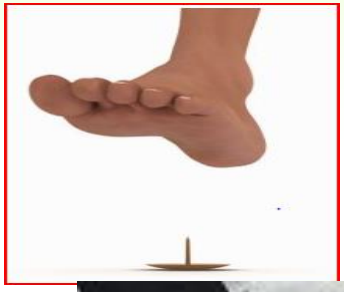
- **A hazard is any biological, chemical, mechanical, environmental or physical agent that is reasonably likely to cause harm or damage to humans, other organisms, or the environment in the absence of its control[1].**

- **Risk is defined as the probability that exposure to a hazard will lead to a negative consequence[2].**

[1] Sperber, William H. (2001). "Hazard identification: from a quantitative to a qualitative approach". *Food Control* **12**: 223–228.
[2] Ropeik, David (2002). *Risk*. New York, New York, USA: Houghton Mifflin Company

Risk assessment - A fundamental part of everyone's lives

- **There is no such thing as no risk...**
  - **risk can be negligible, acceptable or significant but zero risk is unattainable**
  - **avoidance of one risk still leaves or enhances other risks**



- **Balancing risk and benefit...**
  - **taking risk may be acceptable if a benefit is achieved**
  - **the benefit must be clear and exceed the risk**

Ecological Risk Assessment

- ***Ecological risk assessment is the practice of determining the nature and likelihood (probability) of effects of our actions on animals, plants and the environment***

- **Physical (changes to ecological systems, lakes, rivers, forests, draining wetlands)**
- **Chemical (including pesticides, plant proteins)**
- **Biological (Introducing new species, GMOs)**
- **Effects may be local (edge of field), regional, global**

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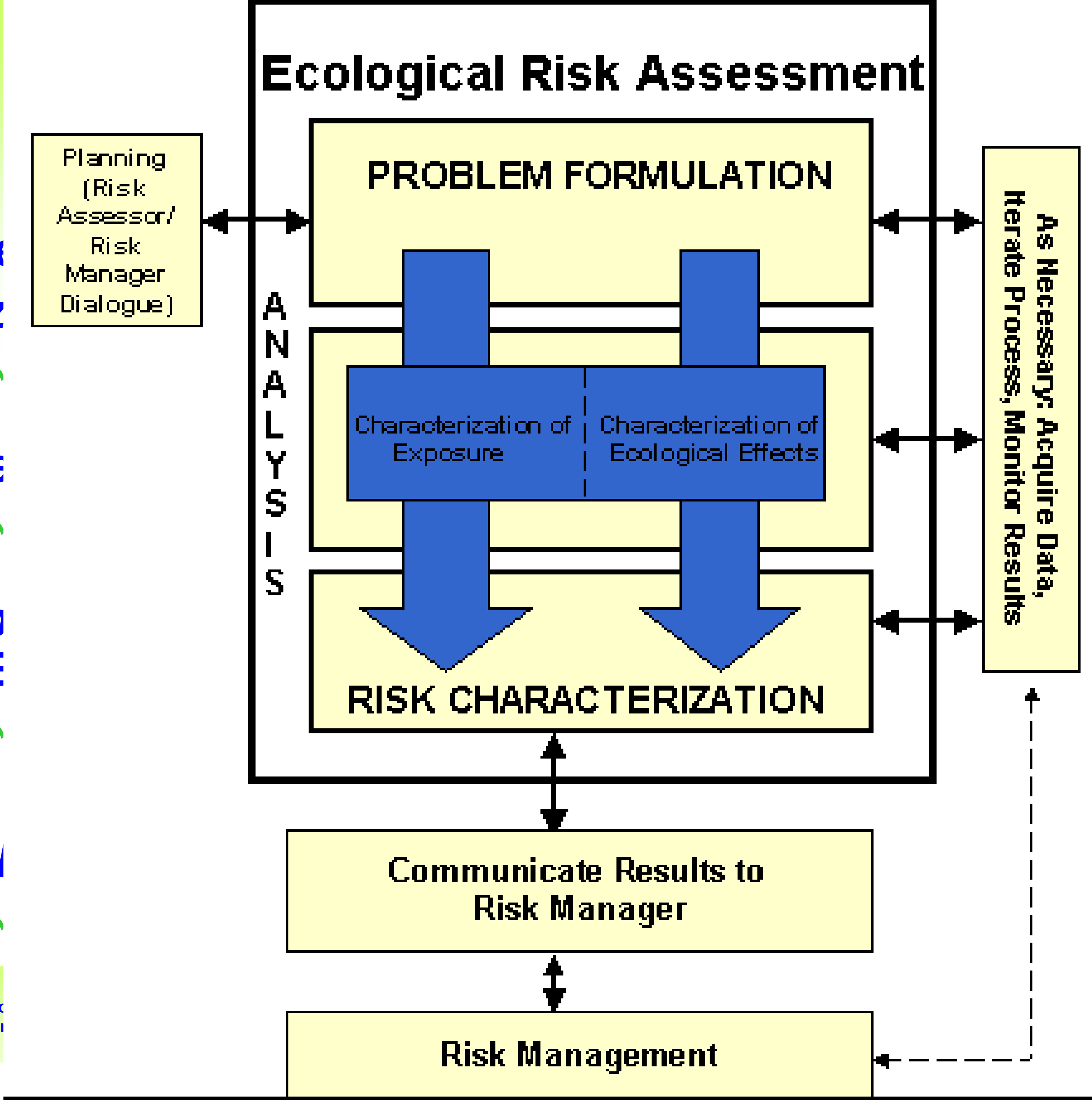

