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South Member States

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WORKING DOCUMENT ON THE WORK-SHARING OF THE SOUTHERN ZONE MEMBER STATES UNDER REGULATION EC 1107/2009

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1. Legal Status

This document describes the specific procedures as well as the national data requirements in order that applications for authorisation of plant protection products are processed according to articles 29-37; articles 40-42 and articles 43-45 in Member States belonging to the Southern Zone. The EU guidance documents SANCO/13169/2010 Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009 and SANCO/2010/13170 Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009 are applicable in the Member States of the Southern Zone

These procedures should be adopted in order to improve mutual recognition and facilitate the development of a registration work-sharing programme.

This document has not been finalised in the Standing Committee on the Plant, Animals, Food and Feed. However, it is intended to be used by the Competent Authorities of the Member States of the Southern Zone.

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.

Annex I of Regulation (EC) 1107/2009 defines the zones for the authorisation of plant protection products Within each zone it is assumed that the agricultural, plant health and environmental (including climatic) conditions are comparable.(as it is indicated in Recital 29 of Regulation (EC) 1107/2009), 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.

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. Zonal evaluation - Procedure (Article 33)

3.1 Appointment of zRMS and contacts with applicants

It is the competence of the steering group of SMS (SMS-SC) (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.

Southern Member States (SMS) accept to be ZRMS following the proposal of the applicant and based on their capacities, majority of SMS take the applications in order of their arrival.

ZRMS informs applicant on the expected date for starting the evaluation. Applicants should avoid applications only for one MS, except in case of extension of uses for minor uses.

When applicants did not receive a positive answer from the ZRMS the allocation of the ZRMS is established by the SMS-SC.

ZRMS shall update excel table available in CIRCABC [*Group of interest PPP Zonal > Library > Zonal Steering Committee South > Application tables*]: "*New application+Label Extension_SouthMS. xlsx*" until the Plant Protection Products Application Management System PPPAMS will be available.

3.2 Pre-submission meetings

Following the acceptance of the ZRMS (see point 3.1) 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. ZRMS are not obliged to do pre-submission meeting, criteria for the acceptance of a pre-submission meeting are established by each SMS. Physical meetings can be replaced by call conferences or mail exchanges to validate specific matters.

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 are recommended to take place at least 6 months before the actual submission of dossiers**.

ZRMS is responsible to make a completeness check of the dossier once it is submitted.

Only complete applications are admitted for detailed evaluation. ZRMS will inform applicants and SMS of incomplete dossiers. In those cases in which the dossier is considered incomplete no time for completion is foreseen and a new submission is required.

3.3 Risk assessment

Applicants shall include all the uses for which an authorization is applied for in SMS in the DRR, although only the authorization of some of them is requested in the ZRMS.

ZRMS will evaluate all the uses for which a decision shall be taken in the MS of the zone, although applicant only applies for the authorization of some of the uses in the ZRMS. 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 as it is described in SANTE/6895/2009 (rev. 1) 7 October 2016 Guidance document on the presentation and evaluation of dossiers according to annex III of Directive 91/414/EEC in the format of a (draft) Registration Report1
[http://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_doss_reg-report-draft.zip]

The registration report shall take into account all intended uses in SMS and it is focused on the worst case uses/scenarios (applicable for all sections except for efficacy). Predictably, there will be cases in which more than one worst-case scenario 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 I: REPORTING TABLE (TRADE NAME) zRMS (MEMBER STATE*))** to the other MS of the zone for comments, uploading these documents on CIRCABC. In that respect the zRMS is sending an email message to the contact points (***Appendix III: Contact points***) of the other SMS in the agreed standardised format (***Appendix II: Emailing standards***). 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 8 months after the submission of application. If during this period ZRMS considers necessary the requirement of additional information/data/studies, ZRMS shall communicate it to the

applicant, a report explaining the reason for the requirements should be produced by ZRMS and a deadline for submission of the additional information/data/studies shall be established by the ZRMS. This deadline shall not be superior than 6 months. Immediately ZRMS will inform the other SMS of that the clock of the assessment procedure has been stopped, this will be made electronically by email, updating the Excel tables or using the Plant Protection Products Application Management System PPPAMS when available

Comments by MS as well as the applicant on the dRR are submitted within 6 weeks to the zonal contact points of the ZRMS **(Appendix III: Contact points)** by filling the appropriate column of the reporting table. **No additional studies/data will be accepted during and /or after the commenting period, applicant only can comment on "factual issues" and reasons and justifications can be submitted.** Following the receipt of comments the zRMS shall consider all the comments and shall answer them in the reporting table. When there are different opinions between ZRMS and a MS on a specific point that could change final decision, bilateral contacts between ZRMS and the MS shall be taken in order to approach positions.

3.4 Taking a decision

In the light of the risk assessment conducted, the zRMS takes a decision as soon as possible (max 1 year after application + any stop-the-clock period up to 180 days). The decision along with part A, and final B and C of the RR and the approved label is uploaded on CIRCABC 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 applicant receives a copy of the files that have been uploaded on CIRCABC.

The zonal RMS may grant or refuse the authorisation, and this decision shall be made available to the other MS in the zone by the inclusion of the official decision in the PART A of the RR. Either way, the conclusions of the assessment of the zonal RMS should still be used by the concerned MS as the basis for their decisions. Therefore, if the zonal RMS has come to the unambiguous conclusion that the use of a given plant protection product is acceptable in the zone in principle, but not in its own territory for conditions specific on that territory, this conclusion should be considered a positive assessment by the "zonal Rapporteur". On the basis of this positive assessment the Member States in the zone to which an application was sent shall grant authorisations unless the provisions of Article 36(3) are applicable.

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

Because **data protection** is decided at national level under Regulation (EC) No 1107/2009 the ZRMS will not be able to conclude on data protection for all studies to be submitted and for all MSs.

4. Data requirements

4.1 EU data requirements and guidance documents

Applicants are expected to submit a full dossier covering all points as requested by Article 33 of Regulation (EC) 1107/2009 and following Commission regulation (EU) No 284/2013 of 1 March 2013. 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 data related to the active substance (Regulation (EU) No 283/2013) to cover the specific requirements. **The submission and evaluation of this new active substance data (Reg EU No 283/2013) should be justified according to the Guidance Document SANCO 10328/2004**.

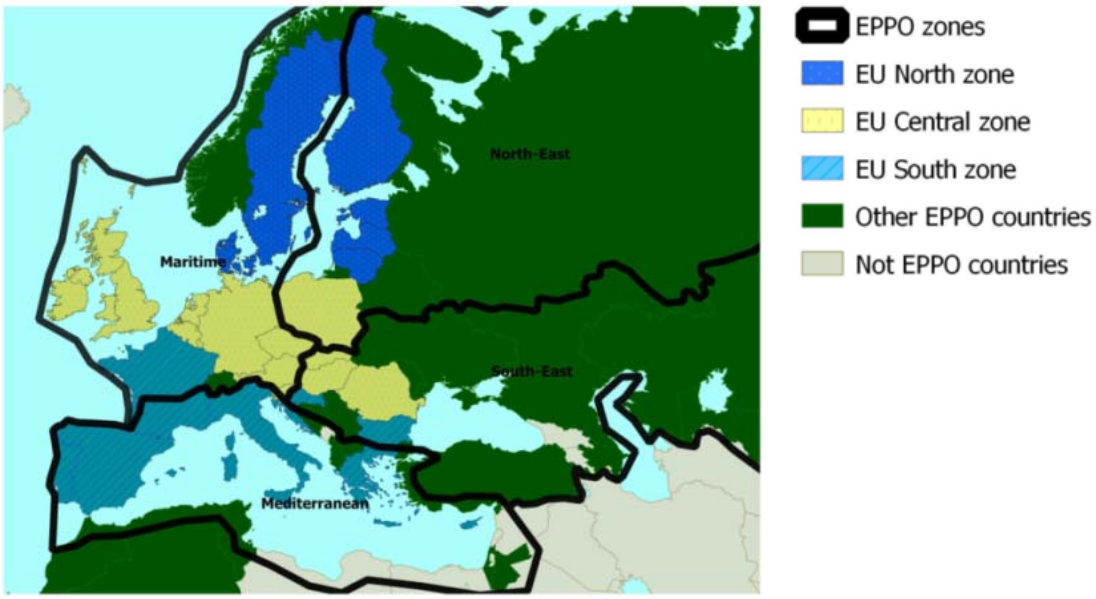
If for a particular point the applicant claims that this is not necessary or that data already exist that are out of protection, a justification shall be provided in the respective point of the dRR.

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, provided that the use of the latest version of the EU guidance does not contradict the EU guidance used in the evaluation for approval of the active substance. 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 Efficacy data requirements and guidance documents

Efficacy evaluation of PPP in SMS is made according to the EPPO standards. Applicants shall take into consideration the EPPO standard PP 1/241 Guidance on comparable climates, which provides guidance to regulatory authorities and applicants in determining comparability of climatic conditions between geographical areas where efficacy evaluation trials on plant protection products are performed. It describes in particular four climatic zones in the EPPO region, within each of which climatic conditions may be considered comparable.

It is recognised that the EPPO climatic zones do not match with the regulatory EU zones defined in the Regulation 1107/2009 and applicants shall take this into consideration when preparing the efficacy data package.



As it is shown in the above figure, EU SMS includes three EPPO Zones:

- Maritime;
- Mediterranean;
- South-East.

EPPO Standard PP 1/226 *Number of efficacy trials* provides guidance on the number of trials in target crops needed to demonstrate the efficacy of a plant protection product at the recommended dose. Where authorization is sought across a range of diverse conditions, such as across an authorization zone (PP 1/278 Principles of zonal data production and evaluation), then the number of trials conducted may need to increase. These trials should be done across the range of climatic and environmental conditions likely to be encountered, and over at least 2 years.

When the application of the authorization of a PPP is in SMSs that belongs to different EPPO climatic zones, applicants shall submit sufficient efficacy trials in all the EPPO climatic zones. Data from different EPPO climatic zones should be presented separately in the core dRR. ZRMS shall evaluate all the efficacy trials although ZRMS does not belong to some of the EPPO zones. Conclusion of the ZRMS will include considerations on the number of trials and shall be based on sufficient efficacy trials to demonstrate the efficacy in the different climatic EPPO zones of the EU-SMS.

As a general approach according to the EPPO Standard PP 1/226(2) *Number of efficacy trials* the following number of trials are required for each EPPO zone in SMSs:

Table 1. Basic number of direct efficacy trials in an area of similar conditions required. Extracted from EPPO Standard PP 1/226 (2) *Number of efficacy trials*

	Fully supportive results required
Major pest on major crop	10 (range 6–15)
Minor uses	3 (range 2–6)
Major pest; protected conditions	6 (range 4–8)

In some situations, there may be scientific arguments which could allow to perform a lower number of trials and a case may be made for this. For more details, refer to the 4 bullet points in EPPO Standard PP 1/226 *Number of efficacy trials*, section on “Reduced number of trials”.

SMSs have agreed a position on efficacy section, this position is described in ***Appendix VIII: GENERAL CONSENSUS ON EFFICACY SECTION IN THE SMS***.

This SMSs positon on efficacy section is based on the efficacy evaluators’ experience on evaluation during the last years and the consensus points of the outputs of their annual Meetings (Paris, 2015; Athens 2016; Madrid 2017). The position was circulated among the efficacy experts of SMS to progress in the harmonization of efficacy risk assessment. It includes also lines of future work among SMS in order to reach a harmonized approach for zonal evaluations were identified.

4.3 National data requirements

Despite the fact that data requirements for plant protection products are described in detail in the Implementing Regulation (EC) n.º 284/2013 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 the relevant data should be submitted.

In ***Appendix IV: National data requirements for dossiers of plant protection products*** 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.

Comparative assessment for products containing actives candidates for substitution shall be conducted in all cases by all MSs individually every time an application for renewal of authorisation is made. Such assessments should address the criteria foreseen in Article 50(1). ZRMS can circulate, only for information, its Comparative assessment when starting the commenting round.

