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Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"

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This document has been conceived as a guidance document by the Commission Services, and was elaborated in co-operation with the Member States. It does not intend to produce legally binding effects and by its nature does not prejudice any measure taken by a Member State within the implementation prerogatives under Annex II, III and VI of Council Directive 91/414/EEC, nor any case law developed with regard to this provision. Nor does this document preclude the possibility that the European Court of Justice may give one or another provision direct effect in the Member States.

1. LEGAL STATUS

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2 INTRODUCTION & BACKGROUND

With the application of the “one safe use” principle in the assessment of active substances for inclusion in Annex I of Directive 91/414/EEC, a substantial number of uses that are authorised by MS must be re-assessed at MS level in order to come to a decision on whether Uniform Principles are met or not.

It is acknowledged that the current re-registration and new authorisation procedure to plant protection products creates a high workload in MS, in particular where older authorisations were not granted according to the Uniform Principles. This process in some cases, especially for those plant protection products with multiple crops and GAPs, may result in a considerable amount of work for risk assessors and regulators. Hence, approaches must be developed to keep the workload at an acceptable level. Nevertheless, it should be kept in mind that the procedures established now must still be sufficient and appropriate for general use for product authorisations under the new Regulation (EC) No 1107/2009 in future. Risk assessment, risk management and decision-making on applications for authorisation of products need to be comprehensive and transparent.

Such a possibility is offered by the “risk envelope approach” that is described below in detail.

This working document describes the procedure and the rational to be followed by applicants for the preparation and submission of dossiers according to the “risk envelope approach”

3 GENERAL INFORMATION ABOUT THE “RISK ENVELOPE APPROACH”

Generally speaking, the risk envelope approach is not something new in the process of authorisation of plant protection products. It is already used by MS e.g. in the case of multiple applications (independent applications from more than one manufacturers or joint applications) with similar formulations and GAPs in an effort to reduce the workload.

The risk envelope as is presented in this Guidance Document is a concept which exploits the idea that in each area of assessment the supported uses of a product can be grouped taking into account certain criteria (e.g. crop, application rate, number of applications, timing, etc.) and the assessment can be targeted at the group rather than at individual uses. Beyond that, it may be possible to identify a 'worst case group' for a specific field of assessment, which can be assessed as representative for all other groups, i.e. the assessment of this worst-case use or group will cover all other situations where the GAP is less critical or the same.

This is in principle applicable to all sections of dossiers while for efficacy and residues, for which assessment should be based on individual crops, the approach might not always be useful but there is still the possibility to reduce the workload (see below). The risk envelope approach is also relevant to the approval of active substances where always a product and representative uses are evaluated and full risk assessments are to be conducted. Notifiers or applicants for authorisation should be responsible for a reasonable grouping of intended uses. Member states may authorise uses which are covered by identified worst case scenarios without asking the zRMS for evaluation e.g. uses where the application rates supported are posing less risk to humans or the environment or uses for which the risk assessment performed by the zRMS can be extrapolated.

Finally, this approach offers the possibility, under certain conditions, to extrapolate risk assessment for one formulation to other formulations with the same active substance and the same composition for which a less critical GAP is supported. In this case bridging data and argumentation will be required.

4 DESCRIPTION OF THE PROCESS

The entire process includes the following steps:

Step 1 (analysis of current or planned uses)
Initially, the applicant should present an overview of all planned uses in each MS of the zone for which authorisation is applied (or for the EU if proposed uses fall under the provisions of Article 33.2 (b) e.g. in greenhouses, post harvest treatment etc.). This analysis includes all information that is normally included in GAPs.

In order to facilitate crop groupings at Step 3 below for each area of the risk assessment it is important at this stage that all uses included in the GAP table are precisely described and are coherent with the information appearing throughout the dossier. For example the use should not just state "Broadcast foliar" in the GAP table and later on in the operator exposure assessment to be specified as application by airblast and/or tank with lance.

Step 2 (rationalisation of uses)
On the basis of this analysis and taking into account the conditions and restrictions for Annex I inclusion, the applicant makes his decision as to the authorised or planned uses that will be supported for re-registration or new authorisation by available Annex III data for the Zone. As a result, applicants rationalise the uses to be supported in each MS.

It is important during this process for transparency reasons not to loose track of the uses that are to be supported in the individual MS of the Zone. This will facilitate the authorisation process since authorised uses must be reported in the authorisation certificate as well as in the label of the product and this information is made publicly available in the databases of authorised plant protection products.

In the case of multiple applications (independent applications from more than one manufacturer or joint applications) to facilitate the implementation of this process and in an effort to reduce the workload, it is recommended that applicants should come to an agreement upon the uses which will be supported in each zone.

Step 3 (definition of the risk envelopes for each area of assessment)
This is the crucial step in the process and includes the identification of those uses that represent the critical (worst case) situation for each area of assessment and cover the entire Zone.

Applicants are required to explain the rationale followed for the identification of worst case scenarios in each area of assessment. This is a quite important issue and needs to be transparent for the better understanding of risk assessors and regulators.

Pre-submission meetings are playing an important role in the identification of critical scenarios. In that respect it is recommended that during these meetings applicants submit the background information as well as the rational developed in proposing the critical scenarios in each area of risk assessment. For instance, in the operator risk assessment calculations with different scenarios and crops should be included in the background information to enable the understanding of the rational followed for the selection of the worst-case scenarios.

To facilitate and to streamline the discussions between the zRMS and applicants it is recommended that the background information is presented in a harmonised EU format.

During the initial phase of the zonal authorisation process the possibility should also be explored, to organise pilot projects with the participation of experts from different MS in the pre-submission meetings. This will be done in an effort to reach as far as possible an agreement on the rational used by applicants for the identification of critical scenarios in particular in those areas on which currently there are no EU harmonised approaches.

The aim of pre-submission meetings should be to:

1) identify the critical GAPs for each area of assessment and
2) reduce the possibility that selected critical GAPs result in a negative decision

The identification of critical GAPs is not a straightforward process and is very much dependant on certain parameters that vary considerably from one product to the other. For instance the parameters that should be taken into account for the identification of critical GAPs for each area of assessment for a product that is used in open field is quite different from those to be examined in the case of a product that it is proposed to be used for indoor crops.

As a result of this process, individual crops are grouped into categories that represent the worst case situation for each area of assessment. In Section 7 below the key parameters for each area of risk assessment should be considered for the identification of worst case scenarios are presented.

It should be stressed that the **core dossier** that is submitted to the zRMS and to all other MS of the zone on which authorisation is sought contains only those Annex II data (see SANCO/10328/2004-rev 6, 30-3-2006) or/and Annex III data that are agreed at EU level. The risk envelope is developed on the basis of these data and the risk assessment by the zRMS is limited only to these data. Nevertheless, Annex III data that have been generated following Annex I inclusion in order to address certain points identified from the risk assessment should normally be included in the core dossier because they are relevant to all MS of the zone. This is for instance the case when in the inclusion Directive it is stated that *“MS should pay particular attention to a certain group or compartment and to include appropriate mitigation measures”*.

Data requirements or scenarios that have been specifically developed to address national conditions should be included in the **national addenda** which is attached to the core dossier and submitted to the concerned MS. These data <u>are not</u> assessed by the zRMS and should be considered by the concerned MS in order to be able to finalise the assessment for the national authorisation.

Further on, it should be noted that some higher tier data and refinement of the risk assessment use parameters that are restricted to certain regions or habitats that are not relevant to all MS of the zone. Therefore, these data should not be included in the core dossier but rather in the national addenda.

Finally, the risk envelope approach for some special categories of plant protection products e.g. low risk products or products that contain micro-organisms might not be applicable to certain parts of dossiers or to the entire dossier and in this case risk envelope needs to be adapted accordingly or not to be followed at all.

5 APPROACH TO BE TAKEN IN CASE “WORST CASE” SCENARIOS LEAD TO AN UNACCEPTABLE RISK

It is in the interest of the applicant to prove the safety of the product for which they apply taking into account all possible scenarios in the GAP. The zRMS has to check if the risk is acceptable in all relevant scenarios for a given area of assessment.

Even if only one scenario gives an acceptable risk, the assessment should proceed as at least one MS of the zone may be able to grant an authorisation. For all other scenarios/uses assessed by the zRMS the results should be reported in the dRR since another MS in the zone could be able to grant an authorisation by using appropriate mitigation measures.

In those cases where the risk assessment conducted by the zRMS concludes that no safe uses could be identified or that risk mitigation measures are needed that lead to severe restrictions in the use of the product, this should be notified as soon as possible to the applicant giving him the opportunity to use the provisions of Article 37.1. The applicant has the possibility to submit additional data to address the concerns identified or to lift the mitigation measures needed and to submit a revised risk assessment taking into account the second worst case scenarios or a revised risk assessment.

In principle, during this phase, the revision of the originally supported GAP should be avoided since it is required the repetition of the risk assessment in several parts of the dossier. This creates a considerable amount of work for the zRMS that is unacceptable given the strict deadlines specified in the Regulation (EC) 1107/2009 for finalisation of the risk assessment and issuing a decision.

6 PROPOSALS FOR RISK MITIGATION MEASURES

Risk mitigation measures are often needed to enable authorisation of uses connected with identified risks. However, currently Member States use very different measures; the degree of harmonisation is low despite the fact that this issue will be further discussed in other fora with the aim to reach a better level of harmonisation.

As the risk mitigation measures vary between different MS, it is suggested that the zRMS considers risk mitigation factors expressed as the reduction in percentage (e.g. 50%, 75%, 90%) necessary to reach an acceptable level of risk. In the environmental fate and ecotox areas it is also recommended to propose mitigation measures expressed in distances e.g. 30 m buffer zone. It should then be the responsibility of the concerned MS to decide upon the effectiveness and availability of risk mitigation measures, taking into account specific national conditions.

