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Guidance document on zonal evaluation and mutual recognition, withdrawal and amendment of authorisations under Regulation (EC) No 1107/2009

COMMISSION STAFF WORKING DOCUMENT – DOES NOT NECESSARILY

REPRESENT THE VIEW OF THE COMMISION SERVICES

This guidance has been developed in co-operation with the Member States. It does not intend to produce legally binding effects and by its nature does not prejudice any measure taken by a Member State within the implementation prerogatives under Regulation (EC) No 1107/2009, nor any case law developed with regard to this provision. This document also does not preclude the possibility that the European Court of Justice may give one or another provision direct effect in Member States.

This document and Appendix provides Member States (MS) and applicants with guidance on the procedures and policies surrounding various elements of applications for plant protection product (PPP) authorisations. It considers the practical application of the legal provisions laid down in Chapters III, V and XI of Regulation (EC) No 1107/2009. Throughout the document references to Articles refer to Regulation (EC) No 1107/2009 (the Regulation) unless otherwise stated.

This Guidance document does not produce any legally binding effects. It is without prejudice to interpretation of Union law by the Court of Justice of the European Union.

Since the adoption of the first Guidance document[1] in 2010, Member States have gained experience and the document should be updated. This document has been finalised in the Standing Committee on Plants, Animals, Food and Feed on 25/01/2021. It will apply to applications submitted from 1st of March 2021 onwards.

Revision history

The following parts have been revised compared to the first version of the document dating from 2010.

When	What
February 2013	Applications for zonal and inter-zonal uses Notification form included as an appendix Mutual recognition of amended Good Agricultural Practices (GAP) Acceptance of comparability assessments Not commenting on all applications Zonal independent areas of the risk assessment Updated info on steering committees Clarification where refused by zonal Rapporteur Member State New schematic including Maximum Residue Level (MRL) notification
July 2013	Appendix 5 regarding types of applications and commenting requirements has been included.
July 2014	Clarification regarding Article 37.3 has been added in chapter 2.2.6.1.
January 2021	References to Articles 34, 43, 44, 45 and 46 References to SANCO guidance 6895/2009. Format of a draft Registration Report – version 2015 Point 2.2.4 Exemption from the submission of studies Point 5. Withdrawal and amendment of authorisations according to Article 44 Point 6. Withdrawal and amendment of authorisations according to Article 45 Point 7. Grace period according to Article 46 Point 8. Procedures for low-risk PPPs (Article 47) Point 9. Harmonisation Point 10. Transitional measures Appendix 4 of rev 9 Form to notify intended zonal applications under Regulation (EC) No 1107/2009 has been removed as independent document Appendixes have been renumbered

[1] Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009

	Appendix : Types of application and commenting requirements, - has been updated Appendix 2: The Inter-zonal Steering Committee, - has been updated Appendix 3: The zonal Steering Committees, - has been updated Appendix 4: Recommendations for applications for extension of uses - new Appendix Appendix 5: Mixed applications (indoor /outdoor)- new appendix Appendix 8: Timelines evaluation and amendment of authorisation according Article 44 when an endpoint of the active substance (a.s.) is amended – new appendix Appendix 9: Timelines evaluation and amendment of authorisation according Article 44 when an endpoint of the active substance is amended new appendix Appendix 10: Template to request for certain information to be kept confidential (Article 63.2 of Regulation (EC) 1107/2009 amended by Regulation (EU) No 2019/1381) – new appendix Added chapter on low-risk products Added specific points on authorisations granted in the interest of the general public

Contents

1. Background

1.1 General considerations

1. This guidance document has been developed to elaborate the procedures laid down in Regulation (EC) No 1107/2009 for zonal evaluation (Articles 33 – 39) and mutual recognition (Articles 40 – 42). The procedure to be followed when an application for withdrawal or amendment of an authorisation is submitted is described in Articles 44 to 46 of the Regulation. The procedure to be followed when an application for authorisation of low-risk plant protection product (Article 47). The procedure for the renewal of authorisations is laid down in the Guidance Document[2] on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009. The Regulation (EC) No 1107/2009 provides for a more efficient system of mutual recognition, which is built on the assumption that any assessment which was already done by one Member State (MS) shall not be repeated by another MS when recognising an authorisation, except for clearly defined circumstances.

