DRAFT

DRAFT WORKING DOCUMENT ON THE VOLUNTARY WORK-SHARING OF THE SOUTHERN ZONE MEMBER STATES IN THE RE-REGISTRATION OF PLANT PROTECTION PRODUCTS FOLLOWING INCLUSION OF AN ACTIVE SUBSTANCE IN ANNEX I OF COUNCIL DIRECTIVE 91/414/EEC

Σφάλμα! Δεν βρέθηκαν καταχωρήσεις ευρετηρ

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1. Legal Status

This document describes the procedures as well as the national data requirements in order that applications for authorisation of plant protection products are processed according to the voluntary work-sharing programme between Member States belonging to the Southern Zone. As with all such guidance documents, it will not be a statutory requirement for all MS to adopt the procedures, although it is recommended that these procedures should be adopted in order to improve mutual recognition and facilitate the development of a registration work-sharing programme. All MS will, of course, retain the right to follow their own internal procedures or to request data more urgently and take decisions earlier if necessary.

This document has not been finalised in the Standing Committee on the Food Chain and Animal Health. However, it is intended to be used by the Competent Authorities of the Southern Zone Member States in the context of the voluntary work sharing framework and that it might be updated as a result of the experience gained.

2. Introduction

Before the adoption of Regulation (EC) 1107/2009 competent authorities of South Member States (SMS), given the limited resources available, made an effort on a voluntary basis to share and to mutually recognise the work for the risk assessment of plant protection products intended to be placed on the market or/and for the re-registration of products following the inclusion of their active substances into Annex I of Directive 91/414/EEC.

With the adoption of Regulation (EC) 1107/2009 the division of the European Union into 3 zones: North, Central and South is foreseen.

Within each zone it is assumed that the climatic and agronomic conditions are comparable while for the uses in greenhouses, storage places, post-harvest and seed treatment it is assumed that there are no differences between the climatic and agronomic conditions throughout the EU, therefore for these uses EU is considered as one zone.

Regulation (EC) 1107/2009 has also introduced a system of obligatory mutual recognition of authorisations between MS belonging to the same zone or even to other zones but in the latter case only on a voluntary basis.

The basic principle that is introduced with Regulation (EC) 1107/2009 is an enhanced cooperation between MS within each zone but also between zones in an effort to make efficient use of the available resources for the risk assessment of plant protection products.

Despite the fact that Regulation (EC) 1107/2009 has introduced a system for the zonal evaluation of new PPPs for which an application is submitted after 14 June 2011 (date that the Regulation applies), the procedure is not the same for the re-registration of PPPs following the inclusion of an a.s. in Annex I of Directive 91/414/EEC or the approval of an a.s. according to Regulation 1107/2009.

In this guidance document an effort is made to describe the procedure to be followed by the competent authorities for the assessment of PPPs following the inclusion of an a.s. in Annex I of Directive 91/414/EEC.

Certain parts of this document e.g. national data requirements, mitigation measures acceptable at national level are applicable to applications made under Regulation (EC) 1107/2009 also despite the fact that procedures for handling these applications are described in Guidance Document SANCO 13169/2010.

3. Procedure

3.1 Appointment of zRMS and contacts with applicants

It is the competence of the steering group of SMS (see below) to appoint zonal rapporteurs (zRMS) for products containing a specific substance. For the efficiency of the system the following procedure and timeframe is agreed:
Following the compliance check (phase I of the re-registration process) individual MS should make the necessary contacts with registration holders possessing a valid registration certificate asking them to fill in the information sheet **(Appendix I)** with the information available. Replies from each registration holder will be collected so that in one table appears the information requested for all products containing a specific substance. Such table should be sent out at the latest 4 months after finalisation of the compliance check to the chair and the vice-chair of the SMS steering group. The chair should distribute this information to all SMS.

Appointment of zRMS by the steering group should be made at least 12 months in advance of the expiring date for submission of Annex III dossiers (i.e. see point 5.2.1 of the re-registration guidance document) on the basis of the resources available as well as the existence of a valid authorisation in that MS. During the allocation of zRMS the steering group should try to make a fare division of the work.

The minimum requirement is that the product has a valid authorisation in at least 3 SMS. The reason is that one MS will be interested in taking part in a project only if it is relevant to its own conditions. The larger the geographical area the product is to be used the biggest are the chances for work-sharing and equal distribution of workload.

The zRMS should contact as soon as possible registration holders to discuss their applications and to streamline the process. In that context zRMS should send a letter to each authorisation holder as the model letter **(Appendix II)**.The evaluation of all products containing a specific substance should be organised by rapporteurs as an individual project setting specific deadlines for all stakeholders and allocating in advance the necessary resources for the fulfilment of the obligations. zRMS should encourage registration holders to prepare a common dossier in the format of a Registration Report according to guidance document SANCO/6895/2009 rev 1 following the risk envelope approach.

3.2 Pre-submission meetings

Following the acceptance to participate in the program (see point 3.1) above applicants could contact the zRMS to get details about the organisation of the project or to ask for a pre-submission meeting to be organised to streamline the submission of dossiers.
Before a pre-submission meeting is organised it is expected by applicants to raise specific questions on scientific/technical matters related to their intended applications. Availability of a first draft of the dRR at this stage is desirable in order to streamline the discussions and to solve at an early stage any outstanding questions. In that context, pre-submission meetings could take place at least 6 months before the actual submission of dossiers.

zRMS is responsible to make a completeness check of the application. Only complete applications are admitted for detailed evaluation. ZRMS will inform applicants and SMS of incomplete dossiers and a deadline for completeness will be established. A timeframe for completion of the evaluation of data and submission of the Registration Report to the other MS of the zone for comments (see also section 3.3 below) with milestones is set up and communicated to applicants.

3.3 Risk assessment

Following the completeness check of the dossier a detailed evaluation of the data submitted is conducted by the zRMS.
The procedure followed is specified by the individual MS and in that context applicants are invited to have close contacts with the zRMS.

Risk assessment of individual tests and studies is presented in the form of a Registration Report[1]. The registration report takes into account all authorised /intended uses in SMS and it is focused on the worst case uses/scenarios. Predictably, there will be cases in which more than one worst case scenarios exist.

To facilitate mutual acceptance and understanding it is agreed that Registration Reports should be prepared in English.

Once the risk assessment is completed the zRMS is making available parts B and C of the dRR along with the reporting table **(Appendix III)** to the other MS of the zone for comments by uploading these documents on CIRCA. In that respect the zRMS is sending an email message to the contact points (**Appendix V**) of the other SMS in the agreed standardised format **(Appendix IV)**. In parallel, the dRR is made available to the applicant for providing his comments on that.

