

Assessment of topics with regard to specific agricultural use in the Netherlands

Introduction

In the November meeting in 2015, the Board prescribed 'national specific elements' for the Netherlands (see C-283.I.11).

To achieve European harmonisation, the Board supports the line of policy to deviate as little as possible at the national level from European authorisations for plant protection products. Regarding WERG (mutual recognition) and CMS (Concerned Member State) applications, the Ctgb generally adopts the authorisations of other EU Member States. The 'national specific elements' that are assessed, if relevant, are:

- leaching to groundwater
- wind speed
- drinking water from surface water

In addition, and as agreed in the November 2015 Board meeting, the Board may conduct an additional assessment or refuse the authorisation of a product in case of a potential unacceptable risk to people, animals or the environment.

As a result of the Board decisions described above, the Board secretariat has implemented a new procedure for the assessment of WERG and CMS applications. In the case of WERG and CMS applications, a Dutch addendum now only needs to be provided for the FATE and ECOTOX aspects.

There are also a number of more technical topics related to specific agricultural use in the Netherlands, and these have not been previously communicated, explicitly and jointly, externally. If the evaluating Member State applies different agricultural principles compared to the Netherlands, these topics must be assessed for the application in the Netherlands. Although common practice for many years, the topics – if this is not already the case – need to be included in the evaluation manual.

Assessment of topics with regard to specific agricultural use in the Netherlands

Technical topics related to specific agricultural use in the Netherlands were not included in the 'WERG and CMS applications' memorandum, as this focused on national specific elements. The topics are however relevant as they may make national assessment (full or partial) necessary or explain deviations from the label compared with the original authorisation of the WERG or CMS dossier. Although common practice for many years, this has not yet been communicated transparently and in its entirety.

A list of topics is given below along with a description of how each topic is included in the Dutch addendum per application type. In the case of applications for which the Netherlands is the zonal rapporteur (zRMS), these topics are also relevant to the Dutch addenda. The table therefore also shows the application types for which the Netherlands is the zRMS.

1. Specification/differentiation of country-specific 'drinking water from surface water' element

Analysis method for surface water with an LOQ of 0.1 µg/l (analytical methods for post-registration monitoring)

As surface water in the Netherlands is used for drinking water preparation, an analytical method is required for all compounds in the residue definition for monitoring for surface water, with an LOQ of 0.1 µg/l, or lower. If such an analytical method is unavailable, a suitable method should be provided.

2. Mitigating measures

Mitigating measures and applicability in the Netherlands (all aspects)

The mitigating measures proposed in the assessment of the evaluating Member State must be translated into measures that are realistic for agricultural use in the Netherlands.

An evaluating Member State assessment may, for example, propose a 20-metre no-spray buffer zone for an arable crop. It is then up to each Member State to translate this measure into a national label. However, this measure is not realistic in the Netherlands as crop-free zones rather than no-spray zones are applied (among others, for enforcement reasons), and a 20-metre crop-free zone does not represent realistic agricultural practice.

Additional mitigation measures for the Netherlands could consist of a combination of drift-reducing techniques and additional crop-free zones of a realistic size. The mitigating measures/ conditions of use described on the label for the Netherlands are actively aligned with the Netherlands Food and Consumer Product Safety Authority (NVWA).

3. Agricultural use in the Netherlands

3a. The Dutch extrapolation table (efficacy aspect)

Evaluating Member States often leave extrapolation up to the individual Member States. In theory, the extrapolation applied by other Member States (based on EPPO) is translated and followed by the Netherlands in the case of WERG applications, but it must be realistic for Dutch agricultural practise; the organism for which the product is intended must for example be present in the Netherlands.

As far as CMS applications are concerned, the Dutch extrapolation table usually makes more extrapolations possible than the EPPO tables, and the Netherlands is also more flexible regarding extrapolations proposed in the EPPO lists. Other Member States often interpret the EPPO tables very strictly and do not permit extrapolations from one major crop to another major crop.

Work is currently being carried out to harmonise the national extrapolation tables (EPPO extrapolation table) and to produce a label/WG for each Member State. For example, in some Member States, every tested weed is listed separately for herbicides, while in the Netherlands the whole group of weeds is listed if several representative weeds have been tested. This is therefore an extrapolation to a broader application made at the national level. The decision has also been made in the Netherlands not to list many restrictions and warnings that fall under efficacy on the WG, as these are reported as recommendations or good agricultural practise in the Netherlands. If the evaluating Member State proposes restrictions, the decision needs to be made whether they are relevant for listing on the WG in the Netherlands and, if so, whether they need to be translated.