7 KEY PARAMETERS IN EACH AREA OF RISK ASSESSMENT THAT NEED TO BE CONSIDERED IN DEVELOPING AN APPROPRIATE RISK ENVELOPE

Hereafter guidance is given on the parameters which should be examined by applicants in the case of spraying applications for the definition of critical GAPs in each area of risk assessment. It should be noted that so far the experience in this approach is very limited therefore it is expected that this part will be changed in future in the light of the experience gained.
To make the process more clear applicants are invited to examine the case study provided in Annex I.

7.1 Chemistry section and analytical methods

The risk envelope approach is not applicable to these sections. Indeed, the range of varying GAP parameters (application rates, formulation types, PHI, spraying techniques etc) would not influence the assessment of analytical methods and the same methods are applicable in all these cases while physico-chemical properties comprise of data that are product specific and are normally used in other areas of risk assessment.

7.2 Toxicology

7.2.1 Operator exposure

It should be noted that in the risk assessment for operator exposure the combination of the highest application rate with the lowest water volume is not always possible, because for some crops the spray concentration is very important. That means the critical GAP could be a combination of the lowest application rate with the lowest spray volume and the highest rate with the highest volume. If amount of water/ha is not considered relevant for operator exposure estimation, max. application rate is determining the highest operator exposure.

In exposure models currently used water volume is taken into consideration only in UK-POEM and EUROPOEM[1], while German model does not take into account this parameter. Nevertheless in the UK-POEM model, it is an important parameter because when water volume increases, the predicted exposure usually decreases and thus the lowest recommended water volume on the product should be used in the calculations.

The overall exposure of operators resulting from the use of the product as recommended on the label occurs during mixing, loading and application.
Further on, it should be noted that in the case of similar products that are supported by different dermal absorption data (or no data) this parameter can have a significant bearing on the risk envelope when reading across the different products.

[1] EUROPOEM is a model that is currently used for the operator risk assessment but it is not harmonized at EU level. In the context of this guidance document it is used as an example.

In UK POEM the size and design of the packaging can also affect the predicted exposure. The grouping of uses may be differentiated with regard to crop or use, e.g. smaller packaging for hand-held equipment than tractor mounted/trailed equipment as the amount of product used and applied will be lower.

Exposure is dependent upon many factors but the key parameters used are usually:

- Application method and equipment,
- Application rate,
- Water volume
- Pack size
- Personal protective equipment

Application method/equipment	Application rate	Water volume	Pack size	PPE	Crop Group

7.2.2. Worker exposure

Worker exposure can occur via three main routes:

- maintenance activities, e.g. crop inspection and pruning
- harvesting activities, either mechanical or by hand
- other activities such as packaging, sorting and bundling.

The potential for accumulation of dislodgeable foliar residues (DFR) from successive treatments needs to be considered where products are applied on a number of occasions to the same crop. In terms of picking the "theoretical" worst case this is represented by crops which have the highest maximum total dose rather than the highest maximum individual dose.

When identifying the worst case scenario it is also necessary to consider the "transfer coefficient" (TC) i.e. the intensity of the workers contact with the treated crop. In the EUROPOEM re-entry model (which is the chosen exposure model in the EFSA OP-EX guidance document) indicative TC values are given for four crop groups:

Vegetables: 2500 cm^2/h

Strawberries: 3000 cm^2/h

Tree fruit: 4500 cm^2/h and

Ornamentals: 5000 cm^2/h

These TC values can be extrapolated to other crop groups where the intensity of a workers contact with the crop is judged to be similar.

The worst case in this area is therefore represented by a combination of the DFR and the TC values.

Further on, it should be noted that in the case of similar products with individual dermal absorption data (or no data) this parameter can have a significant influence on the risk envelope when reading across the different products.

A potential problem that could be faced by applicants in this area is that when they develop the rationale for the worst case probably some crops/uses do not clearly fall under one of the above four categories e.g. vines therefore, there is an uncertainty on the appropriate TC value to be used. It is advised that applicants consult the zRMS during the pre-submission meetings to find an agreement on this aspect.

It is also important that the applicants identify the task duration. 2-hour crop inspection time would be appropriate to crops which are mechanically harvested and no other crop activity could be identified. If crops are hand-harvested the assessment will cover a full working day (e.g. 8 hours).

The type of work to be done and the point of time for re-entering relative to the time of application of the pesticide may vary from crop to crop. However, the following are considered as the key parameters:

- Harvesting method
- Application rate
- Number of applications
- Minimum spray interval
- Transfer Coefficient values

Harvesting method/Task duration	Application rate	No of applications	Minimum spray interval	TC	Crop Group

7.2.3 Bystander exposure

Bystanders are exposed to spray drift at the time of application. Predicted levels of dermal and inhalation exposure will therefore be highest from exposure to the highest in-use spray solutions. If amount of water/ha is not considered relevant for bystander exposure estimation, max. application rate will determine the highest bystander exposure.

Dermal absorption is also a key parameter since low water volumes (i.e. high spray concentrations) are not necessarily worst case as dermal absorption values may be low (e.g. 1%). In contrast, a less concentrated spray may be the worst case with higher dermal absorption values (e.g. 10%). Therefore, for this area of assessment the key parameters are:

- Application equipment and method/spray drift
- Application rate
- Water volume and dermal absorption

Application method/spray drift	Application rate	Water volume/dermal absorption	Crop Group

For plant protection products applied as gases and those that act through significant vapour action the submission of specific data is required in order to address the risk to bystanders and a risk envelope approach will be more difficult to apply in these circumstances.

7.2.4 Resident exposure

There is limited experience in this area since it has only recently been added as a requirement under Regulation (EC) 1107/2009.
Currently there are no harmonised models at EU level for the assessment of resident exposure. The available guidelines are:
a. The UK approach to bystander and resident exposure [2] and
b. Martin et al.; 2008: *Guidance for Exposure and Risk Evaluation for Bystanders and Residents exposed to Plant Protection Products during and after Application*[3]

In this guidance document the UK approach is used as an example. According to the UK approach for low volatility products exposure of bystanders and residents occurs mainly via three routes:

- spray drift
- inhalation via volatilisation of the applied product from the crop or soil surface
- contact with contaminated surfaces (e.g. product that is deposited in private gardens as a result of off target deposition)

For the resident exposure model which considers children's exposure to spray fallout on to private garden, as the exposure model considers dislodgeable foliar residues, the worst case is represented by the maximum total dose and not by the maximum individual dose. The method of application is also important as spray drift from an orchard airblast sprayer will be higher than from a boom sprayer.
The following are considered as the key parameters:

- Application equipment and method/spray drift
- Maximum total dose
- Water volume and dermal absorption

Application method/spray drift	**Maximum total dose**	**Water volume**	**Crop Group**

For plant protection products applied as gases and those that act through significant vapour action the submission of specific data is required in order to address the risk to residents and a risk envelope approach will be more difficult to apply in these circumstances.

7.3 Residues and dietary risk assessment

In the assessment of Residues the possibilities offered by the "risk envelope approach" are limited because the assessment is linked to individual crops (or closely related crops) and uses. The methodology is already described in

[2] CRD to provide reference
[3] J. Vebr. Lebensm., Vol 3, No 3, p. 272-281, August 2008

Appendix D (extrapolation document 7525/VI/95) of the EU working document and the procedures are laid down in Regulation (EC) 396/2005 which also contains the lists with all fixed crop/MRL combinations.

Nevertheless, it is acknowledged that even for the aspect Residues it is possible to identify the worst case use for a given crop (or a set of closely related crops if extrapolation is applicable) by selecting the use which leads to the highest residues critical GAP based on application method, amount of active substance applied, type of formulation, number of applications, application interval and PHI. This approach is already applied in MRL setting.

For each GAP, it is accepted to cover the use with trials deviating from GAP with regard to one application parameter such as dose rate or PHI (25% below and above is acceptable).

To decide whether a new GAP is covered by the existing risk envelope residue trial results should be compared to the residue trial data set underlying the risk envelope: it should be within 25% from the dose rate or PHI from the trial data.

A risk envelope already exists with respect to the location of residue trials. According to the EU working document 1607/VI/97, within Europe two field zones are distinguished for residues: Northern Europe and Southern Europe.
For seed treatment, application in greenhouses, post harvest uses and treatment of empty stores, Europe is not divided into zones according to (EC) Regulation 1107/2009 but entire Europe is one zone.

In principle, for each zone/use a complete set of trials has to be submitted. When one or more zones/circumstances are clearly less worst-case than others based on a partial data set, it might be sufficient if only the more critical data set is completed and all less critical uses in that particular crop or closely related crops are then covered by the risk envelope.

The key parameters determining the risk envelope for Residues are the following:

Crops covered	**Represen-tative crop (trial data)**	**EU residues zone**	**Application parameters for crop grouping (critical GAP)**				
			Method (foliar spray, soil treatment, post harvest use, etc)	**Application Rate (kg a.s./ha)**	**Max. No. applications**	**Minimum Spray Interval (d)**	**PHI (d)**

One difficult sub-part of the residues assessment in zonal authorisation procedures is the calculation of the dietary burden. The risk envelope approach would be useful to derive the dietary burden for the zone. Clear guidance is, however, needed in due course concerning the question on which uses this calculation should be based: On the uses which are authorised in whole EU (e.g. this information could be easily obtained from EFSA after the MRL assessment according to art. 12(1) or 12 (2) has been finalized)? On uses which are authorized in all countries belonging to the zone? Or on all uses authorized in the zRMS?

For dietary risk assessment a risk envelope approach is already applied by calculating the risk for all European consumer groups for which data are contained in EFSA PRIMo and by basing the decision and the MRL proposal on the most critical result.