The applicant should add a section to the application presenting the benefits of the products to be considered by authorities when conducting comparative assessment with alternative control solutions.

This should be presented in the format of the template provided in the appendix to the Guidance document on Comparative Assessment and Substitution of Plant Protection Products in accordance with Regulation (EC) No 1107/2009 (SANCO/11507/2013) or using the National Guidance Documents that each SMS have developed **(*Appendix IV: National data requirements for dossiers of plant protection products*).** Applicant should then submit Comparative assessment in compliance with the existing national guidelines, and including national specificities (templates, comparative assessment taking into account national registered PPP, etc.)

4.4 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 V: List of mitigation options accepted in the countries belonging to the southern zone*** the mitigation options accepted by each MS are presented.

SMSs have developed a document with the basis for refinements in southern zone for the risk assessment on birds and mammals of the use of PPP. This document is based on the experience of the last years and the outputs were circulated among the experts of SMS to progress in the harmonization of risk assessment and risk management and also lines of future work among SMS in order to reach a harmonized approach for zonal evaluations were identified. The conclusion of the discussions are listed in (***Appendix VI: BASIS FOR REFINEMENTS IN SOUTHERN ZONE FOR THE RISK ASSESSMENT ON BIRDS AND MAMMALS OF THE USE OF PPP***).

5. Renewal of authorisations - Procedure (Article 43)

The EU guidance document SANCO/2010/13170 Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009 are applicable in the Member States of the Southern Zone

5.1 Appointment of zRMS and contacts with applicants

SMSs have developed an Excel Table to be filled in by Registration Holders with their intentions for renewal of authorization of PPP. Registration holders of PPP authorized in SMS will be asked for the submission of details of their intention for the renewal of authorization of the PPP at the latest once the EFSA opinion on the peer review for the renewal of the active substance has been published. With this information, registration holders will submit their proposals of ZRMS. It is encouraged registration holders to coordinate inside

the companies the submission of the information in order to avoid duplications.

Once all the information is received, SMS SC allocate the ZRMS. Criteria taken into account in the allocation of ZRMS are the following:

- Proposal of the applicant;
- PPP shall be registered in the ZRMS;
- Capacities and available resources of the MS;
- Applicability of the risk envelope strategy between applications.

Final allocation of ZRMS is available in the excel table in CIRCABC in the following route: Library > Expert Groups and Ongoing Projects > Zonal Evaluation and Mutual Recognition > Steering Group South > Application tables.

AIR II: Art43-AIR2-renewal products-SouthMS.xls
AIR III: Art43-AIR3-renewal-SouthMS.xlsx

Once the allocation of ZRMS has been agreed in the SMS SC each ZRMS is responsible to inform registration holders about the allocation of ZRMS.

5.2 Submission of applications

Within 3 months of the date of application of the renewal of approval of an active substance all authorisation holders must apply to renew the authorisations of plant protection products containing that active substance in the MS where they have an existing authorisation and wish to renew it.

An application to renew the authorisation should include (according to Article 43(2)):

- A copy of the authorisation;
- Any new information required as a result of amendments in data requirements, guidance in place by the time of the application date and criteria (changes to endpoints arising from the active substance renewal);
- Evidence/justification that the new data submitted are the result of data requirements, new guidance in place by the time of the application date or criteria which were not in force when the authorisation of the plant protection product was granted or necessary to amend the conditions of approval;
- Any information to demonstrate that the product complies with the requirements (conditions and restrictions) set out in the Regulation on the renewal of the approval of the active substance;
- A report on the monitoring information, where the authorisation was subject to monitoring;

- A comparative assessment dossier should be submitted according to the relevant guidance, where necessary.

Furthermore, applicants should submit the following information to the ZRMS in southern Zone:

- ✓ List of the authorised GAPs of the PPP in each SMS (in English);
- ✓ A signed declaration by the registration holder confirming that the authorised PPP and uses are in compliance with the conditions and restrictions of the renewal of approval of the active substance;
- ✓ A signed declaration by the manufacturer that there has not been any modification with regard to the composition of the authorized product under uniform principles, or justification of the need to make a minor change due to the renewal of the approval of the active;
- ✓ Updated DRR (Part A; B and C) indicating where there is new information not previously reviewed in the zone
- ✓ Justification for each data point for which not all information can be submitted;
- ✓ List of cat. 4 studies and submission date and justification for each of them with a proof that the studies have been initiated or commissioned;
- ✓ A statement confirming accessing to Annex II data. (SANCO/10796/2003)

Appendix VII: CoCh REPORT of this guidance includes the CoCh Report template that shall' be used by the applicants in their submission and by the ZRMS.

ZRMS will evaluate the completeness of the dossier, all the information and justifications required shall be submitted, CoCh Report (Appendix VII) will be produced by the ZRMS and distributed by email to all the contact points in the SMS. The conclusion of the acceptance of category 4 studies of the ZRMS will be followed and accepted by the cMS in the Southern Zone. In cases where the plant protection product contains two or more active substances and the approval of the second active substances expire within 12 months of the first one, the DRR and the dossier shall be submitted 3 months after the entry into force of the renewal of the second active substances, this is applicable also in the case of the submission of cat 4 studies.If Cat 4 studies are accepted this shall be immediately informed to the cMS in the zone (using the CoCh Report). The date of finalization of the cat 4 studies shall be indicated in the CoCh report and the date of DRR submission should be based upon the date the latest study available + 3 months. The need for an extension of the authorisation is stated (up to 5 years or till the renewal of the PPP).

If the cat.4 studies are not accepted or conditions of the application under article 43 are not satisfied the applicant can be given an extra 3 months to react and to submit an amended DRR. If after this 3 months no information is submitted or the conditions of application under article 43 are still not satisfied, the application shall be rejected and zRMS should inform the other MSs via email using the CoCh Report.

The data matching table will be assessed by the RMS of the active substance in the conditions described in the EU guidance document SANCO/2010/13170.

If no dossier is submitted for the PPP, the authorization will expire in line with article 32, i.e. one year after the entry into force of the renewal regulation of the a.s.

There is no “stop the clock” under Art. 43 but a zRMS may request information or clarification but should not request or accept new studies.

5.3 Risk assessment

Applicants shall include all the uses for which a renewal of authorization is applied for in SMS in the DRR, although only the renewal of the authorization of some of them is requested in the ZRMS. ZRMS will evaluate all the uses for which a decision shall be taken in the MS of the zone, although applicant only applies for the renewal of authorization of some of the uses in the ZRMS.

Following the completeness check of the dossier, ZRMS will evaluate only the new information included in the DRR and marked in yellow by the applicant. For products containing two or more active substances -and when the 1st substance is renewed- data related to the 2nd substance will not be evaluated. ZRMS will include a statement in the DRR.

Risk assessment of individual tests and studies is presented in the form of a Registration Report as it is described in SANTE/6895/2009 Guidance document on the presentation and evaluation of dossiers according to annex III of Directive 91/414/EEC in the format of a (draft) Registration Report:

[http://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_doss_reg-report-draft.zip]

The registration report shall take into account all registered uses in SMS and it is focused on the worst case uses/scenarios (for all sections except efficacy). Predictably, there will be cases in which more than one worst case scenarios exist.

For efficacy section, in the cases that there is no change in the GAP, compared with the already registered uses under Uniform Principles, no efficacy evaluation will be conducted by the zRMS, hence a complete efficacy

data package is not required, only an update on the assessment of the risk of appearance of resistances is considered necessary.

New efficacy trials are not necessary in the following cases:

- The dose is changed within the authorised range in the zone (additional data could be required case by case)
- Reduction of number of applications in the zone
- Change of application time within the period of application already authorized in the zone

In the three cases mentioned above, applicants shall provide a dRR (the available *voluntary worksharing* FRR, from the evaluation according to Uniform Principles) with a complete efficacy section highlighting only the new information (i.e. resistance update or data supporting the GAP change).

In case of an existing RR from authorities (in English), it is advised to submit an update of this existing RR.

Where a GAP change is necessary (due to change of endpoint in active substance renewal, typically dose reduction linked to risk assessment), efficacy data addressing the revised GAP should be assessed (reduced dataset with dose comparison, only on major/representative uses could be submitted) and update of the resistance status.

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 I)** to the other MS of the zone for comments by uploading these documents on CIRCABC. In that respect the zRMS is sending an email message to the contact points (**Appendix III**) of the other SMS in the agreed standardised format **(Appendix II)**. 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 **4 months** after the application has been declared complete. If during this period ZRMS considers necessary the requirement of additional information/data/studies, ZRMS shall communicate it to the applicant, a report explaining the reason for the requirements should be produced by ZRMS and a deadline for submission of the additional information/data/studies shall be established by the ZRMS. Under the procedure of Art 43 it is not possible to stop the clock of the assessment.

Comments by MS as well as the applicant on the dRR are submitted within **3 weeks** to the zonal contact points of the ZRMS **(Appendix III)** by filling the appropriate column of the reporting table. No additional studies/data will be accepted during and /or after the commenting period, applicant only can comment on “factual issues” and reasons and justifications can be submitted.

Following the receipt of comments the zRMS shall consider and answer all the comments in the reporting table. When there are different opinions between ZRMS and a MS on a specific point that could change final decision, bilateral contacts between ZRMS and the MS shall be taken in order to approach positions.

5.4 Taking a decision

In the light of the risk assessment conducted the zRMS takes a decision in **6 months from the application date (or from the dRR+cat.4 study submission date)**. The decision along with part A, B and C of the RR and the approved label is uploaded on CIRCABC 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 applicant receives a copy of the files on CIRCABC.

The zonal RMS may grant or refuse the authorisation, and this decision shall be made available to the other MS in the zone by the inclusion of the official decision in the PART A of the RR. Either way, the conclusions of the assessment of the zonal RMS should still be used by the concerned MS as the basis for their decisions. Therefore, if the zonal RMS has come to the unambiguous conclusion that the use of a given plant protection product is acceptable in the zone in principle, but not in its own territory for conditions specific on that territory, this conclusion should be considered a positive assessment by the "zonal Rapporteur". On the basis of this positive assessment the Member States in the zone to which an application was sent shall grant authorisations unless the provisions of Article 36(3) are applicable.

The competent authorities of the other SMS take their own decisions within 90 dayson the basis of the risk assessment and the decision conducted by the zRMS and their national conditions.

Comparative assessment for products containing active substances candidates for substitution shall be conducted in all cases by all MSs individually every time an application for renewal of authorisation is made. Such assessments should address the criteria foreseen in Article 50(1).

The applicant should add a section to the application presenting the benefits of the products to be considered by authorities when conducting comparative assessment with alternative control solutions.