It is agreed that part B and C of the dRR are made available for comments to the other MS and the applicant at least 5 months before the deadline for re-registration of plant protection products as stated in the respective Directive of inclusion or Implementing Regulation.

[1] See guidance document SANCO/6895/2009 rev 1

Comments by MS as well as the applicant on the dRR are submitted within 6 weeks to the zonal contact points **(Appendix V)** by filling the appropriate column of the reporting table.

Following the receipt of comments the zRMS prepares a revised (final) version of part B and C of the RR within 30 days. The revised (final) version of part B and C of the RR and the reporting table with the responses of the zRMS to the comments received are uploaded on CIRCA while a message is sent to the contact persons of the SMS informing them about the availability of the final version of the RR.

The revised (final) version of part B and C of the RR together with the reporting table with the response of the zRMS to the comments received is sent to the applicant for his information.

3.4 Taking a decision

In the light of the risk assessment conducted the zRMS takes a decision as soon as possible. The decision along with part A of the RR and the approved label is uploaded on CIRCA for information of the other SMS. An email message is sent to the contact points of the other SMS informing them about the availability of these documents.

The competent authorities of the other SMS take their own decisions within 120 days on the basis of the risk assessment conducted by the zRMS and their national conditions The decision of the zRMS can be taken as a basis for their own decisions.

4. Data requirements

4.1 EU data requirements and guidance documents

Applicants are expected to submit a full Annex III dossier covering all points as requested by Regulation (EC) 545/2011. For some sections and this is in particular the case for the fate & behaviour in the environment as well as ecotoxicology, it might be that applicants submit Annex II data to cover the specific requirements. The submission and evaluation of this new Annex II data should be justified according to the Guidance Document SANCO 10328/2004.

If for a particular point the applicant claims that this is not necessary or that data already exist that are out of protection, a justification should be provided in the respective point of the dRR.

It is generally agreed that the latest version of the EU guidance documents in force at the time of submission of the dossier should be used by applicants. Nevertheless, in order to avoid unnecessary testing or repetition of tests applications made based on earlier versions of guidance documents might be accepted if there is a scientific justification for that and the justification is accepted by the rapporteur. Applicants are strongly recommended to contact zRMS in order to discuss these cases before starting the preparation of dossiers.

4.2 National data requirements

Despite the fact that data requirements for plant protection products are described in detail in the Implementing Regulation (EC) 545/2011 covering all sections of dossiers, there are environmental conditions or/and agricultural practices that are specific to each MS.

It is therefore necessary in order to ensure a high level of protection for humans and the environment that each MS sets and makes publicly available the national data requirements and the conditions under which these should be submitted.

In **Appendix VI** these national data requirements are described. Applicants are invited to consult this section of the document before they start preparing their dossiers for the registration or re-registration of a PPP.

4.3 Mitigation measures accepted by each MS of the southern zone

To minimise the risk for humans or/and the environment from the use of PPPs there are available different options. Risk mitigation measures are left to the individual MS. Nevertheless, it is important for applicants to know in advance the mitigation measures that are accepted by each MS in order to prepare their dossiers accordingly. In **Appendix VII** the mitigation options accepted by each MS are presented.

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Appendix I: Information about intended support of ppp's containing existing a.s. for which an Annex III dossier is expected to be submitted[2]

Active substance:
Member State:

Trade Name	Type of formulation	Content of a.s.	Authorisation holder	Authorisation number	Authorised uses/Intended uses	Manufacturer

[2] Please fill in on the basis of the information available

Appendix II: Model letter to applicants

RE: Re-registration of XXXX (product name) containing XXXX (active substance) within the voluntary work-sharing programme between South Member States

Dear Sir/Madam,

In the context of the voluntary work-sharing program adopted between South Member States we are contacting you to explore your availability to participate in the said programme for the re-registration of plant protection products containing XXXXX (name of the active substance) as an active substance with a view on the possible application for the re-registration of your products.

Although the procedure of re-registration of plant protection products following the inclusion of an active substance in Annex I of Directive 91/414/EEC or its approval under Regulation 1107/2009 is to be dealt with at national level, this work-sharing program has been designed in order to improve the efficiency of the process of re-registration. It relies on the sharing of the work among Member States of the same zone involved in the evaluation of new data, particularly Annex III data, and respective risk assessment for the authorised uses produced within the context of re-registration of the product(s) across the Southern Member States where it(they) is(are) authorised.

This procedure aims therefore at the rationalisation of products and uses (GAPs) across the EU and is based primarily on the identification by the Southern Member States' Steering group of a lead member state in the zone that will undertake the core assessment of the new Annex III data on behalf of other Member States within the zone.

Consequently, it is expected by accepting to participate in the program, the submission of a re-registration dossier reflecting the conditions of the southern zone in the form of a draft Registration Report as described in SANCO/6895/2009 rev. 1, 2 October 2009 guidance document following the risk envelope approach.

For the products containing XXXX (name of the active substance) the Southern Member States Steering Committee has appointed XXXX (name of the MS) as the zonal Rapporteur Member State (zRMS).

In this context and on behalf of the Southern Member States Steering Group we are kindly inviting you to indicate your availability to participate in this work-sharing program.

In the event that your company is willing to participate in this program and in the interest of a better predictability and management of workloads involved we would appreciate to get a response to this letter within 60 days from receipt of this letter. We would appreciate if in your response you include information about the efforts you have made to cooperate with other registration holders of products containing XXXX (name of the a.s.) as an active substance in order to submit a common dossier or/and to defend a common GAP.

It is not compulsory to participate in this program however doing so will help us to improve the planning of our work and facilitate the re-evaluation process.

In the meantime, if you have any questions relating to your re-registration application, or any concerns regarding the process, please do not hesitate to contact us directly.