7.4 Environmental fate & behaviour

Grouping of GAPs and identification of the worst case group/GAP for the application of the risk envelope approach is based on the actual amount of active substance reaching the specific environmental compartments under consideration. In most cases this exposure assessment is an important input for the ecotoxicological risk assessment but especially for groundwater the predicted concentrations are evaluated on their own due to specific assessment criteria laid down in the Uniform Principles.

7.4.1 Soil

The predicted environmental concentration in soil (PEC_{soil}) in the treated field (in-crop) is determined by the amount of active substance reaching the soil. The key parameters are the application rate and the proportion of active substance intercepted by the treated crop. For multiple applications the maximum PEC is affected by the dissipation rate of the active substance, in particular for persistent substances where a possible accumulation in soil following use over several years has to be evaluated.

If the GAP covers applications under cold climate conditions and the PEC_{soil} is determined on the basis of degradation rates measured in laboratory studies, the degradation rate determined in laboratory studies might have to be corrected for a temperature representative for the application time.

Grouping of GAPs is therefore depending on the following parameters:

- Application rate
- Number of applications
- Interval between applications
- Specific interception values related to the crop and its growth stage

Application rate	Number of applications	Interval between applications	Growth stage/interception values	Crop Group

In certain cases the soil depth to be assumed for PEC_{soil} calculation has to be adjusted, e.g. where the application method includes incorporation into soil or where long-term PEC over several years have to be calculated for persistent compounds accounting also for soil cultivation.

PEC_{soil} is the basis for the risk assessment for soil organisms (cf. ecotoxicology section). In the case of persistent active substances possible effects on succeeding crops and residues in succeeding crops have also to be evaluated according to the Uniform Principles.

7.4.2 Groundwater

Estimation of the predicted environmental concentration in groundwater (PEC_{gw}) is driven by the same factors as PEC_{soil} determining the quantity of active ingredient reaching the soil. Additional important parameters are those affecting the degradation rate in soil and the leaching behaviour of the soil water (mainly temperature, precipitation, evapotranspiration). GAP related parameters are therefore the treated crop and succeeding crops as well as the timing of the application(s). For the prediction of concentrations in groundwater according to FOCUS guidance the crop also determines the scenarios to be used in the model simulations with FOCUS-PEARL, FOCUS-PELMO, FOCUS-PRZM or FOCUS MACRO. Therefore, the key factors in this area for crop groupings are the following:

- Application rate
- Number of applications
- Crop
- Specific interception values related to the crop and its growth stage
- Timing of each application
- Application type (to the crop canopy, injection, incorporation

Application rate	**Number of applications**	**relevant crop interception (FOCUSgw)**	**Timing of each application**	**Application type**	**Crop Group**

Even if these parameters allow defining the worst-case quantity reaching the soil and a probable worst case timing of the application, the degradation and sorption behaviour of active ingredients and their metabolites is a complex phenomenon with many various factors related to soil type and weather conditions that are taken into account by complex models (e.g. according to FOCUS guidance), so that the possibility for a reasonable grouping based on the above mentioned parameters may be limited.

Regarding the evaluation of active substances and relevant metabolites together it should be kept in mind that assumptions considered to represent a worst case with regard to behaviour of the parent molecule (i.e. high DT_{50}) will not represent worst case conditions as to the evaluation of metabolites.

7.4.3 Surface water

The prediction of environmental concentrations in surface water and a grouping of GAPs in this respect is complicated by the fact that different routes of entry have to be taken into account.

The various models used to calculate the predictable estimated concentrations of active ingredients and metabolites in surface water (PEC_{SW}), such as FOCUS models, consider spray drift, run-off and drainage as the main routes for contamination of surface water.

The key parameters influencing the entry into adjacent surface water via **spray drift** are: application rate, number of applications and drift scenario. In addition, the choice of drift figures is affected in the case of rapidly dissipating active substances (i.e. DT_{90} in surface water is lower than the application interval).

Since entry via **run-off** is related to the amount of active substance in soil on the treated field the same parameters are of importance as for PEC_{soil}.

As regards entry via **drainage** flow the main factors are comparable to those for PEC_{gw} since the active substance has to be translocated into deeper soil layers.

As an additional route of entry **volatilisation** of the active substance from the treated field followed by dry deposition in adjacent surface waters may be taken into account for the estimation of PEC_{sw}. For the grouping of GAPs this aspect can be regarded of minor importance since volatilisation is mainly driven by the active substance's properties and therefore the exposure is directly related to the application rate.

If the routes of entry are evaluated separately, the key parameters in this area for crop grouping are therefore the following:

Spray drift:

- Application rate
- Number of applications
- Interval between applications
- Spray drift scenario

Application rate	Number of applications	Interval between applications	Spray drift scenario	Crop Group

Run-off:

- Application rate
- Number of applications
- Interval between applications
- Specific interception values related to the crop and its growth stage

Application rate	Number of applications	Interval between applications	Growth stage/interception values	Crop Group

Drainage

- Application rate

- Number of applications
- Crop
- Specific interception values related to the crop and its growth stage
- Timing of each application
- Application type (to the crop canopy, injection, incorporation

Application rate	Number of applications	relevant crop interception (FOCUSgw)	Timing of each application	Application type	Crop Group

If, however, the different routes of entry mentioned above are quantified concurrently in a complex model or combination of models (e.g. according to FOCUS guidance) fate and behaviour of the active ingredients and their metabolites involving several compartments (soil, water) may be influenced by various factors taken into account by these models. In that case the possibility for a reasonable grouping based on the above mentioned parameters may be limited.

PEC_{sw} is the basis for the risk assessment for aquatic organisms (cf. ecotoxicology section). Regarding the evaluation of active substances and relevant metabolites together it should be kept in mind that assumptions considered to represent a worst case with regard to degradation of the parent molecule (i.e. high DT_{50}) will not represent worst case conditions as to the evaluation of metabolites.

The case study in Annex I illustrates an example where crop grouping and identification of worst case exposure are rather simple due to the properties of the active substance. Run-off and drainage are assumed to be no relevant routes of entry as the substance is very rapidly degraded in soil. Due to the very rapid dissipation of the active substance in surface water (DT_{90} < application interval) for the entry route spray drift only single applications have to be evaluated. In addition, no formation of relevant metabolites is assumed.

In other cases the environmental behaviour of the active substance under consideration may be more complicated. For more persistent substances which are also mobile in soil PEC_{SW} due to run-off and/or drainage flow may be higher compared to spray drift. If relevant metabolites have to be assessed with regard to their effects on aquatic organisms a differentiation has to be made concerning the source of the metabolites. Where the metabolite is formed in surface water there is no impact on crop grouping since PEC_{SW} of the metabolite is directly related to PEC_{SW} of the active substance. Where the metabolite is formed in soil possible routes of entry are run-off and drainage flow which may lead to different crop groupings compared to those related to the active substance where spray drift might be the most important entry route. This applies also to metabolites which are formed in sediment.

In such cases the application of the risk envelope approach should be considered with great care and might even not be feasible since for the identification of the worst case exposure every single use has to be evaluated separately.

7.5 Ecotoxicology

Generally, the risk envelope approach aims to identify the GAP that leads to the highest exposure of non-target organisms to plant protection products or in the opposite case to the lowest toxicity exposure ratios or the highest Hazard Quotient values.

As the methods and models for the calculation of the exposure are specified in the relevant guidance documents, generally, the relevant guidance documents have to be applied in order to identify the critical GAP.

The risk envelope approach explores the idea that the critical GAP can be identified based on some key parameters, which have a great influence on the expected exposure level. The key parameters for the different groups of organisms are outlined below. Nevertheless, for some groups of organisms it might be necessary to perform almost a complete risk assessment in order to be able to identify the worst-case GAP.

It further should be considered that in case that the relevant trigger values according to Annex VI are breached by the worst-case GAP a refined risk assessment is required which might take into account more realistic assumptions as specified in the respective guidance documents or mitigation measures should be proposed. As such refinement steps often are very specific for a crop, region, application timing, etc. it should be carefully considered whether these assessments still cover the lower risk GAPs. If this is not the case the identification of the critical GAP should be started again excluding the GAP addressed by the refined assessment.

7.5.1 Birds and mammals

Currently the Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/41/EEC (SANCO/4145/2000, final 2002) and the Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA (EFSA Journal 2009; 7(12):1438) might be applied in order to assess the risk for birds and mammals. As a first step, the Guidance document which is intended to be followed for the evaluation should be selected.

7.5.1.1 Identification of the critical GAP based on the Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/41/EEC (SANCO/4145/2000, final 2002):

According to this guidance document the different crops of the GAP are allocated to five crop groups including grassland, cereals, leafy crops, orchard/vine/hops and seed treatment. No further crop grouping should be performed.

A comparison of these crop groupings might be possible to a certain extent based on the standard residue and food intake rate values assuming a normalised application scheme.

According to this procedure grassland, cereals early and orchards/vine/hops (without considering interception) represent the scenarios with the highest expected exposure for mammals, followed by leafy crops and cereals late.

For birds leafy crops represent the highest exposure scenario, followed by grassland and cereals early, and cereals late and orchard/vine/hops. A pre-selection might therefore be based on this order, presumed that applied uses are comparable. Seed treatments should always be treated separately.

Within the crop groupings the following key parameters determined by the formula to calculate the Estimated Theoretical Exposure (ETE) should be considered for the identification of the worst case GAP **for the first tier assessment**:

- Application rate
- Interception (dependent on the crop, the growth stage and the diet)
- Number of applications
- Application interval

Application rate	Interception values	Number of applications	Application interval	Crop Group

Risk assessment for fish-and earthworm eating birds and mammals:
The key parameters for the estimated theoretical exposure calculation for birds and mammals are the PECsoil and the PEC surface water.

Drinking water
The drinking water assessment is driven by the single worst-case application rate and the water volume.