This should be presented in the format of the template provided in the appendix to the Guidance document on Comparative Assessment and Substitution of Plant Protection Products in accordance with Regulation (EC) No 1107/2009 (SANCO/11507/2013) or using the National Guidance Documents that each SMS have developed **(Appendix IV).**

Appendix I: REPORTING TABLE (TRADE NAME) zRMS (MEMBER STATE)

Data point	Member State/ Industry	Comment	Reply of responsible subgroup
dRR - overall GENERAL COMMENTS			
dRR – Part A			
dRR – Part B			
Section B.0 – Product background, regulatory context and GAP information			
Section B.1 – Identity: Section B.2: Physical and chemical properties; Section B.4: Other information			
Section B.3 – Efficacy data and information			
Section B.5 – Analytical Methods			

Data point	Member State/ Industry	Comment	Reply of responsible subgroup
Section B.6 - Mammalian Toxicology			
Section B.7 – Metabolism and Residues			
Section B.8 – Environmental Fate			
Section B.9 - Ecotoxicology			
Section B.10 - Groundwater Metabolites			
Part C			

Appendix II: 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	minor use
change in composition	composition change
re-registration (STEP II)	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”

…

Appendix III: Contact points

CONTACT POINTS OF SMS

Member State	Contact Point
BULGARIA	**Authority**: Bulgarian Food Safety Agency Plant Protection Products Directorate **Address:** 17, Hristo Botev Blvd, 1606 Sofia, BULGARIA **Title, Name and Surname**: Mrs Kalinka Marinova **e-mail**: kp_marinova@bfsa.bg **Title, Name and Surname: Mr** Zdravko Popdimitrow e-mail: z_popdimitrov@bfsa.bg **Title, Name and Surname**: Petya Grigorova **e-mail**: p.grigorova@bfsa.bg Prz@bfsa.bg **Authority**: Risk Assessment Center on Food Chain (RACFCh) Plant Protection Products, Active Substances, Safeners and Synergists Directorate **Address:** 136, Tsar Boris III Blvd, 1618 Sofia, BULGARIA **Title, Name and Surname**: Mrs. Nevena Petrova **e-mail**: NPPetrova@mzh.government.bg **Tel.** +359888717649 **Title, Name and Surname**: Mrs. Lilyana Peneva **Address:** 136, Tsar Boris III Blvd, 1618 Sofia, BULGARIA **e-mail**: lpeneva@mzh.government.bg
CROATIA	**Title, Name and Surname:** Ph.D. Gorana Peček Ms Žana Žalac Ms Mirela Šarčević **Authority:** Ministry of Agriculture **Address:** Ulica grada Vukovara 78, 10000 Zagreb, Croatia **Tel:** +385 1 610 9509 (Gorana Peček) +385 1 610 9636 (Žana Žalac) +385 1 610 6656 (Mirela Šarčević) **Fax:** + 385 1 610 9189 **E-mail**: gorana.pecek@mps.hr; zana.zalac@mps.hr; mirela.sarcevic@mps.hr **Title, Name and Surname:**

Member State	Contact Point
	Ms Rajka Turk **Authority:** Institute for Medical Research and Occupational Health **Address:** Ksaverska cesta 2, 10000 Zagreb, Croatia **Tel:** +385 1 468 2614 **Fax:** + 385 1 234 8385 **E-mail**: rturk@imi.hr **Title, Name and Surname:** Ms Zdravka Sever, Ms Tina Fazinić **Authority:** Croatian Centre for Agriculture, Food and Rural Affairs, Institute for Plant Protection **Address:** Gorice 68b, 10000 Zagreb, Croatia **Tel:** +385 1 2311 640 **Fax:** + 385 1 2447 799 **E-mail**: zdravka.sever@hcphs.hr, tina.fazinic@hcphs.hr
CYPRUS	**Title, Name and Surname:** Lyssandros Lyssandrides Officer of Agriculture **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	**Authorisation / Decision purpose:** **Title, Name and Surname:** Claude Vergnet **Authority:** ANSES – Direction des Autorisations de Mise sur le Marché (DAMM) **Address :** 14 rue Pierre et Marie Curie, 94700 Maisons Alfort - France **Tel:** +33 1 49 77 21 77 **E- mail:** claude.vergnet@anses.fr **Title, Name and Surname:** Bertrand Bitaud **Authority:** ANSES – Direction des Autorisations de Mise sur le Marché (DAMM) **Address :** 14 rue Pierre et Marie Curie, 94700 Maisons Alfort - France **Tel:** +33 1 49 77 21 28 **E- mail:** bertrand.bitaud@anses.fr **Title, Name and Surname:** Sophie Poupardin **Authority:** ANSES – Direction des Autorisations de Mise sur le Marché (DAMM) **Address :** 14 rue Pierre et Marie Curie, 94700 Maisons Alfort - France **Tel:** +33 1 49 77 37 56 **E- mail:** sophie.poupardin@anses.fr

Member State	Contact Point
	Evaluation purpose: **Title, Name and Surname:** Thierry Mercier **Authority:** ANSES – Direction de l'Evaluation des Produits Réglementés (DEPR) **Address:** 14 rue Pierre et Marie Curie, 94700 Maisons Alfort - France **Tel**:+33 (0)1 49 77 21 51 **E-mail:** thierry.mercier@anses.fr **Title, Name and Surname:** Eric Truchot **Authority:** ANSES – Direction de l'Evaluation des Produits Règlementés **Address:** 14 rue Pierre et Marie Curie, 94700 Maisons Alfort - France **Tel**:+33 (0)1 49 77 21 74 **E-mail:** eric.truchot@anses.fr **Title, Name and Surname:** Jovana Deravel **Authority:** ANSES – Direction de l'Evaluation des Produits Règlementés **Address:** 14 rue Pierre et Marie Curie, 94700 Maisons Alfort - France **Tel**:+33 (0)1 77 74 17 78 **E-mail:** jovana.deravel@anses.fr ppp.zonal.depr@anses.fr
GREECE	**Title, Name and Surname: Mrs. Danae Pitarokili** **Authority:** Ministry of Rural Development & Food **Address:** Sygrou 150, 17671 Athens **Tel:** +30 210 928 7254 **Fax:** +30 210 9212 090 **E-mail:** dpitarokili@minagric.gr **Title, Name and Surname: Mrs. Maira Gaspari** **Authority:** Mistry of Rural Development & Food **Address:** Sygrou 150, 17671 Athens **Tel:** +30 210 9287250 **Fax:** +30 210 9212 090 **E-mail:** mgaspari@minagric.gr **Title, Name and Surname: George Zimcheris** **Authority** Benaki Phytopathological Institute **Address:**Stef. Delta 8 14561 Kifisia **Tel:** +30 210 8180334

Member State	Contact Point
	Fax :+30 210 8077506 **E-mail:** pcdepartment@bpi.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, Art. 43, re-registration **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.**: a.desalvo@sanita.it, j.mastrostefano@sanita.it **3)** Major label extension, Authorization Modifications, Minor uses authorizations **E-mail:** contactpoint.ppp@postacert.sanita.it **c.c.** d.scricciolo@sanita.it, f.micolucci-esterno@sanita.it **4)** RR request for mutual recognition **E-mail:** contactpoint.ppp@postacert.sanita.it **c.c.**: a.desalvo@sanita.it, j.mastrostefano@sanita.it, f.caprio-esterno@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)** IT cMS Art. 43 **E-mail:** contactpoint.ppp@postacert.sanita.it **c.c.**:l.verticchio@sanita.it, **7)** Authorization requests of mutual recognition in Italy **E-mail:** contactpoint.ppp@postacert.sanita.it **c.c.**: d.scricciolo@sanita.it, f.micolucci-esterno@sanita.it **8)** Parallel import **E-mail:** contactpoint.ppp@postacert.sanita.it **c.c.** d.scricciolo@sanita.it; f.eusepi-esterno@sanita.it **9)** Sustainable use directive **E-mail:** contactpoint.ppp@postacert.sanita.it **c.c.** g.manzocchi@sanita.it;

Member State	Contact Point
MALTA	**Title, Name and Surname:** Ms. Ingrid Borg Ms. Joanne Borg Galea Ms. Nicole Cilia **Authority:** Malta Competition and Consumer Affairs Authority **Address:** Mizzi House, National Road, Blata l-Bajda HMR 9010, Malta **Tel:** +356 2395 2000 **Fax:** +356 2124 2406 E**-mail :** ingrid.borg@mccaaa.org.mt joanne.borg-galea@mccaa.org.mt nicole.cilia@mccaa.org.mt
PORTUGAL	**Title, Name and Surname:** **Msc. Bento Carvalho or Msc. Miriam Cavaco** **Authority:** Direção-Geral de Alimentação e Veterinária Divisão de Gestão e Autorização de Produtos Fitofarmacêuticos **Address:** Quinta do Marquês, 2780-155 Oeiras **Tel:** +351 2 14 46 40 00 **Fax:** +351 2 14 42 06 16 **E-mail:** miriamcavaco@dgav.pt bcarvalho@dgav.pt
SPAIN	**Title, Name and Surname: Ms. Gema Pérez Avilés** **Authority:** Ministerio de Agricultura y Pesca, Alimentación y Medio Ambiente Dirección General de Sanidad de la Producción Agraria Subdirección General de Sanidad e Higiene Vegetal y Forestal **Address:** C/ Almagro, 33. 28071 Madrid. **Tel:** +34 91 3478272 **Fax:** +34 91 3478316 **E-mail:** gperezav@mapama.es **Generic email address:** notifitosUE@mapama.es **Title, Name and Surname: Ms. María García Pérez** **Authority:** Ministerio de Agricultura y Pesca, Alimentación y Medio Ambiente Dirección General de Sanidad de la Producción Agraria Subdirección General de Sanidad e Higiene Vegetal y Forestal

Member State	Contact Point
	Address: C/ Almagro, 33. 28071 Madrid. **Tel:** +34 91 3474131 **Fax:** +34 91 3478316 **E-mail:** mgarciape@mapama.es **Generic email address:** notifitosUE@mapama.es **Title, Name and Surname: Ms. Carmen Fernández Felipe** **Authority:** Ministerio de Agricultura y Pesca, Alimentación y Medio Ambiente Dirección General de Sanidad de la Producción Agraria Subdirección General de Sanidad e Higiene Vegetal y Forestal **Address:** C/ Almagro, 33. 28071 Madrid. **Tel:** +34 91 3474131 **Fax:** +34 91 3478316 **E-mail:** cfernandez@mapama.es **Generic email address:** notifitosUE@mapama.es **Title, Name and Surname:** Dra. Angustias Herrera **Authority:** Ministerio de Sanidad, Servicios Sociales e Igualdad Subdirección General de Sanidad Ambiental y Salud Laboral. **E-mail:** aherrera@msssi.es **Generic email address:**sanifitos@msssi.es **Title, Name and Surname: Dr. José Luis Alonso Prados** **Authority:** INIA – DTEVPF **Address:** Ctra de La Coruña Km 7. 28040 Madrid. **Tel:** +34 91 3471473 **Fax:** +34 91 347 3903 **E-mail:** prados@inia.es **Generic email address:** fitos@inia.es **Title, Name and Surname: Dra. Ana Patricia Fernandez-Getino** **Authority:** INIA – DTEVPF **Address:** Ctra de La Coruña Km 7. 28040 Madrid. **Tfno:** +34 91 347 8756 **Fax:** +34 91 347 3903 **E-mail:** fgetino@inia.es **Generic email address:** fitos@inia.es

Appendix IV: National data requirements for dossiers of plant protection products
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.

Comparative risk assessment:

2. France
Please refer to the documents available in the ANSES website **https://www.anses.fr/fr/content/documents-dinformation-pour-la-constitution-de-dossiers-pour-les-produits**

Comparative risk assessment:

The Guidance document on the comparative assessment of plant protection products in France is available on the ANSES website. The steps of the comparative assessment process, the information to submit and the data submission format expected in France are provided in annex of this Guidance document.
Please include information linked to comparative assessment, in English, in the dedicated section of Part A of the dossier submitted by the applicant if France is the zonal Rapporteur Member State (zRMS), or in a national addendum to Part A if France is not the zRMS.

3. Greece

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	YES		N	Benaki Phytophatological Institute e-mail: pc department@bpi.gr
Comparative risk assessment:	Not enforced (draft guidance document under discussion)			
Phys. Chem. properties and anal. method				
Toxicology	NO	**No specific data requirements.** **In general the following are considered acceptable:** **FOR APPLICATIONS TILL END 2015** **<u>Operator exposure – Field application</u>** - UK predictive operator exposure model (UKPOEM, revised UK MAFF, 2003) - German BBA model (Lundehn *et al.*, 1992, or the revised PSD version) 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.		

