PLANT PROTECTION

DOSE EXPRESSION FOR VERTICAL CROPS IN BELGIUM

Guidance document

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DOCUMENT INFORMATION

Dose Expression for Vertical Crops in Belgium
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1. Introduction

This guidance document explains and confirms how Belgium has been dealing, now for many years, with the expression of the doses per hectare (ha) Leaf Wall Area (LWA)[*] for the application of plant protection products to the canopy of vertical crops. Unfortunately this dose expression is not the standard one in the EU, and as an example, the dose expression for vertical crops in some other EU Member States is given here:

- UK: kg/ha ground surface
- DE: kg/ha ground surface and /m crown height (fruit trees)
- NL: kg/hl and maximum l water/ha ground surface
- FR: kg/ha ground surface

Although doses/ha LWA have been in use for several years in Belgium, time was needed to get familiar with the consequences and to develop adapted methodology. This explains why this is the first guidance document that is published by the Belgian authorities on this matter.

With this document, the Belgian competent authorities **essentially want to ask applicants to provide more details on the dimensions of the crop and information on the application methodology in their trials and dossiers**, in order to allow for a correct determination of the dose/ha LWA. This guidance document should therefore be taken into consideration at an early stage in the development of the dossier. Furthermore, some adaptations of the application procedure are introduced, allowing for a faster treatment of the application.

The definition of "ha LWA" that is used in Belgium is identical to the definition of ha LWA described in the **EPPO standard PP 1/239(2)**. More information on this standard can be retrieved in ANNEX I.

In efficacy trials, the concept of dose expression for vertical crops /ha LWA is more and more accepted. On the basis of efficacy trials, the Minimum Effective Dose (MED) is determined. In principle, the MED should be reflected in the dose rate proposed by the applicant, however it is acknowledged that the outcome of risk assessments could lead to proposing other dose rates. More information on the **determination of the MED** can be found in ANNEX II.

[*] **Abbreviations used**:
LWA = Leaf Wall Area
GAP = Good Agricultural Practice
MS = Member State
MED = Minimum Effective Dose

Doses expressed /ha LWA can be converted into doses expressed /ha ground surface on the condition that details on the dimensions of the crop are available. More information on this conversion and examples are given in ANNEX III.

2. Procedure

In an ideal situation, all MSs would use the same dose expression /ha LWA for vertical crops. First, the minimum effective dose/ha LWA for a certain crop would be determined on the basis of efficacy trials. In a second step, this dose would then be recalculated into doses /ha ground surface, considering the crop dimensions in the MS where the authorisation is sought. These doses would then be the basis for the toxicological, residues, environmental fate and ecotoxicological risk assessments.

However, according to current practices, the concept of dose expression /ha LWA is not (yet) the standard one, neither in the EU, nor at broader international level. Furthermore, the maximum dose rate is more and more driven by risk assessment outcome rather than efficacy. Therefore, a compromise procedure was elaborated, consisting of slightly different procedures for applications in a zonal assessment context, in a strictly national context and for mutual recognition.

For any category of upward or sideward directed spray application, the applicant needs to propose a dose/ha LWA for crops where this is relevant. Basically, these are all crops with vertical development (see ANNEX IV and V for an overview). The accepted dose/ha LWA will be mentioned on the authorisation certificate. For apple and pear orchards, also the dose/ha ground surface of a standard orchard has been mentioned on the authorisation certificate until now, as this dose expression was commonly used by fruit growers (see ANNEX IV for further explanation). In order to stimulate the transition towards application of the LWA concept by farmers, this exception for orchards will no longer be applied and mentioned on the authorisation certificates.

2.1 Procedure for a Zonal Dossier (BE = zRMS or cMS)

The applicant proposes a worst-case dose (risk envelope approach) for the zone, expressed per ha ground surface, for evaluation in Part B of the dRR (core risk assessment). Based on the outcome of the part B evaluations, the applicant proposes a dose rate per ha ground surface for authorisation in part A of the dRR.