7.5.1.2 Identification of the critical GAP based on the Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA:

According to the new guidance document for birds and mammals, crops are again allocated to crop groups represented by indicator species. A comparison between these scenarios is allowed by the calculation of a dietary dose which is done by multiplying the single application rates with the shortcut values and respective multiple application factors (MAF) in case that the product is applied two or more times. These calculations should be performed for the acute exposure based on the MAF for 90th percentile residue data and for the long-term exposure with the MAF for the 50th percentile.
Following this procedure the key parameters for the first tier assessment are:

- Application rate
- Number of applications
- Application interval

Interception is covered by the shortcut values.

Indicator species	Maximum rate / Minimum interval	MAF_{50} Or MAF_{90}	Effective rate	Short cut value	Crops	Crop group

Risk assessment for fish-and earthworm eating birds and mammals:
The key factors for the estimated theoretical exposure calculation for birds and mammals are PEC_{soil} and $PEC_{surfacewater}$.

Drinking water
The drinking water assessment is driven by the single worst-case application rate and the concentration of the spray solution.

The risk envelope approach might not be applicable for uses like seed treatments and granular formulations. However, in most of theses cases it is also not expected that the risk envelope approach is necessary, as the variation within the intended application rates and crops is often quite limited.

For the refinement of risk assessment higher tier data are usually used e.g. measured residue data, proportion of the time the animal spends in the crop or the proportion of its diet.

As already mentioned, such refinement steps often are very specific for a crop, region, application timing, etc. therefore they should not be included in the core dossier for assessment by the zRMS.

<u>*7.5.2 Aquatic organisms*</u>
The identification of the critical GAP for aquatic organisms generally is driven by the predicted environmental concentrations in surface water (PEC_{sw}).

<u>*7.5.3 Honeybees*</u>
The input parameter for the first tier risk assessment for bees is the maximum single application rate.
Tier 1 risk assessment considers direct exposure through oral and contact routes for HQ calculation which depends mainly on:

- Application method (e.g. spray, soil incorporation, …)
- Growth stage
- Application rate

Application method	Growth Stage	Application rate	Crop Group

Crop may be also a relevant parameter in certain cases e.g. systemic substances: flowering vs. non-flowering crops, risk of honeydew; seed treatment: sowing method and coating type may influence the risk from dust exposure.

7.5.4 Non-target arthropods

In the risk assessment for arthropods other than bee exposure in-field and off-field should be calculated. For **in-field** risk assessment the following are considered as key parameters:

- Application method
- Growth stage
- Application rate
- Number of applications
- Interval between applications

In-field exposure

Application method	Growth stage	Application rate	Number of applications	Interval between applications	Crop Group

Off-field exposure

Predicted environmental concentrations for terrestrial **off-field** habitats are the basis for the risk assessment for non-target arthropods and terrestrial non-target plants (see below).

Predicted environmental concentrations for terrestrial off-crop habitats are usually expressed as a rate (kg or gr a.s./ha). The main route of entry is spray drift predominantly influenced by application rate, number of applications and drift scenario.

For multiple applications dissipation of active substances on surfaces like leaves is taken into account by using multiple application factors (MAF) depending also on the application interval.

As an additional route of entry volatilisation of the active substance from the treated field followed by dry deposition in adjacent habitats may be taken into account for the estimation. For the grouping of GAPs this aspect can be regarded of minor importance since volatilisation is mainly driven by the active substance's properties and therefore the exposure is directly related to the application rate. The key parameters in this area for crop grouping are therefore the following:

- Application rate
- Number of applications
- Spray drift scenario (which is dependant on the crop and timing of application)

Rate (No. of apps x max rate, kg a.s./ha)	**Number of applications**	**MAF**	**Spray drift scenario**	**Crop Group**

7.5.5 *Soil organisms*

The exposure of soil organisms is based on the predicted environmental concentration in soil (PEC_{soil}) which is mainly driven by:

- Application rate
- Number of applications
- Interval between applications
- Specific interception values related to the crop and its growth stage

Application rate	Number of applications	Interval between applications	Growth stage/interception values	Crop Group

It may be possible to cover the maximum predicted environmental concentration and if this is acceptable then this can be extrapolated to other uses.

7.5.6 *Non-target plants*

The key parameters should be considered in defining crop groupings in this area of risk assessment are the same as for non-target arthropods in off-field (see section 7.5.4 above). In addition, DT_{50} is a key parameter in case there is a need for refinement of the risk assessment.

It should be noted that it is still not yet harmonised whether the maximum application rate or the multiple application factors (MAF) should be used. Applicants are advised to consult on this aspect the zRMS during the pre-submission meetings.

7.5.7 *Biological sewage treatment*

Information from biological sewage treatment should be summarised.

7.6 Efficacy

The risk envelope approach is not applicable to this section. Indeed, efficacy is not a risk even if it is clearly the basis for GAPs setting. Nevertheless, it is still possible to reduce the workload in this area by making use of the relevant extrapolation guidelines or in the case of multiple applications with similar formulations and GAPs to extrapolate the risk assessment from the “master product”.

8 KEY PARAMETERS FOR OTHER CATEGORIES OF PRODUCTS OR USES

8. 1 Key parameters for the determination of risk envelopes in the case of plant protection products with different formulation types **(to be added *at a future date*)**

9 CASE STUDIES

To facilitate the understanding of the “risk envelope” approach in Annex I a case study is presented. This approach, despite the fact elaborated by the applicant and MS experts, does not exclude that different approaches might be applied by MS.
It is anticipated that this part of the document will be amended in future to include further case studies in the light of the experience gained.

ANNEX I

Case study: Foliar pesticide

Step 1

An analysis was conducted of the existing authorisations in the MS of the zone and GAPs were compared. This analysis showed that approximately 40 crops were registered across the zone.
These crops were grouped into sub-categories on the basis of the availability of data to support their re-registration as well the possibilities offered to make use of the extrapolation guidelines.
The strategy was to give emphasis to those crops which are supported by available data while for the other crops it was decided to make use as far as possible of the possibilities given for extrapolation and as a last resource to generate the required data.

Step 2
Following the analysis in step 1 the applicant decided to rationalise the GAPs that will be supported across the zone. In the following table is given the GAP that the applicant has decided to support.

List of Intended Uses

Formulation Information
Name: XXX Fungicide, Code: XXXX, Concentration and Type: 800 g a.s./kg WP
Country: EU XX Zone

Crop and/or situation	Pests controlled	Application				Application rate per treatment		Pre-Harvest Interval (days)	Remarks
		Type/Method	BBCH Growth stage	Maximum Number per Season	Minimum Interval (days)	kg a.s./ha	Water Volume (L/ha)		
Potato	PHYTIN, ALTESO	Field/Broadcast foliar	15-90	8	7	1.6	150 to 1000	7	
Apple	VENTIN	Field/Broadcast foliar	15-85	4	10	1.6	500 to 1500	28	Apply every 10 days in tank mixture with complementary fungicides such as XXXX or XXXX
Apple	VENTIN	Field/Broadcast foliar	15-85	4	14	1.6	500 to 1500	28	Apply every 14 days in alternation with other protectant fungicides such as XXXX.
Pear	VENTIN	Field/Broadcast foliar	15-85	4	10	1.6	500 to 1500	28	Apply every 10 days in tank mixture with complementary fungicides such as XXXX or XXXX
Pear	VENTIN	Field/Broadcast foliar	15-85	4	14	1.6	500 to 1500	28	Apply every 14 days in alternation with other protectant fungicides such as XXXX.
Ornamental Trees	ZZYYFF	Field/Broadcast foliar	15-85	4	10	1.6	500 to 1500	--	
Cherry	TRANPS, VENTCA, BLUMJA, CLADSP	Field/Broadcast foliar	19-77	4	10	1.6	500 to 1500	30	
Plum	TRANPS, VENTCA	Field/Broadcast foliar	19-77	4	10	1.6	500 to 1500	30	
Peach	TRANPS, VENTCA	Field/Broadcast foliar	19-81	4	10	1.6	500 to 1500	30	
Nectarine	TRANPS, VENTCA	Field/Broadcast foliar	19-81	4	10	1.6	500 to 1500	30	

Formulation Information
Name: XXX Fungicide, Code: XXXX, Concentration and Type: 800 g a.s./kg WP
Country: EU XX Zone

Crop and/or situation	Pests controlled	Application				Application rate per treatment		Pre-Harvest Interval (days)	Remarks
		Type/Method	BBCH Growth stage	Maximum Number per Season	Minimum Interval (days)	kg a.s./ha	Water Volume (L/ha)		
Walnut	GNOMLE	Field/Broadcast foliar	15-85	4	10	1.6	500 to 1500	45	
Grape	PLASVI, GUIGBI, PSPZTR	Field/Broadcast foliar	15-85	4	10	1.6	200 to 1000	28	
Tomato	ALTETO, CLADSP, PHYTIN	Field/Broadcast foliar	13-89	5	7	1.6	500 to 1000	3	
Peppers	PEROSP, ALTESP	Field/Broadcast foliar	16-84	4	7	1.6	500 to 1000	3	
Eggplant (Aubergine)	ALTETO, CLADSP, PHYTIN	Field/Broadcast foliar	13-89	5	7	1.6	500 to 1000	3	
Zucchini	COLLLA, CLADCU, PSPECU	Field/Broadcast foliar	15-89	4	7	1.6	500 to 1000	3	
Gherkin	COLLLA, CLADCU, PSPECU	Field/Broadcast foliar	15-89	4	7	1.6	500 to 1000	3	
Cucumber	COLLLA, CLADCU, PSPECU	Field/Broadcast foliar	15-89	4	7	1.6	500 to 1000	3	
Squash	COLLLA, CLADCU, PSPECU	Field/Broadcast foliar	15-89	4	7	1.6	500 to 1000	3	
Melons	COLLLA, CLADCU, PSPECU	Field/Broadcast foliar	15-89	4	7	1.6	500 to 1000	3	
Onion, bulb (Dry bulb)	PERODE, ALTESP, PUCCAL	Field/Broadcast foliar	12-49	4	7	2.0	200 to 1000	28	
Leek	PERODE, ALTESP, PUCCAL	Field/Broadcast foliar	12-49	3	7	2.0	200 to 1000	28	