Yours sincerely

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Section 1. Identity, physical and chemical properties

1.1. Identity of the plant protection product

POINT	COMMENT	RMS RESPONSE	OUTCOME

1.2. Physical and chemical properties of the plant protection product

POINT	COMMENT	RMS RESPONSE	OUTCOME

Section 2. Methods of analysis

POINT	COMMENT	RMS RESPONSE	OUTCOME

Section 3. Toxicology; Operator Exposure

3.1. Acute toxicity (IIIA 7.1)

POINT	COMMENT	RMS RESPONSE	OUTCOME

3.2. Dermal absorption (IIIA 7.3)

POINT	COMMENT	RMS RESPONSE	OUTCOME

3.3. Available toxicological data relating to non-active substances (IIIA 7.4)

POINT	COMMENT	RMS RESPONSE	OUTCOME

3.4. Exposure assessments

POINT	COMMENT	RMS RESPONSE	OUTCOME

Section 4. Residues, Consumer risk assessment

4.1. Stability of residues

POINT	COMMENT	RMS RESPONSE	OUTCOME

4.2. Metabolism, distribution and expression of residues in plants

POINT	COMMENT	RMS RESPONSE	OUTCOME

4.3. Metabolism, distribution and expression of residue in livestock

POINT	COMMENT	RMS RESPONSE	OUTCOME

4.4. Definition of the residue

POINT	COMMENT	RMS RESPONSE	OUTCOME

4.5. Use pattern

4.6. Identification of critical GAPs

POINT	COMMENT	RMS RESPONSE	OUTCOME

4.7. Residues resulting from supervised trials

POINT	COMMENT	RMS RESPONSE	OUTCOME

4.8. Effects of industrial processing and/or household preparation

POINT	COMMENT	RMS RESPONSE	OUTCOME

4.9. Livestock feeding studies

POINT	COMMENT	RMS RESPONSE	OUTCOME

4.10. Residues in succeeding or rotational crops

POINT	COMMENT	RMS RESPONSE	OUTCOME

4.11. Maximum Residue Levels

POINT	COMMENT	RMS RESPONSE	OUTCOME

4.12. Estimation of potential and actual dietary exposure through diet and other means

POINT	COMMENT	RMS RESPONSE	OUTCOME

Section 5. Environmental Fate and Behaviour; PECs; PECsw and PECgw

5.1. General comments

POINT	COMMENT	RMS RESPONSE	OUTCOME

5.2. Fate and behaviour in soil. Estimation of predicted environmental concentrations in soil (PECsoil)

POINT	COMMENT	RMS RESPONSE	OUTCOME

5.3. Fate and behaviour in water. Estimation of predicted environmental concentrations in water and sediment (PECsw/ PECsed)

POINT	COMMENT	RMS RESPONSE	OUTCOME

5.4. Fate and behaviour in water. Estimation of predicted environmental concentrations in groundwater (PECgw)

POINT	COMMENT	RMS RESPONSE	OUTCOME

5.5. Fate and behaviour in air

POINT	COMMENT	RMS RESPONSE	OUTCOME

Section 6. Ecotoxicology

6.1. General comments

POINT	COMMENT	RMS RESPONSE	OUTCOME

6.2. Effects on birds - risk assessment

POINT	COMMENT	RMS RESPONSE	OUTCOME

6.3. Effects on aquatic organisms. Aquatic risk assessment

POINT	COMMENT	RMS RESPONSE	OUTCOME

6.4. Effects on terrestrial vertebrates other than birds – risk assessment

POINT	COMMENT	RMS RESPONSE	OUTCOME

6.5. Effect on Bees – risk assessment

POINT	COMMENT	RMS RESPONSE	OUTCOME

6.6. Effects on arthropod species other than bees – risk assessment

POINT	COMMENT	RMS RESPONSE	OUTCOME

6.7. Effects on earthworms – risk assessment

POINT	COMMENT	RMS RESPONSE	OUTCOME

6.8. Effects on other soil not-target macroorganisms – risk assessment

POINT	COMMENT	RMS RESPONSE	OUTCOME

6.9. Effects on soil micro-organisms – risk assessment

POINT	COMMENT	RMS RESPONSE	OUTCOME

6.10. Effects on non-target plants – risk assessment

POINT	COMMENT	RMS RESPONSE	OUTCOME

Section 7. Efficacy

POINT	COMMENT	RMS RESPONSE	OUTCOME

Appendix IV: Emailing standards

(… Standard format for naming e-mails in the zonal procedures? Use similar rules as for naming documents on CIRCA? There is need to identify these emails easily within the daily amount of received emails. (point by SK, see documents attached) …)

As amount of notification on commenting period is anticipated, standard naming of e-mails in „Subject“ of e-mails can ease sorting and identifying actions that need to be done in quite short and strict deadlines set by Regulation 1107/2009.

Notification e-mails are sent to all contact points as they are published at web (http://ec.europa.eu/food/plant/protection/evaluation/dir91-414eec_en.htm, column “K” “Zonal/Interzonal”), not only to one per member state.

Identification of possible types of notification:

Description	e-mail subject
commenting period for dRR (as prepared by zRMS) has started (deadline 6 weeks)	dRR commenting
reply from concerned member state to dRR (as prepared by zRMS)	reply to dRR
final RR uploaded to CIRCA by zRMS	final RR
…	

Every submitted application should go through all (three) types of notifications as stated above.

Identification of possible types of application submitted by companies:

Description	e-mail subject
authorisation of new plant protection product	new product
equivalence/new source of active substance	equivalence
extension of use (crop, pest)	extension

minor use change in composition re-registration (STEP II) …	minor use composition change re-registration

Naming convention (based on SANCO/04846/2009 rev. 7)

Subject of e-mail:

General:

1) The posted documents are Word versions
2) The words in the document name are separated by spaces
3) Following order is respected (only relevant wording will be mentioned in the document name):
   a) Type of notification
   b) Type of application
   c) Name of the product typed by **UPPER CASE**. In case active substance is concerned, then name of active substance typed by **lower case.**

Specific:

The official English name is used for active substance.

Body of e-mail (based on CRD):

Dear MS zonal contacts,

The **(MS)** would like to inform you that the evaluation (dRR) of the following has been finalised:

Product name (product code)	
Active substances	
Applicant	
Application reference code of zRMS (if available)	
Application for (type of	

application)	
Concerned member states	
Direct link to the completed assessment uploaded to CIRCA	
Direct link to part C uploaded to CIRCA	
6 weeks deadline for comments	

Please note that any comments submitted after the above deadline may not be accepted.

