French Agency for Food, Environmental
and Occupational Health & Safety

Dose expression in EU efficacy assessment, Dose expression in France

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irst steps from a French methodological working group: to facilitate LWA implementation in France

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=> CEB: French Committee on Biological trials.

DOSE EXPRESIONS currently registered in high growing crops (vertical spraying) in national decisions

/ha ground – DK, FI, LT, CZ, HU, PL, SI, SK, UK, FR

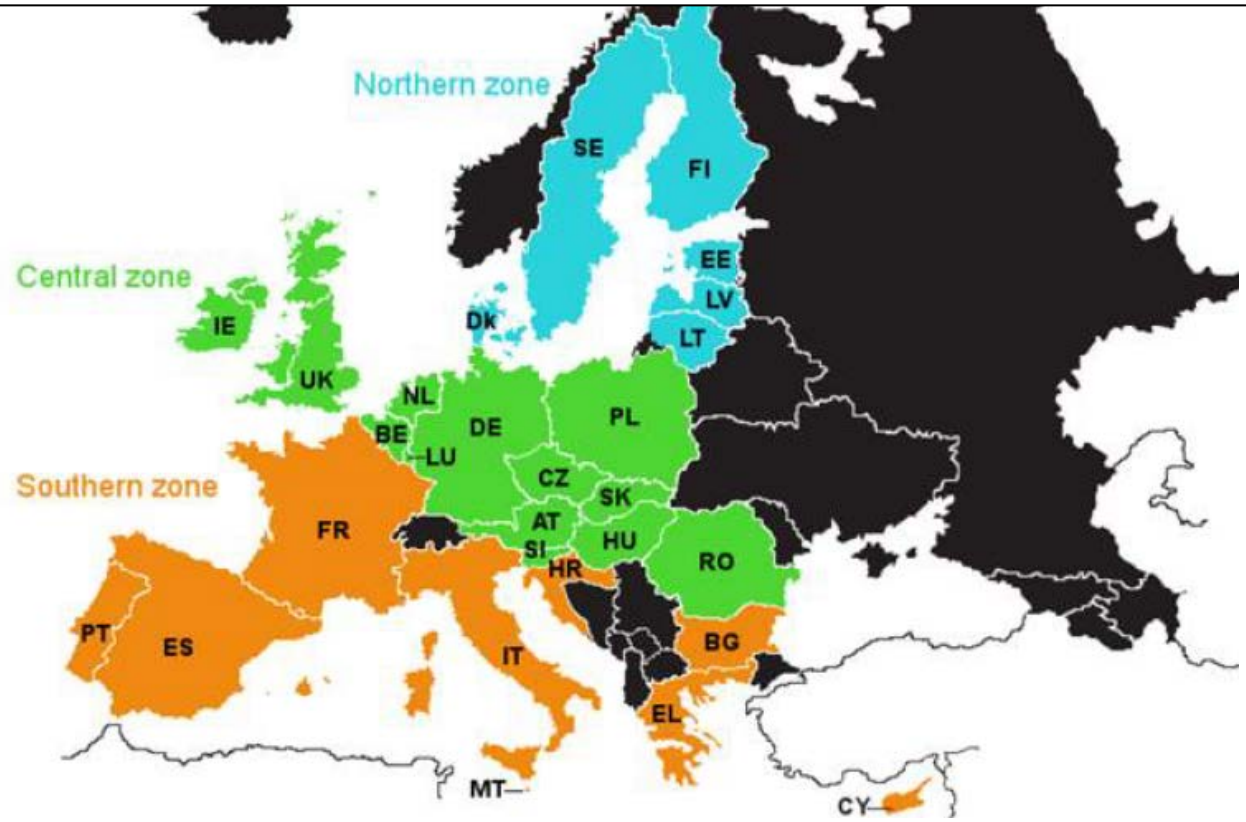
/hL (concentration %) – ES, EL, HR, IT, PT, DK, FI, LT, NL