Formulation Information
Name: XXX Fungicide, Code: XXXX, Concentration and Type: 800 g a.s./kg WP
Country: EU XX Zone

Crop and/or situation	Pests controlled	Application				Application rate per treatment		Pre-Harvest Interval (days)	Remarks
		Type/Method	BBCH Growth stage	Maximum Number per Season	Minimum Interval (days)	kg a.s./ha	Water Volume (L/ha)		
Garlic	PERODE, ALTESP, PUCCAL	Field/Broadcast foliar	12-49	4	7	2.0	200 to 1000	28	
Shallot	PERODE, ALTESP, PUCCAL	Field/Broadcast foliar	12-49	4	7	2.0	200 to 1000	28	
Ornamental flowers	PUCCSP	Field/Broadcast foliar	15-89	4	7	1.6	200 to 1000	--	
Lettuce, head	BREMLA	Field/Broadcast foliar	12-49	4	7	1.6	200 to 1000	28	
Asparagus	PUCCAS, STEMSP	Field/Broadcast foliar	15-89	4	14	1.6	200 to 1000	--	Apply in year prior to next season harvest
Carrot	COLLLD, ALTEDA, PLASCR	Field/Broadcast foliar	12-49	4	14	1.6	200 to 1000	30	
Salsify	COLLLD, ALTEDA, PLASCR	Field/Broadcast foliar	12-49	4	14	1.6	200 to 1000	30	
Cauliflower	ALTEBI, PEROPA	Field/Broadcast foliar	12-49	4	14	1.6	200 to 1000	30	
Broccoli	ALTEBI, PEROPA	Field/Broadcast foliar	12-49	4	14	1.6	200 to 1000	30	
Wheat, Spring	SEPTTR	Field/Broadcast foliar	30-65	3	14	1.6	200 to 400	--	PHI is not specified for cereals
Wheat, Winter	SEPTTR	Field/Broadcast foliar	30-65	3	14	1.6	200 to 400	--	PHI is not specified for cereals
Bean, Field (Dry)	PUCCSP, ASCOPI, COLLLD	Field/Broadcast foliar	13-75	1	--	1.6	200 to 400	28	
Pea, Field (Dry)	PUCCSP, ASCOPI, COLLLD	Field/Broadcast foliar	13-75	1	--	1.6	200 to 400	28	
Olive	CLADSP, CYCLOL	Field/Broadcast foliar	19-91	1	--	2.4	500 to 1500	21	
Lemon	PHYTCO, ZZYYFF	Field/Broadcast foliar	19-89	1	--	2.4	500 to 1500	14	

Formulation Information Name: XXX Fungicide, Code: XXXX, Concentration and Type: 800 g a.s./kg WP Country: EU XX Zone									
Crop and/or situation	**Pests controlled**	**Application**				**Application rate per treatment**		**Pre-Harvest Interval (days)**	**Remarks**
		Type/Method	**BBCH Growth stage**	**Maximum Number per Season**	**Minimum Interval (days)**	**kg a.s./ha**	**Water Volume (L/ha)**		
Orange, Seville	PHYTCO, ZZYYFF	Field/Broadcast foliar	19-89	1	--	2.4	500 to 1500	14	
Mandarin	PHYTCO, ZZYYFF	Field/Broadcast foliar	19-89	1	--	2.4	500 to 1500	14	
Grapefruit	PHYTCO, ZZYYFF	Field/Broadcast foliar	19-89	1	--	2.4	500 to 1500	14	
Currants, Black	DREPRI	Field/Broadcast foliar	13-97	4	10	1.6	400 to 1000	30	
Gooseberry	DREPRI	Field/Broadcast foliar	13-97	4	10	1.6	400 to 1000	30	

Supported uses are all outside uses, applicant does not support the glasshouse use of XXXX products

Step 3: Risk envelopes in each area of risk assessment

1. Toxicology

1.1 Operator exposure

Rationale for crop groupings:

Method of application

Applications of the product on potatoes, field crops, and cereals will be achieved using tractor-mounted/-trailed boom sprayer: hydraulic nozzles (‘boom’). Applications to tree fruits, citrus and vines will be achieved using tractor-mounted/-trailed broadcast air-assisted sprayers (‘airblast’). Water is the intended diluent/carrier.

The key factor in this area is the method of application. In the example we are examining the applicant is proposing two methods of application: Boom and Airblast. The crop groupings covering the worst case scenarios would be:

Method of Application	Application Rate		Water Volume (L/ha)	Crop Grouping
	Active (kg/ha)	Product (kg/ha)		
Boom [∞]	2.0	2.5	200	Potatoes[∞] Field crops* Cereals[#]
Airblast [$]	1.6	2.0	200	Tree fruit[$] Citrus[†] Vines
Airblast [$]	2.4	3.0	500	Tree fruit[$] Citrus[†]

[∞] covers Peas, Beans, Tomato, Zucchini, Pepper, Aubergine, Gherkin, Cucumber, Squash, Melon, Lettuce, Asparagus, Carrot, Salsify, Cauliflower, Broccoli, Onion (bulb), Leek, Garlic, Shallot, Onion, Ornamental flowers, Wheat (spring and winter)
[$] covers Apple, Pear, Cherry, Plum, Peach, Apricot, Nectarine, Walnut, Ornamental trees,
[†]Olive, Lemon, Orange, Mandarin, Grapefruit, Vines

1.2 Worker exposure

Rationale for crop groupings:

Field crops - covering potatoes, cereals, broccoli, cauliflower, gherkin, squash, chicory, lettuce, asparagus, carrot, salsify, bean, pea, onion (bulb), leek, garlic, shallot, onion, melon, zucchini
The re-entry crop grouping ‘Field crops’ also includes potatoes. The re-entry crop grouping ‘Field crops’ uses potatoes as a worst-case field crop for re-entry risk assessment as it has a maximum of 8 applications per season. An appropriate transfer coefficient (TC) for field is considered to be 2500 cm^2/h (EUROPOEM II, 2002) and is considered applicable to all crops in this crop grouping.

Ornamental flowers - An appropriate transfer coefficient (TC) for this group of crops is considered to be 5000 cm^2/h (EUROPOEM II, 2002).

Solanaceae - covering tomatoes, aubergines and peppers. An appropriate transfer coefficient (TC) for this group of crops is considered to be 4500 cm^2/h (EUROPOEM II, 2002).

Tree fruit/Citrus– covering cherry, plum, apple, pear, peach, apricot, nectarine, walnut, ornamental trees, olive, lemon, orange, mandarin, grapefruit,:
The re-entry activities include pruning, harvesting and fruit thinning. An appropriate transfer coefficient (TC) for tree fruits is considered to be 4500 cm^2/hr (EUROPOEM II, 2002) and is considered applicable to all crops in this crop grouping.

Vines – The transfer coefficient (TC) for vines is not harmonised yet and needs to be discussed and agreed with the zRMS.

In the light of the above for the example we are examining the crop groupings covering the worst case scenarios would be:

Harvesting method/ Task Duration (h)	Application rate (Kg/ha)	No of applications	Minimum spray interval (days)	TC (cm^2/h)	Crop Group
8 or 2 to crops where only crop inspection is identified	1.6	8	7	2500	field crops
8	1.6	4	10	4500	Tree crops/citrus/
8	2.0	5	7	5000	onion, leek etc.
8	1.6	5	7	4500	solanaceae
8	1.6	4	10	to be harmonize d	Vines

1.3 Bystander exposure

Rationale for Crop Groupings:

Boom – covering potato, peas, beans, tomato, aubergine, peppers, zucchini, gherkin, cucumber, squash, melon, chicory, lettuce, asparagus, carrot, salsify, cauliflower, broccoli, onion (bulb), leek, garlic, shallot, onion, ornamental flowers, wheat (spring and winter):
Potato has been used to assess potential bystander exposure from application of a.s to field crops because the worst-case application parameters for potatoes (i.e. 1.6 kg a.s./ha and 150 L/ha) results in the highest in-use spray concentration of a.s. (10.67 mg a.s./mL). As water volume is only affecting the respiratory exposure, potato is only the worst case with low dermal absorption values (e.g. 1%). With higher dermal absorption values (e.g. 10%), the application rate of 2.0 kg a.s./ha with 200 L/ha is the worst case.

Airblast – covering cherry, plum, apple, pear, ornamental trees, peach, apricot, nectarine, walnut and vines:
The worst case will be given by the use having the highest spray concentration as exposure occurs via drift from the applied spray solution. The use on grapes (1.6 kg a.s in 200 litres water) gives a higher spray concentration than the tree fruit uses (2,4 kg a.s. in 500 litres water) therefore this represents the worst case. If amount of water/ha is not considered relevant for bystander exposure estimation, max. application rate is determining the highest bystander exposure.

Application method/spray drift	Application rate Kg a.s./ha	Water volume L/ha	Group
Boom	1.6	150	Field crops/ Cereals*
Boom	2.0	200	Field crops/ Cereals**
Airblast	1.6	200	Vines
Airblast	2.4	500	Olive/Citrus trees

* with low dermal absorption values (e.g. 1%)
** with high dermal absorption values (e.g. 10%)

1.4. Resident exposure

Rationale for Crop Groupings:

For spray drift at the time of application the worst case is given by the application method giving the highest level of spray drift (orchard air blast) combined with the highest spray solution concentration. In this example the worse case is represented by use on grapes. Some uses have a marginally higher spray concentration (potato, garlic, shallot) but these crops are all applied via boom sprayers where the spray drift levels will be lower.