If the efficacy assessment for the original authorisation is based on a product used in a bridging study, it needs to be investigated whether the bridging product identified by the applicant is authorised for the Netherlands. This is required due to data protection and the label/WG. For CMS applications, if the applicant is able to show in a limited number of trials that the efficacy and crop safety of the product is identical to that of the bridging product, the entire claim for that label (including restrictions and conditions for use) may be copied. The EPPO is currently working on improving the guidance document for bridging dossiers.

Data protection:

The bridging product must not be subject to data protection and everything must be copied exactly, including restrictions. Bridging is only possible between products that contain the same active ingredient or ingredients. If a bridging product is authorised for use in the Netherlands, it is possible that the product is no longer subject to data protection in the evaluating Member State, but that it is in the Netherlands. In this case, bridging is not permitted, unless there is a LoA.

Label/WG:

As described above, in the case of a WERG the label of the other Member State is adopted, including restrictions and conditions of use, but this must match the Dutch label/WG format. Dosage systems (for climbing crops) vary, for example, between Member States.

For a CMS application, the label is changed to match the Dutch WG format with more applicability to the Dutch situation, as the Netherlands is more directly involved in the assessment. All changes must meet the zRMS-assessed Core.

Climate and other influences may also apply in a certain zone. The Dutch authorisation is therefore more applicable in practise than labels from other Member States. For a product applied to *Phytophthora infestans*, for example, it would be unwise to copy the Czech label, even though the Czech Republic is located in the same climate zone. This is because the dosage for *P. infestans* and the number of re-applications are higher for existing authorisations in the Netherlands than in the south-east of the maritime zone as disease levels are higher, due to the larger acreage of potato plants and the maritime climate. The EPPO guidance states that such differences must, where relevant, be taken into account within a zone.

3b. The Scope of permitted use for plant protection products definition list (DTG) and the Terms of legal conditions for use definition list (DTW) (efficacy aspect)

These lists are used to translate the label from the evaluating Member State into the Dutch situation as closely as possible. However, the lists are not harmonised, which means that a Dutch label may differ from a label from another Member State. Definition lists differ between Member States: the crops can often be translated, but many Member States apply a crop group hierarchy with different categorisations. Harmonisation would require major, national labelling projects and the training of end users, as they are not acquainted with the categorisations and crop groups in other Member States.

In addition, different countries place different accents in the lists, for example in the case of ornamentals, horticulture and tulips are important in the Netherlands but many other Member States do not apply these practises or grow these crops. The DTG list makes such translation easier, so that the final authorisation matches the assessment by the original Member State as closely as possible.

3c. The Crop cycles list (all aspects)

This list is not harmonised at the European level. The Ctgb uses this list to assess whether the GAP table is realistic for the Netherlands. The number of crop cycles may vary between Member States, due to climate factors and differences in cultivation systems. If, in the assessment of the evaluating Member State, the number of crop cycles does not match common practise in the Netherlands, a restriction clause will be added to the WG regarding the authorised number of crop cycles per year, matching the number tested in the other Member State. If the applicant does not wish this restriction clause to be added, he/she may pay for a risk assessment in the national addendum for the Dutch situation.

3d. Bulb immersion fluid absorption list (all aspects)

This list is not harmonised at the European level. The Ctgb uses this list to calculate how much fluid is absorbed by different types of bulbs and therefore transferred to the field in which they are grown. This uptake can differ between different types of bulb, and the results are used in the FATE assessment. Bulb immersion takes place primarily in the Netherlands and not in other Member States. Through the NVWA, the Netherlands could propose the inclusion of this list in EPPO for harmonisation purposes. However, in practise we receive very few WERG or CMS applications with bulb immersion applications.

3e. Dutch spraying volume list (efficacy and human TOX aspects)

The spraying volume list shows the spraying volume for each crop for the Netherlands. This list has not been harmonised at the European level but is referred to in daily practise by all users. It therefore contains the spraying volumes commonly applied in the Netherlands. The spraying volume determines the concentration of the active substance, and dermal absorption depends on the concentration of the active substance. The concentration of the active substance is also a parameter in exposure models and partly determines exposure (e.g. by bystanders and residents).