/ha and m canopy height (CH) – DE, AT

/10 000 m^3 tree row volume (TRV) - *CH*

/10 000 ² leaf wall area (LWA) –BE, …

variability

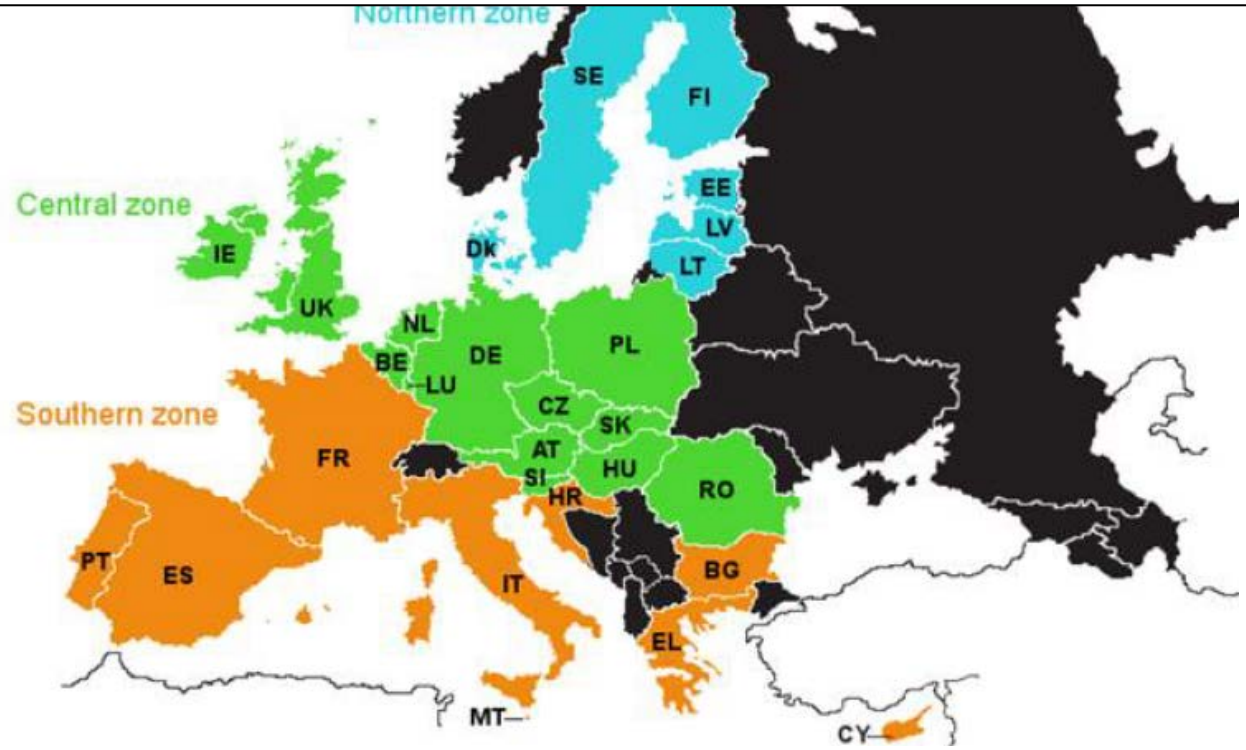


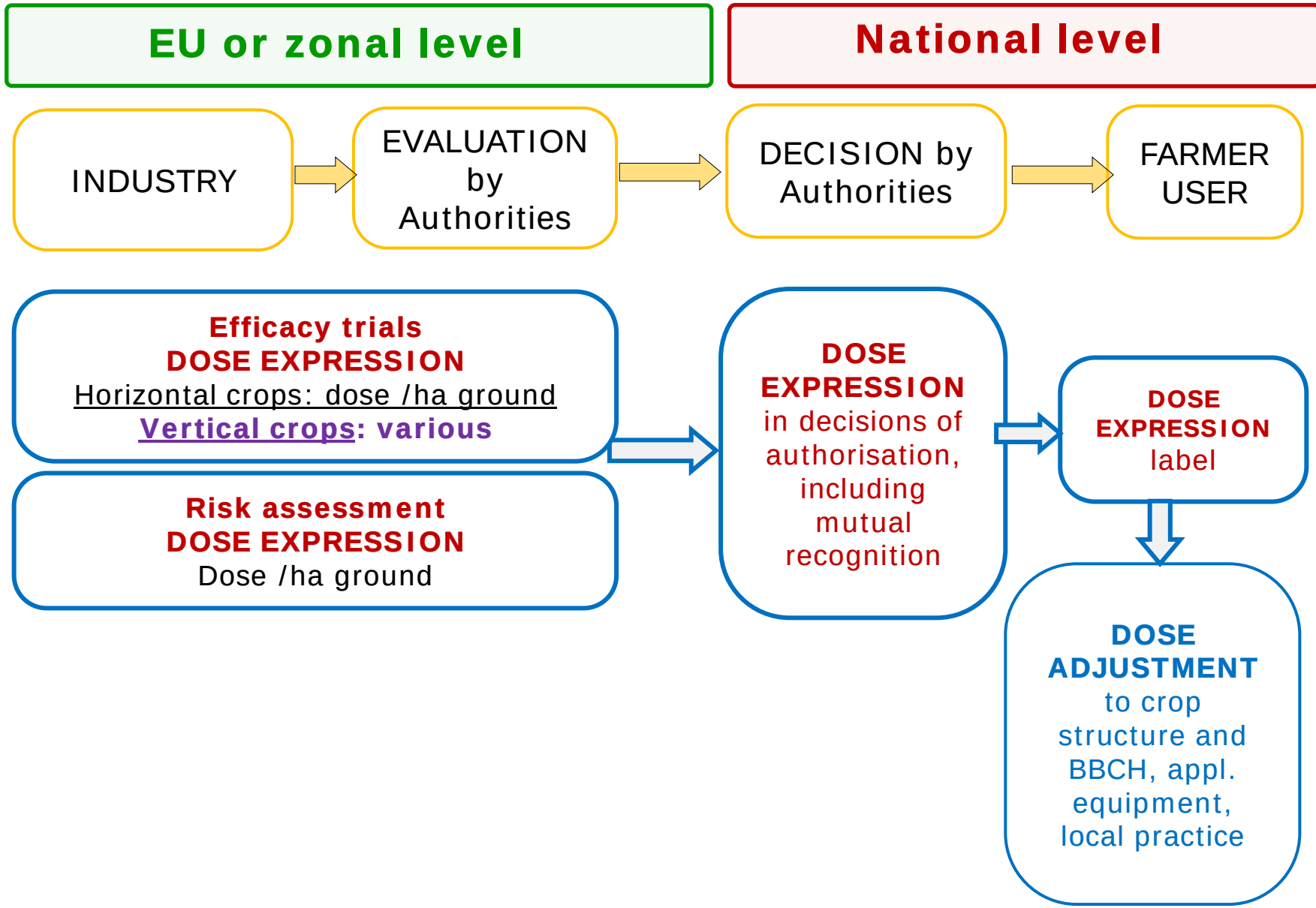
THE PRINCIPLE OF ZONAL ASSESSMENT, and MUTUAL RECOGNITION