2. The Regulation (EC) No 1107/2009 provides for a general system of zonal evaluation. Mutual recognition is an important part of this. Under Regulation (EC) No 1107/2009 an authorisation in one MS can be used for mutual recognition in another MS. Therefore it seems appropriate to set out procedures for the zonal evaluation in more detail. In principle, all applications for new authorisations should be dealt with via the full zonal procedure and thus be subject to commenting from other MS in the zone. In Appendix 1 - Types of applications and commenting requirements, the types of applications are listed and it is indicated if commenting is required or not.

3. It applies for applications which are made, or due to be made, after the date of application of the Regulation (EC) No 1107/2009 (14 June 2011). Transitional measures are also covered in the document.

2. Zonal authorisations

2.1 Legal basis

4. The procedure to be followed when an application for a new authorisation is submitted is provided in Articles 33-39 of the Regulation (EC) No 1107/2009. Please refer to the Guidance document[2] on the Renewal of Authorisations to understand the differences in the process for "new" products and "renewal". The special case of low-risk PPPs (Article 47) is specifically covered in chapter 8. Articles 44-46 includes provisions for the withdrawal of authorization and grace period

5. An applicant shall apply to each MS where the plant protection product is intended to be placed on the market. It is clear from the wording of Article 33.2 (a) that applications for authorisation shall include all the intended uses in each zone and the MS to which they intend to apply.

6. When an application is submitted applicants should also make a proposal as to which MS they expect to evaluate the application (the zonal RMS – "zRMS") in each concerned zone (Article 33

[2] Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009 (SANTE/2010/13170 rev. 13 or later, https://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_en)

(2) paragraph (b)). In principle, the MS that was originally proposed by the applicant will act as zRMS unless another MS in the same zone agrees to examine it. The other MS in the same zone to which an application has been submitted shall, at the request of the zRMS, cooperate to ensure a fair division of the workload (Article 35).

7. In case of applications for uses described below, only one MS (Interzonal RMS – "iRMS") shall evaluate the application considering all zones (Article 33.2 paragraph (b)). The same principle applies to MRLs, which according to Regulation (EC) No 396/2005[3], are linked to the active substance and the critical GAP of each crop in all zones.

   - Greenhouses as defined in Article 3.27;
   - post-harvest treatment as defined in Article 3.28;
   - treatment of empty storage rooms with a view to preserving and/or protecting plants and plant products as laid down in Article 2.1;
   - seed treatment.

8. Article 34 provides the details for the **exemption from the submission of studies** that are referred to in Article 33.3, under the circumstances that an access to data has been granted by a Letter of Access or that the data protection period has expired, and that the MS have the studies referred to. However some information shall be provided by applicants, this information is included in Article 34.2.

9. Once the zRMS has been appointed the other MS ("concerned MS") in the zone **shall refrain from proceeding with the assessment of their applications, waiting for the assessment from the zRMS** (Article 35 third subparagraph), in order to avoid duplication of work.

10. In those cases that an application for authorisation of a PPP is submitted at the same time in more than one zone, the **zRMS** in the different zones shall come to an agreement as to which MS will evaluate the data which are not related to the environmental and agricultural conditions (the core dossier) (Article 35 subparagraph 4).

11. During the assessment of an application the zRMS/izRMS shall give all MS in the concerned zone(s) the opportunity to submit comments for consideration in the assessment. (Article 36.1).

12. The zRMS shall **decide within twelve months of receiving the application** whether the requirements for authorisation are met making use of the Uniform Principles. When additional data are requested, **this period is prolonged for a maximum of six months** (Article 37.1).

13. In line with Article 37.2, in case of applications for authorisation of PPPs containing **sources of active substance other than those assessed for approval the active substance**, the deadlines for taking a decision are suspended while applying the procedure of Article 38 (assessment of equivalence) for not more than 60 days.