Concrete naming conventions and examples
Subject of e-mail:
“dRR commenting_new product_FALCON 460 EC”
“final RR_equivalence_nicosulfuron”
…

November 2011,
Peter Knap
UKSUP - SK

Appendix V: Contact points

CONTACT POINTS OF SMS FOR IMPLEMENTATION OF WORK-SHARING PROGRAMMES

MS	CONTACT POINT
BULGARIA	**Neli Mancheva**, Director of Plant Protection Products Directorate, Bulgarian Food Safety Agency, Hristo Botev Blvd 17, 1040 Sofia, BULGARIA **Toma Horozov**, expert at Plant Protection Products Directorate, Bulgarian Food Safety Agency, Hristo Botev Blvd 17, 1040 Sofia, BULGARIA
CROATIA	**Title, Name and Surname:** Žana Žalac and Mirela Šarčević **Authority:** Ministry of Agriculture **Address:** Ulica grada Vukovara 78, 10000 Zagreb, Croatia **Tel:** +385 1 610 9636 (ŽŽ), +385 1 610 6656 (MŠ) **Fax:** + 385 1 610 9189 **E-mail**: zana.zalac@mps.hr ; mirela.sarcevic@mps.hr **Title, Name and Surname:** Gorana Peček **Authority:** Croatian Centre for Agriculture, Food and Rural Affairs, Institute for Plant Protection **Address:** Rim 98, 10000 Zagreb, Croatia

	Tel: +385 1 6430 808, + 385 1 2311 640 **Fax:** + 385 1 2447 799 **E-mail:** gorana.pecek@hcphs.hr
CYPRUS	**Title, Name and Surname:** Officer of Agriculture Mr. Lyssandros Lyssandrides **Authority:** Department of Agriculture **Address:** Loukis Akritas Av., 1412 Nicosia **Tel:** +357 22 77 21 26 **Fax:** + 357 22 44 91 97 **E-mail:** llyssandrides@da.moa.gov.cy
FRANCE	**Title, Name and Surname:** Anne Duval **Authority:** Ministère de l'Agriculture - Direction Générale de l'Alimentation - SDQPV – BRMMI **Address :** 251, rue de Vaugirard, 75 732 PARIS Cedex 15 - France **Tel:** +33 1 49 55 86 27 **Fax:** +33 1.49.55.59.49 **E- mail:** anne.duval@agriculture.gouv.fr **Title, Name and Surname:** Jérémy Pinte **Authority:** Ministère de l'Agriculture - Direction Générale de l'Alimentation - SDQPV – BRMMI **Address :** 251, rue de Vaugirard, 75 732 PARIS Cedex 15 - France **Tel:** +33 1 49 55 81 46 **Fax:** +33 1.49.55.59.49

	Title, Name and Surname: Thierry Mercier **Authority:** ANSES – Direction des Produits Réglementés **Address:** 253 avenue du Général Leclerc 94704 Maisons-Alfort cedex – France **Tel**:+33 (0)1 49 77 21 51 **E-mail:** thierry.mercier@anses.fr **Title, Name and Surname:** Léa Riffaut **Authority:** ANSES – Direction des Produits Règlementés **Address:** 253 avenue du Général Leclerc 94704 Maisons-Alfort cedex – France **Tel**:+33 (0)1 49 77 21 83 **E-mail:** lea.riffaut@anses.fr **Title, Name and Surname:** Sophie Gallotti **Authority:** ANSES – Direction des Produits Règlementés **Address:** 253 avenue du Général Leclerc 94704 Maisons-Alfort cedex – France **Tel**:+33 (0)1 49 77 21 40 **E-mail:** sophie.gallotti@anses.fr
GREECE	**Title, Name and Surname:** Mr. Kostas Markakis **Authority:** Mistry of Rural Development & Food **Address:** Sygrou 150, 17671 Athens **Tel:** +30 210 928 7226 **Fax:** +30 210 9212 090 **E-mail:** syg061@minagric.gr

	Title, Name and Surname: Ms. Chara Panagopoulou **Authority:** Ministry of Rural Development & Food **Address:** Sygrou 150, 17671 Athens **Tel:** +30 210 928 7161 **Fax:** +30 210 9212 090 **E-mail:** syg036@minagric.gr
ITALY	**Title, Name and Surname:** _____ **Authority:** Ministero della Salute Dipartimento per la Sanità Pubblica Veterinaria, della Sicurezza Alimentare e degli Organi Collegiali per la Tutela della Salute, Direzione Generale per l'igiene e la Sicurezza degli Alimenti e della Nutrizione- Ufficio VII – Prodotti fitosanitari ex DGSAN **Address:** Viale Giorgio Ribotta, 5 - 00144 Roma **Tel:** +39 06 5994 6825 **Fax:** + 39 06 5994 6627 **1)** IT RMS: new authorization, reregistration, Major label extension **E-mail:** contactpoint.ppp@postacert.sanita.it **c.c.**: p.cavallaro@sanita.it, s.digiorgi-esterno@sanita.it **2)** IT cMS: new authorization **E-mail:** contactpoint.ppp@postacert.sanita.it **c.c.**: s.desalvo@sanita.it, v.socci-esterno@sanita.it **3)** IT cMS: Major label extension, Authorization Modifications, Minor uses authorizations **E-mail:** contactpoint.ppp@postacert.sanita.it **c.c.** d.scricciolo@sanita.it **4)** RR request for mutual recognition **E-mail:** contactpoint.ppp@postacert.sanita.it

	c.c.: s.desalvo@sanita.it, j.mastrostefano@sanita.it **5)** IT cMS reregistration in worksharing **E-mail:** contactpoint.ppp@postacert.sanita.it **c.c.**: p.gragnoli@sanita.it, l.verticchio@sanita.it, f.caprio-esterno@sanita.it **6)** Provisional authorization (art. 80) and provisional major label extension (art. 80) **E-mail:** contactpoint.ppp@postacert.sanita.it **c.c.**: g.manzocchi@sanita.it **7)** Authorization requests of mutual recognition in Italy **E-mail:** contactpoint.ppp@postacert.sanita.it **c.c.**: l.verticchio@sanita.it **8)** Parallel import **E-mail:** contactpoint.ppp@postacert.sanita.it **c.c.** mc.amico@sanita.it; f.eusepi-esterno@sanita.it
MALTA	**Title, Name and Surname:** Mr. Tristan Camilleri Ms. Joanne Galea **Authority:** Ministry for Finance, the Economy and Investment Malta Standards Authority Regulatory Affairs Directorate Foodstuffs, Chemicals, Cosmetics and Pesticides Unit. **Address:** Second Floor, Evans Building, Merchants Street, Valletta VLT 1179, MALTA **Tel:** +356 2395 2000 **Fax:** +356 2124 2406 E**-mail :** tristan-charles.camilleri@msa.org.mt

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Appendix VI: National data requirements for Annex III dossiers
Information contained in this Appendix is applicable to applications made under Regulation (EC) 1107/2009 also