NEED OF HARMONISED APPROACH IN THE ASSESSMENTS

The assessment should be comprehensible for all concerned Member States.

NEED OF HARMONISED DOSE EXPRESSION in high growing crops




EU or zonal level
National level
INDUSTRY
EVALUATION by Authorities
DECISION by Authorities
FARMER USER
Efficacy trials
DOSE EXPRESSION
Horizontal crops: dose /ha ground
Vertical crops: various
Risk assessment
DOSE EXPRESSION
Dose /ha ground
DOSE EXPRESSION in decisions of authorisation, including mutual recognition
DOSE EXPRESSION label
DOSE ADJUSTMENT to crop structure and BBCH, appl. equipment, local practice

Principle of EU evaluation of the minimum effective dose

The maximum registered rate should be:

« minimized »
Efficacy trials comparing different doses => not apply unuseful product

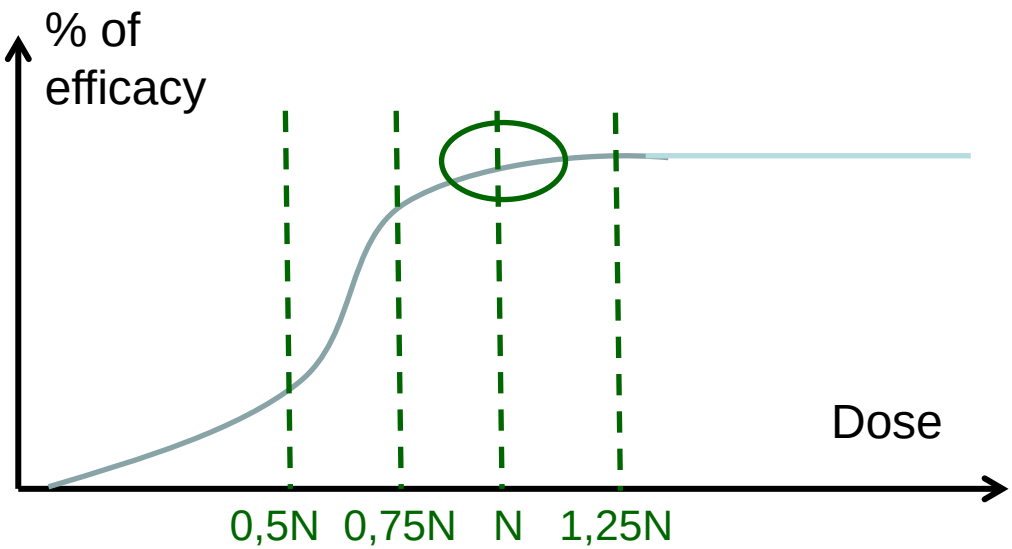
AND

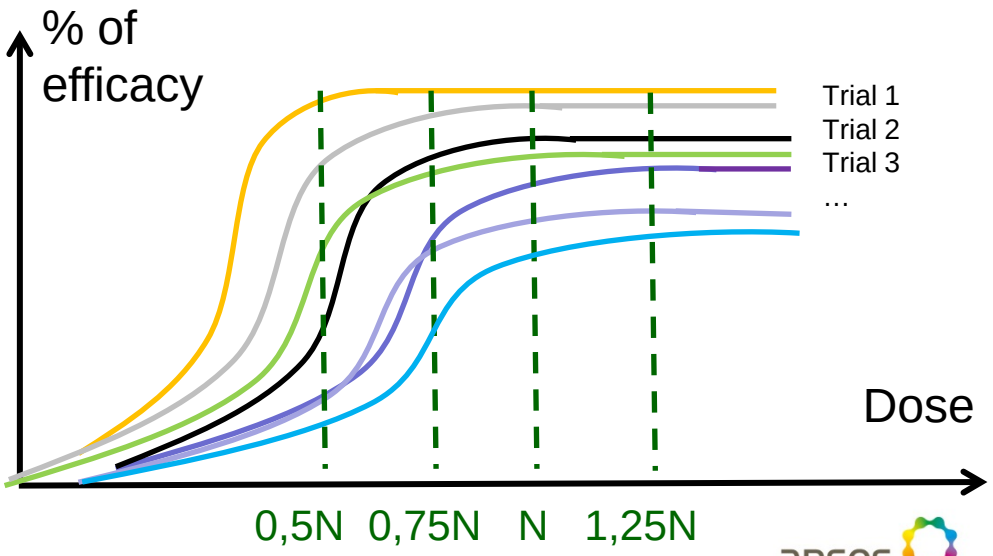
« efficient » in all situations, including on :

- full vegetative stages,
- intensive crops,
- at national or zonal level,
- under high disease / pest infestations