14. In those cases where an application is received for the representative product containing an active substance that has not yet been approved, the zRMS in each zone should start its

[3] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC

assessment as soon as it has received the DAR from the RMS for the active substance. In this case and if the application refers to the **same formulation and the same uses (representative formulation and representative uses for approval of the active substance), the zRMS should decide on the authorisation at the latest within six months of the active substance being approved** (Article 37.3). If the formulations or uses are different, however, the twelve month timeline would apply from the date of application (DOA) of the approval of the active substance. zRMS should consider that the endpoints proposed by the RMS of the active substance sometimes are not confirmed during the European Food Safety Authority (EFSA) peer review and could be changed, that is the reason why the final EFSA opinion of the active substance peer review shall be taken into account.

15. The zRMS, once it has concluded its assessment of the application, shall **make available its assessment**, through CIRCABC, to the other MS of the zone.

16. The concerned Member State (cMS) of the zone shall grant or refuse an authorisation on the basis of the conclusions of the assessment of the zRMS within 120 days of receipt of the assessment report and the copy of the authorisation (Articles 36.2 and 37.4). By way of derogation, appropriate conditions and other risk mitigation measures may be imposed deriving from specific conditions of use.

    In case of refusal of an authorisation because of unacceptable risk to human or animal health or the environment the cMS who refused the authorisation is obliged to inform immediately the applicant and the Commission providing a technical or scientific justification (Article 36.3 and 37.4).

17. For the special case of **low-risk products –** once identified **–** the procedure remains the same as for the conventional products but the timeframe is reduced (120 days + max 6 months if additional data are requested). (See Chapter 8).

18. In principle, the same procedure (1 year evaluation plus possibly extended by up to 6 months) shall be followed for applications for amendment of an existing authorisation e.g. extension of use, change of conditions of use, change of composition, although where no technical risk assessment is involved, shorter timelines may apply (see Guidance Documents on significant and non-significant changes[4]).

2.2 Detailed procedures

2.2.1 Steering Committees

19. Communication within zones and between zones is critical to effective operation of the zonal system and is facilitated by the establishment of the following structure:

    - One inter-zonal steering committee, which should operate according to the provisions laid down in Appendix 2 - The Inter-zonal Steering Committee.

[4] Guidance Document on significant and non-significant changes of the chemical composition of authorised plant protection products under Regulation (EC) No 1107/2009 – SANCO 12638/2011, https://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_en

- Three zonal steering committees, one per zone, which should operate according to the provisions laid down in Appendix 3 - The zonal Steering Committees.

20. Within each MS there are at least two zonal contact points identified, which are recorded in the contact point table.

2.2.2 Applications and Plant Protection Products Application Management System (PPPAMS)

21. The Plant Protection Products Application Management System (PPPAMS) is currently under development in the Commission, together with experts from MS. Currently, only those applications for authorisation of PPP (Article 33) and mutual recognition (Articles 40-42) (in addition to applications for emergency authorisation submitted under Article 53) can be submitted via the PPP Application Management System[5] once the Application Management System is legally implemented to do so, however applicants are encouraged to already submit those application types via the system. Work remains ongoing to enable the submission of other application types. PPPAMS enables industry users to create applications for plant protection products and submit these to Member States for evaluation. Member States then manage these applications within the system, concluding with authorisation of the plant protection product or refusal of the application. The system is being designed to support Member States in fulfilling their legal obligations under Regulation (EC) No 1107/2009, notably Article 57.1 and 2, before industry submits an application (notification).

22. At least six months before the application is due to be made it is recommended that the applicant should submit to the zRMS/izRMS and cMS a summary of the products for which authorisation will be sought, detailing in which MSs the authorisation is envisaged. A common format[6] has been developed and should be used by applicants. This will help organise the allocation of work to MS and speed up the process.