1. Bulgaria
The EU data requirements and models are accepted. No national specific data requirements are required.

2. France -
Please refer to the document **Advices to applicants of plant protection product dossiers (PPP) in the framework of Regulation (EC) n°1107/2009** available in the ANSES website http://www.anses.fr/**. Direct access to the document : http://www.anses.fr/sites/default/files/documents/DPR-Ft-AdvicesApplicants.pdf**

3. Greece 28/09/2012
An English version of the national data requirements can be found under the following link:
http://www.minagric.gr/index.php/el/for-farmer/crop-production/fytoprostasiamenu/egkriseisfarmakamenu/826-odhgiesegriseis.html
the document can be accessed directly under the following link:
http://www.minagric.gr/images/stories/docs/agrotis/Georgika_Farmaka/Egriseis/national_requirements_for_PPP.pdf

Section	Supplementary data requirements for Annex III dossier (YES/NO)	Goal(s) of Guidance document	Guidance Document available Y/N and Language of the document	Address or contact point to obtain GD
General		We accept the use of QSAR (Quantitative Structure-Activity Relationships) models. Refinement steps for toxicity assessment may also include QSAR models, which may be useful to supplement the risk assessment. QSAR methods can be used to evaluate the toxicity effects for instance of metabolites and transformation products, or as supplementary evaluation on other animals which have been non-tested. For this purpose the QSAR methods should have been validated, checked on pesticides, and indicate the boundaries for which they are not applicable. Some examples have been recently proposed within the EC project DEMETRA (www.demetra-tox.net).	N	
Phys. Chem. properties and	No	For the Chemical Control of PPPs, there aren't any additional national	N	

Section	Supplementary data requirements for Annex III dossier (YES/NO)	Goal(s) of Guidance document	Guidance Document available Y/N and Language of the document	Address or contact point to obtain GD
anal. method		requirements, beyond those required for inclusion of the active substance in Annex I to Regulation (EC) No. 1107/09		
Toxicology		- *Operator exposure – field application*: For the intended uses not covered by the UKPOEM and the German models, other calculations or exposure data must be submitted, to be evaluated on a case-by-case basis. - *Operator exposure – indoor application*: • DUTCH Greenhouse model • EUROPOEM data • Combination of different scenarios from the available models • Field or greenhouse studies conducted with the same or similar product and the same application method, e.g. Mich, G. (1996). - *Worker exposure*: Calculations based on acceptable data (published or not) concerning the spray drift and the dislodgeable foliar residues. - *Bystander and resident exposure:* the approach described by the «Chemicals Regulation Directorate	N	

Section	Supplementary data requirements for Annex III dossier (YES/NO)	Goal(s) of Guidance document	Guidance Document available Y/N and Language of the document	Address or contact point to obtain GD
		(UK authorities) guidance» or the use of data derived from Martin et al (2008) are acceptable after appropriate justification		
Residues	YES	For the Evaluation of Residues in or on treated products, food and feed, in addition to the requirements mentioned in Regulation 544/2011 and in the relevant Guidance Documents, the following national requirements apply: 1) Grapes (Table and wine grapes): In cases where this is required (in accordance with Annex Point 6.5 of Regulation 544/2011), processing studies are necessary to be submitted on the effects on the nature of residues in raisins produced from the processing of grapes, in order to estimate the corresponding transfer factors from grapes to raisins. 2) Cotton: In cases where this is required (in accordance with Annex Point 6.5 of Regulation 544/2011), processing studies are necessary to be submitted on the effects on the nature of residues during processing of cotton seed for production of cotton oil and cotton cake, in order to estimate	N	

Section	Supplementary data requirements for Annex III dossier (YES/NO)	Goal(s) of Guidance document	Guidance Document available Y/N and Language of the document	Address or contact point to obtain GD
		the corresponding transfer factors from cotton seed to cotton oil and cotton cake. 3) Vine leaves: Supervised residue trials are necessary to be submitted in accordance to the requirements set for minor crops supporting the critical Good Agricultural Practice (cGAP) which is related to vine leaves. 4) Finally, Regulation 396(2005) provides for the establishment of the Maximum Residue levels (MRLs) for feed for which the determination of data requirements is pending at EU level.		
Fate and behaviour				
Ecotoxicology	YES	**Birds and mammals** **Acute Toxicity** • Use of geomean is acceptable only for acute toxicity and only across different species of birds or mammals. When more than one value are available for the same species, the geomean of these values may be used as an acute toxicity endpoint for this species • When reassessed RUD and PT values are utilized, the 90th		

Section	Supplementary data requirements for Annex III dossier (YES/NO)	Goal(s) of Guidance document	Guidance Document available Y/N and Language of the document	Address or contact point to obtain GD
		percentile of these values will be used if the studies submitted are considered reliable. When the studies are not considered reliable enough, values are to be finalized on a case by case basis. • For substances and products of high acute toxicity, reassessment of PT, PD and use of mixed diet (omnivorous) scenario is not advised, unless further and sufficient justification is provided. In these cases, the worst case scenario (highest ETE) is considered **Chronic Toxicity** • When reassessed RUD and PT values are utilized, the 50th percentile (mean value) of these values will be used if the studies submitted are considered reliable. When the studies are not considered reliable enough, values are to be finalized on a case by case basis • Refined PT values <1 but also >0.5 are generally acceptable for all crops • Refined chronic toxicity endpoints		

Section	Supplementary data requirements for Annex III dossier (YES/NO)	Goal(s) of Guidance document	Guidance Document available Y/N and Language of the document	Address or contact point to obtain GD
		may be represented not only by the lowest toxicological endpoint (Section 3) but also by the ecotoxicologically relevant toxicological endpoint (see also 5.7, SANCO/4145/2000, 25 September 2002). **Focal species** In case of refined RA by using focal species, its representativeness for the Hellenic conditions should be justified according to GD EFSA, 2009 §6.1.3.2.Detailed information can be found on the link of the Ministry of Rural Development & Food (see top of this section for Greece). Table I includes focal species which are not considered acceptable for various crops for Hellenic situations (for spring and summer period), unless additional supportive data are provided by the applicant which unequivocally show the presence of these species in relevant Hellenic crop fields. Bridging data between species of Table I and focal species representative of Hellenic conditions are also acceptable. Table I will be updated according to new available knowledge.		