For WERG applications, we follow the evaluating Member State and a condition for use is stated on the label, in other words, the spraying volume of the Member State is adopted and added to the WG. This represents a change as, until recently, calculations made in the Dutch addendum were based on the Dutch spraying volume list.

In the case of CMS applications, it is checked whether the Dutch spraying volume list is covered by the Core assessment during the commenting round. If not, a comment is added (because the worst-case scenario must be covered). If the zRMS does not change the spraying volume, an assessment is carried out for the Dutch situation.

3f. Field-use scenarios in the Netherlands (human TOX aspect)

The field-use scenarios with regard to upward versus downward spraying and mechanical versus handheld application in the Netherlands are described on the Ctgb website. This list contains the techniques commonly applied in the Netherlands. If the application method in the evaluating Member State assessment does not cover the application method in the Netherlands, the Ctgb will include a restriction on the WG.

For example: the list states that application on roses (depending on the application method) may be carried out both upward and downward, mechanically and by hand in the Netherlands. If only mechanical upward application is assessed in the evaluating Member State assessment, a restriction will be added to the WG stating that handheld upward and downward application and mechanical downward application are not

authorised. If the applicant does not wish this restriction to be added, the applicant may pay for a risk assessment in the national addendum for the situations not assessed in the evaluating Member State assessment.

3g. Risk assessment for bystanders and residents (human TOX aspect)

An assessment is made for bystanders and residents for authorisation in the Netherlands. The method applied depends on the submission date of the original authorisation: for applications made before 1 January 2016, the German (DE) model and British (UK) method are applied; for applications made after 1 January 2016, the new EFSA (OPEX) guidance document applies.

In the DE model, a choice must be made regarding the size of the buffer zone (= distance from last crop row to bystander/resident). It is unclear which buffer zone must be selected and based on what the Member States make a choice, as this has not been harmonised. A buffer zone cannot be chosen in the UK method as the data in this model are based on a single, fixed distance.

We suggest using the new EFSA Guidance document to determine the buffer zone in the DE model. This EFSA Guidance document distinguishes between downwards and upwards application: for downward application, the guidance document states that the shortest buffer zone (2 m in the EFSA model) must be taken as the most realistic, worst case scenario. However, this distance is not available in the DE model as a choice must be made between 1 and 5 metres. Because distances of less than 5 metres are possible in the Dutch situation, we suggest applying a 1 metre distance in the DE model. For upward application, the EFSA model is based on old data that are also used in the UK model. These data are based on a distance of 8 metres: 3 metres between the last crop row and the end of the parcel of land (the edge of the field along which the tractor drives) plus a bystander/resident at 5 metres from the edge of the parcel. In the EFSA model, these data are used for the 5 and 10 metres distances (the 8 m data is the worst-case scenario for the 10 metre). In theory, therefore, the EFSA model assumes a 5 metre distance. It is proposed to also apply this to calculations based on the DE model and therefore to also apply a buffer zone of 5 metres in the DE model.

This means that if a larger distance is applied in the Core dossier (for CMS) or the original authorisation (for WERG), an assessment will be carried out.

Table: Standard method for topics with regard to specific agricultural use in the Netherlands per application type*

	WERG	CMS**	zRMS
Analysis method for surface water with an LOQ of 0.1 µg/l	assess	assess	Assess
Mitigating measures and applicability in the Netherlands	ASSESS	ASSESS	n/a
The Dutch extrapolation table	follow	individual WG	assess
The scope of permitted use for plant protection products definition list (DTG) and the Terms of legal conditions for use definition list (DTW)	follow (used for translation)	follow (used for translation)	assess
Crop cycle list	follow	follow	assess
Bulb immersion fluid absorption list	not seen in practise	not seen in practise	assess
Dutch spraying volume list	follow	individual WG	assess
Field-use scenarios in the Netherlands	follow	individual WG	assess
Risk assessment for bystanders and local residents	assess	Assess	assess

*as described above, it is possible – following consultation with the applicant – for an assessment to be carried out in a number of areas for a specific WERG/CMS.

**individual WG = within the Core limits for CMS in the national addendum.