23. Regulation (EC) No 1107/2009 states that the application must also include a proposal for the zRMS. However, for efficient operation of the system the zRMS should be appointed before the application arrives. Therefore, it is expected that a proposal for the zRMS is already included in the notification. Based on this proposal the zonal steering committee will make a recommendation of who will act as zRMS which will be fed back to the applicant, if the proposed zRMS declines to be zRMS.

24. During the notification the applicant should identify which studies could fall under the provisions to avoid duplicative testing and sharing of tests involving vertebrate animals (Article 62)[7]. The zRMS should make an indicative list of studies available to all applicants on request.

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[5] https://ec.europa.eu/food/plant/pesticides/authorisation_of_ppp/pppams_en

[6] Template to notify intended zonal applications under Article 33 of Regulation (EC) No 1107/2009 (SANCO/12544/2014) rev 2. Available on: https://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_en

[7] COMMISSION NOTICE Technical Guidelines on Data Protection according to Regulation (EC) No 1107/2009 (2019/C 229/01) OJ 229 1-22; 8.7.2019

25. To make the zonal system work efficiently (organise the allocation of work and speed up the process) the applicants should notify their intention to each MS where an authorisation is envisaged at the same time. Wherever possible applicants' preference for choice of zRMS should be taken into consideration. Final decision on the allocation of zRMS should be communicated to the applicant by the agreed zRMS, as soon as the decision is taken at the zonal steering committee. Allocation of zRMS needs to take into account a fair and proportional distribution of applications amongst the MS in the zone. In addition, the following should also be taken into account:

    - identity of the original RMS for the approval of the active substance (noting that it will not always be possible to allocate the work to the original RMS),
    - MS where authorisation is sought,
    - relevance/importance of the products in each MS,
    - impact of products containing more than one active substance (e.g. if a MS has evaluated a product containing one of the active substances and thereby gained knowledge it would be efficient if the same MS also evaluated the next product),
    - resource availability in each MS, and
    - if a MS has previously examined the application and rejected it due to the fact that the missing data could not be received within the time limits.

26. For application of authorization of a plant protection product to be used in greenhouses, as seed treatment, as post-harvest treatment, or for treatment of empty storage rooms , only one zRMS should be proposed for the whole EU.

27. For products with multiple uses where some uses would qualify for assessment treating the EU as a single zone the application may be split up by the applicant. In any case only one zRMS shall examine the greenhouses, seed treatment uses, post-harvest treatment and treatment of empty storage rooms. A separate draft registration report (dRR) must be submitted for these uses. The identification of the RMS for the inter-zonal evaluation could be facilitated by the inter-zonal steering committee (see paragraph 39 and Appendix 5).

28. MS should discuss possible problems in the proposed zonal application with the applicants to improve the quality of, and review the strategy for, the zonal application. To facilitate this, requests for pre-submission meetings, to be held around 6 months prior to submission, should be addressed to the envisaged zRMS. Pre-submission meetings are not mandatory, and MSs have not the obligation to do them but they are highly recommended for complex applications/groups of applications.

29. Applicants should consider the use of the risk envelope approach, where appropriate, in the core assessment to minimise the number of individual uses assessed and to maximise the value and relevance of the core assessment to all MS. Choice of uses should be optimised to best reflect uses across the zone and possible differences in risk mitigation. The risk envelope is a concept which exploits the idea that within a group of products and uses there will be certain uses which

represent the worst-case situation in each area of assessment/compartment. This can be different for the various areas of the assessment. The assessment of this worst-case product/use will cover all other situations where the GAP is less critical or the same. By establishing the risk envelope, it is possible to minimise the number of individual product/use assessments that need to be completed. The risk envelope concept is laid down in a separate guidance document[8] and it will be further developed as experience is gained.

30. Applicants are required, in the context of the work-sharing framework, to propose the uses and critical GAPs which establish the zonal risk envelope in each area of the assessment (whilst also highlighting all the uses authorised/required within the zone). Assessors should consider the proposal to establish the risk envelope as part of their assessment, considering the assessment available of the representative use submitted under the approval procedure. Note, however that the core assessment must cover all uses applied for in the whole zone, to allow the concerned MS within the zone to decide on their uses within the 120-day period. This approach should take minor uses into account.