Section	Supplementary data requirements for Annex III dossier (YES/NO)	Goal(s) of Guidance document	Guidance Document available Y/N and Language of the document	Address or contact point to obtain GD
		Table II contains focal species of birds and mammals which are acceptable for various crops and Hellenic national level. Table II will be updated according to new available knowledge. **<u>Aquatic organisms</u>** The RA should be performed according to PECsw initial values. The use of PECsw twa values, the presence of the sediment in trials and the reduction of uncertainty should be justified according to (EFSA J., 2005, 178, 1-45 and EFSA J., 2005, 301, 1-45)). Proposals from the E-link project are accepted. Evaluation of RA for all scenarios Focus SW steps 3 and 4 should be performed. For the final decision, emphasis should be given on R3, R4, D4 and D6 scenarios. Risk mitigation measures proposed: • For approval of the formulation, the maximum buffer zone proposed is **40** m for orchards, vines and leafy crops and **20** m field crops, taking into account that application (spraying) is performed using: 1) conventional nozzles, 2) drift		

Section	Supplementary data requirements for Annex III dossier (YES/NO)	Goal(s) of Guidance document	Guidance Document available Y/N and Language of the document	Address or contact point to obtain GD
		reduction nozzles, or 3) combined 1 and 2. • FOCUS modeling (step 4) is accepted and the FOCUS Landscape and mitigation factors in aquatic ecological risk assessment, SANCO/10422/2005, version 2.0, September 2007 for runoff and drainage. **Bees** For insecticides in seed treatment applications the RA through the dust should be addressed **Non target arthropods**Buffer zone distance needed to ensure acceptable risk to non-agricultural land is **10** m for orchards and vines and **5** m for field crops and leafy crops, taking into account that application (spraying) is performed using: 1) conventional nozzles, 2) drift reduction nozzles, or 3) combined 1 and 2. **Non target plants** Risk mitigation measures proposed: • Use of no sprayed buffer zones:		

Section	Supplementary data requirements for Annex III dossier (YES/NO)	Goal(s) of Guidance document	Guidance Document available Y/N and Language of the document	Address or contact point to obtain GD
		As buffer zone is defined the safety distance between the limit of the cultivated field (fences included) and the inner side of the cultivated field/ orchard. Buffer zone distance needed to ensure acceptable risk to non-agricultural land is **10** m for all crops, taking into account that application (spraying) is performed using: 1) conventional nozzles, 2) drift reduction nozzles, or 3) combined 1 and 2.		
Efficacy		A guidance document on the efficacy requirements set out by Greece is uploaded in the website of the Ministry of Agriculture & Rural Development (see top of this section for Greece).		

4. Spain

Please refer to the document Avices to applicants of plant protection product dossiers (PPP) in the framework of Regulation (EC) nº 1107/2009, available in the MAGRAMA website:
http://www.magrama.gob.es/agricultura/pags/fitos/registro/fichas/pdf/nuevo_formulario.pdf
and
http://www.magrama.gob.es/agricultura/pags/fitos/registro/fichas/pdf/RPF01N00A.pdf

Section	Supplementary data requirements for Annex III dossier (YES/NO)	Goal(s) of Guidance document	Guidance Document available Y/N and Language of the document	Address or contact point to obtain GD
Phys. Chem. properties and anal. method	NO			
Toxicology	YES	• Co-formulants unacceptable for inclusion in PPP (**See Annex I**). Annex I Spanish Negative List of cofor • **Exposures Assessment:** **a) Operator:** - POEM, BBA, EUROPOEM II, Seedtropex, RISKOFDERM, ECPA greenhouse model, and PHED. **b) Worker: Europoem II** *EUROPOEM II* *(If no data are available on the degree of dissipation Scientific Opinion of EFSA's PPR Panel* is applied). **c) Bystander: Europoem II.**	Yes, Spanish	• Exposure assessment criteria: http://www.insht.es/SectorAgrario/Contenidos/Promocionales/Plaguicidas/Ficheros%20Colaboracion%20con%20el%20Ministerio/INSHT-CriteriosEvaEexposicionProdFitosanitarios-(Rev1-13-11-2012).pdf • Draft Guidance Notes for the estimation of dermal absorption values. Environmental Directorate. Organisation for Economic Co-Operation and Development. Paris 2008.

Section	Supplementary data requirements for Annex III dossier (YES/NO)	Goal(s) of Guidance document	Guidance Document available Y/N and Language of the document	Address or contact point to obtain GD
		EUROPOEM II *Martin et al (2008)* • **Dermal absorption:** a) Dermal absorption values below 1% should not be considered. b) When available the so-called “triple pack” approach (i.e. rat *in vitro* and *in vivo* data and human *in vitro* data) the worst-case assumption should be used (**See Annex II**). Annex II spanish Assessment of Derma		
Residues	NO			
Fate and behaviour	YES	PECsw following FOCUS guidance document, or with a validated scenario representing agroclimatological conditions including drift, runoff/erosion and drainage PECgw following FOCUS guidance document Specific calculation is required for intended use on Banana	N	
Ecotoxicology	YES	For PPP to be used in rice crop we require a study of Bioacumulation in	N	

Section	Supplementary data requirements for Annex III dossier (YES/NO)	Goal(s) of Guidance document	Guidance Document available Y/N and Language of the document	Address or contact point to obtain GD
		Procambarus clarkii		
Efficacy	NO			

5 .Portugal (04/10/2012)

Section	Supplementary data requirements for Annex III dossier (YES/NO)	Goal(s) of Guidance document	**Guidance Document available Y/N and Language of the document**	Additional remarks
Phys. Chem. properties and anal. method	NO			
Toxicology	YES	Operator exposure Both the UK POEM and the German operator exposure model are used.	N	--
Residues	NO			
Efficacy	YES	No guidance document Relevance of efficacy trials covering national agronomic conditions	N	-
Fate and behaviour	YES	PEC groundwater PECgw following FOCUS guidance document, preferred models PEARL & PELMO, relevant scenarios: Piacenza, Sevilha, Porto and Thiva PEC surface water PECsw with FOCUS sw calculations	N	--
Ecotoxicology	NO	Birds and mammals Short-term and long-term risk assessment for birds and mammals in line with the older EPPO guidance with LC50 and NOEC expressed in mg/kg food, but with scenario's and updated values for FIR/bw, RUD, MAF as agreed in the EU guidance document. Risk mitigation for aquatic organism	N	Birds and mammals There is a lack of guidance for refined risk assessment in the EU guidance document. It is felt that the increase of conservation with the introduction of the daily dose short-term and long-term toxicity endpoint is not supported by evidence that the older EPPO guidance is not protective. PT and PD refinements are accepted to a limited extent. Relevant focal species for Portugal are not known

Section	Supplementary data requirements for Annex III dossier (YES/NO)	Goal(s) of Guidance document	**Guidance Document available Y/N and Language of the document**	Additional remarks
		Maximum acceptable buffer zone 50m; drift reducing nozzles accepted as mitigation		

6. Croatia

National requirements for registration of plant protection products:

1. PHYSICAL-CHEMICAL PROPERTIES

Data requirements are the same as set out by Regulation (EC) No. 1107/09 and additional data are not required.