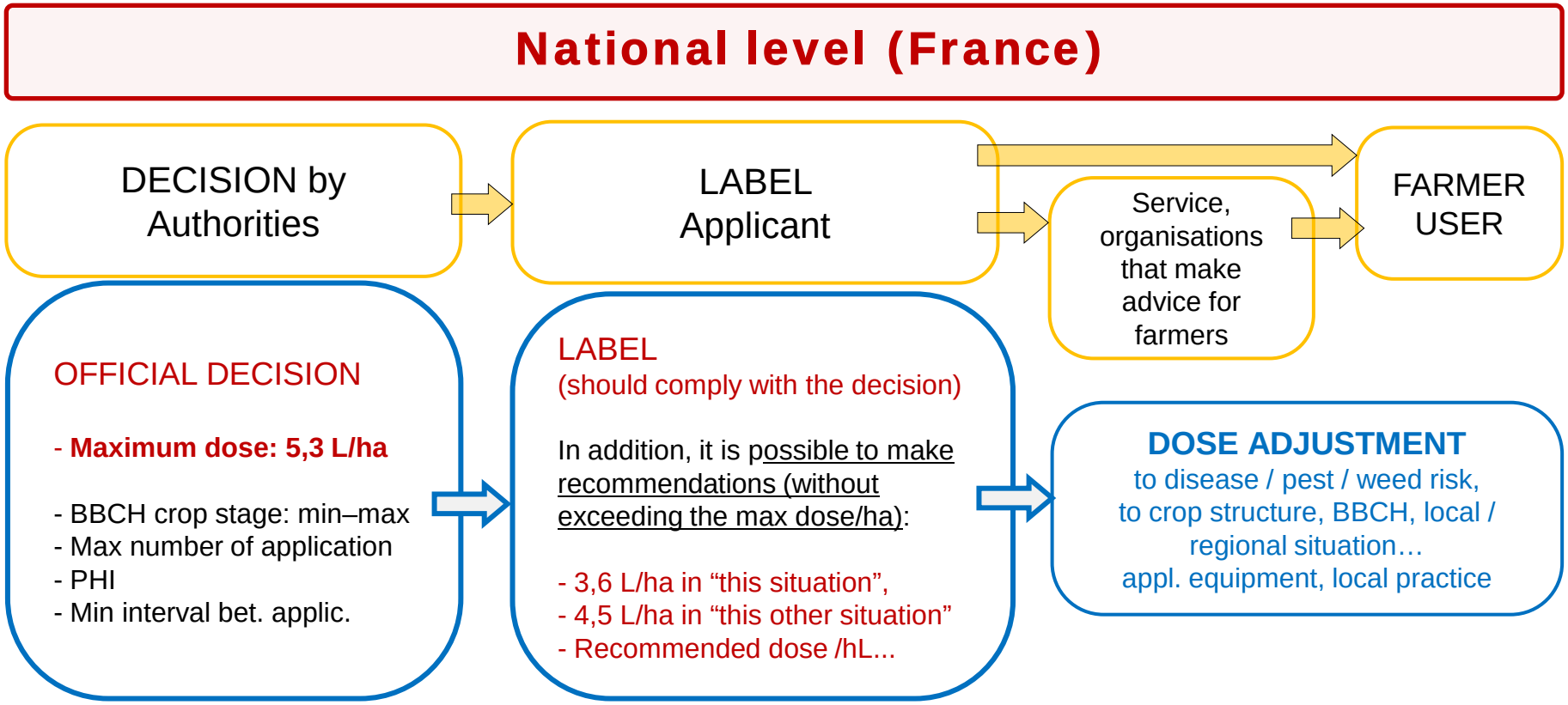
EPPO 1/225 Minimum effective dose

In principle, the applicant ask for the most efficient dose, but other aspects (other than efficacy) are involved: e.g. risk limitations (toxicology, ecotox, efate, residues…)…





France: background about dose expression



In practice: the max dose/ha can be understood at a “fixed dose”, and therefore “not adjusted”.

France: Example

Zonal Efficacy assessment

Crop and/ or situation	Countries	**Pests or Group of pests controlled**	**method kind** (f-h)	**growth stage & season** (j)	**nu mb er**	min interval betw. applic. (days)	**L product/ ha** a) **max. rate** per appl.	**g a.s./ha** a) **max. rate** per appl.	**Water L/ha** min/ max
Stone fruits: **Almond**, Apricot, Cherry, Peach, Nectarine, Plum	BG, HR, EL, CY, FR, IT, SP, PT	Monilia sp MONISP	Spraying Foliar application	BBCH 57-89	6	5	8 L/ha	50 – 100 g/ha	500 / 1500

Decision (national)

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)
12103203 Amandier*Trt Part.Aer.*Monilioses	**8 L/ha**	**6/an**	entre les stades BBCH 57 et BBCH 89	3
Culture palissée : dose d'application de 2,6 L/ha et par mètre de hauteur de v Intervalle minimum entre les applications : 5 jours.				

Label

Table with « legal » conditions of use

Label recomendations (in the text):
4,0 L/ha at these « crop stages »,
6,0 L/ha in function of disease pressure, meteorological conditions, eventual tank mix.