For vertical crops as mentioned in ANNEX III, the applicant should also propose a dose expressed per ha LWA. This dose rate should correspond with the proposed dose per ha ground surface. For the applicant, this implies adding a national addendum for efficacy (or integrating this addendum into the core evaluation).

More details are given in the following chapters.

2.1.1 Efficacy

The applicant draws up a **national addendum** for Belgium to part B3 (Efficacy Data and Information) of the dRR. In this national addendum, the applicant integrates all available information in order to determine a dose per ha LWA for Belgium, corresponding to the proposed dose per ha ground surface.

This determination will mostly be based on the submitted efficacy trials and BAD, but as explained above, restrictions coming forth from the risk assessment in the other parts B could interfere. Efficacy trials not containing the necessary parameters in order to determine a dose per ha LWA could still be taken into account by means of the Belgian conversion factors. These factors take into account the standard dimensions of the crop cultivation systems in Belgium and can be found in ANNEX IV. An overview of cropping systems is given in ANNEX V.

It is also allowed to integrate this addendum into the core evaluation, as long as the determination of the dose per ha LWA is available in the application for authorisation in Belgium; in this case the zRMS (be it BE or not) is expected to confirm or adapt the proposed application rate.

The Belgian authority efficacy expert will evaluate the submitted data and the underlying rationale, and confirm the proposed dose rates per ha ground surface and dose rates per ha LWA or propose modified dose rates for authorisation (as long as covered by the risk assessment in all sections).

2.1.2 Tox/Ecotox/Fate

The authority tox, ecotox and fate experts base their evaluation on the zonal worst-case dose per ha ground surface (i.e. applicant's proposal in dRR parts B).

In **Part A of the dRR**, the different authority experts (tox, ecotox, fate) compare the dose per ha ground surface that was proposed by the applicant and confirmed/modified by the authority efficacy expert (see 2.1.1) with the dose per ha ground surface that was evaluated in part B. For each crop, the expert concludes whether dose per ha ground surface proposed for authorisation is covered by the dose per ha ground surface evaluated in part B of the dRR (core assessment or potentially submitted national addendum for tox/ecotox/fate).

In case the conclusion is positive, the proposed dose is considered to be covered by the risk assessment.

In case the conclusion is negative, the proposed dose is considered to be more critical than the dose evaluated in part B of the dRR (core assessment). In this case, there are two options: the proposed dose is lowered or the application is refused and the applicant needs to submit a new application. The dose per ha ground surface could possibly be lowered e.g. by limiting the maximum crop height to be treated or by simply imposing a lower maximum application rate on the label of the product. Such restrictions will however need to be justified and agreed with the applicant in order to guarantee the efficacy of the product.

2.1.3 Residues

The authority residues experts base their evaluation on the dose per ha ground surface proposed in part B, which should normally concur with the dose per ha ground surface that is proposed and confirmed for authorisation (dRR part A). The residues experts should verify if the residue trials (expressed /ha ground surface) are compliant with this dose.

2.2 Procedure for National Dossiers

This procedure is followed for all applications that are not undergoing the zonal evaluation procedure. It is specifically valid for minor use extensions.

2.2.1 Efficacy

As for zonal dossiers (cf. 2.1.1), the applicant integrates all available information in order to determine a dose per ha LWA for Belgium, corresponding to the proposed dose per ha ground surface. This can be the dose per ha ground surface authorised in other Member States and/or for comparable products or crops. In case no other information is available, which will usually be the case, the proposed dose per ha LWA needs to be calculated using the BE conversion factors. These factors take into account the standard dimensions of the crop cultivation systems in Belgium, which can be found in ANNEX IV.

The Belgian authority efficacy expert will evaluate the submitted data and the underlying rationale, and confirm the proposed dose rates per ha ground surface and dose rates per ha LWA or propose modified dose rates for authorisation (as long as covered by the risk assessment of all sections).