2. TOXICOLOGY AND OPERATOR EXPOSURE

2.1 Dermal absorption

Dermal absorption for concentrated product and in-use dilution should be estimated according to the *Guidance on Dermal Absorption* (EFSA Journal 2012;10(4):2665.)

If no dermal absorption data are available, a default values from the Guidance should be used. A default 10% value for dermal absorption may only be used if set in the EU Review Report for the active substance.

The results of dermal absorption from a different or similar formulation of the same active substance may be used if adequately justified, including the comparison of composition and toxicological properties for both formulations (primarily skin irritation). The use of the results of dermal absorption for a different dilution of the same or similar formulation of active substance should be equally justified.

2.2. Operator exposure

An estimation of operator exposure using a suitable calculation model must be completed for each type of application method (spraying, in-stem application, drenching etc.) and application equipment (boom, knapsack, hand-held, air assisted sprayers etc.) proposed for use of the plant protection product. This must take account of the Personal Protective Equipment (PPE) requirements resulting from the implementation of the classification and labelling provisions for chemicals for handling the undiluted or diluted product as well as the different types and sizes of containers to be used, mixing, loading operations, and application of the plant protection product. At first estimation must be made with the assumption that the operator is not using any PPE and, where appropriate, also an estimation shall be made with the assumption that the operator is using effective and readily obtainable PPE. For amateur products only exposure estimation without PPE is relevant.

Suitable calculation models of operator exposure acceptable for the agricultural conditions in Croatia are: BBA (German model) and UK POEM, SeedTropex (seed treatment), US PHED (granular application), biocide exposure models from TNsG (Trigger Spray, Dustable formulation, Granule application), IVA generic model (protected use), other generic models. Representative exposure studies can also be provided. For amateur use UK POEM home garden spray model (5 l tank) and biocidal exposure models may be used, depending on the application method.

For the less common uses, operator exposure should also be estimated by the appropriate model.

2.3. Bystander exposure and resident exposure

An estimation of bystander exposure must take account of:

- exposure to spray drift: calculation based on data from exposure studies Lloyd & Bell 1983 and 1987; for dermal exposure in-use dilution values should be used,

- vapour exposure: calculation based on generic data from studies conducted by California EPA EPA (California Environmental Protection Agency, Air Resources Board, (1998), Report for the Application and Ambient Air Monitoring for Chlorpyrifos (and the Oxon Analogue) in Tulare County During Spring/Summer 1996.) and Sibers et al. 2003. (J. Siebers, R. Binner, K.P. Wittich. Investigation on downwind short-range transport of pesticides after application in agricultural crops. Chemosphere 2003:51; 397–407). Substances of high volatility would require specific data to quantify air concentrations,

- entry into treated crops and exposure to surface deposits in children, calculated as the sum of components from dermal absorption, hand to mouth transfer and object to mouth transfer.

2.4. Worker (re-entry exposure)

An estimation of worker exposure must be made for each crop and task to be carried out (for example crop inspection, harvest, handling treated soil etc.). For worker exposure estimates a calculation based on the EUROPOEM re-entry model (DFR and TC values) can be used (Post Application Exposure of Workers to Pesticides in Agriculture, Report of the Re-entry Working Group, EUROPOEM II Project, FAIR3-CT96-1406, December 2002). The body weight of the worker is 60 kg, dermal absorption data are taken from the in-use dilution of the product and the use of PPE is not taken into consideration. If necessary, calculation can be refined using data on residues of active substance on treated crops or dissipation data. Based on calculations appropriate re-entry period for workers may be selected. The exposure of persons re-entering public areas where PPP have been applied (e.g. parks, lawns etc.) must also be considered (US EPA Standard Operating Procedures for Residential Pesticide Exposure Assessment, 2012).

2.5. Combined risk assessment

Combined risk assessment should be performed for PPP with two or more active substances. If the sum of fractions (or %) of the AOEL for all active substances is >1 (or >100%), possible common mechanism of toxicity or target tissues should be considered and a scientifically justified case on the potential for interaction presented. If the toxic effect of concern for the combined risk assessment is identified, the critical NOAEL should be then derived for that effect, and an effect specific AOEL estimated using an appropriate safety factor. Estimated exposure for each active substance should then be compared to the effect specific AOEL for each substance and presented as a fraction (or percentage). If the sum of the fractions is ≤1 (or ≤100%), exposure of the operator is acceptable. If the sum of the fractions >1 exposure is not shown to be acceptable and further specific data will need to be generated to address the concern. This might include operator monitoring data, *in vitro* or *in vivo* testing of the combination.

3. RESIDUES

For the evaluation residues in or on treated products, food and feed national requirements for additional data are related to Alfalfa. Alfalfa is not listed in Table 1 of the Guidance Document as a major crop (SANCO 7525/VI/95 - rev.9, Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MLRs). In Croatia, alfalfa is listed as major crop therefore minimum of eight (8) residues studies in/on alfalfa are required.

4. FATE AND BEHAVIOUR

4.1. Groundwater

Predicted environmental concentrations of the active substance and relevant metabolites in groundwater (PECgw) should be calculated according to FOCUS guidelines for groundwater. Calculations should be done with two FOCUS models, PEARL (obligatory) and PELMO (recommended, however note must be taken that other FOCUS models for groundwater can also be acceptable). Although higher relevance is given to certain scenarios (Châteaudun, Hamburg, Kremsmünster, Okehampton and Piacenza), because of the great diversity of pedo-climatic conditions in Croatia, for calculation of PECgw values for active substance and relevant metabolites in groundwater, all nine existing FOCUS scenarios are important and required.

4.2. Surface water

For the calculation of the predicted environmental concentrations of the active substance and relevant metabolites in surface water (PECsw), exposure by spray drift is considered. PECsw values should be calculated with CRD Excel spreadsheet and using *Rautmann et. al.* (2001) drift values.

5. ECOTOXICOLOGY

5.1. Aquatic organisms

Aquatic risk assessment using PEC_{sw} values calculated by the CRD Excel spreadsheet and using *Rautmann et. al.* (2001) drift values should be submitted.