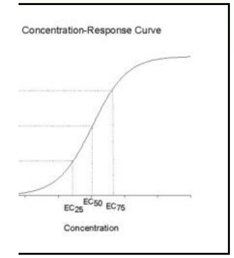

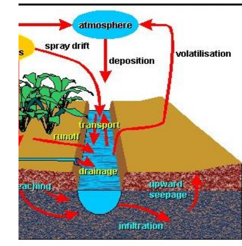

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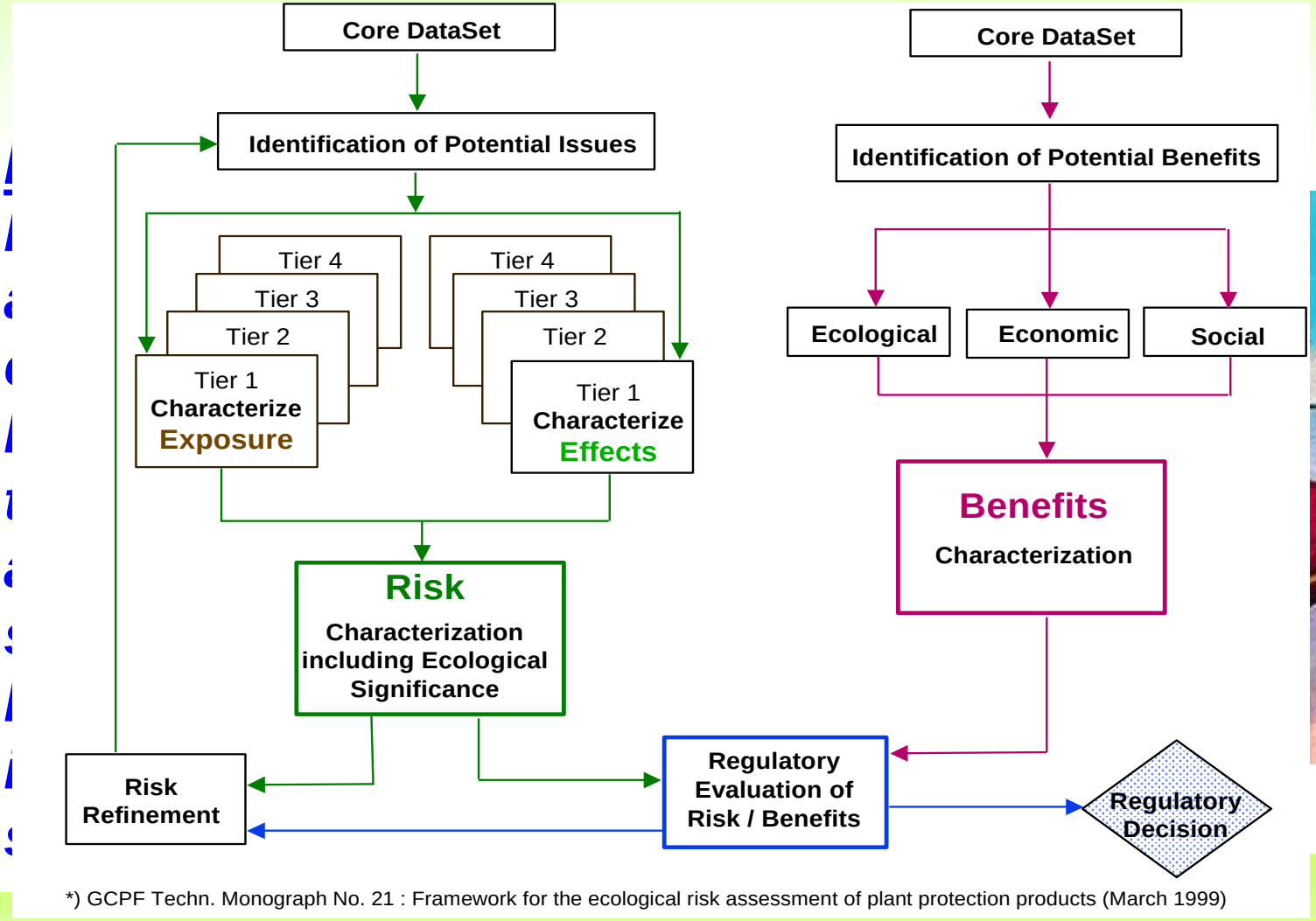
Beyond the ERA: Risk Management



*) GCPF Techn. Monograph No. 21 : Framework for the ecological risk assessment of plant protection products (March 1999)

Beyond the ERA: Risk Communication

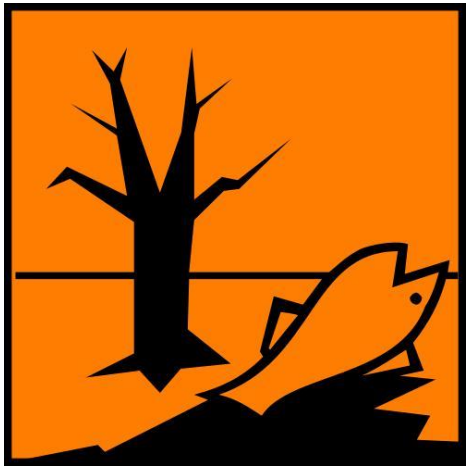
Importance of ERA for pesticides

1. **Amount?**
   - **> 500.000.000 kg each year are applied worldwide.**
   - **Other chemicals are produced in much greater amounts (e.g. yearly polyethylene production is 80.000.000.000 kg).**

pesticides

Importance of ERA for pesticides

2. **Aim**
   - **To eradicate (i.e. to kill) populations of undesired living organisms (weeds, fungi, arthropods or other invertebrates).**
   - **Conceived as toxicants: their toxicity is not a collateral effect, it is the main goal of their production!!**



Importance of ERA for pesticides

3. **Application**
   - **Pesticides are (almost) entirely destined to the environment.**
   - **Once again, the emission of pesticides into the (agro)ecosystems is not a collateral effect, they are intentionally released into the environment.**

Pesticides evolution

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Pesticides evolution

	Yesterday	Today
Chemicals	• High persistence • Medium-low toxicity • Generalist active ingredients • Few available chemicals	• Low persistence • Medium-high toxicity • Specific active ingredients • Many available chemicals
Application	• Few applications per year • High application rates • No control of application techniques • Poor operator and bystander protections	• Many products applied many times per year • Low application rates • Continuous engineering innovation in sprayers, nozzles, etc. • Great care in operator and bystander protections
Regulation	• No environmental concern in registration process • Almost free production and sell	• Detailed environmental risk assessment • Strictly regulated registration process, which allow specifically detailed uses (app.rates, timing, etc)

ERA - Considered organisms

- **Terrestrial Organisms**
  - -Birds and Mammals
  - -Bees
  - -Non-target arthropods - IPM
  - -Earthworms & other soil macrofauna
  - -Soil micro-organisms
  - -Non-target plants
- **Aquatic Organisms**
  - -Fish
  - -Aquatic invertebrates
  - -Algae and macrophytes