31. It should be noted that it may be difficult to define a risk envelope for all areas of the assessment (e.g. for fate and ecotoxicology there are for the time being, still national assessment requirements which mean that it is not always possible to define a risk envelope relevant to the zone). In this case the MS requesting additional information should explain the additional request to the applicant and justify why they consider the risk envelope approach not applicable in this particular case.

2.2.3 Industry application

2.2.3.1 *Application*

32. The applicant should make their application to each MS where an authorisation is envisaged at the same time. ZRMS shall be indicated in the application and all other MS for which authorisation is foreseen sought be indicated as cMS. The application must include a list of all intended uses in each MS of the zone where the applicant has applied. Differences within the same use for different MS should be justified.

33. The application must also include the assigned zRMS/izRMS (see paragraphs 25-26).

34. In those cases that an application for authorisation of a PPP is submitted at the same time in more than one zone, the zRMS in the different zones could come to an agreement as to which MS will evaluate the data which are not related to the environmental and agricultural conditions (the core dossier, sections concerned are physico-chemical properties, analytical methods, confidential information, toxicology, all study evaluations) (Article 35 subparagraph 4). Industry should identify potential applications for authorisation of a PPP in more than one zone at the same time, to help Member States share the work related to the zonal independent areas of the assessment. Applicant should send to all the zRMS the relevant contact details for that application within the other zone(s).

[8] Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach" (SANCO/11244/2011 rev. 5, 14 March 2011 or later, available on https://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_en)

2.2.3.2 *Dossier to be submitted*

35. Basic requirements for an application are set out in Article 33.

a) a list of intended uses in each zone and the Member States where the applicant has made or intends to make an application;

b) a proposal of the zRMS/izRMS

c) where relevant, a copy of any authorisations already granted for that plant protection product in a Member State;

d) where relevant, a copy of any conclusion of the Member State assessing equivalence of the technical active substance/s included in the plant protection product

c) a complete and a summary dossier for each point of the data requirements of the plant protection product;

d) for each active substance, safener and synergist contained in the plant protection product, a complete and a summary dossier for each point of the data requirements of the active substance, safener and synergist;

e) for each test or study involving vertebrate animals, a justification of the steps taken to avoid animal testing and duplication of tests and studies on vertebrate animals;

f) the reasons why the test and study reports submitted are necessary for first authorisation or for amendments to the conditions of the authorisation;

g) where relevant a copy of the application for a maximum residue level as referred to in Article 7 of Regulation (EC) No 396/2005 or a justification for not supplying such information;

h) an assessment of all information submitted (dRR);

g) a draft label.

36. Also the following will be required:

- Covering letter;
- A draft core assessment and the national addenda (see paragraph 65) as provided in the technical guidance documents [9].
- Data underlying the core assessment and national addendum or alternatively a letter of access (if applicable) or reference to non-protected existing data;
- Full list of tests and studies, including all references (also studies already evaluated on EU-level), which should support the assessment of the plant protection product under consideration;
- Other administrative national requirements (application forms etc.) relevant to the receiving MS;
- Confidential information and claim confidentiality for certain information;
- Letter of access (if applicable).

37. The draft registration report format will be required for each product as set out in the relevant guidance[9]. It should be noted that the new dRR template should be used from January 2016, according to the technical guidance documents mentioned above[9].

38. In the case of extension of uses, only the new studies/new information provided by the applicant which are necessary for the applied extension shall be included in the dRR. Reference to the original dRR can be made for the uses which are covered by the risk envelope approach established by existing uses and if the existing assessment is still up to date. It is recommended to wait for the initial authorisation before submitting the dossier for the extension of use (See Appendix 4).

39. For products with multiple uses, some of which will be assessed treating the whole EU as one zone, separate draft registration reports will need to be prepared for the inter-zonal uses (to be submitted to a single zRMS) and the zonal outdoor uses. (See paragraph 26 and Appendix 5 for details).