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
		<u>Operator exposure – indoor application</u> o DUTCH Greenhouse model: Van Golstein Brouwers Y.G.C., Marquart J., Van Hemmen J.J. (1996) Assessment of occupational exposure to pesticides in agriculture. Part IV. Protocol for the use of generic exposure data. TNO Nutrition and Food Research Institute, The Netherlands. TNO Report V 96.120 • EUROPOEM data: EUROPOEM Operator Exposure data Base; EUROPOEM II Project FAIR3-CT96-1406, 2002 • Combination of different scenarios from the available models, e.g. • mixing/loading: use the tractor scenario (boom sprayer) data available in German BBA model & UK POEM • application: use the handheld equipment scenario data available in German BBA model (high crop) or UK POEM (low crop) • Field or greenhouse studies conducted with the same or similar product and the same application method, e.g. • Mich, G. (1996): Operator Exposure in Greenhouses During Practical Use of Plant Protection Products; Project EF 94-02-03; June 6, 1996; ECON GmbH Ingelheim.		

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
		<u>Worker, bystander and resident exposure</u> Calculations based on acceptable data (published or not) concerning the spray drift and the dislodgeable foliar residues. The submitted studies must be followed by complete justification of all the assumptions that have been made. As far as the bystander and resident exposure is concerned, the approach described by the «Chemicals Regulation Directorate (UK authorities) guidance» or the use of data derived from Martin *et al* (2008) are acceptable after appropriate justification. **FOR APPLICATIONS SUBMITTED FROM 1-1-2016** **<u>Operator exposure – Field application</u>** EFSA Guidance (2014) is followed in al cases In case of submission of experimental data or/and calculations for the level of exposure following a different approach from the one proposed in the above guidance document a full justification must be submitted, to be evaluated on a case-by-case basis. **<u>Operator exposure – indoor applicaton</u>** • DUTCH Greenhouse model: Van Golstein		

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
		Brouwers Y.G.C., Marquart J., Van Hemmen J.J. (1996) Assessment of occupational exposure to pesticides in agriculture. Part IV. Protocol for the use of generic exposure data. TNO Nutrition and Food Research Institute, The Netherlands. TNO Report V 96.120 • ECPA Southern European Greenhouse Model **Note:** Field/Greenhouse studies conducted taking into account the general provisions of EFSA Guidance (2014) e.g. for PPE. In any case a full justification must be submitted, to be evaluated on a case-by-case basis. **<u>Worker, bystander and resident exposure</u>** EFSA Guidance (2014) In case of submission of experimental data or/and calculations for the level of exposure following a different approach from the one proposed in the above guidance document a full justification must be submitted, to be evaluated on a case-by-case basis • Dermal absorption The EFSA Guidance (EFSA Journal 2012;10(4):2665) is followed.		

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 use of the new EFSA Guidance Document on dermal absorption (EFSA Journal 2017;15(6):4873) is also acceptable by EL. However, it is noted that the European Commission has not yet decided regarding the implementation time for the mandatory use of this guidance in the regulatory context.		
Residues		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 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		

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
		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		There are no particular specific national requirements for this section, other than the standard data package assessed for active substance approval. This should include: • For PEC groundwater calculations, using both FOCUS PELMO and PEARL tools, 5 out of 9 scenarios should be < 0.1 µg/L including Piacenza, Porto, Sevilla and Thiva. • R2, R3, R4, D4 and D6 FOCUS SW scenarios are more representative for the Hellenic conditions. • Approved active substances with high probability of leaching to ground waters, due to increased soil mobility and / or the high half-life in soil (soil DT_{50}) and applied to vulnerable soils, will be included in national monitoring programs in cooperation with competent bodies. The results of these programs may cause changes in the registration of the products containing these active substances		

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
		If on the basis of the results from monitoring studies on ground water residues > 0.1 µg/l are found on >10% of the samples taken then the Coordinating Competent Authority undertakes administrative measures for the plant protection products containing those substances in order to minimize the impact on the environment including the withdrawal from the market in such cases that it is not possible to manage the risk on acceptable levels with other measures like the reduction of the number of applications, application rates, period of use of the product, prohibition of the use on certain crops etc.		

<table>
<tr><th>Section</th><th>Supplementary data requirements for Annex III dossier (YES/NO)</th><th>Goal(s) of Guidance document</th><th>Guidance Document available Y/N and Language of the document</th><th>Address or contact point to obtain GD</th></tr>
<tr><td>Ecotoxicology</td><td>YES</td><td><u>Birds and mammals</u>
General issues
For more than one applications, MAF (multiple application factor) may take the value of 1 (food items: seeds, plant matter, arthropods) when application interval is sufficiently high. This will be examined on a case by case basis
<u>Vole scenario issues</u>: Acceptable risk to mice and to lagomorphs for the species-relevant BBCH is of high importance. Regarding voles, risk assessment is considered to be covered through the assessment of other small mammalian species for the following reasons
High fecundity and population recuperation of the vole
Primary source of food outside crops fields for the vole
Necessity of population control measures since the vole is considered a crop pest when high population levels are reached
Other agricultural techniques being also means of population control

Refinement of RUD values (plant matter, arthropods)
An extended database in EFSA GD, 2009 exists for RUD for monocotyledonous plants, thus its replacement with other experimental values is not advised.
RUD replacement by experimental values should be supported with at least two trials of</td><td>• EFSA, 2009 (Risk Assessment for Birds and Mammals, EFSA Journal 2009; 7(12): 1438), for applications submitted after the 14th of June 2011
• SANCO, 2000 (SANCO/4145/2000, 25 September 2002) for applications submitted before the 14th of June 2011

Birds and mammals species NOT accepted as “focal species” for all the crops in Hellas for spring and summer.
<table>
<tr><th>Hellenic bird and mammal name</th><th>English bird and mammal name</th><th>Scientific bird and mammal name</th></tr>
<tr><td>Σταρήθρα</td><td>Skylark</td><td>Alauda arvensis</td></tr>
<tr><td>Αρουραίος της Μεσογείου</td><td>Common vole</td><td>Microtus arvalis</td></tr>
<tr><td>Αρουραίος</td><td>Mediterranean pine vole</td><td>Microtus duodecim</td></tr>
<tr><td>Αρουραίος</td><td>Savi’s Pine Vole</td><td>Microtus savii</td></tr>
<tr><td>Αρουραίος</td><td>Field vole</td><td>Microtus agrestis</td></tr>
<tr><td>Μυγαλίδα</td><td>Common shrew</td><td>Sorex araneus</td></tr>
<tr><td>Μυγαλίδα</td><td>Greater white toothed shrew</td><td>Crocidura russula</td></tr>
<tr><td>Ποντίκι</td><td>Algerian</td><td>Mus spretus</td></tr>
</table></td><td></td></tr>
</table>

<table>
<tr><th>Section</th><th>Supplementary data requirements for Annex III dossier (YES/NO)</th><th>Goal(s) of Guidance document</th><th>Guidance Document available Y/N and Language of the document</th><th>Address or contact point to obtain GD</th></tr>
<tr><td></td><td></td><td>which at least one should have been performed in South Zone
Bridging RUD values for plant matter between different crops is acceptable according to SANCO 7525/VI/95-rev.9, March 2011)

The following remarks should also been taken into account:
Use of Body Burden Model for higher Tier assessment is acceptable
Use of Population Modeling for higher Tier assessment is not acceptable unless accompanied by relevant Expert Opinion position paper

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 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 <u>high acute toxicity</u>, reassessment of PT, PD and use of mixed diet (omnivorous) scenario is not</td><td>
<table>
<tr><td></td><td>Mouse, Western Mediterranean Mouse</td><td></td></tr>
</table>
Birds and mammals species accepted as “focal species” for all the crops in Hellas
<table>
<tr><th>Crop scenario</th><th>Hellenic bird and mammal name</th><th>English bird and mammal name</th><th>Scientific bird ar</th></tr>
<tr><td>Arable crops (all BBCH levels) Spring (4th-5th yearly month)</td><td>Τσιφτάς</td><td>Corn bunting</td><td>Miliaria calandra</td></tr>
<tr><td>Arable crops (all BBCH levels) Summer (6th-9th realy month)</td><td>Κατσουλιέρης
Σπιτοσπουργίτης</td><td>Crested lark
House sparrow</td><td>Galerida cristata
Passer domesticus</td></tr>
<tr><td>Winter cereals BBCH <13 Winter (11th-12th yearly month)</td><td>Σταρήθρα
Τσιφτάς</td><td>Skylark
Corn bunting</td><td>Alauda arvensis
Miliaria calandra</td></tr>
<tr><td>Winter</td><td>Λιβαδικε</td><td>Meado</td><td>Anthus pratensis</td></tr>
</table>
</td><td></td></tr>
</table>

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
		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 may be represented not only by the lowest toxicological endpoint (Section 3) but also by the ecotoxicologically relevant 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. 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	*cereals* BBCH=30 Spring (3rd yearly month; before arrival of migratory birds)	λάδα Σταρήθρα	w pipit Skylark	*Alauda arvensis*	

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
		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. 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>** Water bodies protected: All water bodies except those which fall dry over longer periods in the year. The routes of exposure for the aquatic organisms should be reported. 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 R2, R3, R4, D4 and D6 scenarios.		

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
		Risk mitigation measures proposed: • Buffer zones from surface waters: As buffer zone is defined the distance between the limit of the cultivated field/ orchard and the surface waters. • For approval of the formulation, the maximum buffer zone proposed is **50** m for orchards, vines and leafy crops and **20** m field crops, taking into account • At fields with <2% slop the use of Vegetative Buffer Strips up to 20 m is acceptable (The VBS can consist of spontaneous vegetation or planted vegetation or a combination of both • that application (spraying) is performed using: 1) conventional nozzles, 2) drift reduction nozzles, or 3) combined 1 and 2. For the risk mitigation measures proposed the Coordinating Competent Authority follows the FOCUS Landscape and mitigation factors in aquatic ecological risk assessment, SANCO/10422/2005, version 2.0, September 2007 for runoff and drainage as it is in force by the date of submission of the application. In particular it should be pointed out that risk mitigation measures that are proposed by applicants should be practically enforceable		

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
		and are not related to economic parameters while in those cases that a combination of measures is proposed e.g. buffer zone plus drift reduction nozzles such measures should not lead to an overall reduction that exceeds 95% In addition, for the time being vegetative buffer strips as a mitigation measure are not accepted. This option will be reexamined in the light of the experience that will be gained from the application of existing risk mitigation measures and the results achieved in the context of Law 4036/2012 concerning the sustainable use of pesticides • 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 plant protection products (mainly insecticides) in seed treatment applications the RA through the dust should be addressed. **Non target arthropods** Risk mitigation measures proposed: Use of not sprayed buffer zones: As buffer zone is defined the safety distance between the limit		

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
		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 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. **Soil organisms** There are no additional national requirements, other than the standard data package assessed for active substance approval. **Non target plants** Risk mitigation measures proposed: Use of no sprayed buffer zones: 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. **General** The submitted folder should include: The GAP, which should include all the relevant details, including the growth stages (BBCH code), application rate (in Kg or gr a.s./ha) and		

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
		intervals, remarks. The original reports from relevant trials which have been used for the support of RA for non-target organisms, if these have not been evaluated during the procedure for the approval of the a.s.I. These should be given preferably in electronic form, and if not available in such, as a hard copy. The representativeness for the Hellenic conditions of the data provided in order to support the risk assessment should be clarified by the applicant (for the relevant intended uses and growth stages). Information on the necessity of performing additional studies with the formulation or the metabolites, according to aforementioned guidelines (GD on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Dir 91/414/EEC, SANCO/221/2000 –rev.10, 25 February 2003). • For the case of mixtures of substances, the potential synergistic effect should be clarified by the applicant (e.g. birds and mammals). • Update table with the studies using the formulations (references relied on, Annex III).		