France: Dose expressions

Pome fruits

Project for ccl of the assessment

Dose /hL → Max dose /ha ground (+ Dose /hL) → Max dose /ha ground (+ Dose /LWA)

- Principle of the dose /hL: water volume adapted to the foliar area to be sprayed.
- By definition, the dose /hL is based on high water volumes = **till run-off**.

- Issue:
  - New spraying equipments delivering **constant and low water volumes**: growers apply the dose they was applying before in **1000 L/ha** into a volume of e.g. 300 L/ha (they « concentrate »).

Grape

Project for ccl of the assessment

Max dose /ha ground → Max dose /ha ground (+ Dose /LWA)

First steps from a French methodological working group: to facilitate LWA implementation in France

VERONIQUE MIRONET,
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CEB working group, on LWA dose expression on high growing crops

Végéphyl, Association for plant health (formerly AFPP)
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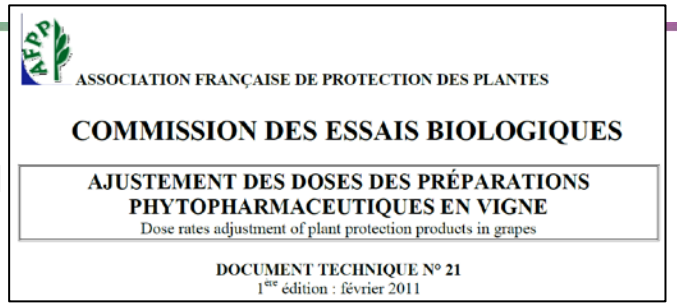

ASSOCIATION FRANÇAISE DE PROTECTION DES PLANTES

COMMISSION DES ESSAIS BIOLOGIQUES

AJUSTEMENT DES DOSES DES PRÉPARATIONS PHYTOPHARMACEUTIQUES EN VIGNE
Dose rates adjustment of plant protection products in grapes

DOCUMENT TECHNIQUE N° 21
1ère édition : février 2011

CEB Working group: about 30 persons,
from scientific, technical institutes, PPP companies, testing facilities involved in efficacy trials, authorities.