The exposure model for inhalation via volatilisation of the applied product from the crop or soil surface does not differentiate between application method or application rate. A single assessment will therefore cover all uses.

The resident exposure model considers children's exposure to spray fallout on to private garden. This exposure model predicts dermal and oral exposure arising through contact with dislodgeable foliar residues on turf. As there is potential for these DFR to accumulate where a number of treatments are made to an adjacent crop, the worst case in terms of dose rate is represented by use(s) having the highest maximum total dose rather than the maximum individual dose. The method of application is also important. If rates of use are similar across all supported uses, the worse case will be represented by crops treated with an orchard airblast sprayer, as levels of drift will be higher from this method of application than from equivalent applications made using boom sprayers. In the case study example, pome and stone fruit are treated with an orchard airblast sprayer and for this method of application these uses have the highest maximum total dose. For potato, levels of drift from boom spray applications are expected to be lower than from airblast sprayers. However, potato crops may receive up to 8 individual treatments so the maximum total dose is significantly higher than applied to the pome/stone fruit uses. The risk envelope approach would therefore require a resident (children's exposure) assessment for the pome/stone fruit (orchard airblast) and the potato (boom sprayer) uses.

Application method/spray drift	Maximum total dose kg a.s./ha	Water volume (L/ha)	Crop Group
Airblast	6.4	500	Tree crops
Boom	12,8	150	Potatoes

2. Residues

In the specific example we need to examine the following crop groupings which are identified based on EU working document Appendix D: extrapolation document 7525/VI/95:

1. Citrus Fruits: within the crop group citrus separate residue trial sets need to be evaluated for "big" and "small" citrus fruits (orange and mandarin, respectively).
2. Pome fruit: a residue data set for apples or pears is needed and can be extrapolated from one to the other
3. Stone fruits: Even if the same GAP is proposed for the group, separate residue trial sets need to be evaluated for peach/nectarine, plums and cherries.
4. Walnut: a residue trial set with walnut is needed or trials with two representative tree nuts is needed
5. Olives (table and oil): a residue trial set with olives.
6. Grapes (table and wine): a residue trial set with grape is needed
7. Carrot, salsify: a residue trial set with carrot is needed and can be extrapolated to salsify
8. Onion (bulb), garlic, shallot: a residue trial set with bulb onions is needed and can be extrapolated to onions, shallot and garlic
9. Potato: a residue trial set with potatoes is needed
10. Broccoli and cauliflower: a combined residue trial set with both crops is needed and can be extrapolated to both crops
11. Tomato, aubergine: a residue trial set with tomatoes is needed and can be extrapolated to aubergine
12. Peppers: a residue trial set with sweet pepper is needed to cover the whole group of peppers
13. Zucchini, gherkin, cucumber, squash: a residue trial set with cucumber or squash is needed and can be extrapolated to the whole group of cucurbits with edible peel
14. melon: a residue trial set with melons
15. lettuce: a residue trial set with lettuce
16. asparagus: a residue trial set with asparagus
17. bean, pea: a residue trial set with peas and/or beans is needed
18. leek: a residue trial set with leek is needed
19. Cereals: a residue trial set with wheat is needed (and can be extrapolated to rye).

Parameters determining the risk envelope:

Crops covered	Represen-tative crop (trial data)	EU zone	Application parameters for crop grouping (critical GAP)				
			Method	Application Rate (kg a.s./ha)	Max. No. applications	Minimum Spray Interval (d)	PHI (d)
Citrus	Mandarin and orange	Southern	Foliar spray	2.4	1	-	14
Stone fruits	Peach, nectarine	Southern	Foliar spray	1.6	4	10	30
Stone fruits	Plum	Southern	Foliar spray	1.6	4	10	30
Stone fruits	cherries	Southern	Foliar spray	1.6	4	10	30
Walnut	Walnut or 2 other representative tree nut species	Southern	Foliar spray	1.6	4	10	45
Apple, pear	Apple or pear	Southern	Foliar spray	1.6	4	10	28
Olives	olives	Southern	Foliar spray	2.4	1	-	21
Grape	grape	Southern	Foliar spray	1.6	4	10	28
Black currants and gooseberries	Black currants	Southern	Foliar spray	1.6	4	10	30
Carrot, salsify	carrot	Southern	Foliar spray	1.6	4	14	30
Onion shallot, garlic	onion	Southern	Foliar spray	2.0	4	7	28
Potato	Potato	Southern	Foliar spray	1.6	8	7	7
Broccoli, cauliflower	Broccoli and cauliflower	Southern	Foliar spray	1.6	4	14	30
Tomato, aubergine	Tomato	Southern	Foliar spray	1.6	5	7	3
peppers	Sweet pepper	Southern	Foliar spray	1.6	4	7	3
Cucurbits edible peel	Cucumber and/or squash	Southern	Foliar spray	1.6	4	7	3
Melon	Melon	Southern	Foliar spray	1.6	4	7	3
Head lettuce	Head lettuce	Southern	Foliar spray	1.6	4	7	28
Asparagus	Asparagus	Southern	Foliar spray	1.6	4	14	-
Bean, pea	Bean and/or pea	Southern	Foliar spray	1.6	1	-	28
Leek	Leek	Southern	Foliar spray	2.0	3	7	28
Wheat	Wheat	Southern	Foliar spray	1.6	3	14	-

3. Environmental fate & behaviour

In order to identify the worst-case use pattern for the different environmental compartments, GAPs are grouped with respect to the key factors specified in subchapter 7.4.

3.1 Soil

Grouping of crops with regard to PEC_{soil} is outlined in the following table. The crop group potato can be regarded as worst case followed by bulb vegetables.

Crop Group	**Crops Included**	**Rate** (No. of apps x max rate, kg a.s./ha)	**Crop growth stage (BBCH)**	**Relevant crop inter-ception (FOCUS)**	**Effective application rate reaching the soil**
Potato	Potato	8 x 1.6	15-90	15 %	8 x 1.36 = 10.88
Pome/stone fruit, ornamental tree and bushberry	Apple, Pear, Cherry, Plum, Peach, Apricot, Nectarine, Walnut, Blackcurrant, Gooseberry, Ornamental Trees	4 x 1.6	15-85	65 %	4 x 0.56 = 2.24
Grape and fruiting vegetable	Grape, peppers, zucchini, gherkin, cucumber, squash, melons	4 x 1.6	15-85 16-84 15-89	50 %	4 x 0.8 = 3.2
Fruiting vegetable	Tomato, Aubergine	5 x 1.6	13-89	50 %	5 x 0.8 = 4.0
Bulb vegetable	Onion, Garlic, Shallot,	4 x 2.0	12-49	10 %	4 x 1.8 = 7.2
Leek	Leek	3 x 2.0	12-49	10 %	3 x 1.8 = 5.4
Leafy vegetable, Root vegetable, ornamentals	Lettuce, Chicory Cauliflower, Broccoli, , Carrot, Salsify, Ornamental Flowers	4 x 1.6	12-49 15-89	25 %	4 x 1.2 = 4.8
Asparagus	Asparagus	4 x 1.6	15-89	10 %	4 x 1.44 = 5.76
Cereal	Winter wheat, Spring wheat	3 x 1.6	30-65	70 %	3 x 0.48 = 1.6
Legume/Pulse	Field bean, Field pea,	1 x 1.6	13-75	25 %	1 x 1.2 = 1.2
Citrus	Orange, Lemon, Mandarin, Grapefruit,	1 x 2.4	19-91	70 %	1 x 0.72 = 0.72
Olive	Olive	1 x 2.4	19-91	30 %	1 x 1.68 = 1.68

3.2 Groundwater

Grouping of crops with regard to PEC_{gw} is the same as outlined for soil assuming that application in all crops will take place during the growing season (spring/summer). If winter wheat is treated in autumn the uses in cereals would divide into two groups: winter cereals and spring cereals. Again, the crop group potato can be regarded as worst case followed by bulb vegetables.

Additional crop grouping may be considered where following FOCUS modelling simulations, uses in field beans and field peas at 1 x 1.6 kg/ha are covered by use in winter wheat at 3 x 1.6 kg/ha as a worst-case. The uses in tomatoes (5 x 1.6 kg/ha) or onions (4 x 2.0 kg/ha) are considered to cover the use in leafy vegetables at 4 x 1.6 kg/ha. Other uses with multiple applications that give a higher total seasonal application rate, particularly 4 x 1.6 kg/ha in pome/stone fruit and vines, are considered to be sufficiently protective to cover the single use at 2.4 kg/ha in citrus and olives.

3.3 Surface water

Due to the rapid degradation of the active substance in soil and surface water (DT_{50} < 1 d) the grouping of GAPs with regard to PEC_{sw} in this case is determined by the entry route spray drift considering single application rates and the spray drift scenario relevant to the crop. Grouping of crops is outlined in the following table. The crop group “Citrus, olive” can be regarded as worst case followed by “ Pome/stone fruit, ornamental tree”.

Crop Group	**Crops Included**	**Single application rate** (kg a.i./ha)	**Spray drift scenario**
Citrus, Olive	Orange, Lemon, Mandarin, Grapefruit, Olive	2.4	Orcharding early
Pome/stone fruit, ornamental tree	Apple, Pear, Cherry, Plum, Peach, Apricot, Nectarine, Walnut, Ornamental Trees	1.6	Orcharding early
Grape, bushberry and fruiting vegetable	Grape, Blackcurrant, Gooseberry, Tomato, Aubergine, peppers, zucchini, gherkin, cucumber, squash, melons	1.6	Vine
Bulb vegetable	Onion, Garlic, Shallot, Leek	2.0	Field crops
Potato, Leafy vegetable, Root vegetable, ornamentals, Cereal, Legume/Pulse	Potato, Lettuce, Chicory Cauliflower, Broccoli, , Carrot, Salsify, Asparagus Ornamental Flowers, Winter wheat, Spring wheat, Field bean, Field pea	1.6	Field crops

4. Ecotoxicology

4.1 Birds and mammals

In this case study it is proposed a crop grouping taking into account both guidance documents in place.