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
Efficacy	YES	The legislation in force, enacted by the European Commission and the National Coordinating Authority, as well as the available General and Specific EPPO Standards should be taken into consideration for the evaluation of the biological data of PPPs in accordance with the Regulation (EC) No 1107/2009. Specifically, regarding the extrapolation of efficacy and phytotoxicity data, the relevant documents to be taken into consideration are a) the EPPO Standard PP1/257 along with the EPPO extrapolation tables and b) the document of the European Commission *Sanco Technical Report*: *Proposals for extending and harmonizing efficacy and crop safety extrapolations to reduce the need for efficacy trials on minor crops* (DG SANCO/D3/SI2.395857). This document sets the National Requirements concerning the Biological Control of PPPs, according to which, the submission of experimental data from Greece is considered necessary. In particular, efficacy or/and phytotoxicity trials carried out in Greece, are required in the following cases: **I) Differentiations in national agricultural practices or/and soil-climatic conditions, affecting the biology of the target organisms** and consequently the effectiveness of the PPP under evaluation. These cases include national crops of major	Yes in Greek and English	

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
		importance (e.g. cotton, olive trees) as referred in Appendix I. In each of these cases 2-4 efficacy/phytotoxicity trials are required. Specifically, as regards PPPs intended for the control of the olive fruit fly by means of bait application(s) or mass trapping, the methodology to be followed in the Greek efficacy trials is defined by the Specific EPPO Standard PP1/280 and the relevant document in Appendix II in case of bait application, and the National Experimental Protocols of Hellenic Ministry of Rural Development and Food (MRDF) in case of mass trapping. Additionally, in case of PPPs intended for use in crops that include cultivars of national importance, as those specified in Appendix III, at least 2 Greek phytotoxicity trials must be submitted to support the safe use of the PPP under evaluation in at least one of the listed cultivars for each crop. **II) Compatibility of the PPP under evaluation with other registered products in spraying programs.** In case where a PPP is intended for use in specific spraying programs, the efficacy must be demonstrated considering the Greek agricultural practices. **III) Integrated Plant Protection Programs (IPM).** In case of specific IPM recommendations in the proposed label of a PPP or in case of crops in which indigenous natural enemies are established or beneficial		

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
		arthropods have been released, experimental/bibliographic data demonstrating the absence of negative effects on these beneficial arthropods as well as recommendations for the management of potential risk must be submitted. **IV) Crops/cultivars of national importance** [e.g. table grapes (var.: Soultanina), olive trees (var.: Koroneiki, Kalamon, Konservolia),] **in order to support the absence of negative effects of the PPP under evaluation on the quality/sensory characteristics of** fresh or/and processed **plants and plant products.** In this case, data following the General (PP1/135, PP1/242, PP1/243 and PP1/268) and Specific EPPO Standards must be submitted. If such data are not available, a scientifically justified statement based on the physicochemical properties of the product, the residue studies etc. must be submitted. **APPENDIX I** PESTS Crop / Pest / Pest-scientific name Olive tree / Olive fruit fly [1, 2] / *Bactrocera oleae* Cotton / Cotton bollworm [2] / *Heliothis armigera* Vegetables / Root-knot nematodes [2, 3] / *Meloidogyne* spp. MICROBIAL PESTICIDES		

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
		Experimental efficacy data to support the use on representative crops (nationally important) are required. SUBSTANCES CAUSING INDUCTION OF PLANT RESISTANCE (Elicitors) Experimental efficacy data to support the use on representative crops (nationally important) are required. [1] Insect control using bait application(s) or mass trapping [2] Major pest on major crop [3] Estimation of the level of the nematode population in soil is required in the experimental data set. **APPENDIX II** Concerning efficacy evaluation trials of PPPs intended for the control of the olive fruit fly using ground spraying bait applications, the following are proposed, supplementary to the EPPO Standard PP1/280: In point *1.3 Design and lay-out of the trial*, the plot size recommended by EPPO in cases of high population pressure, i.e. 5 ha (1.000 trees), must be followed for safer conclusions due to the behavior of this insect (biology, mobility etc.). In addition, in this case, untreated control is not required due to the large size of plots. Regarding the number of trials, the EPPO Standards PP1/181 and PP1/226 should be taken into account, thus the trials should be done across a range of climatic and environmental conditions likely to be encountered, and over at least two years. In		

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
		case of olive trees, due to alternate bearing, trials carried out at the same year but in different areas can be accepted, provided that they satisfy the prerequisites of a large fruit bearing and high level of olive fruit fly population. In point 2.3.1 Type of application, taking into account the total large size of the experimental olive orchard, the spraying of the entire experimental area should be completed in five (5) days *at* the latest. In addition, marking of the treated trees is recommended. In point *2.3.3 Time and frequency of application,* following the EPPO Standard PP1/280 "*Bactrocera oleae* – bait application", which mentions that, where available, locally established thresholds, monitoring practices and warning systems should be used, it is noted that monitoring of the olive fruit fly population in bait applications in Greece is carried out with Mc Phail traps (1/500-600 trees or 2/500-600 trees in areas with high population pressure); the applications is foreseen to be carried out based on the number of captured adults in Mc Phail traps as well as on the application thresholds existing in each specific area, provided that the environmental conditions are suitable (temperature < 28oC, wind speed < 4 bf). Especially for the first application, the following criteria should also be taken into account: reproductively mature		

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
		females > 5%, ratio of females to males > 1, the beginning of hardening of the olive fruit kernel. In point *3.2.1 Type (of assessment),* *Large plots (Sampling olive fruit to assess infestation),* the sampling is recommended to be carried out at the center of each plot and the sampled trees to be marked. Double sample size (20 olive fruits per tree) is recommended for samplings in September-November. During these samplings, both active (live) infestation (eggs, live L1-3, nymphs and exit holes) and dead infestation (non hatched eggs, infertile oviposition stings, suberized mines and dead L1-3) are estimated. The sum of active and dead infestation is the total infestation. In point 3.2.2 Time and frequency, the olive fruit infestation is estimated by five samplings of the tree canopy during the first 10 days of July, August, September, October and November. In point *3.5 Quantitative and qualitative recording of yield,* the estimation of yield decrease due to the olive fruit fly infestation is an additional indication of the efficacy of the test product and it can be performed as follows: The initial yield is estimated by an initial sampling at the end of June-beginning of July. Thereafter monthly samplings of fallen fruits are conducted from four random trees located at the center of each plot from August until the		

<table>
<tr><th>Section</th><th>Supplementary data requirements for Annex III dossier (YES/NO)</th><th>Goal(s) of Guidance document</th><th>Guidance Document available Y/N and Language of the document</th><th>Address or contact point to obtain GD</th></tr>
<tr><td></td><td></td><td>beginning of harvest.
<u>APPENDIX III</u>
<table><tr><th>Crop</th><th>Cultivars[1]</th></tr><tr><td>Olive trees</td><td>Kalamon, Koroneiki</td></tr><tr><td>Pear trees</td><td>Krystalli, Kontoula</td></tr><tr><td>Vine[2]</td><td>Soultanina, Corinthian raisin</td></tr><tr><td colspan="2">[1]FEK 468/2011, regarding determination of promoted species, tree crop cultivars and other activities
[2]Decision of MRDF (protocol number: 247771, 04.03.2010), concerning the classification of vine cultivars (FEK 381/B/6.4.2010)</td></tr></table></td><td></td><td></td></tr>
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4. Spain

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

and

http://www.mapama.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
Comparative risk assessment:	YES	Comparative Assessment of PPP	YES (Spanish/English)	http://www.mapama.gob.es/agricultura/pags/fitos/registro/fichas/pdf/Guía+complementaria+de+evaluación+comparativa+en+España.pdf
Phys. Chem. properties and anal. method	NO			
Toxicology	YES	**Unacceptable Co-formulants** for inclusion in PPP Information available in the MSSSI website: https://www.msssi.gob.es/ciudadanos/saludAmbLaboral/fitosan/home.htm Currently the document is being modified to include new unacceptable co-formulants and to correct some errors in order to change restrictions of crystalline silica. The document will be uploading in the website.	Yes, Spanish	**CO-FORMULANTS UNACCEPTABLE for inclusion in PPP**: Information available in the MSSSI website: https://www.msssi.gob.es/ciudadanos/saludAmbLaboral/fitosa tm **EXPOSURES ASSESSMENT:** Coming soon, will be published the document with the c Spanish) in the web of the Ministry of Health: http://www.msssi.gob.es/ciudadanos/saludAmbLaboral/fitosar m EFSA Guidance, 2014: Guidance on the assessment of exposure of operators,

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
		• **Exposures Assessment:** In general terms all indications collected in EFSA Guidance, 2014 will be taking into account, and the attached Excel calculator will apply. For scenarios not covered by the EFSA Guidance, 2014, the following models will apply: **Operator- PROFFESIONAL USES:** **Greenhouses:** AOEM for mixing and loading, and EUROPOEM II database for spray applications: High crops: Body: 852 mg/Kg a.i. applied/ Hands: 72 mg/Kg a.i. applied/ Inhalation: 0,770 mg/Kg a.i. applied. Low crops: Body: 196 mg/Kg a.i. applied/ Hands: 57.8 mg/Kg a.i. applied/ Inhalation: 0,443 mg/Kg a.i. applied. For applications with Trolley Sprayer: Body: 176 mg/Kg a.i. applied/ Hands: 72 mg/Kg a.i. applied/ Inhalation: 0.4246 mg/Kg a.i. applied. (based on Trolley study and EUROPOEM II data base. For granules applications: EFSA calculator (PHED database).		residents and bystanders in risk assessment for plant products. EFSA Journal 2014;12(10):3874 http://www.efsa.europa.eu/en/efsajournal/pub/3874.htm Trolley study: Methoxyfenozide. Determination of Dermal and Inhalation Exp Applicators during application with Runner an SC Formul Methoxyfenozide, 240 g/l resulting from Trolley Application Crops in Greenhouses- Spain 2012. Biocides Guidance: TNsG on Human exposure to Biocidal Products –Guid exposure estimation (June 2002). Proposal AEPLA- AGRUPOST: ADENDA A LA PROPUESTA AEPLA-AGRUPOST "Estimac Exposición del Trabajador en Postcosecha de Frutos Cítric Febrero de 2006. Higher tier assessment: field studies – Guidelines and documents: US EPA Series 875 - Occupational and Residential Expo Guidelines. (Group A – Applicator Exposure Monitor Guidelines) y (Group B – Postapplication Exposure Monito Guidelines) https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-875-occupational-and-residential-exposure Scientific Issues Associated with Worker Reentry Assessment presented jointly to the FIFRA Scientific Advisory US Environmental Protection Agency, Health Canada and Environmental Protection Agency, 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
		Manual spraying in enclosed areas: Biocides Guidance- Spray model 1 or 2. **Seed Treatment:** SEEDTROPEX model (75 th= French version). **Aerial application:** PHED. **Stem injection:** AOEM (knapsack- only mixing and loading). **Powder for dusting:** Loading -> AOEM Application-> It is necessary to provide a field study of actual exposure. **Post harvesting treatment** (Drencher, line pulverization, dipping – automated) : AOEM (only mixing/loading) **Paintbrush:** Mixing and loading -> AOEM (knapsack). Application -> Biocides Guidance-Consumer product painting Model 2 **Operator- NON PROFFESIONAL USES:** **Spray applications (knapsack):**		US Environmental Protection Agency Office of Pesticide Science Advisory Council for Exposure(ExpoSAC) Policy 3 January, 2017 http://www.epa.gov/pesticide-science-and-assessing-pesticide risks/science-advisory-council-exposure-exposac-policy-3 GUIDANCE FOR DETERMINATION OF DISLODGEABLE RESIDUE By Susan Edmiston, Senior Environmental Scientist Sally Powell, Senior Environmental Research Scier Spencer, Associate Environmental Research Scientist Cynth Environmental Research Scientist. November 27, 1990 Revis February 20, 2002. California Environmental Protection Department of Pesticide Regulation Sacramento, California 95 http://www.cdpr.ca.gov/docs/whs/pdf/hs1600.pdf Iwata, Y., J.B. Knaak, R.C. Spear and R.J. Foster (1977 Reentry Into Pesticide Treated Crops. I. Procedures Determination of Dislodgeable Pesticide Residues on Foli Environ. Contam. Toxicol. 18, 649. •

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 POEM- "Home garden sprayer (5 L tank). Outdoor low level target". **Ready to use products:** Aerosol and Trigger Sprays-> CRD (Chemicals Regulation Directorate –UK) Amateur use model 2. Powder for dusting -> CRD Amateur use model 2. PUFFER PACK MODEL Granules-> CRD Amateur use model 2. PUFFER PACK MODEL. Paintbrush-> Biocides Guidance-Consumer product painting Model 2. **Worker:** In general terms, EFSA model. **Seed Treatment:** SEEDTROPEX model (75 th= French version). **Post harvesting treatment:** Exposure of treated fruit handlers based on the proposal AEPLA- AGRUPOST is calculated. **For non-professional uses**, the following parameters are taken into account: Insecticide / fungicide (Ready to Use): TC =5000 and T = 2 hours. Insecticide / fungicide (knapsack): TC =5000 and 8 hours.		