40. In those cases where an application is received for the representative product containing an active substance that has not yet been approved, the dRR provided by the applicant should be submitted once the endpoints are fixed (i.e. after the peer review, when EFSA´s conclusion is made available). The endpoints proposed by the RMS may be changed by EFSA during the peer review, however they are not usually changed post-peer review.

41. Whilst the draft registration report should be prepared in English, the official application may be submitted in the national language, where required. Whenever information is not provided in English, a translation into English should be provided. Information on use and label should be provided in the national languages of the MS in which an authorisation is applied for.

42. It should be noted, that the quality of the dRR prepared by the applicant affects the efficiency of the MS and their ability to produce their assessment within the regulatory deadline. This means:

    - One dRR for one zone including all the uses of the zone (one BAD);
    - The dRR must be a 'standalone document' (a single reference to evaluations of other products is not allowed, the complete evaluation or a robust summary of the related product must be taken up in the dRR[9]);
      For dRR prepared by a generic company/3rd parties, they should include as much information as possible (use "official" documents like EFSA conclusion, DAR, public/available registration reports…);
    - Each active substance of the product to be addressed;

[9] Technical guidance documents on the presentation and evaluation of plant protection product dossiers in the format of a (draft) Registration Report (SANCO/6895/2009 rev 2.2, from 26 January 2018, https://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_en)
Please note the template provided above refer to products containing chemical active substances and that a specific Template dRR for micro-organisms has been developed in September 2012 and can be downloaded at https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_doss_temp-reg-rprt_micro-organisms.zip. The guidance provided in the technical guidance documents apply to all plant protection products regardless to the nature of the active substances they contain. All applications for product authorisations submitted after 1 July 2018 should use the revised dRR format.

- Reference to EFSA conclusion and Draft Assessment Report (DAR) or Renewal Assessment Report (RAR) including a short summary of the EFSA conclusion or the assessment and justification where appropriate[9];
- In principle only information relevant for the uses applied for in the zone of application should be included.

43. Where an applicant wishes to amend the authorisation of an already authorised product via Article 33 or Article 45 of Regulation (EC) No 1107/2009, they need to supply data and assessment only in those areas relevant to the new crop/new use or amended use/s. The applicant should refer to the previous assessment (if it is still up to date) and only provide documentation relevant to the new crop/new use or amended use/s. The Addendum to the dRR submitted should include in the cover page the text "extension of use/amending use" which can be selected in brackets below "Core Assessment/ National Addendum" to clearly separate it from the original.

2.2.4 Exemption from the submission of studies

44. Article 34.1 states that "applicants shall be exempted from supplying the test and study reports referred to in Article 33.3 where the Member State to which an application is made has the test and study reports concerned and the applicants demonstrate that they have been granted access in accordance with Article 59, 61 or 62 or that any data protection period has expired".

45. In order to facilitate the assessment of applications where reference is made to Article 34 of Regulation (EC) No 1107/2009 the following general provisions are always applicable:

    - Details must be provided to **allow for the identification of the reference product** (to which the applicant has a Letter of Access or to which the unprotected data belong) e.g. authorisation number and trade name in each concerned Member State in which they apply for authorisation.

    - In addition, the applicant should make a comparison of the effects caused by the reference product and of their own product. Article 34.2 (c) states that applicants shall provide on the request of the concerned Member State, the data needed to demonstrate that the plant protection product has comparable effects to the plant protection product for which they show access to the protected data. The interpretation of the provision is that **reference to more than one authorised plant protection product within the same application is not possible**.

    - In the submitted DRR, applicants should provide **a list of studies or data** which, for each data point for the active substance(s) and formulation, are available to support the application, or a correct reference to the registration report of the reference product. This list could include the studies that are covered by the Letter of Access (LoA), or data out of protection, as well as own studies to justify the data requirements. The list should also contain a justification as to why, the data are considered unprotected. This justification shall be supported by the list of test and study reports made available by MS (Article 60) for which the applicant of the reference product claimed data protection under Article 59.