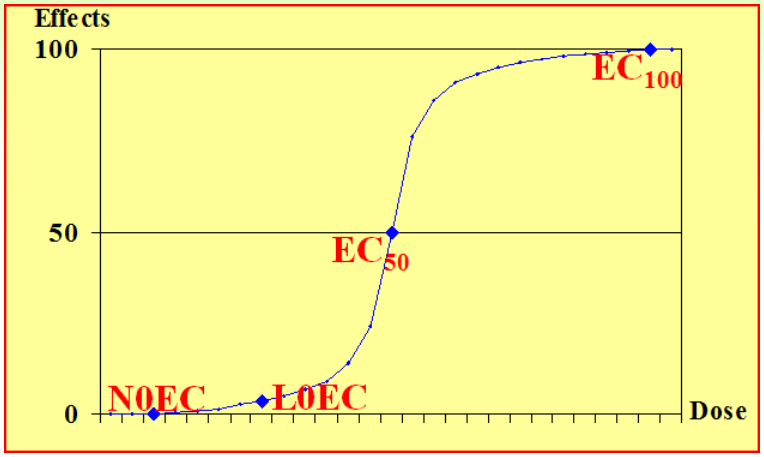
ERA - Guidelines

Terrestrial vertebrates	Birds and mammals	SANCO/4145/2000 (74 pp.)	
Aquatic organisms	Fish, aquatic invertebrates, algae, aquatic macrophyte	SANCO/3268/2001 (62 pp.)	
	Sediment organisms		
Terrestrial organisms	Bees	SANCO/10329/2002 (39 pp.)	
	Non-target arthropods		
	Soil organisms (earthworms and other soil macro-organisms)		
	Soil microorganisms		
	Non-target terrestrial plants		

ERA - Acute Toxicity Testing

Acute – short-term in laboratory,
defined & controlled conditions

- ✓ Range of test concentrations, doses, rates + control(s) or limit test
- ✓ Covers range 100 to 0 % effect (often, but not always mortality)
- ✓ Endpoints: LC/EC50 - LD50 – LR/ER50 (Conc which effects 50% of the test population)



-L= lethal; E= effect (e.g. reproduction, development)
-C= concentration; D= dose; R= application rate

May also derive NOEC/NOER/NOEL and LOEC

-NOEC highest concentration with no effect relative to the control
-LOEC - concentration above the NOEC

ERA – Chronic Toxicity Testing

Chronic – long-term lab studies, generally a requirement, may be triggered based on exposure or (acute) toxicity

- ✓ **Range of test concentrations (rates/doses) + control, maybe chosen by rangefinding or acute toxicity data, rarely done as limit tests**
- ✓ **Endpoints: NOEC/LOEC based on survival, growth, development, reproduction (ecologically relevant parameters)**

ERA - Semi-field/ Field Tests

- May have range of concentrations (dose response design) or applied under field conditions
- Endpoints focussed at population, community, ecosystem level – NOEC and/or NOAEC (No observed adverse effect concentration)
- Generally, compare treatments to control to determine whether any effects. If effects occur, what is the incidence and severity of effect and time to recovery
- Field studies are relevant for the conditions (region, climate) under which they were conducted. Need to extrapolate to other regions.

ERA - Field Studies

- ✓ **Long history in ecotoxicity testing, as high tier exposure/effects assessments**
- ✓ **Legislation protects of field populations/communities/ecosytsems**
- ✓ **Better simulation of exposure**
- ✓ **Effects on communities, species interactions, population dynamics, recovery**

ERA - Exposure

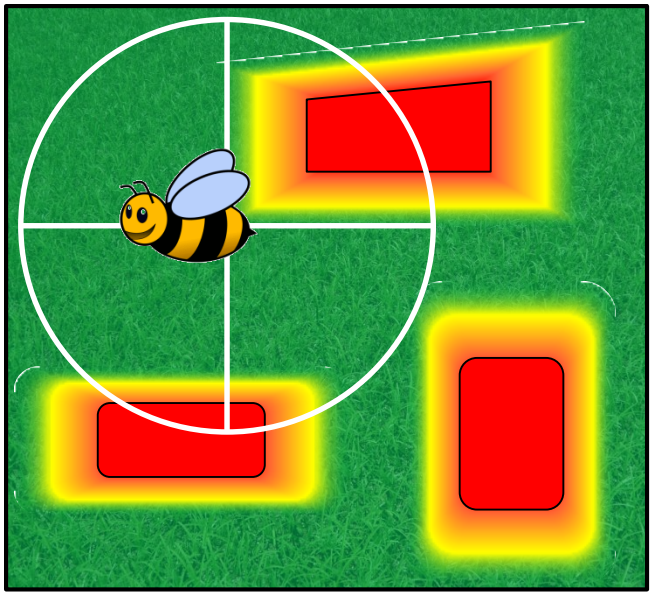
- **Direct (e.g. contact bees, non-target arthropods, non target terrestrial plants)**

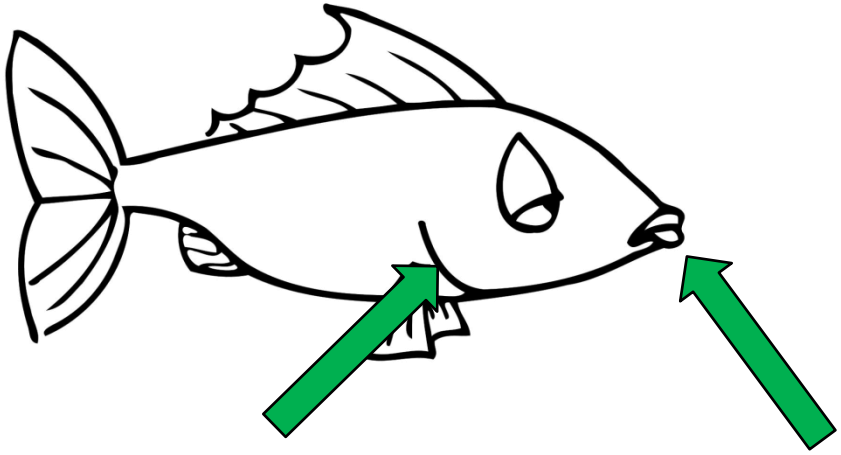
- **Indirect (e.g. birds and mammals, oral bees)**

- **Environmental (e.g. aquatic and soil organisms)**

How do organisms get exposed?