6. EFFICACY

Data requirements are the same as set out by Regulation (EC) No. 1107/09 and additional data are not required.

Appendix VII
List of mitigation options accepted in the countries belonging to the southern zone
Information contained in this Appendix is applicable to applications made under Regulation (EC) 1107/2009 also

Bulgaria	**Mitigation options**	**Comments**
General		
Toxicology		
Operator exposure		
Worker exposure		
Bystander exposure		
Residents exposure		
Residues		
Fate		
Surface water		
Ground water		
Ecotoxicology		Drift reduction nozzles (if yes please specify 50%, ….?)
Birds and mammals		
Aquatic organisms		
Non target organisms		
Non target		

plants		
Bees		
Soil organisms		
Efficacy		
Biological efficacy		
Phytotoxicity		
Resistance		

Cyprus	Mitigation options	Comments
General		
Toxicology		
Operator exposure		
Worker exposure		
Bystander exposure		
Residents exposure		
Residues		
Fate		
Surface water		
Ground water		
Ecotoxicology		Drift reduction nozzles (if yes please specify 50%, ….?)
Birds and mammals		
Aquatic organisms		
Non target organisms		
Non target plants		
Bees		
Soil organisms		
Efficacy		

Biological efficacy		
Phytotoxicity		
Resistance		

France	Mitigation options	Comments
General	**Contact point : brmmi.sdqpv.dgal@agriculture.gouv.fr**	
Toxicology		
Operator exposure		
Worker exposure		
Bystander exposure		
Residents exposure		
Residues		
Fate		
Surface water		
Ground water		
Ecotoxicology		
Birds and mammals		
Aquatic organisms		
Non target organisms		
Non target plants		
Bees		
Soil organisms		
Efficacy		

Biological efficacy		
Phytotoxicity		
Resistance		

Greece	Mitigation options	Comments
General		**Detailed information about the risk mitigation options that are acceptable in Greece can be found on the following link:** http://www.minagric.gr/index.php/el/for-farmer/crop-production/fytoprostasiamenu/egkriseisfarmakamenu/826-odhgiesegriseis.html the document can be accessed directly under the following link: http://www.minagric.gr/images/stories/docs/agrotis/Georgika_Farmaka/Egriseis/national_requirements_for_PPP.pdf
Toxicology		
Operator exposure		
Worker exposure		
Bystander exposure		
Residents exposure		
Residues		
Fate		
Surface water		
Ground water		
Ecotoxicology		
Birds and mammals		
Aquatic organisms		
Non target organisms		

Non target plants		
Bees		
Soil organisms		
Efficacy		
Biological efficacy		
Phytotoxicity		
Resistance		

Italy	**Mitigation options**	**Comments**
General		
Toxicology		
Operator exposure		
Worker exposure		
Bystander exposure		
Residents exposure		
Residues		
Fate		
Surface water		
Ground water		
Ecotoxicology		Drift reduction nozzles (if yes please specify 50%, ….?)
Birds and mammals		
Aquatic organisms		
Non target organisms		
Non target plants		
Bees		
Soil organisms		
Efficacy		

Biological efficacy		
Phytotoxicity		
Resistance		

Malta	Mitigation options	Comments
General		
Toxicology		
Operator exposure		
Worker exposure		
Bystander exposure		
Residents exposure		
Residues		
Fate		
Surface water		
Ground water		
Ecotoxicology		Drift reduction nozzles (if yes please specify 50%, ….?)
Birds and mammals		
Aquatic organisms		
Non target organisms		
Non target plants		
Bees		
Soil organisms		
Efficacy		

Biological efficacy		
Phytotoxicity		
Resistance		

Portugal	Mitigation options	Comments
General		
Toxicology		
Operator exposure	Complete PPE during mixing, loading and application; use restricted to professionals;	
Worker exposure	Re-entry intervals	
Bystander exposure	Drift reducing nozzles	
Residents exposure	Buffer zones	
Residues	Revised GAP supported by available data	
Fate		
Surface water	Drift reducing nozzles up to 75% reduction; vegetated buffer zones;	
Ground water	Restriction to non vulnerable soils; limitation of use on permeable sufaces/soils, on soils with low organic matter content,...	
Ecotoxicology		
Birds and mammals	No mitigation	
Aquatic organisms	Risk mitigation for surface water contamination as appropriate	
Non target organisms	Risk mitigation for surface water contamination as appropriate	
Non target plants	Drift reducing nozzles; buffer zones	
Bees	Measures forseen under Annexes IV and V of Directive 91/414/EEC	
Soil organisms	Revised GAP supported by available data	
Efficacy		

Biological efficacy		
Phytotoxicity		
Resistance		

Spain	Mitigation options	Comments
General		
Toxicology		
Operator exposure	Protection factors applied for use of PPE can be found in the following link: http://www.insht.es/SectorAgrario/Contenidos/Promocionales/Plaguicidas/Ficheros%20Colaboracion%20con%20el%20Ministerio/INSHT-CriteriosEvaEexposicionProdFitosanitarios-(Rev1-13-11-2012).pdf)	
Worker exposure	Protection factors applied for use of PPE can be found in the previous link. Re-entry intervals and intervals between applications.	
Bystander exposure		
Residents exposure		
Residues	No mitigation options. GAP must compile with EU MRL	
Fate		
Surface water	Buffer zones (20 m) and drift reduction nozzles (95%). Vegetative Buffer zones for runoff and soil erosion reduction: **VBS up to 20 m (80 % runoff reduction and 95% sediment reduction)**	
Ground water	To limit the number of applications per year or include restrictions of use in vulnerable zones in the label	
Ecotoxicology		
Birds and mammals	Reduction of dose rate and/or number of appl . Not application during breed season Avoid spillage Incorporation in soil	
Aquatic organisms	Buffer zones (20 m) and drift reduction nozzles (95%). Vegetative Buffer zones for runoff and soil erosion reduction	

	VBS up to 20 m (80 % runoff reduction and 95% sediment reduction)	
Non target organisms	Restriction of use, buffer zones and drift reduction nozzles; non treated areas inside the treated area in order to promote the recovery of the populations of NTA	
Non target plants	Buffer zones and drift reduction nozzles	
Bees	Restriction of use , not apply PPP during flowering. Include specific provision in the label regarding the management of hives.	
Soil organisms	To limit the number of applications per year and reduction of application rate	
Efficacy		
Biological efficacy	Minimum effective dose must be demonstrated	
Phytotoxicity	Restriction of use	
Resistance	Alternate products a proposal of resistance management should be provided by the applicant	