- Uses applied for shall be the same or reduced than the reference product, extension of uses are not allowed in this type of applications. Once the product is registered applicant can apply for an extension of uses

46. **The comparison of the formulations of the two products will be conducted by the zRMS and cMS must not re-evaluate it**. Where it is concluded that the product is not comparable a submission of appropriate tests and study reports in accordance with Article 33.3 will be required.

47. The reference product must have been authorised according to the current endpoints after an evaluation according to Directive 91/414/EEC or Regulation (EC) No 1107/2009 and to the Uniform principles.

48. In order to reduce the processing time by the member states, a dRR needs to be provided by the applicant. In addition to paragraph 42, for data points that have been already addressed during the evaluation of the active substance and reference product and when the applicant can show access to the same data used for evaluation of the reference product, a suitable reference in the dRR will be sufficient. However, a number of data points -especially those related to the identification of the plant protection product[10] including the detailed composition (Part C of the DRR)- should always be addressed by providing the requested data and/or information. In principle, there is no need to update the risk assessment for those areas for which no technical evaluation is considered necessary.

49. If fewer studies than in the reference product evaluation are available for a specific data point, it needs to be demonstrated by the applicant that **the data set is still sufficient to show a safe use**. In this case, the applicant needs to show that the product can still be considered safe in the light of current scientific and technical knowledge and the guidance documents. Furthermore, the exemptions set forth in Article 34 do not allow an exemption from requirements set forth by Article 36.1 for the product. The evaluation of the reference product should be accessible for cMS.

2.2.5 Zonal RMS evaluation

2.2.5.1 *Completeness check*

50. A completeness check is not a direct legal requirement in Regulation (EC) No 1107/ 2009. However Regulation (EC) No 1107/2009 sets out in Article 33 and 34 the requirements for the application. If any of these elements are missing then the application should not be accepted which implies that a completeness check to establish the completeness of the application is carried out.

51. This completeness check must be conducted within the overall timeframe for evaluation and should therefore be confined to an administrative check to establish that the required elements of the application are present (see 2.2.3.2). The check shall be **conducted by the zRMS** and should be **finalised within 6 weeks** after the submission of the application.

[10] Guidance Document on significant and non-significant changes of the chemical composition of authorised plant protection products under Regulation (EC) No 1107/2009 – SANCO 12638/2011

52. At this stage MS should also check whether the decision on the assigned zRMS is still valid. This may trigger an exchange with the applicant.

2.2.5.2 *Timelines*

53. There is a total of one year to complete the evaluation from the date the application is submitted. This period may be extended by 6 months if additional information is requested. In addition the timelines can be suspended if the procedure in Article 38 (assessment of equivalence) is necessary (see paragraph 57). The maximum timeframe for the assessment of applications for which reference is made to Article 34 will be the same as for any other zonal applications made under Article 33 of Regulation (EC) No 1107/2009, however, the duration of the zRMS' evaluation should reflect the amount of data and technical assessments requiring evaluation therefore shorter timelines may apply.

54. To allow for the commenting phase envisaged in Article 36.1 (see section 2.2.5.5) the initial assessment should be completed within 8 months of the date of submission of the application.

55. During the assessment it is not uncommon to have issues to resolve with the applicant. This can be simple clarification or may involve the submission and assessment of new data. Whilst both are acceptable, the zRMS should specify a maximum period of six months for the clarification of these issues/submission of new data by the applicant. The duration of this period should be set considering the nature of the additional information requested. The initial 1-year assessment period as provided in Article 37 will be extended accordingly. In order to allow sufficient time to deal with new information in the evaluation. It is recommended that further requirements are identified no later than 6 months after the submission of the application. Several requests for information can be made, up to a maximum of six months. Further minor clarifications can be permitted without 'stopping the clock'.