Exposure depend to a large extent on the compartment the organism is living in. Exposure in water is usually constant in space but brief in time (especially moving water bodies). On the contrary terrestrial organisms can be exposed to spatially heterogeneous conditions, sometimes for longer periods.





Respiration/contact

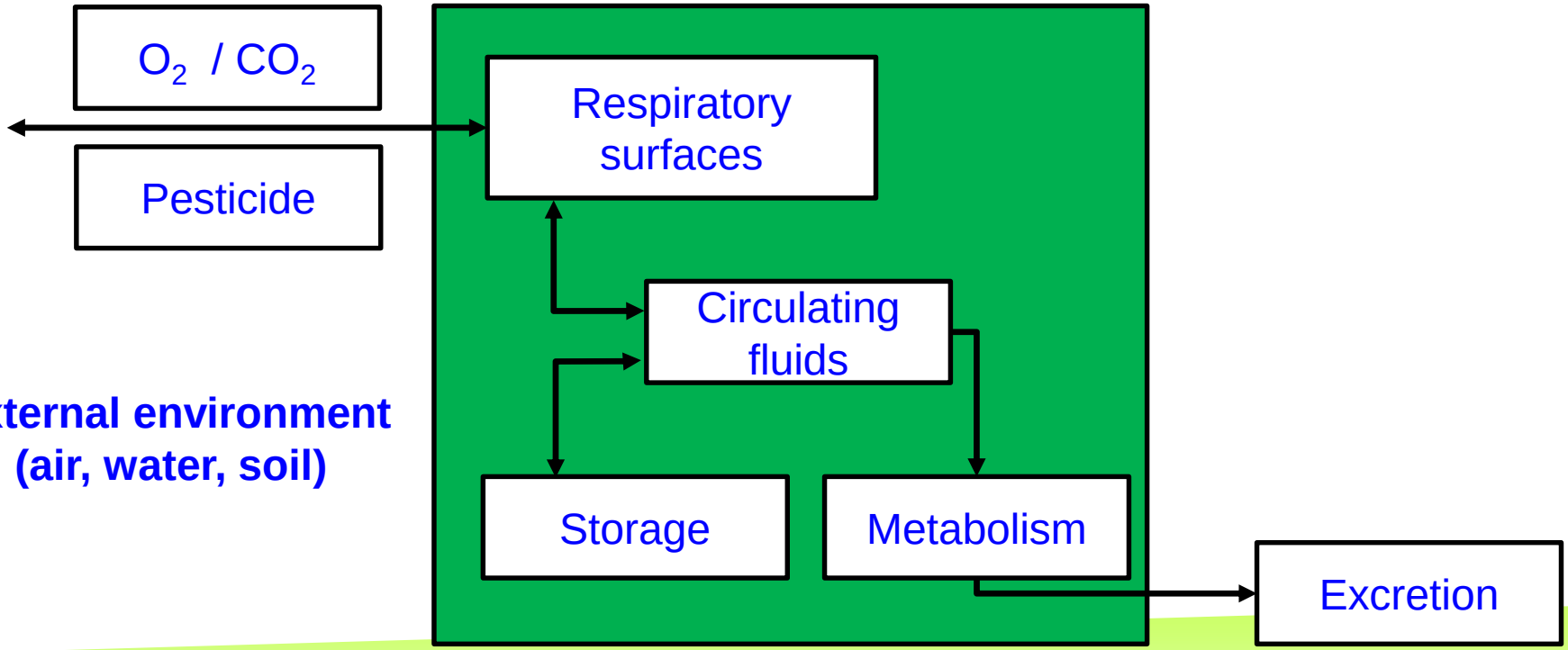
Food ingestion

The two main exposure routes for animals are food ingestion and contact/respiration.

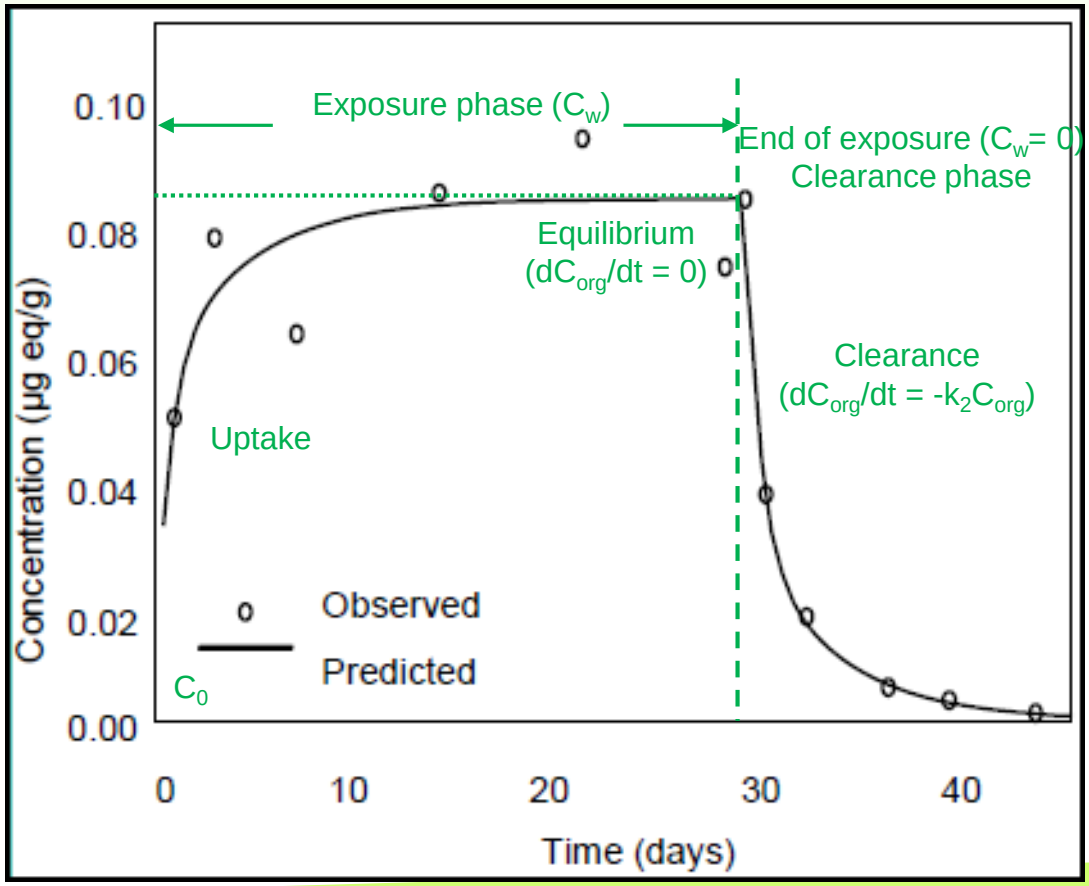
Bioconcentration

Definition

Indicate the increase of the concentration of a chemical in a living organism in relation to the **environment** (water, air, soil) where it is living. It occurs mainly through respiratory surfaces. It can be explained simply by physical-chemical partitioning.