2.2.2 Tox/Ecotox/Fate

As for zonal evaluations (cf. 2.1.2), the authority tox, ecotox and fate experts base their evaluation on the proposed and confirmed dose per ha ground surface. In the case of minor use extensions, the experts will need to check whether this dose per ha ground surface is covered by the risk envelope and if not, assess the risk for this higher dose.

2.2.3 Residues

As for zonal evaluations (cf. 2.1.3), the authority residues experts base their evaluation on the proposed and confirmed dose per ha ground surface. The doses applied in the residue trials are usually also expressed per ha ground surface.

2.3 Procedure for a Mutual Recognition

In case of mutual recognition outside the zonal evaluation system of a use for a vertical crop, or any other application based on finalised evaluations, the GAP authorised in the reference MS needs to be **translated into a GAP in accordance with the Belgian dose expression (/ha LWA)**. It is the responsibility of the applicant to describe the proposed GAP conversion (considering the dimensions of the crop and the information on the application method/time of application in the reference MS) in the dossier. Any available and useful information can be added to the dossier. In practice however, this information is not always available and this conversion into /ha LWA is not straightforward. It is the task of the authority expert in efficacy to finally decide what conversion should be applied and to determine the dose rate per ha LWA to be authorised.

The evaluation of the other sections (tox, ecotox, fate, residues) should start from the dose per ha ground surface (as authorised in the reference MS). The experts check whether or not the intended GAP in Belgium is covered by the evaluation performed by the reference MS.

3. Implementation and Transition Period

Regardless of the procedure followed, it is essential to dispose of details of the crop dimensions and the application methodology for the submitted trials in order to determine the dose per ha LWA. For many years, only trials that allow for this determination have been taken into account for new applications for authorisation in Belgium. Applicants should take this up with their efficacy and residue trial contractors to foresee those details into the submitted trial reports.

Application rates reported in study reports should clearly specify whether they refer to ha ground surface or to ha treated LWA.

As a note, some environmental higher tier trials such as field studies on non-target arthropods would also benefit from a clear description of the crop dimensions and the application methodology in order to determine the dose/ha LWA to which these organisms were exposed.

Applications submitted after 31st December 2018 need to comply with the procedure under point 2. This concerns hence only the formatting of the dRR and the presentation of the proposed dose rates, not the reporting of the trials themselves.

Applications submitted before this date will continue to be dealt with by Belgian authorities applying this procedure themselves taking into account available data. For the time being, complementary information will continue to be requested (if necessary) on a case-by-case basis during the evaluation process in order to determine the correct dose per ha LWA.

For the sake of completeness, and hence regardless of this national guidance document, attention is drawn to the fact that on central zone level the following has been decided :

- The leaf wall area (LWA) concept should first become effective in the efficacy evaluation in grapevine, pome fruit and high growing vegetables;
- In these crops, application dossiers for new products (under Article 33) will only be accepted when trials were planned and carried out based on LWA (to become effective from **01.01.2020**);
- Accordingly, the respective trials must be planned and carried out based on LWA (to become effective from **01.01.2018**);
- The LWA dose rate shall be added in column 14 (remarks) or 10 - 12 (application rate) of the GAP table. It is restricted by the maximum rate per ha ground area and the range of possible concentrations resulting from columns 11-13 of the GAP table.