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
		Herbicide: TC= 1400 and t = 2 hours. **Bystander and Resident:** Outdoors applications: Professional Uses: Martin et al (2008). Coming soon, EFSA model. Non-Professional Uses: Martin et al, 2008 - Home and allotment garden area (HG). Re-entry of children into treated gardens-> CRD (Chemicals Regulation Directorate – UK) Amateur use model 2. See OPERATOR EXPOSURE GUIDANCE FOR AMATEUR (HOME GARDEN) PESTICIDES. Indoors it is considered that there is no exposure **Other considerations:** Combined Exposure: The combined exposure is performed when the product contains active substances classified as CMR or when they have some common target organ. Higher tier assessment: If refinements are necessary through field studies (actual exposure of operators, workers, residents & bystanders, DFR/DT_{50}), the published international guides and related documents will follow.		

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
Residues	NO	List of minor uses National procedure for the extension of use to minor use	Y (Spanish)	http://www.mapama.gob.es/agricultura/pags/fitos/registro/fichas/pdf/MinorCrops_actualizado_rev6.pdf http://www.mapama.gob.es/agricultura/pags/fitos/registro/fichas/pdf/PROC%20UM%20DICIEMBRE%202014.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
Fate and behaviour	YES	PECsw following FOCUS guidance document, or with a validated scenario representing agroclimatological conditions including drift, runoff/erosion and drainage The following FOCUS SW scenarios are relevant for Spain: **D4, D5, D6, R1, R2, R3 and R4** PECgw following FOCUS guidance document The following FOCUS GW scenarios are relevant for Spain: **Châteaudun** **Hamburg** **Piacenza** **Porto** **Sevilla** **Thiva** Specific calculation is required for intended use on Banana	N	
Ecotoxicology	NO		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
Efficacy	NO Data on deposit of active substance per foliar area (ng a. s./cm^2) shall be recorded (it is proposed to follow the standard ISO/FDIS 22522) and included in the efficacy trials. In the biological dossier, data on spray volume, as well as application equipment used in the trials shall be recorded for the validation of the dose rate and dose adjustment.	List of minor uses National procedure for the extension of to minor use	Y (Spanish)	http://www.mapama.gob.es/agricultura/pags/fitos/registro/fichas/pdf/MinorCrops_actualizado_rev6.pdf http://www.mapama.gob.es/agricultura/pags/fitos/registro/fichas/pdf/PROC%20UM%20DICIEMBRE%202014.pdf

5 .Portugal

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
Comparative risk assessment	YES	Comparative Assessment of PPP	Y	www.dgav.pt
Phys. Chem. properties and anal. method	NO			
Toxicology	YES	Operator exposure Both the UK POEM and the German operator exposure model are to be 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 STEP 1 to STEP 4 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	N	Birds and mammals **EFSA, 2009** (Risk Assessment for Birds and Mammals, EFSA Journal 2009; 7(12): 1438), for applications submitted after the 14th of June 2011 **SANCO, 2000** (SANCO/4145/2000, 25 September

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
		food, but with scenarios and updated values for FIR/bw, RUD, MAF as agreed in the EU guidance document. The Risk assessment for non-target aquatic organisms should be conducted taking into account the 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)). Risk Mitigation measures should be practically enforceable and may include drift reducing nozzles or vegetated buffer strips. FOCUS Landscape and mitigation factors in aquatic ecological risk assessment, SANCO/10422/2005, version 2.0, September 2007 for runoff and drainage as it is in force by the date of submission of the application is accepted. The proposal of use of drift reduction nozzles with overall drift reduction above 75% should be accompanied by experimental field data. For non-target arthropods, risk mitigation measures may include buffer zones and other application management techniques such as		2002) for applications submitted before the 14th of June 2011 Bees: Studies should be conducted according to valid study protocols. **OEPP/EPPO (2010)** EPPO Standards PP1/170(4) Efficacy evaluation of plant protection products. Side-effects on honeybees. *Bulletin OEPP/EPPO Bulletin;* **OEPP/EPPO (2010**) EPPO Standards PP 3/10 (3) Chapter 10: Honeybees. Environmental risk assessment scheme for plant protection products. *Bulletin OEPP/EPPO Bulletin*

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
		alternate row applications or non-application in border rows. Drift reducing nozzles accepted however buffer zones should not exceed**10** m for orchards and vines and **5** m for field crops and leafy crops. This is also applicable for the protection of non-target plants. For the purpose of RA for bees, SANCO/10329/2002 rev 2 final Draft Working Document Guidance Document on terrestrial Ecotoxicology Under Council Directive 91/414/EEC and for higher tier RA (field and semi-filed)chapter 10 of the EPPO scheme (2010) is preferred as EFSA (2013) has not been noted so far.		

6. Croatia

There are no national requirements for authorisation of plant protection products in Croatia.
Requests for documentation for the authorization of plant protection products are based entirely on data that are officially required by the EU Regulations and guidelines concerning the authorization of plant protection products.

Comparative risk assessment:
GD on comparative assessment HR.docx

Major uses: wheat, barley, maize (except for sweet corn, popcorn (Zea mays everta), seed corn), oat, potato, olive, grapevine, apple, mandarin (Citrus reticulata), plum, soybean, sunflower, sugar beet, oilseed rape, tomato and onion (Allium cepa var. cepa).

No national requirements for efficacy.

No national extrapolation tables; EPPO extrapolation tables are used.

7. Malta

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

8. ITALY

Generally the EU data requirements and models are accepted. These are integrated by the following:

TOPIC	GUIDANCE
Comparative Assessment guidance for information to be submitted by Companies	COMPARATIVE ASSESSMENT GUIDA
Efficacy: efficacy and selectivity studies for registration and renewal of registrations of PPPs	http://www.salute.gov.it/imgs/C_17_pubblicazioni_2508_allegato.pdf
Minor uses: list of minor crops	IT Decreto 16 09 1999_ Utilizzazioni mir
Co-adjuvants: data requirements and criteria to authorize co-adjuvants to be used in combination with PPPs	http://www.salute.gov.it/imgs/C_17_pubblicazioni_2479_allegato.pdf

Appendix V: 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	PPE during mixing, loading and application; use restricted to professionals; three categories of users	
Worker exposure	PPE	
Bystander exposure	Drift reducing nozzles; Buffer strip	
Residents exposure	Drift reducing nozzles; Buffer strip	
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	The use of plant protection products on agricultural and forestry crops, perennial and roadside crops and melliferous plants during flowering and period of producing honeydew is prohibited. /Bulgarian law for bee keeping/2014/	
Soil organisms		
Efficacy		
Biological efficacy		
Phytotoxicity		
Resistance		

Croatia	Mitigation options	Comments
General	Revised GAP supported by available data. Label restriction for PPPs used for seed treatment: On packaging with treated seed further restriction must be stated: Seed treated with PPP, must not be treated again with the same PPP or other PPPs containing the same active substance/s. Treated seed must not be used for food or feed, even after mixing with untreated seed. To protect birds/wild mammals the treated seed must be entirely incorporated in the soil, including the end of rows. Scattered seed must be collected and removed immediately. Treated seed must not be left on soil surface.	
Toxicology		
Operator exposure	PPE for M&L and application if feasible; Closed cab only option if resulting from EFSA calculator; no drift reduction nozzles only option unless also the only option for granting authorisation in ecotox assessment but then restriction to trained professionals only; amateur uses restricted to low hazard PPP and no PPE needed for safe use	
Worker exposure	No PPE for re-entry as risk mitigation measure approved; realistic re-entry intervals for maintenance workers and/or PHI for harvesters	
Bystander exposure		
Residents exposure		
Residues		

Fate		
Surface water		
Ground water	Restrictions of use in karst areas on the label.	
Ecotoxicology	Drift reduction nozzles up to 95 %. Risk assessment must also always be performed without drift reduction nozzles. If not, the use of drift reduction nozzles will be mandatory.	
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		
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 points :** **contact.damm@anses.fr** Please refer to the documents available in the ANSES website **https://www.anses.fr/fr/content/documents-dinformation-pour-la-constitution-de-dossiers-pour-les-produits**	
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		
General		**For the non-dietary exposure assessment, the acceptable risk mitigation options included in the EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874) are considered acceptable.** *The EFSA Model provides specific dermal exposure values for operators wearing trousers and a long sleeved shirt during application of the spray. Standard figures are used for the penetration of such clothing. From this basic assumption, the reduction of exposure from the use of protective equipment (e.g. gloves, goggles, head-gear, body garment, etc.) can be calculated. Reduction in inhalation exposure may be achieved by additional protection specifically designed to reduce exposure during handling or application.* http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2014.3874/epdf
Operator exposure		Apart from what is stated above, in case other models are used and not the EFSA Calculator the PPE considered in each model are in general acceptable taking into account the intended use conditions. In order to conclude on the recommended PPE and/or the use of working clothing the hazardous properties of the active substance(s) and the formulation are also taken into

		account. It is noted that in case of the non-professional use of plant protection products there are specific provisions at national level regarding both the hazardous properties and the PPE to be considered.
Worker exposure		▪ For the reduction of the worker exposure during harvesting activities, protective gloves can be used. ▪ For maintenance type activities (e.g. crop inspection/irrigation), the use of gloves on a case by case basis since a relevant transfer co-efficient (TC) is not proposed according to the EFSA Guidance. ▪ If there is an unacceptable risk anticipated for a worker re-entering the field, even with the use of PPE (gloves), a justified refinement is acceptable. More specifically, specific DFR data if available or a re-entry period e.g. use of PHI for harvesting tasks, are considered acceptable. ▪ In case of re-entry tasks in grapes the use of a lower than 10100 cm^2/h TC value considering the use of gloves is considered acceptable. More specifically, as a Tier II the use of a refined TC of 4861 cm^2/h is accepted considering the distribution of residues - Baugher (2005) - and the assumptions presented in detail in BROWSE Worker Deliverable 2.4 (2014); https://secure.fera.defra.gov.uk/browse/software/documentation/model_documentation_wp2_final.pdf.
Bystander exposure		▪ The EFSA Guidance is considered, as stated in the General comment, in case an AAOEL has been set for the active substance(s). ▪ In case of applications before the 1st of January 2016 the Martin *et al.* (2008) model is used and the risk assessment is conducted considering the short term AOEL. The exposure assessment is performed considering the different options provided by the model regarding drift values if necessary. ▪ In the EFSA Calculator there is the possibility to consider the use of drift reduction nozzles to refine the exposure to drift. Moreover, there are different options for the use of “buffer strip”.