Bioconcentration: saturation kinetics and clearance



Bioconcentration factor (BCF)

- BCF is the ratio between the concentrations of a chemical in the organism and in the medium at the **equilibrium** ($dC_{org}/dt = 0$).

$$\mathbf{BCF = C_{max} / C_w = k_1/k_2}$$

- BCF is dimensionless and represent the enrichment factor organism/environment due to reversible and passive partitioning processes. Therefore a relationship exists between BCF and partitioning coefficients.

Indeed, for hydrophobic chemicals in aquatic organisms:

$$BCF = L \cdot K_{ow}$$

Where L is the lipid fraction in the organism (around 5% for fish)

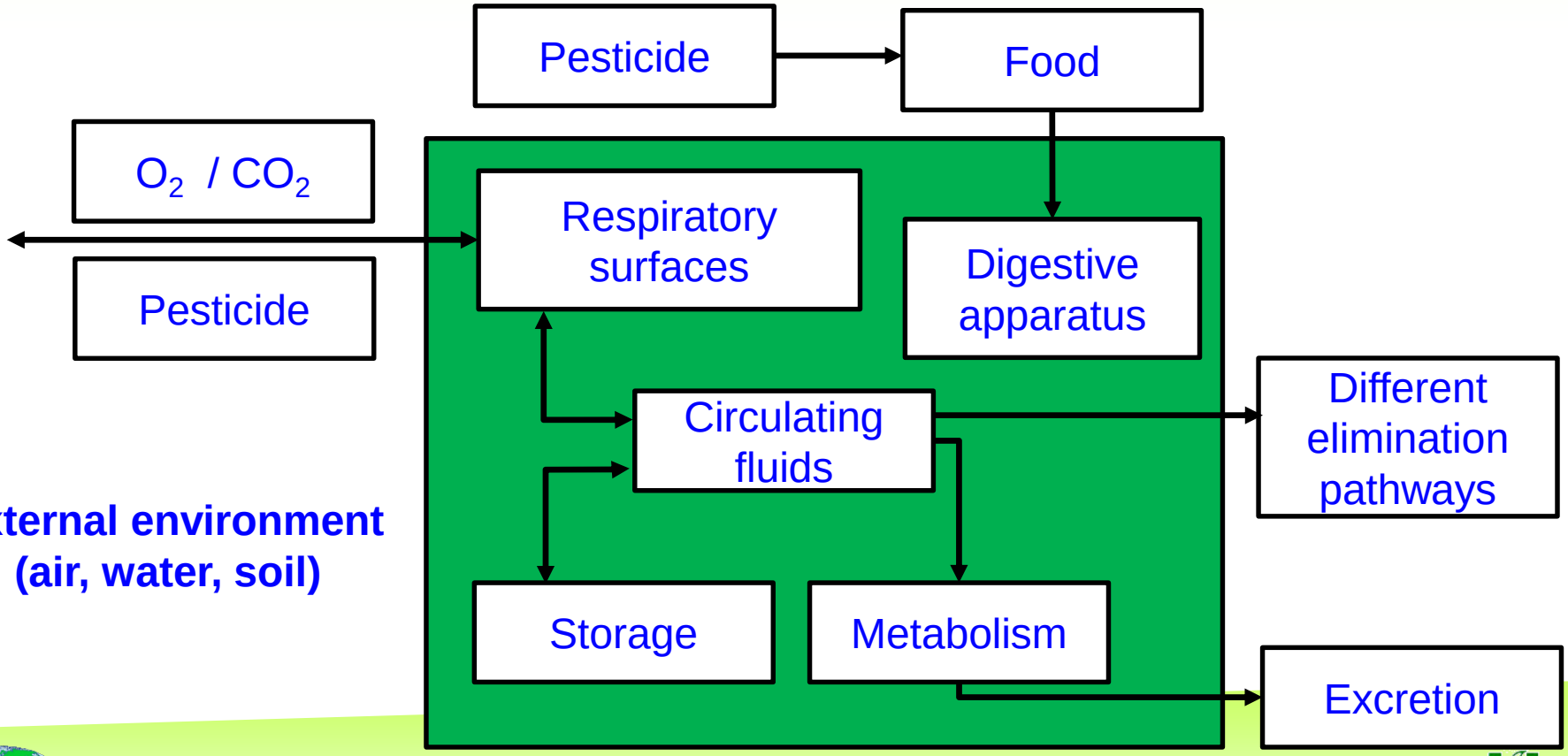
For terrestrial plants:

$$BCF = L \cdot K_{oa}$$

Bioaccumulation

Definition

Indicate the increase of the concentration of a chemical in a living organism through any possible intake route (mainly respiratory surfaces and food ingestion).