Crop grouping according to SANCO 4145/2000: foliar application

Rationale for crop grouping

The risk assessment has been based on a risk envelope approach for the use patterns as summarized in the Table below***,*** which are derived from the master GAP. The risk envelope approach groups use patterns that overlap for parameters such as application rate, number of applications and application interval and for environmental parameters such as indicator species and dietary item. SANCO 4145/2000 divides foliar sprays to crops into four crop groupings and the indicator species are presented for these

Use patterns grouped for avian risk envelope assessment for first tier risk assessment (critical use pattern in bold).

Crop	BBCH Growth Stage	Maximum Number per Season	Minimum Interval (days)	Rate (kg a.s./ha)	Water Volume (L/ha)	Group	Tier 1 Indicator Species
Potato	**15-90**	**8**	**7**	**1.6**	**150 to 1000**	**Potato** (Leafy crops unpalatable)	Insectivorous bird
Tomato	13-89	5	7	1.6	500 to 1000		
Pepper	16-84	4	7	1.6	500 to 1000		
Eggplant	13-89	5	7	1.6	500 to 1000		
Zucchini	15-89	4	7	1.6	500 to 1000		
Gherkin	15-89	4	7	1.6	500 to 1000		
Cucumber	15-89	4	7	1.6	500 to 1000		
Squash	15-89	4	7	1.6	500 to 1000		
Melon	15-89	4	7	1.6	500 to 1000		
Grape	**15-85**	**4**	10	**1.6**	**200 to 1000**	**Orchard/Vine** (Includes berry crops)	Insectivorous bird
Apple	15-85	4	10	1.6	500 to 1500		
Apple	15-85	4	14	1.6	500 to 1500		
Pear	15-85	4	10	1.6	500 to 1500		
Pear	15-85	4	14	1.6	500 to 1500		
Ornamental	15-85	4	10	1.6	500 to 1500		
Trees	19-77	4	10	1.6	500 to 1500		
Cherry	19-77	4	10	1.6	500 to 1500		
Plum	19-81	4	10	1.6	500 to 1500		
Peach	19-81	4	10	1.6	500 to 1500		
Nectarine	15-85	4	10	1.6	500 to 1500		
Walnut	13-97	4	10	1.6	400 to 1000		
Currants, Black Gooseberry	13-97	4	10	1.6	400 to 1000		
Olive	**19-91**	**1**	**--**	**2.4**	**500 to 1500**	**Olive/Citrus** (Orchard/vines/ hops)	Insectivorous bird
Lemon	19-89	1	--	2.4	500 to 1500		
Orange, Seville	19-89	1	--	2.4	500 to 1500		
Mandarin	19-89	1	--	2.4	500 to 1000		
Grapefruit	19-89	1	--	2.4	500 to 1500		
Onion, bulb	**12-49**	**4**	**7**	**2.0**	**200 to 1000**	**Onion, bulb** (Leafy crops)	Insectivorous bird Medium herbivorous bird
Leek	12-49	3	7	2.0	200 to 1000		
Garlic	12-49	4	7	2.0	200 to 1000		
Shallot	12-49	4	7	2.0	200 to 1000		
Asparagus	15-89	4	14	1.6	200 to 1000		
Carrot	**12-49**	**4**	**14**	**1.6**	**200 to 1000**	**Carrot** (Leafy crops)	Insectivorous bird Medium herbivorous bird
Salsify	12-49	4	14	1.6	200 to 1000		
Broccoli	**12-49**	**4**	**14**	**1.6**	**200 to 1000**	**Broccoli** (Leafy crops)	Insectivorous bird Medium herbivorous bird
Cauliflower	12-49	4	14	1.6	200 to 1000		
Lettuce, head	**12-49**	**4**	**7**	**1.6**	**200 to 1000**	**Lettuce** (Leafy crops)	Insectivorous bird Medium herbivorous bird
Wheat, Spring	**30-65**	**3**	**14**	**1.6**	**200 to 400**	**Wheat** (Cereals, late)	Large Insectivorous bird
Wheat, Winter	30-65	3	14	1.6	200 to 400		
Bean, Field (Dry)	**13-75**	**1**	**--**	**1.6**	**200 to 400**	**Bean, Field** (Leafy crops)	Insectivorous bird Medium herbivorous bird
Pea, Field (Dry)	13-75	1	--	1.6	200 to 400		
Ornamental flowers	**15-89**	**4**	**7**	**1.6**	**200 to 1000**	**Flowers** (Leafy crops)	Insectivorous bird Medium herbivorous bird

Several factors were considered in grouping crops under the risk envelope approach and in selecting the critical use for the group: 1) field crops with toxic and unpalatable foliage; 2) orchard and vine crops for which the insectivorous bird is the Tier 1 indicator species; 3) field crops with similar foliage characteristics and where extrapolation between the crops can be agreed and for which at least one member of the group has measured foliage residue data; 4) generic crops which cannot be otherwise grouped. Justifications for crop groupings based on these factors are presented below. Often however the simplest approach is to group crops on the basis of the crop types given in SANCO 4145/2000 and consider the maximum rates and maximum number of applcatios.

A number of crops have toxic and unpalatable foliage including the Solanaceae (potatoes, tomatoes, peppers, eggplant) and the Cucurbitaceae (zucchini, gherkin, cucumber, squash, melon).

Based on the anti-feedant effects of the bitter taste and the significant acute and long term toxicity of cucurbitacins found in cucurbit foliage, it can be concluded that cucurbit foliage would not constitute a relevant portion of the diet of herbivorous birds or mammals. Furthermore, weeds are not prevalent in cucurbit fields due to the active management against weeds by use of herbicides and the use of plastic mulch technology (Zaragoza, 2003). Therefore, the relevant Tier 1 indicator species for solanaceous and cucurbit applications are insectivorous species.

The representative critical use for orchards, grape and berry crops is the grape use pattern involving 4 applications at 1.6 kg a.s./ha on a 10 day interval. This is the critical use for this group because it represents the maximum individual and total dose

The representative critical use for olives and citrus is the olive use pattern involving 1 application at 2.4 kg a.s./ha. This application scenario covers all citrus application scenarios as well.

The representative critical use for bulb vegetables is the onion, bulb (dry bulb) use pattern (4 applications at 2.0 kg a.s./ha, 7 day interval). Asparagus is included in this grouping because of similarity in leaf morphology (thin, waxy, upright leaves; Kramer, 2007). The other crop groupings—root crops, brassica, cereals, lettuce, legumes—are based on crop foliage and growth pattern similarity and the fact that at least one crop in each group has measured residue data. Ornamental flowers, treated separately because of the wide diversity of possible foliage types within this group, utilize average residue values (RUD and DT50) over all crops studied. It should be noted that the ornamental flowers use pattern refers to use of the product in commercial production of ornamental flowers, not residential use.

Crop grouping according to EFSA 2009 Guidance Document

Crop grouping for the acute **risk assessment for birds** is outlined in the following table. Crop groups are arranged with regard to indicator species and related short cut value for the calculation of the daily dietary dose (determined by the crop). Within these groups further grouping of GAPs results from the effective application rate that is calculated from the maximum single application rate and default 90th percentile multiple application factors (determined by number and interval of applications).

Crop group	Crops	Indicator species	**Maximum rate** (kg a.s./ha) **Minimum interval**	MAF_{90}	**Effective rate** (kg a.s./ha)	**Short cut value**
Orchard	Apple, Pear, Cherry, Plum, Peach, Apricot, Nectarine, Walnut, Ornamental Trees	small insectivorous bird	4 x 1.6 10 d	1.5	2.4	46.8
	Orange, Lemon, Mandarin, Grapefruit, Olive	small insectivorous bird	1 x 2.4	1	2.4	46.8
Vine	Grape	small omnivorous bird	4 x 1.6 10 d	1.5	2.4	95.3
Bushberry	Blackcurrant, Gooseberry	small frugivorous bird	4 x 1.6 10 d	1.5	2.4	46.3
Onion	Onion, Garlic, Shallot	small omnivorous bird	4 x 2.0 7 d	1.8	3.6	158.8
Leek	Leek	small omnivorous bird	3 x 2.0 7 d	1.6	3.2	158.8
Fruiting vegetable, potato	Tomato, Aubergine	small omnivorous bird	5 x 1.6 7 d	1.9	3.04	158.8
	Potato	small omnivorous bird	8 x 1.6 7 d	1.9	3.04	158.8
Fruiting vegetable, lettuce, ornamental flower	peppers, zucchini, gherkin, cucumber, squash, melons	small omnivorous bird	4 x 1.6 7 d	1.8	2.88	158.8
	Lettuce, Ornamental Flowers	small omnivorous bird	4 x 1.6 7 d	1.8	2.88	158.8
Vegetables, cereals	Cauliflower, Broccoli, Carrot, Salsify, Asparagus	small omnivorous bird	4 x 1.6 14 d	1.3	2.08	158.8
	Winter wheat, Spring wheat	small omnivorous bird	3 x 1.6 14 d	1.3	2.08	158.8
Pulses	Field bean, Field pea	small omnivorous bird	1 x 1.6	1	1.6	158.8

Crop grouping for the **reproductive risk assessment for birds** is outlined in the following table. GAPs are grouped taking into account the relevant key factors for first tier risk assessment according to EFSA Guidance Document 2009. Crop groups are arranged with regard to indicator species and related short cut value for the calculation of the daily dietary dose (determined by the crop). Within these groups further grouping of GAPs results from the effective application rate that is calculated from the maximum single application rate and default median multiple application factors (determined by number and interval of applications).