ANNEX I – EPPO STANDARD PP 1/239(2)

A dose expression /ha LWA for vertical crops is recommended at EPPO level. Its main advantages are reduction of unnecessary emission of plant protection products in the environment, harmonization and better exchange of data between countries, prevention of residue problems and key issues like the need to record all the relevant information on the applied dose. The distinction, on one side, of the dose for the efficacy evaluation and the various risk assessments and on the other side, the GAP communicated to the growers, are clearly summarized in the introduction of the EPPO Standard PP 1/239(2) (2012) "*Dose expression for plant protection products*", as indicated in the following extract of this introduction:

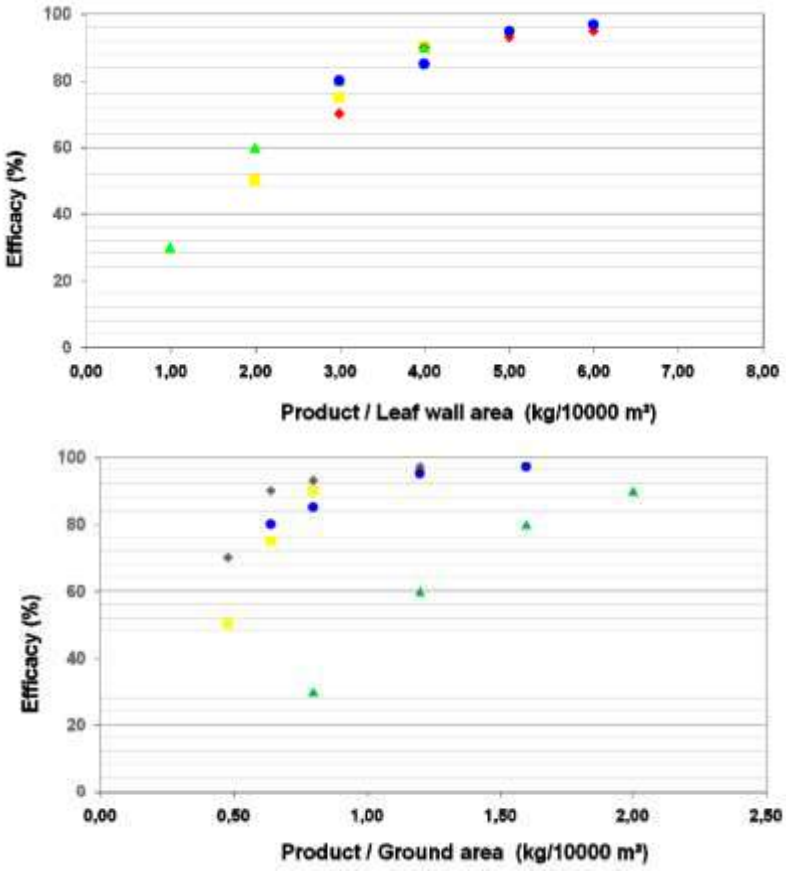
> "One very commonly used expression of doses in three dimensional crops is concentration of the formulated product in the spray volume (e.g. dose per hL or %). However, a dose expressed in this way may give highly variable deposits of active substance, mainly due to crop structure, to application (spraying) technique and to the volume of water used. This is particularly true for high-growing crops of variable size in various planting systems (e.g. orchards). As such, it is recognized that this expression is no longer sufficient.
>
> At the present time, great efforts are being made to obtain optimum efficacy from the applied product and to avoid unnecessary emission of products into the environment and residues in feed and food. The best way to achieve this is to adapt the dose to the area where the treatment is needed (e.g. crop canopy) and its structure.
>
> Scientific studies examining the deposit of products on the targeted crop area have led to the development of various models in use in some countries, (Rueegg et al., 2001, 2012) and trials carried out for the biological dossier in these countries are based on these models. **To allow better exchange of data between countries, to avoid unnecessary repetition of trials and to prevent residue problems between countries, dose expression should be harmonized in trial reports**. This can be achieved if the reports contain all relevant information allowing calculation of the applied dose whatever the model chosen by the registration authority. The same consideration applies to residue trials.
>
> This need for a harmonized approach has even more importance following the implementation of the EC Regulation 1107/2009 (EC, 2009), which is based on zonal assessments and authorizations of plant protection products. As such, both regulators and industry require a common simplified approach to dose expression in order to

facilitate the authorisation of products and Mutual Recognition between EU Member States.