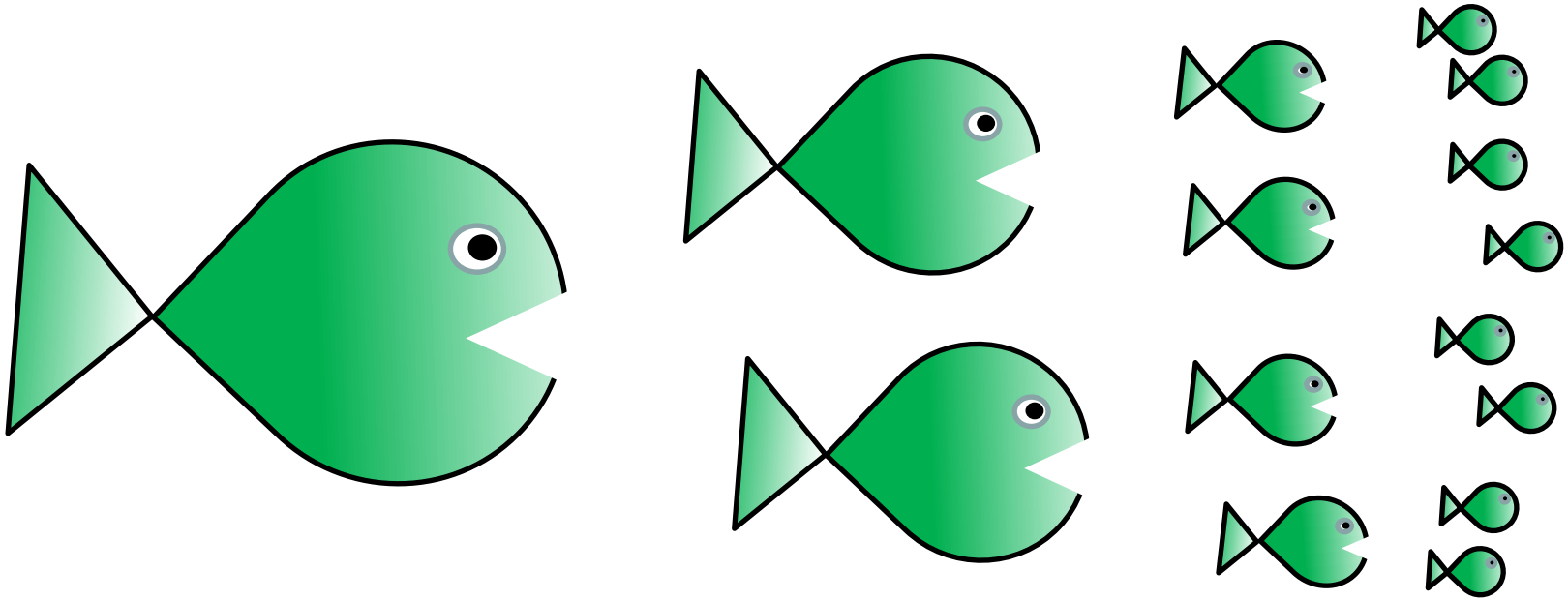


External environment (air, water, soil)

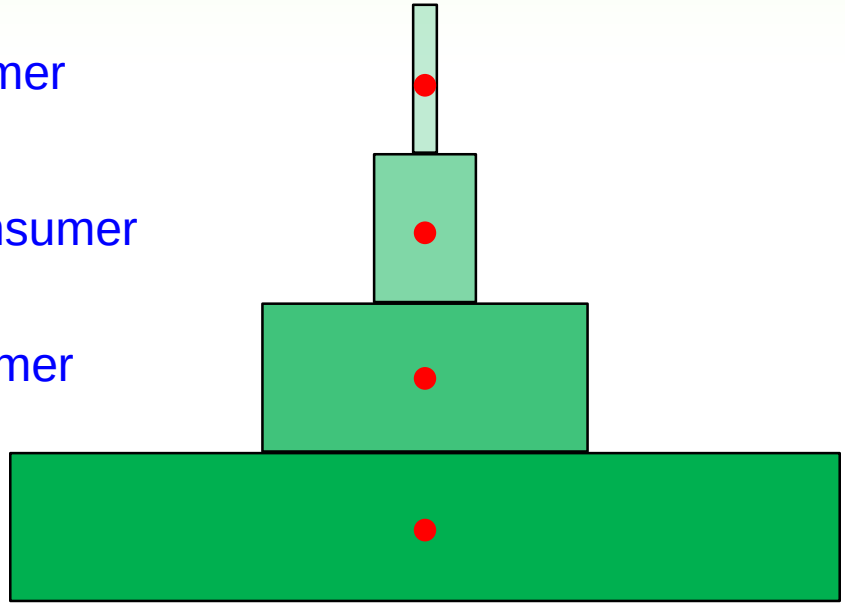
Biomagnification

Definition

Indicate the increase of chemical concentration from a lower to an higher trophic level, due to transfer through the **food chain**.



Biomagnification mechanism



If a certain chemical is almost entirely transferred from one trophic level to the other, the same amount (weight) of a pesticide can reach much higher concentrations at higher trophic level, due to a reduction of total biomass

ERA - Risk Characterisation

- **Toxicity Exposure Ratio:**

  TER = endpoint / exposure → acceptable if > Trigger

- **Hazard Quotient:**

  HQ = exposure / endpoint → acceptable if < Trigger

Trigger, indicated in the Annex VI of Directive 91/414, intended as safety factor

ERA- Tiered approach

TIER I → **Acceptable Risk** ✓

Potential Risk ↓

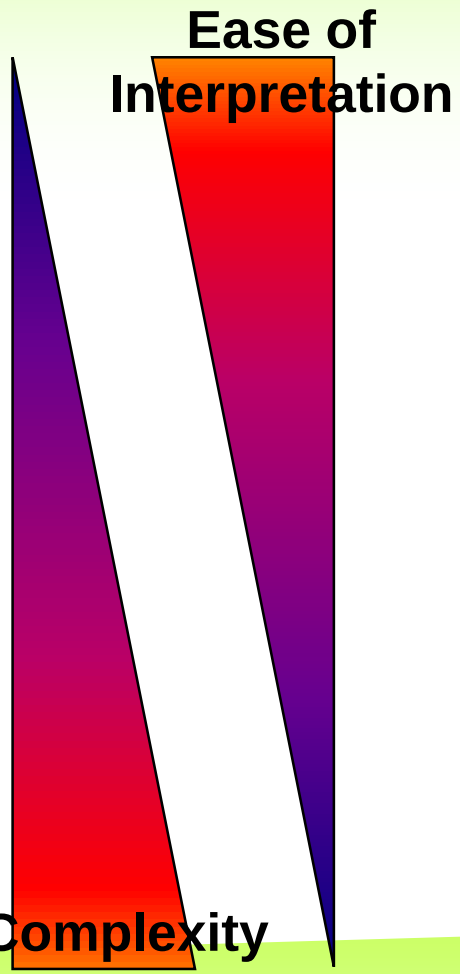
TIER II → **Acceptable Risk** ✓

Potential Risk ↓

TIER III → **Acceptable Risk** ✓

Potential Risk ↓

Risk Management



ERA ...nals

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Crop group	Crop species
Bare soil	All arable crops (BBCH < 10)
Bulbs and onion like crops	Bulbs (like tulips etc.), onions, garlic, shallots, etc.
Bush and cane fruit	Blackberry, dewberry, loganberry, raspberry, gooseberry, red and blackcurrant, etc.
Cereals	Wheat, barley, oats, rye, rice, millet, sorghum, triticale, etc.
Cotton	Cotton
Fruiting vegetables	Tomatoes, peppers, chilli peppers, aubergines, cucumber, gherkins, courgettes, melons, squashes, watermelons, etc.
Grassland	Grass