Crop group	Crops	Indicator species	**Maximum rate** (kg a.s./ha) **Minimum interval**	MAF_m	**Effective rate** (kg a.s./ha)	**Short cut value**
Orchard	Apple, Pear, Cherry, Plum, Peach, Apricot, Nectarine, Walnut, Ornamental Trees	small insectivorous bird	4 x 1.6 10 d	1.9	3.04	18.2
Citrus, olive	Orange, Lemon, Mandarin, Grapefruit, Olive	small insectivorous bird	1 x 2.4	1	2.4	18.2
Vine	Grape	small omnivorous bird	4 x 1.6 10 d	1.9	3.04	38.9
Bushberry	Blackcurrant, Gooseberry	small frugivorous bird	4 x 1.6 10 d	1.9	3.04	23.0
Onion	Onion, Garlic, Shallot	small omnivorous bird	4 x 2.0 7 d	2.2	4.4	64.8
Leek, potato	Leek	small omnivorous bird	3 x 2.0 7 d	2.0	4.0	64.8
	Potato	small omnivorous bird	8 x 1.6 7 d	2.5	4.0	64.8
Fruiting vegetable,	Tomato, Aubergine	small omnivorous bird	5 x 1.6 7 d	2.4	3.84	64.8
Fruiting vegetable, lettuce, ornamental flower	peppers, zucchini, gherkin, cucumber, squash, melons	small omnivorous bird	4 x 1.6 7 d	2.2	3.52	64.8
	Lettuce, Ornamental Flowers	small omnivorous bird	4 x 1.6 7 d	2.2	3.52	64.8
Vegetables	Cauliflower, Broccoli, Carrot, Salsify, Asparagus	small omnivorous bird	4 x 1.6 14 d	1.6	2.56	64.8
cereals	Winter wheat, Spring wheat	small omnivorous bird	3 x 1.6 14 d	1.5	2.4	64.8
Pulses	Field bean, Field pea	small omnivorous bird	1 x 1.6	1	1.6	64.8

Crop grouping for the **acute risk assessment for mammals** is outlined in the following table. GAPs are grouped taking into account the relevant key factors for first tier risk assessment according to EFSA Guidance Document 2009. Crop groups are arranged with regard to indicator species and related short cut value for the calculation of the daily dietary dose (determined by the crop). Within these groups further grouping of GAPs results from the effective application rate that is calculated from the maximum single application rate and default 90th percentile multiple application factors (determined by number and interval of applications).

Crop group	Crops	Indicator species	**Maximum rate** (kg a.s./ha) **Minimum interval**	MAF_{90}	**Effective rate** (kg a.s./ha)	**Short cut value**
Fruiting vegetable,	Tomato, Aubergine	small herbivorous mammal	5 x 1.6 7 d	1.9	3.04	136.4
Fruiting vegetable, lettuce, ornamental flower	peppers, zucchini, gherkin, cucumber, squash, melons	small herbivorous mammal	4 x 1.6 7 d	1.8	2.88	136.4
	Lettuce, Ornamental Flowers	small herbivorous mammal	4 x 1.6 7 d	1.8	2.88	136.4
Orchard, vine	Apple, Pear, Cherry, Plum, Peach, Apricot, Nectarine, Walnut, Ornamental Trees	small herbivorous mammal	4 x 1.6 10 d	1.5	2.4	136.4
	Orange, Lemon, Mandarin, Grapefruit, Olive	small herbivorous mammal	1 x 2.4	1	2.4	136.4
	Grape	small herbivorous mammal	4 x 1.6 10 d	1.5	2.4	136.4
Pulses	Field bean, Field pea	small herbivorous mammal	1 x 1.6	1	1.6	136.4
Bushberry	Blackcurrant, Gooseberry	small herbivorous mammal	4 x 1.6 10 d	1.5	2.4	81.9
Onion	Onion, Garlic, Shallot	small herbivorous mammal	4 x 2.0 7 d	1.8	3.6	118.4
Leek	Leek	small herbivorous mammal	3 x 2.0 7 d	1.6	3.2	118.4
Potato	Potato	small herbivorous mammal	8 x 1.6 7 d	1.9	3.04	118.4
Vegetables, cereals	Cauliflower, Broccoli, Carrot, Salsify, Asparagus	small herbivorous mammal	4 x 1.6 14 d	1.3	2.08	118.4
	Winter wheat, Spring wheat	small herbivorous mammal	3 x 1.6 14 d	1.3	2.08	118.4

Crop grouping for the **reproductive risk assessment for mammals** is outlined in the following table. GAPs are grouped taking into account the relevant key factors for first tier risk assessment according to EFSA Guidance Document 2009. Crop groups are arranged with regard to indicator species and related short cut value for the calculation of the daily dietary dose (determined by the crop). Within these groups further grouping of GAPs results from the effective application rate that is calculated from the maximum single application rate and default median multiple application factors (determined by number and interval of applications).

Crop group	Crops	Indicator species	Maximum rate (kg a.s./ha) Minimum interval	MAF_m	Effective rate (kg a.s./ha)	Short cut value
Fruiting vegetable,	Tomato, Aubergine	small herbivorous mammal	5 x 1.6 7 d	2.4	3.84	72.3
Fruiting vegetable, lettuce, ornamental flower	peppers, zucchini, gherkin, cucumber, squash, melons	small herbivorous mammal	4 x 1.6 7 d	2.2	3.52	72.3
	Lettuce, Ornamental Flowers	small herbivorous mammal	4 x 1.6 7 d	2.2	3.52	72.3
Orchard, vine	Apple, Pear, Cherry, Plum, Peach, Apricot, Nectarine, Walnut, Ornamental Trees	small herbivorous mammal	4 x 1.6 10 d	1.9	3.04	72.3
	Grape	small herbivorous mammal	4 x 1.6 10 d	1.9	3.04	72.3
Citrus, olive	Orange, Lemon, Mandarin, Grapefruit, Olive	small herbivorous mammal	1 x 2.4	1	2.4	72.3
Pulses	Field bean, Field pea	small herbivorous mammal	1 x 1.6	1	1.6	72.3
Bushberry	Blackcurrant, Gooseberry	small herbivorous mammal	4 x 1.6 10 d	1.9	3.04	43.4
Onion	Onion, Garlic, Shallot	small herbivorous mammal	4 x 2.0 7 d	2.2	4.4	48.3
Leek, potato	Leek	small herbivorous mammal	3 x 2.0 7 d	2.0	4.0	48.3
	Potato	small herbivorous mammal	8 x 1.6 7 d	2.5	4.0	48.3
Vegetables	Cauliflower, Broccoli, Carrot, Salsify, Asparagus	small herbivorous mammal	4 x 1.6 14 d	1.6	2.56	48.3
cereals	Winter wheat, Spring wheat	small herbivorous mammal	3 x 1.6 14 d	1.5	2.4	48.3

4.2 Aquatic organisms

Aquatic risk scenarios were grouped according to use pattern and application rate as outlined for surface water (see subchapter 3.3). Because of the very rapid dissipation of the substance from soil and water/sediment systems, no build up of residues occurs in between applications and therefore, scenarios with different maximum number of applications may be grouped together by application rate and number of applications.

4.3 Honeybees

Rationale for crop grouping

For the case study that is a foliar spray the 1st tier risk assessment is based on the maximum individual application rate (2.4 kg a.s./ha in olives).

4.5 Non-target arthropods

Rationale for crop groupings in-field

Again as for bees for the first tier risk assessment the assessment is based on the maximum individual application rate.

Rationale for crop groupings off-field

Grouping of crops with regard to exposure of terrestrial off-crop habitats is determined by the application rate, number of applications (and corresponding MAF default values according to Escort 2 Guidance as far as specific data on degradation of the active substance on leaves is not available) and the spray drift scenario. Grouping of crops is outlined in the following table. The crop group "Pome/stone fruit, ornamental tree" can be regarded as worst case.

Crop Group	**Crops Included**	**Rate** (No. of apps x max rate, kg a.s./ha)	**MAF**	**Effective rate** (kg a.s./ha)	**Spray drift scenario**
Pome/stone fruit, ornamental tree	Apple, Pear, Cherry, Plum, Peach, Apricot, Nectarine, Walnut, Ornamental Trees	4 x 1.6	2.7	4.32	Orcharding early
Citrus, Olive	Orange, Lemon, Mandarin, Grapefruit, Olive	1 x 2.4	1	2.4	Orcharding early
Grape, bushberry and fruiting vegetable	Grape, Blackcurrant, Gooseberry, peppers, zucchini, gherkin, cucumber, squash, melons	4 x 1.6	2.7	4.32	Vine
Fruiting vegetable	Tomato, Aubergine	5 x 1.6	3.0	4.8	Vine
Potato	Potato	8 x 1.6	3.5	5.6	Field crops
Bulb vegetable	Onion, Garlic, Shallot,	4 x 2.0	2.7	5.4	Field crops
Leek	Leek	3 x 2.0	2.3	4.6	Field crops
Leafy vegetable, Root vegetable, ornamentals	Lettuce, Chicory Cauliflower, Broccoli, , Carrot, Salsify, Asparagus Ornamental Flowers	4 x 1.6	2.7	4.32	Field crops
Cereal	Winter wheat, Spring wheat	3 x 1.6	2.3	3.68	Field crops
Legume/Pulse	Field bean, Field pea,	1 x 1.6	1	1.6	Field crops

4.6 Soil organisms

Rationale for crop groupings

The risk assessment approach is based on the maximum soil predicted environmental concentrations (PEC) as specified in Section 3.1 above.

4.7 Non-target plants

Rationale for crop groupings

Crop groupings proposed here follow the rational developed for the off-field non-target arthropods.