Animators:

IFV, French Wine and Vine Institute,
Sébastien Codis

IRSTEA, National Research Institute of Science and Technology for Environment and Agriculture,
Mathilde Carra

CTIFL, Technical Institute for fruits and vegetables
Florence Verpont

Members belonging to authorities

French Agency for Food, Environmental and Occupational Health & Safety,
Efficacy assessment unit,
Véronique Mironet, Laurent Thibault

French ministry of Agriculture
Ludovic Warangot

CEB working group, on LWA dose expression on high growing crops

Objectives: **Propose technical rules to facilitate the implementation of the LWA dose expression**

In marketing authorization applications:

1) How to **convert the LWA dose** used for efficacy assessment into a maximum dose /ha ground, required for risk assessments?

2) Provide a **methodology** on the specificities of making **field efficacy trials in LWA**

- **Reference products**
- **LWA minimum (at the beginning of the season)?**

In practice, for field use:

3) Propose a way to convert the current maximum dose rate /ha ground (and/or the new products in LWA in the future) in **adjusted doses**, easily usable by growers, with a simple abacus, or a simple tool.

1) How to **convert the LWA dose** used for efficacy assessment into a maximum dose /ha ground, required for risk assessments?

GAP table = Conditions of use of the product

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/or situation** (crop destination/ purpose of crop)	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					Method/ Kind	Timing/ Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	**L product/ ha** a) **max. rate** per appl. b) max. total rate per crop/season	**g a.s./ha** a) **max. rate** per appl. b) max. total rate per crop/season	**Water L/ha** min/ max		
Zonal uses													
1	BG, EL, ES, FR, IT, PT	Wine grapes (VITVI), table grapes (VITVI)	F	*Plasmopara viticola* (PLASVI)	Hydraulic sprayer with/without air assistance Atomizer	BBCH 13-71	a) 2 b) 2	10	a) 1,8 b) 3,6	a) 1020 b) 2040	100 - 1000	56	1,0 L product / 10 000 m² of LWA

Risk assessment
Max dose /ha ground

LWA max / ha ground: 18 000 m²
(just for the example)

Efficacy
Dose in LWA

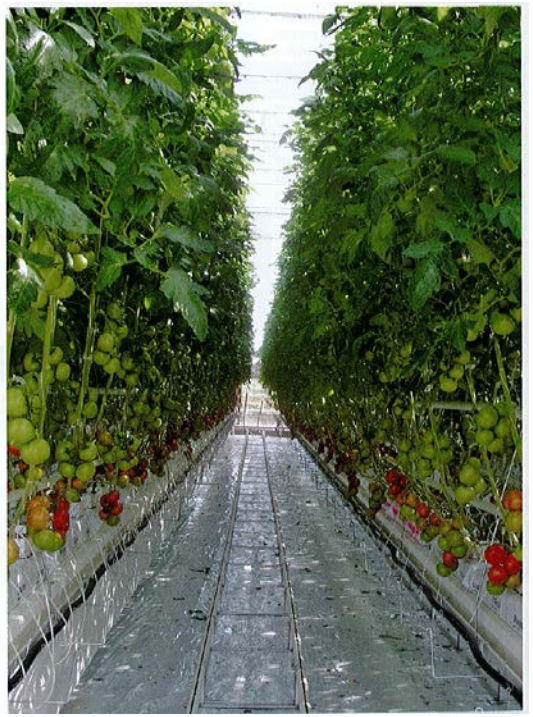
Végéphyl
Association pour la santé des végétaux

Example of the Belgian document

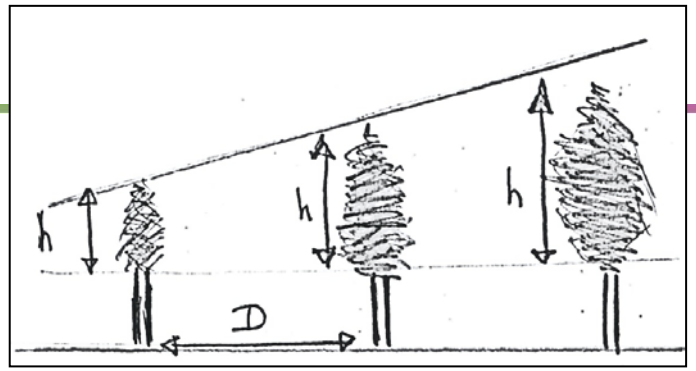
ANNEX IV – STANDARD CONVERSION FACTORS for all dossier aspects (efficacy/tox/ecotox/fate)

BE Conversion factors reflecting the standard crop cultivation systems in Belgium and the LWA/ground surface ratio