		Both measures for reducing the exposure levels of residents and/or bystanders are acceptable by EL. In addition, actual field data, if available, can be considered acceptable on a case by case basis ▪ In case of applications after the 31st of December 2015 the old models such as the German Guidance, i.e. Martin *et al.* (2008), are not considered acceptable for higher tier refinement.
Residents exposure		▪ In case of applications after the 31st of December 2015 the old models such as the German Guidance, i.e. Martin *et al.* (2008), are not considered acceptable for higher tier refinement. ▪ In the EFSA Calculator there is the possibility to consider the use of drift reduction nozzles to refine the exposure to drift. Moreover, there are different options for the use of "buffer strip". Both measures for reducing the exposure levels of residents and/or bystanders are acceptable by EL. In addition, actual field data, if available, can be considered acceptable on a case by case basis.
Residues		
Fate		
Surface water	Risk mitigation measures proposed: ▪ Buffer zones from surface waters: As buffer zone is defined the distance between the limit of the cultivated field/ orchard and the	▪ For the risk mitigation measures proposed the Coordinating Competent Authority follows the FOCUS Landscape and mitigation factors in aquatic ecological risk assessment, SANCO/10422/2005, version 2.0, September 2007 for runoff and drainage as it is in force by the date of submission of the application. ▪ In particular it should be pointed out that risk mitigation measures that are proposed by applicants should be practically enforceable and are not related to economic parameters while in those cases that a combination of measures is proposed e.g. buffer zone plus drift reduction nozzles such measures should not lead to an overall reduction that exceeds 95% ▪ FOCUS modeling (step 4) is accepted and the FOCUS Landscape and mitigation factors

	surface waters. ▪ For approval of the formulation, the maximum buffer zone proposed is 50 m for orchards, vines and leafy crops and 20 m field crops, taking into account ▪ At fields with >2% incline the use of Vegetative Buffer Strips up to 20 mis acceptable (The VBS can consist of spontaneous vegetation or planted vegetation or a combination of both ▪ that application (spraying) is performed using: 1) conventional nozzles, 2) drift reduction nozzles, or 3) combined 1 and 2.	in aquatic ecological risk assessment, SANCO/10422/2005, version 2.0, September 2007 for runoff and drainage.

Ground water		
Ecotoxicology		
Birds and mammals		
Aquatic organisms	As presented in Fate Section above	
Non target organisms	**NTA:** Use of not sprayed buffer zones: 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 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	Use of no sprayed buffer zones: 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	
Bees		
Soil organisms		

Efficacy		
Biological efficacy		
Phytotoxicity		For herbicides in case of crop failure: “In case of crop failure only crop A or crop B can be sown/planted provided that deep ploughing is preceded” ii) For herbicides in case of succeeding crops: “ Do not sow/plant crop A or crop B for C months after the application of PPP” or “Do not sow or plant crops other than the proposed ones in the same field, for x months after application of PPP”. “Crop A and crop B can be sown/planted in autumn (y months after the application) while crop D and crop E can be sown/planted in spring (z months after the application) in the same field, provided deep ploughing is preceded”.
Resistance		For herbicides “Adopt alternative weed control practices (mechanical, cultural etc.) when possible, and herbicide alternation with herbicides of a different mode of action to avoid resistance development.”

Italy	Mitigation options	Comments
General		
Toxicology		
Operator exposure	Generally, the acceptable risk mitigation options included in the EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874) are considered. On a case by case basis the choice of specific PPE, as protective wearing ore use of facial mask with specific filter is indicated, as well as the need of cabin mounted tractors or closed distribution machinery is indicated. In addition, special training for manipulation of toxic gases may be required for particular fumigations.	
Worker exposure	Re-entry intervals for maintenance workers and/or PHI for harvesters are generally applied. In certain cases in addition the indication of applying signposts at the border of treated area is prescribed. On a case by case basis dressing of protective wearing may be indicated.	
Bystander exposure	In certain cases in addition the indication of applying signposts at the border of treated area is prescribed.	
Residents	On a case by case basis a no treatment limit	

exposure	distance from neighbour may be indicated	
Residues		
Fate		
Surface water	Measures to reduce drift and run-off and to protect aquatic organisms. Drift reduction nozzles possible, generally recommended in combination to vegetative buffer strips.	http://www.salute.gov.it/imgs/C_17_pubblicazioni_2644_allegato.pdf Tables: http://www.salute.gov.it/imgs/C_17_pubblicazioni_2644_ulterioriallegati_ulterioreallegato_0_alleg.pdf
Ground water		
Ecotoxicology		Drift reduction nozzles (if yes please specify 50%, ….?)
Birds and mammals		
Aquatic organisms	See point of surface waters.	
Non target organisms		
Non target plants		
Bees		
Soil organisms		
Efficacy	General: measures as recommended by EPPO to avoid resistance and phytotoxicity are applied.	
Biological efficacy		
Phytotoxicity		
Resistance		

Malta

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

Portugal	Mitigation options	Comments
General		
Toxicology		
Operator exposure	Complete PPE during mixing & loading and application; use restricted to professionals; (EFSA Model)	
Worker exposure	PPE (like gloves) Re-entry intervals (EFSA Model)	
Bystander exposure	Drift reducing nozzles (maximum 50%) Buffer zone No go zones (EFSA Model)	
Residents exposure	Drift reducing nozzles (maximum 50%) Buffer zone No go zones (EFSA Model)	
Residues	Revised GAP supported by available data	
Fate		
Surface water	Drift reducing nozzles up to 75% reduction; vegetated buffer zones as foreseen under Regulations 546/2011, 547/2011 and appropriate guidance documents.;	
Ground water	Restriction to non vulnerable soils; limitation of use on permeable	

Portugal	Mitigation options	Comments
	sufaces/soils, on soils with low organic matter content, among other appropriate measures as foreseen under Regulations 546/2011, 547/2011 and appropriate guidance documents....	
Ecotoxicology		
Birds and mammals	No mitigation	
Aquatic organisms	Risk mitigation for surface water contamination as appropriate and foreseen under Regulations 546/2011, 547/2011 and appropriate guidance documents.	
Non target organisms	Risk mitigation for surface water contamination as appropriate and foreseen under Regulations 546/2011, 547/2011 and appropriate guidance documents.	
Non target plants	Drift reducing nozzles; buffer zones and foreseen under Regulations 546/2011, 547/2011 and appropriate guidance documents.	
Bees	Measures foreseen under Regulations 546/2011, 547/2011 and appropriate guidance documents.	
Soil organisms	Revised GAP supported by available data	
Efficacy		
Biological efficacy		
Phytotoxicity		
Resistance		

Spain	Mitigation options	Comments
General		
Toxicology		
Operator exposure	- Personal Protective Equipment, with the penetration factors reported in Table 7 of EFSA Guidance, 2014. Please, note that in this table “workwear” has a penetration factor of 10 %, equivalent to chemical protective coverall type 6. - Tractors with closed cab (included in AOEM/ EFSA model).	
Worker exposure	- Establish Restricted Interval Entry (REI). http://www.insht.es/SectorAgrario/Contenidos/Promocionales/Plaguicidas/Promocional%20a%20Contenido/DocumentacionDivulgacion/ficheros/CalculoExposicionaaaTrabajadorEnRe-entrada-INSHT-v1.xls - Reduce dose and/or number of applications. - Increase the time interval between applications. - Personal Protective Equipment (gloves), only in case that gloves are	

Spain	Mitigation options	Comments
	worn habitually by workers (for example because it was necessitated by other aspects of task being undertaken), according with Regulation (EU) nº 284/2013. The corresponding Transfer Coefficient (TC) value (Table 13 of EFSA Guidance, 2014) will be taken to perform the calculations.	
Bystander exposure	- Drift reduction nozzles (50 %, according EFSA model) - Buffer zones (maximum 10 meters, according EFSA model)	
Residents exposure	- Drift reduction nozzles (50 %, according EFSA model) - Buffer zones (maximum 10 meters, according EFSA model)	
Residues	GAP must compile with EU MRL PHI can be used as mitigation measure Restriction to sown specific crops as succeeding crop Waiting periods for sowing the succeeding crop	
Fate	547/2011; label phrases; specific item: inspection of sprayers;	

Spain	Mitigation options	Comments	
Surface water	Generic buffer zone of 5 m under SUD; Under 1107/2009, buffer zones (up to 50 m) and drift reducing nozzles **Runoff:** vegetated buffer zone of 10 or 20 m according to FOCUS L&M; 547/2011 Treated Seed: Use of deflectors during sowing		▪
Ground water	No use in sandy soils ; limit number of application and/or dose rates; not apply in periods of heavy rains under PPP-law ; Under SUD and national order: 50 m buffer zone to areas for drinking water abstraction (SW and GW);		
Ecotoxicology			
Birds and mammals	SPe5 and 6; for treated seeds and granules; SPe 7; Reduction of dose rate and/or number of appl . Not application during breed season Avoid spillage Incorporation in soil		
Aquatic organisms	Please refer to surface water section		

Spain	Mitigation options	Comments
Non target organisms	Limit of dose, number of applications; unsprayed buffer zone, drift reducing nozzle; non-treated areas in fields to promote recovery; Treated Seed: Use of deflectors during sowing	
Non target plants	Limit of dose, number of applications; unsprayed buffer zone, drift reducing nozzles; non-treated areas in fields to promote recovery (voluntary) Treated Seed: Use of deflectors during sowing	
Bees	Limit of dose, number of applications; No use during flowering or while bees are actively foraging; remove flowering weed; Treated Seed: Use of deflectors during sowing	
Soil organisms	Limit of dose, number of applications; non-treated areas in fields to promote recovery; Treated Seed: Use of deflectors during sowing	
Efficacy		
Biological efficacy	Minimum effective dose must be demonstrated	
Phytotoxicity	Restriction of use Buffer zones for surrounding crops	

Spain	Mitigation options	Comments
	Restriction to sown or plant specific crops in case of crop failure Restriction to sown crop as succeeding crop Waiting periods for sowing the succeeding crop	
Resistance	Alternate products a proposal of resistance management should be provided by the applicant	

Appendix VI: BASIS FOR REFINEMENTS IN SOUTHERN ZONE FOR THE RISK ASSESSMENT ON BIRDS AND MAMMALS OF THE USE OF PPP

Zonal assessment of applications for authorizations of PPP according Regulation 1107/2009 started in June 2011, however the experience of zonal assessment in EU southern zone started in 2004 when the southern member states started the pilot projects for the voluntary worksharing of assessment of PPP. From the experience gained on PPPs, the risk assessment on birds and mammals usually requires higher tier assessments, which leads to a considerable high workload and expertise of the stakeholders.

During 2012 experts from FR, EL, ES and PT discussed the possibility of harmonization of zonal risk assessments on birds and mammals and the outputs of the discussions were presented during Berlin SETAC meeting. This document collects these proposals and aims to establish the basis to agree the possible refinements that we can apply for the risk assessment on birds and mammals.

The outputs were circulated among the experts of SMS to progress in the harmonization of risk assessment and risk management and lines of future work among SMS in order to reach a harmonized approach for zonal evaluations were identified. The conclusion of the discussions are listed below

General management proposals

EFSA, 2009 [European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA. EFSA Journal 2009; 7(12):1438. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu] is accepted for the zonal core dossier:

- For multiple applications, MAF values (insects, seeds, plants) may be estimated on case by case basis (e.g. for long intervals this is not relevant);

- The vole scenario is accepted for SPAIN and PORTUGAL. The selection of vole as focal species depends on the intended use. Further consideration at a management level. For HELLAS and FRANCE the priority is to address the concern for the lagomorphs and mice for the relevant BBCH scales;

- For refinement of residues on Dicotyledonous plants, residues trials may be relevant if well justified by the notifier;

- As for monocotyledonous plants, it is difficult to accept refinement of initial RUD values since the EFSA's database is large enough. In every case, new studies are accepted to refine twa/MAF values for long term risk assessment ;

- To refine residue values (plants, arthropods) at least two studies should be reported (at least one should be conducted under Southern conditions for HELLAS and PORTUGAL, and two for SPAIN). For FRANCE, residue trials conducted in central zone are also accepted.

- Extrapolation according the GD "Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs" (SANCO 7525/VI/95 - rev.9, March 2011) from the residue section might be accepted only for plants;

- Dehusking as a refinement option cannot be used in a quantitative risk assessment without further evidence Body burden modelling accepted at national level (by HELLAS, PORTUGAL and FRANCEExpert judgment needed for SPAIN).