Crop	Indicator species	Shortcut value for acute assessment
Bare soils and hop	Small granivorous bird	24.7
Grassland	Large herbivorous bird	30.5
Bush and cane fruit	Small frugivorous bird	46.3
Orchards and ornamentals/nursery	Small insectivorous bird	46.8
Vineyard	Small omnivorous bird	95.3
Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, and sunflower	Small omnivorous bird	158.8
Cotton	Small omnivorous bird	160.3

× TER>Trigger?

Sunflower	Sunflower
Vineyards	Grape

Leafy vegetables	BBCH ≥ 50	Small granivorous bird "finch"	Serin (Serinus serinus)	3.8	8.2
Leafy vegetables	BBCH 10 - 49	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	10.9	24.0
Leafy vegetables	BBCH ≥ 50	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	3.3	7.2
Leafy vegetables	Leaf development BBCH 10-19	medium herbivorous/grani-vorous bird "pigeon"	Wood pigeon (Columba palumbus)	37.0	90.6
Leafy vegetables	BBCH 10 - 19	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	11.3	26.8
Leafy	BBCH ≥ 20	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	9.7	25.2
forage	- 49	Small granivorous bird "finch"	Linnet (Carduelis cannabina)	11.4	24.7
Legume forage	BBCH ≥ 20	Small granivorous bird "finch"	Linnet (Carduelis cannabina)	3.4	7.4
Legume forage	BBCH 10 - 49	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	10.9	24.0
Legume forage	BBCH ≥ 50	Small omnivorous bird "lark"	Woodlark (Lullula arborea)	3.3	7.2
Legume forage	Leaf development BBCH 21-49	medium herbivorous/granivorous bird "pigeon"	Wood pigeon (Columba palumbus)	22.7	55.6
Legume forage	BBCH 10 - 19	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	11.3	26.8
Legume forage	BBCH ≥ 20	Small insectivorous bird "wagtail"	Yellow wagtail (Motacilla flava)	9.7	25.2
Maize	BBCH 10 - 29	Medium granivorous bird "gamebird"	Partridge (Perdix perdix)	3.0	6.6
Maize	BBCH 30 - 39	Medium granivorous	Partridge (Perdix	1.5	3.3

TIER III

Potential Risk

TER>Trigger?

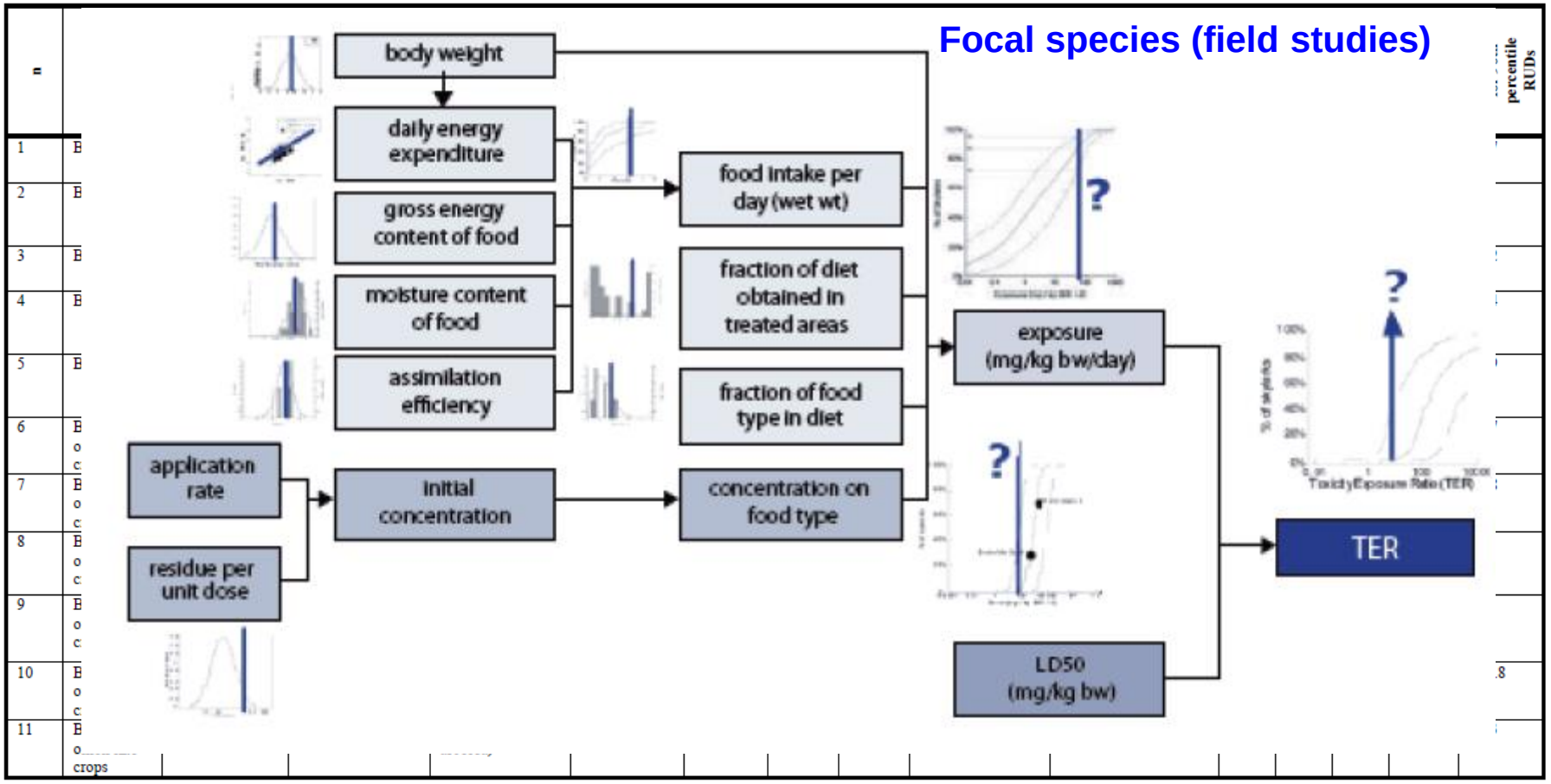
D ... $_{90}$)

