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Assessment methodology/procedure for applications for minor uses under 1107/2009 in the Netherlands

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Agenda

- Definition minor use
- Assessment scenario's
- Dutch specific procedure
- Risk envelope (toxicology)

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Definition “minor use”

General:

Use of a plant protection product in a particular Member State on plants or plant products which are:

- a) not widely grown in that Member State, or
- b) widely grown to meet an exceptional plant protection need

Netherlands: Decision tree to determine a minor use (available at www.ctgb.nl).

- a) Crop area
- b) Exceptional plant protection need

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Authorisation scenario's minor use

- I New authorisation (zonal approach)
- II Extended authorisation for multiple countries (zonal approach)
- III Extended authorisation in NL only (optional national approach)

- Assessment of efficacy and fytotoxicity not obligatory.
- Risks for the user!

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Scenario III – Extension of an authorisation in NL only

- Not zonally
- dRR not necessary
- Risk envelope approach
- Authorisation without further assessment if possible (within risk envelope).
- Assessment framework applied for the most recent full risk assessment of the PPP
- Short assessment time

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Indicative time for the assessment

- Extension not within the risk envelope: 28w
- Extension within the risk envelope: 16 w
- Helpdesk advice: 8 weeks

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Plant protection products Risk assessment (toxicology)

Risk Assessment in basic is a simple method,
based on two values:

1. Health-based acceptable exposure level
(reference dose)
2. Estimated or measured exposure

Acceptable Exposure Level \geq Exposure





Risk envelope/assessment (toxicology)

Risk envelope:

Assessment of the most critical use.

Documentation:

- Guidance document on the preparation and submission of dossiers for plant protection products according to the “risk envelope approach”. (SANCO/11244/2011)
- Dutch Evaluation manual version 1.1



Risk envelope/assessment (toxicology)

Exposure assessment for:

- Operator
- Worker
- Bystander
- Consumers





Exposure assessment

Tiered approach

Basis: Generic or specific models

Refinement:

Measurement of actual exposure for the application under consideration





Exposure assessment

1st step: Application method and equipment

- Indoor v.s. outdoor
- Mechanical upward or downward spraying.
- Manual spraying upward or downward.
- Other application types (seed treatment, dipping, dripping, ect.)





Exposure assessment Operators

Activity / Formulation		Scenario	Preferred generic model	
			<i>dermal</i>	<i>respiratory</i>
mixing and loading	Liquid	mechanical	EUROPOEM I	EUROPOEM I
		manual	EUROPOEM I	NL model
	Powder ¹	mechanical	NL model	NL model
		manual	NL model	NL model
	Granule ²	mechanical	NL model	NL model
		manual	NL model	NL model
Spraying in the field	mechanical upward		EUROPOEM I	EUROPOEM I
	mechanical downward		EUROPOEM I	EUROPOEM I
	manual upward		German model ⁴	German model ⁴
	manual downward		UK model	UK model
Spraying in greenhouses	manual upward and downward ³		NL greenhouse model	NL greenhouse model





Exposure assessment Operators

- Critical parameter for risk envelope:
 - EUROPOEM I: dosage
 - German model: dosage
 - UK POEM: dosage and application volume
 - A non standard application scenario, the most suitable model and parameters are selected



Exposure assessment Operators



Not within risk envelope, further assessment is necessary
(with the greenhouse model)





Exposure assessment Operators

Example 2:

Authorisation in ornamentals (indoor spray application).

Application request in ornamentals, cabbage (indoor dripping, drench)

Within risk envelope, further assessment is not necessary.





Exposure assessment Worker

- Models used
 - EUROPOEM II and NL model (greenhouse)

Critical parameters:

- Dosage
- TC factor (transfer coefficient = residue exchange from plant to hands or body)





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TC factor for roses is higher

Not within risk envelope, further assessment is necessary
for the worker





Exposure assessment Worker

- Example 2:
Authorisation in roses (indoor spray).
Application request in apples (outdoor spray).

TC factor for roses is higher

Within risk envelope, further assessment is not necessary for the worker





Summary

Application within the risk envelop:

- Not possible to compare some intended uses.
- Dosage (application volume)
- Specific factors (e.a. TC value for worker exposure, some cases time of application, etc.)





Conclusion

Application within risk envelope → fast administrative procedure

Application not within risk envelope → further assessment is necessary (not within risk envelope does not mean that there is a risk!)





Questions ?

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Thank you for your attention!

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