Proposals for refinement of acute risk

- Geometric mean of LD50 values from different species is accepted as proposed in EFSA, 2009;
- Values based on the 90th percentiles of RUD, PT and PD are relevant for the risk assessment (only for highly validated studies); **FRANCE does not accept refinement of PT for the acute risk assessment**.
- For highly acute toxic active substances/PPPs, it is difficult to accept refining PT and PD values or a mixed diet (omnivorous scenario) without further argumentation. In the latter case the worst ETE from one diet should be calculated;
- Residues on dead insects should be taken into consideration only for acute toxicity.

Proposals for refinement of long term risk assessment

- Mean values of RUD, PT and PD are relevant for the risk assessment (only for highly validated studies); In France, the mean PT value can be used for LT risk assessment refinement when more than 20 consumer individuals are followed in field trials.
- PT values ≥ 0.8 can be accepted as default value without further evidence; FRANCE does not accept and ask for robust data
- The ecotoxicological relevant value (usually not the worst ecotoxicological value reported in the LoEP) from the toxicological studies can be proposed as a refinement option (for HELLAS and PORTUGAL). In such cases a scientifically based argumentation is required.

Aspects to be considered in the vole scenario

- Natural cyclic population changes with high reproduction capacity and population recovery;
- Primary off-crop habitat. Crop colonization mainly at peak population years: some species can become serious pests in certain crops, (e.g Microtus arvalis in sugarbeet in Spain and Microtus *duodecimcostatus* in citrus) triggering vole control measures;
- Exposure to PPPs occurred only at peak levels.;
- Other factors are influencing in crop populations: irrigation vs dry regime, regular plowing and mowing / weed control, presence of livestock, vole pest control operations Scenario covered by other small mammals taxonomically related.

Identification of needs

- Relevant scenarios for the risk assessment for different Mediterranean crops should be defined: Crop specific “focal species” at given BBCH code as proposed by EFSA GD are not always relevant for risk assessment. Instead, a regional category approach for selection of FS seems to be more appropriate ;

- An excel sheet with proposed southern focal species for standard risk assessment in different crops;

- Development of a more specific RUD database for the South Zone;

Appendix VII: CoCh REPORT

According to *Article 43* of REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC:

Renewal of authorization

Plant Protection Product:

Trade names in MS

Formulation/Developmet code

Registration Holder:
Content of Active substance/es

Type of formulation

ZRMS:
cMS:
Date of submission:

Information	Y/N	Information, summary or justification provided
(a) a copy of the authorisation of the plant protection product;		
(b) any new information required as a result of amendments in data requirements or criteria;		
(c) evidence that the new data submitted are the result of data requirements or criteria which were not in force when the authorisation of the plant protection product was granted or necessary to amend the conditions of approval;		
(d) any information required to demonstrate that the plant protection product meets the requirements set out in the Regulation on the renewal of the approval of the active substance, safener or synergist contained therein;		
(e) a report on the monitoring information, where the authorisation was subject to monitoring.(monitoring information regarding the a.s. approval and national monitoring programs for information)		

Additionally, the following information must be submitted to facilitate the evaluation process:

Information	Y/N	Information, summary or justification provided
A GAP list in english with the already authorized uses in the zone		

Information	Y/N	Information, summary or justification provided
For each GAP, concerned MS must be reported		
A notifier declaration that there is no modification of the GAP requested or justification of the modification (new endpoints, outcome of risk assessment, risk envelop approach)		
Declaration signed by the manufacturer that there has not been any modification with regard to the composition of the authorized product under uniform principles, or justification of the need to make a minor change due to the renewal of the approval of the active		
Updated DRR (Part A; B and C) indicating where there is new information not previously reviewed in the zone		
Justification for each data point for which not all information can be submitted		
List of cat 4 studies and submission date and justification for each of them with a proof that the studies have been initiated or commissioned.		
A signed statement confirming that the authorized plant protection products and uses are in compliance with the conditions and restrictions of the renewal of the approval.		
A statement confirming accessing to Annex II data		

Conclusion of the ZRMS: *[CLICK IN THE GREY BOXES AS APPROPRIATE AND SELECT THE APPROPRIATE TEXT]*

☐ **Complete**

☐ **Not Complete**

The zRMS _____, appointed to coordinate the renewal of authorization of the plant protection product _____, whose authorization holder is _____, on behalf of the SOUTHERN ZONE confirms that the authorization holder applied to renew the authorization of the plant protection product above mentioned within three months after the date of application of the decision on the renewal of the active substance _____.

The zRMS _____, informs that the applicant **has NOT submitted** a justification for which not all information has been submitted at the three months deadline

☐ **Postponed**

The zRMS _____, appointed to coordinate the renewal of authorization of the plant protection product _____, whose authorization holder is _____, on behalf of the SOUTHERN ZONE confirms that the authorization holder applied to renew the authorization of the plant protection product above mentioned within three months after the date of application of the decision on the renewal of the active substance _____.

The zRMS _____, informs that the applicant has submitted a justification for which not all information has been submitted at the three months deadline

[*SELECT AS APPROPRIATE*]

- *due to new endpoints decided at the time of the renewal of approval of the active substance **(cat 4 studies)***
- *due to new guidance document published before the time of the renewal of approval of the active substance **(cat 4 studies)***
- *due to the presence of a second active substance, _____, for which is expected to expire within twelve months of the renewal of approval of _____*

The zRMS _____, has checked the appropriateness of this justification and has considered **ACCEPTABLE** the postponement of the submission of the following studies in the indicated date:

Annex Point	**Study title (if available) or study type**	**Study duration**	**Completion date/report number (if available)**	**Justification accepted by the ZRMS (including if study is a cat4 study)**

In accordance with the assessment of the provisions in the planning of the applicant, the submission of the documentation is expected by *MONTH YEAR in ZRMS*.
This is reported to concerned Member states, to make a decision on the extension of expiry dates of the authorizations of plant protection products which can be affected by this evaluation.

Date and signature

Appendix VIII: GENERAL CONSENSUS ON EFFICACY SECTION IN THE SMS

Data requirements & Evaluation criteria

Distribution & number of trials:

The dRR should facilitate evaluation according to the EPPO climatic Zones for all cMSs.

i.e.

- **Mediterranean Zone** for **EL, ES, IT, PT, CY, MT**
- **Mediterranean Zone + Maritime Zone** for **FR** (including "Central zone" maritime, if no sufficient data covering northern FR)
- **South East Zone** for **BG**
- **South East Zone + Mediterranean Zone** for **HR**

During the evaluation, ZRMS shall identify lack of efficacy trails in the different climatic EPPO Zones, giving the opportunity to applicant to submit additional trials or stop the clock.Data gaps identified by zRMS regarding the distribution and number of efficacy trials per EPPO zone should be communicated to the applicant as soon as possible and they should be addressed by the applicant before the commenting phase.'.

zRMS should try to conclude in the dRR but take into account the cMS opinion for the final conclusion (fRR) and for all the uses claimed in the GAP table. In case there are disagreements by the cMS in the decision for a use, the zRMS conclusion in the RR decision table should be: 'the decision can be made at MS level' when at least one MS has an opposite opinion. The decision 'Rejected' will be selected by the zRMS when all MS agree on the rejection of the use.

Good Agricultural Practices:

Number of applications, BBCH and water volume proposed in the GAP table should reflect as much as possible the parameters tested in the efficacy tests. A detailed explanation should be given by the applicant when the number of applications, BBCH and water volume tested in efficacy trials differs to the intended GAP

Resistance Management:

Restrictions on the number of applications related to the resistance risk can be applied.

Quality of the submitted Efficacy data: BAD, dRR and trials

Trial reports:

The applicant should provide all the reports for all uses (crop x pest) mentioned in the Efficacy Section. The design, statistical analysis, conduct and reporting of trials shall be in accordance with the specific standards of the European and Mediterranean Plant Protection Organisation (EPPO), where available. Deviations from available EPPO guidelines, may be acceptable if the trials design meets the minimum requirements of the relevant EPPO standard, and is fully described and justified. In the absence of specific EPPO standards, related EPPO standards / National Experimental methods / published methodology could be used along with a justification.

Each report shall include a detailed and critical assessment of the data. Statistical analysis of the results in the trial reports is necessary and required by GEP.

Summary Tables & statistical analysis are considered essential in the BAD and dRR:

In case the provided summary tables are considered as not fully satisfying, the zRMS can ask the Applicant to amend summary tables according to the recommendations in the data gap tables

In the dRR, even if not mandatory, statistical analysis of efficacy results is fundamental for the evaluation, particularly for the assessment of the minimum effective dose (number of trials in which the selected dose was statistically '>, < or =' compared to other tested doses). Efficacy data should be presented independently for each EPPO zone based on the statistical analysis per trial, and in case of an analysis for a trial group preferably independently for each EPPO zone.

Selection of assessment date & parameters:

The most appropriate/representative assessment should be justified by the applicant (e.g. regarding the biochemical mode of action of the active substance(s) contained in the plant protection product, residual activity etc).

In the case of herbicides, at least a threshold of 5 plants/m^2 or 5% ground cover is acceptable for the validity of the trials. In a number of trials, the weed density should exceed 10 plants/m^2 (10% ground cover).

For all other types of products, the minimum acceptable level of infestation/infection used for validation of a trial or an assessment date should be specified and justified, scientifically based on available data and/or open or common expert knowledge.

Dose expressions:
In principle, it should be avoided to mix different dose expressions for each use. For example, during product development, when the first trials were carried out at a dose per hectare, it is preferable to keep this dose expression

till the end (but measuring and reporting all parameters allowing dose conversion).

For new products, developed with dose expression as LWA (e.g. pome fruits, grape, high growing vegetables), the same principle applies: keep this dose expression for all the trials. In the EPPO Workshop on harmonized dose expression for the zonal evaluation of plant protection products in high growing crops (Vienna, 2016-10-18/20) it was agreed that:

- ✓ Leaf Wall Area (LWA) is applicable for crops that form "walls" (trellis/hedge) (high growing vegetables; pome fruits, almonds; grapevine; fruit trees in trellis cropping system).
- ✓ LWA is not applicable for globular trees (i.e. trees that that not form "walls" such as citrus, traditional olive).
- ✓ Conversion of different dose expression: concentration (/hl; %) + spray volume] <-> /ha ground <-> /m canopy height <-> / ha leaf wall area LWA <-> 10000 m^3 tree row volume TRV must be submitted
- ✓ For globular trees (e.g. citrus) further data should be collected.

Although it is not a requirement, SMS recognize that in order to validate the minimum effective dose it is useful to include data on deposit of active substance per foliar area (ng a. s./cm^2) in the report of efficacy trials. If this type of data are included it is proposed to follow the standard ISO/FDIS 22522.

All parameters allowing dose conversion should be measured and reported in the BAD (including spray volume, equipment used…).

In case of 2 different dose expressions, evaluation should be done separately for each data set of the same dose expression and then the effective dose for each data set can be converted to the intended dose expression. Different dose expressions should not be mixed in summary tables.

Renewal (art. 43) – Evaluation of efficacy section

In the cases that there is no change in the GAP, compared with the already registered uses under Uniform Principles, no efficacy evaluation will be conducted by the zRMS, hence a complete efficacy data package is not required, only an update on the assessment of the risk of appearance of resistances is considered necessary.

New efficacy trials are not necessary in the following cases:

- The dose is changed within the authorised range in the zone (additional data could be required case by case)
- Reduction of number of applications in the zone
- Change of application time within the period of application already authorized in the zone

In the three cases mentioned above, applicants shall provide a dRR (the available *voluntary worksharing* FRR, from the evaluation according to Uniform Principles) with a complete efficacy section highlighting only the new information (i.e. resistance update or data supporting the GAP change).

In case of an existing RR from authorities (in English), it is advised to submit an update of this existing RR.

Where a GAP change is necessary (due to change of endpoint in active substance renewal, typically dose reduction linked to risk assessment), efficacy data addressing the revised GAP should be assessed (reduced dataset with dose comparison, only on major/representative uses could be submitted) and update of the resistance status.