ERA- Example: birds and mammals

TIER III

Potential Risk

$$TER = \frac{LD_{50}}{DDD}$$



ERA- Example: aquatic organisms

TIER I

↓ Potential Risk

TIER II

↓ Potential Risk

TIER III

↓ Potential Risk

Risk Management

$$TER = \frac{endpoint}{PEC_{SW}}$$

- **PEC_{SW} Step 1**
- **PEC_{SW} Step 2,3,4**

- **Fish: LC_{50} (acute), NOEC (chronic)**
- ***Daphnia*: LC_{50} (acute), NOEC (chronic)**
- **Algae: EC_{50} (chronic)**
- **Aquatic plants: EC_{50} (chronic)**

ERA- Example: bees (old guidance)

$$HQ = \frac{\text{exposure}}{\text{toxicity}}$$

$$OHQ = \frac{\text{application rate (g/ha)}}{\text{oral } LD_{50} \text{ (µg/bee)}}$$

$$CHQ = \frac{\text{application rate (g/ha)}}{\text{contact } LD_{50} \text{ (µg/bee)}}$$

ERA- Example: Non-Target Arthropods

in-field exposure = Application rate * MAF

off-field exposure = Application rate * MAF * (drift factor / vegetation distribution factor)

TIER I

↓ Potential Risk

$$HQ = \frac{exposure}{toxicity}$$

TIER II

$T_{1/2}$: Spray Interval	MAF after n applications, where n =							
	1	2	3	4	5	6	7	8
1 : 16	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
1 : 8	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
1 : 4	1.0	1.1	1.1	1.1	1.1	1.1	1.1	1.1
1 : 2	1.0	1.3	1.3	1.3	1.3	1.3	1.3	1.3
1 : 1	1.0	1.5	1.8	1.9	1.9	2.0	2.0	2.0
2 : 1	1.0	1.7	2.2	2.6	2.8	3.0	3.1	3.2
2.3 : 1	1.0	1.7	2.3	2.7	3.0	3.2	3.4	3.5
4 : 1	1.0	1.8	2.5	3.1	3.6	4.1	4.4	4.7
6 : 1	1.0	1.9	2.7	3.4	4.0	4.6	5.1	5.5
8 : 1	1.0	1.9	2.8	3.5	4.2	4.9	5.5	6.0
16 : 1	1.0	2.0	2.9	3.8	4.6	5.4	6.2	6.9

Basic drift values for one application
Ground deposition in % of the application rate (90th percentiles)

Distance	Field crops	Fruit crops		Grapevine		Hops	Vegetables Ornamentals Small fruit		Field crops
[m]		Early	late	Early	late		Height < 50 cm	Height > 50 cm	Water > 900 l/ha
1	2.77						2.77		4.44
3		29.20	15.73	2.70	8.02	19.33		8.02	
5	0.57	19.89	8.41	1.18	3.62	11.57	0.57	3.62	0.18
10	0.29	11.81	3.60	0.39	1.23	5.77	0.29	1.23	0.05

- **In-field and off-field exposure (correction factor of 10 for off-field)**
- **Trigger = 2**

ERA- Example: NTA

TIER II

↓ Potential Risk

$$HQ = \frac{\text{exposure}}{\text{toxicity}}$$

TIER III

- **Tier 2 on two standard species:**
  - **Aphidius rhopalosiphi (parasitic wasp)**
  - **Typhlodromus pyri (predatory mites)**

<u>And</u> additional species, one for in-field unacceptable risk, two for off-field unacceptable risk (Chrysoperla carnea, Poecilus cupreus, Coccinella septempunctata, Orius laevigatus, ….)

- **Extended laboratory test (leaf disc), effects on mortality and reproduction**
- **In-field and off-field exposure (correction factor of 5 for off-field)**
- **Trigger = 1**

ERA- Example: NTA

TIER III

↓ Potential Risk

$$HQ = \frac{\text{exposure}}{\text{toxicity}}$$

Risk Management

- **Tier 3 on species showing an unacceptable risk at Tier 2**
- **Aged residues studies, effects on mortality and reproduction**
- **Semi-field and field test, recolonisation**
- **In-field exposure (off field source of recolonisation)**

↓

- **Mitigation measures to assure an acceptable off-field risk**

ERA- Example: Earthworms and soil macro-organisms

TIER I

↓ Potential Risk

TIER II

↓ Potential Risk

TIER III

↓ Potential Risk

Risk Management

$$TER = \frac{endpoint}{PEC_{Soil}}$$

- **Maximum PEC_{Soil}**
- **PEC_{Soil} TWA**
- **Field studies**

- **Earthworms, NOEC (chronic)**
- **If unacceptable risk for NTA at Tier 1, if data on Aphidius and Typhlodromus are missing, if product is applied directly to soil, tests on Folsomia candida and Hypoaspis aculifer, NOEC (chronic)**

ERA- Example: soil micro-organisms

- **Tests on soil nitrogen transformation (carbon mineralisation not required any more)**
- **Trigger: 25% effect after 100 days**
- **Direct comparison with application rate or PEC_{soil} (depending on the test outcome)**

ERA- Example: Non-Target Terrestrial Plants

TIER I

↓ Potential Risk

TIER II

$$TER = \frac{endpoint}{AR * drift}$$

× **Drift values**

Basic drift values for one application Ground deposition in % of the application rate (90th percentiles)									
Distance	Field crops	Fruit crops		Grapevine		Hops	Vegetables Ornamentals Small fruit		Field crops
[m]		Early	late	Early	late		Height < 50 cm	Height > 50 cm	Water > 900 l/ha
1	2.77						2.77		4.44
3		29.20	15.73	2.70	8.02	19.33		8.02	
5	0.57	19.89	8.41	1.18	3.62	11.57	0.57	3.62	0.18
10	0.29	11.81	3.60	0.39	1.23	5.77	0.29	1.23	0.05

pesticide

species

seedling

Ma