Crop	distance between rows (in m)	treated height of the plants (in m)	ha Leaf Wall Area / ha ground surface
apple, pear	3.5	3	1.7
cherry, plum, peach	3.5	3	1.7
grape, kiwiberry	2.2	2	1.8
hop	2.8	5	3.6
raspberry, red, black, white currants, gooseberry, blackberry, blueberry (outdoor and under protection)	2	2	2.0
peppers (under protection)	1.6	2	2.5
tomato (under protection)	1.6	2	2.5
aubergine (under protection)	1.6	2	2.5
cucumber (under protection)	1.6	2	2.5
gherkin (under protection)	1.6	1.5	1.9
courgette (under protection)	1.6	1.5	1.9
melon (under protection)	1.6	2	2.5
climbing bean (under protection)	1.6	2	2.5



Végéphyl Association pour la santé des végétaux



In practice, for field use:

3) Propose a way to convert:

Old products

Max dose /ha ground
(+ Dose /hL for orchards)

Future products

Max dose /ha ground
(+ Dose /LWA)

Adjusted doses easily usable by growers, and should ensure a good level of protection:

- including LWA approach (treated height, inter-row spacing),
- also can include other relevant aspects (BBCH crop stage, a crop width indicator, spraying equipment…)

Example (**fictive numbers**)

Max dose /ha ground
(risk assessments)

Dose in L or kg/ha ground		Treated height			
		Inferior to 1 m	1 m – 1,3 m	1,3 m – 1,6 m	Superior to 1,6 m
Inter-row spacing	1 to 1,60 m	1 kg/ha	1,3 kg/ha	1,5 kg/ha	**1,8 kg/ha**
	1,60 to 2,5 m	0,7 kg/ha	1,1 kg/ha	1,3 kg/ha	1,5 kg/ha
	Superior to 2,5 m	0,5 kg/ha	0,9 kg/ha	1,1 kg/ha	1,3 kg/ha

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Association pour la santé des végétaux

- Reference product

EPPO 1/214
Principle of
acceptable efficacy

Which dose to apply for the reference product?
- keep testing it in a dose per hectare?
- convert the registered dose in LWA. If yes how to convert?

Function of the reference product
- A product already on the market, with a well-know efficacy on the target pest, preferably with a similar mode of action,
- It is a positive control; it serves to valid the trial,
- It serves for efficacy comparison accross trial series (« test product » compared to the « reference product »)

- LWA minimum?

To be related to minimum treated high
(1 nozzle: about 35 cm).

Plot	Dose
Untreated control	-
Test Product	0,5 L/ 10 000 m² LWA
Test Product	0,75 L/ 10 000 m² LWA
Test Product	1,0 L/ 10 000 m² LWA
Reference product	Max dose /ha ground? Dose converted in LWA?

CEB working group, on LWA dose expression on high growing crops

- The work is on-going,
- We intend to work in relation with other MS: with central and southern zone

- Different issues encountered according to the “diversity” of m^2/ha for a given crop

This is especially the case of grape.

Propose 2 technical documents:

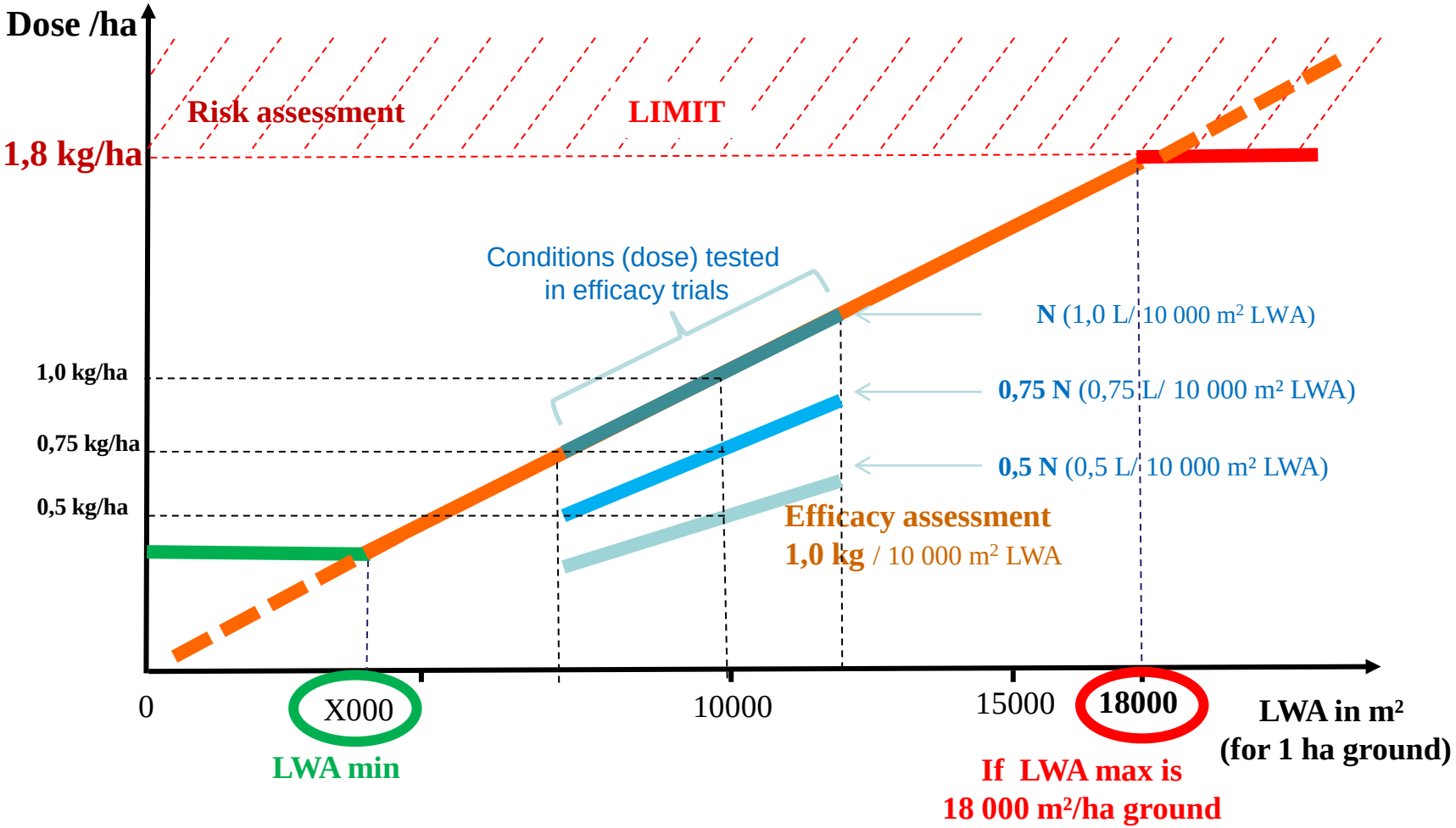
- one dedicated to experimenters (involved in field efficacy trials),

- and one providing tools for growers for dose conversion and dose adjustment.

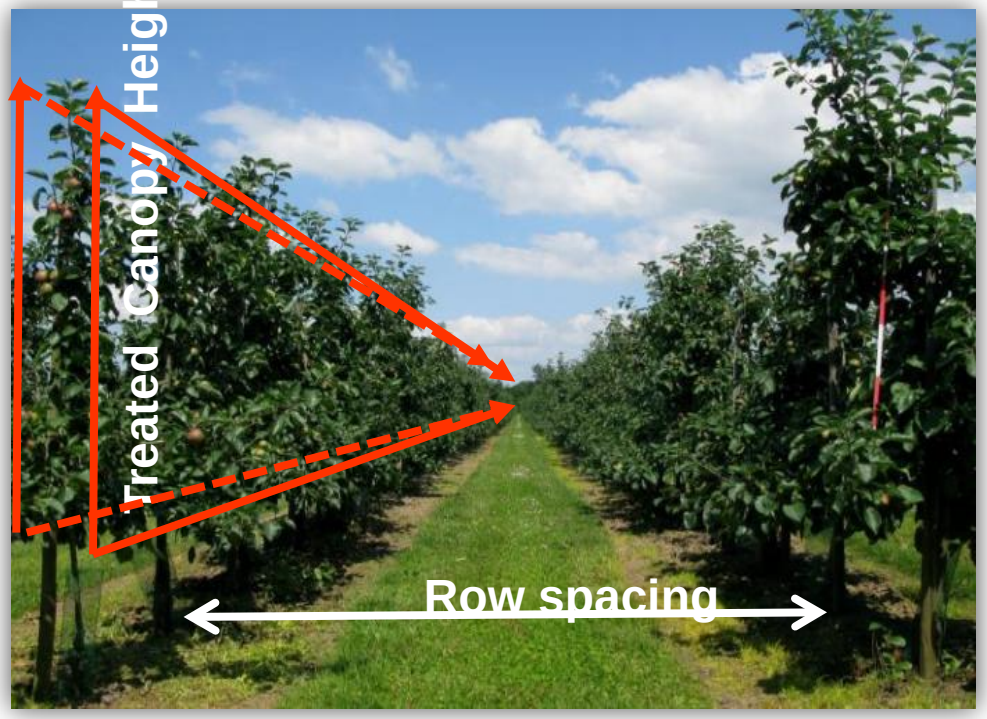
The documents will be a concrete proposal for the ministry

“Willingness to consider foliar area and crop structure, to rationalize the use of PPP (Ecophyto Plan, reduction of pesticide use…).”

Linearity between « dose /ha ground » and « LWA »



Thanks for your attention



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