In doing so, the requirements of growers that are familiar with their own dose expression terms, should still be taken account of, and as such, imposing one scheme may risk practical difficulties. The previously mentioned EPPO Standard notes that 'per treated leaf wall area unit' (LWA) is becoming a common dose expression method in 3 dimensional crops. However, the EPPO Standard also provides (in Appendix 1) a method to convert between the main country dose expression methods. This approach therefore both encourages a common dose expression method to be used in trials for generating data and when conducting assessments, whilst allowing the retention of country specific dose expression terms on national labels. It should be emphasized that this approach will only be successful if **all relevant parameters of crop structure are recorded, to allow the appropriate dose expression conversions to be made**. As additional information, the dose of active substance per hectare of ground area should be calculated and reported."

ANNEX II – DETERMINATION OF THE MED

On the basis of efficacy trials, the Minimum Effective Dose (MED) is determined. When the doses are expressed /ha leaf wall area and when the dose (in ha leaf wall area) is plotted against the efficacy, the MED can easily be observed on the graph (just before or when the curve reaches a plateau). When the doses are expressed /ha ground surface, it is very difficult to determine the MED because a lot of variability is added (due to the different dimensions of the crops in the different trials). When the dose (in ha ground surface) is plotted against the efficacy, the points are scattered and it is not possible to fit a curve through them or to determine when the plateau starts (see figures below).



Nevertheless, it should be noted that especially in old efficacy trials, the information on crop dimensions was not always available and therefore, it is in those cases difficult to derive a correct MED expressed /ha leaf wall area. In some cases – especially for older active substances – it may even be impossible to verify on which basis a MED was established.

It is therefore very important in efficacy trial reports to always record the dimensions of the crop and all the information on the applications (actual amount of product, actual spray volume).

ANNEX III – CONVERSIONS AND EXAMPLES

There are two formulas to determine the conversion factor between a dose expressed /ha LWA and a dose expressed /ha ground surface. This conversion factor gives an idea of how many ha LWA correspond to one ha ground surface. What formula to be used, depends on what information is available.

Abbreviations

N: number of plants in the field
D: distance between 2 plants within the row (in m)
E: distance between 2 parallel rows (in m)
H: treated height of the plants (in m) (the non-treated trunk has to be excluded from the calculation)
2 (for the 2 sides of the hedge)

The ratio ha LWA / ha ground surface = **(2 x H)/E**

Example:

An apple orchard with trees of 3 m (treated canopy) height and 4m distance between the rows.
Conversion factor = (2 x 3)/4 = 1.5
1 ha ground surface corresponds to 1.5 ha LWA

The ratio ha LWA / ha ground surface = **2 x N x D x H**

Example:

An apple orchard of 1 ha with 2000 trees of 3m (treated canopy) height and 1.5 m distance between the trees in the row.
2 x 2000 x 1.5 x 3 = 18000 m^2 = 1.8 ha
1 ha ground surface corresponds to 1.8 ha LWA

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

ANNEX V – CROPS AND THEIR CULTIVATION PRACTICES

The table below gives an overview of the crops (professional uses) and their cultivation system (horizontally and/or vertically). For crops that can be grown vertically as well as horizontally, it is very important to clearly indicate in the trials (efficacy trials/residue trials) what cultivation system was used.

Crop		Horizontal	Vertical
Tomato	~~Field~~*		
	Under protection		x
Pepper	~~Field~~*		
	Under protection		x
Eggplant and pepino	~~Field~~*		
	Under protection		x
Cucumber	~~Field~~*		
	Under protection		x
Gherkins	Field	x	x
	Under protection	x	x
Courgette, squash with edible peel	Field	x	
	Under protection	x	x
Pumpkin	Field	x	
	Under protection	x	
Melon	~~Field~~*		
	Under protection	x	x
Bean	Field	x	
	Under protection	x	x
Pea	Field	x	
	Under protection		x

* No field (open air) cultivation of this crop in Belgium