56. If providing the missing information takes longer than six months the application shall continue with only those uses that can be supported without the additional information or applicant can consider the possibility to remove the application at this stage and a new application can be submitted with the additional information. Where a new application is submitted at later stage the MS should accept it with the missing data and refer to the removed application, in order to continue the evaluation work. The 1- year assessment period as provided in Article 37 re-starts in such cases although the duration of the zRMS' evaluation should reflect the amount of new data requiring evaluation.

57. In line with Article 37.2, in case of applications for authorisation of PPPs containing sources other than those assessed for approval, the deadlines for taking a decision are suspended while applying the procedure of Article 38 (assessment of equivalence) for not more than 60 days, unless the equivalence check has already been performed. (Refer to the Guidance Documents for chemical active substances[11] or micro-organisms[12]).

[11] Guidance Document on the assessment of the equivalence of technical materials of substances regulated under Regulation (EC) No 1107/2009 (SANCO/10597/2003 –rev. 10.1 from 13 July 2012 or later). https://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_en

58. In line with Article 37.3 an applicant should be able to apply for non-representative products/uses before the date of application of the approval regulation, but the 12 month timeline for taking a decision only applies from the date of entry into force of the regulation on the approval of the active substance.

59. For applications according to Article 37.3, it is possible to apply for a PPP containing a substance not yet approved before the assessment report or EFSA´s conclusion is made available. Application should be made at the time the DAR is submitted to EFSA. zRMS shall start the evaluation as soon as the assessment report is made available, however zRMS should consider that the endpoints proposed by the RMS of the active substance sometimes are not confirmed during the EFSA peer review and could be changed, that is the reason why the final EFSA opinion of the active substance peer review shall be taken into account. The zRMS has to conclude on the application within 6 months after the date of application of the regulation approving the active substance where the application refers only to the representative uses and representative formulation described in the assessment report. The concerned MSs have 120 days from the decision of the zRMS to conclude on their applications. The preliminary assessment performed by the zRMS has to be submitted for comments 4 months after the entry into force of the regulation at the latest. A shorter time for commenting may be appropriate since the representative uses and formulations were already considered during the peer-review.

60. A schematic representation is in Appendix 6.

2.2.5.3 *Contingency measures*

61. The expectation is that the zRMS will deliver their evaluation within the deadline specified. However if due to unforeseen circumstances the zRMS is unable to deliver their assessment they should alert the applicant, the cMS and the Zonal Steering Committee as soon as possible. The Zonal Steering Committee should consider whether re-allocation or assistance to zRMS is possible and appropriate. This may present some practical difficulties, including fees and charges, which would have to be resolved between MS. The zRMS should update the zonal database/application spreadsheet accordingly.

62. The Registration Report should be prepared in English. Where necessary, translation into the national language for Part A and national addenda (Part B) can be added. The national authorisations which complement the assessment can be drafted in national language.

2.2.5.4 *Assessment format*

63. The evaluation should be presented by the zRMS, according to the relevant guidance[9].

64. The assessment must be to uniform principles and should cover all the intended uses of a product in the zone with no additional uses. The assessment must use **the EU agreed endpoints for the active substance(s)**, as taken up in the in force EFSA conclusion and any conditions as laid down in the regulations of the approval or renewal of approval of the active substances involved, at the date the application was submitted. The risk assessment should **reflect guidance**

[12] Guidance Document for the assessment of the equivalence of technical grade active ingredients for identical microbial strains or isolates approved under Regulation (EC) No 1107/2009 (SANCO/12823/2012 – rev. 4 from 12 December 2014 or later)
https://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_en

applicable at the date that the application was received by the zRMS. Assessments must be supported by appropriate data, and reflect consideration of all active substances in the product. New endpoints proposed in a draft Renewal Assessment Report, or in EFSA Conclusions on the peer review of an on-going renewal assessment shall not be used for authorisation decisions taken before the renewal of the active substance(s). However if decision on renewal of the active substance is taken before finalization of the evaluation and as the new endpoints are applicable, the assessment of the plant protection product shall be based on the new endpoints.

65. In cases where a MS clearly identified specific national assessment requirements (differing from or extending the core assessment) which are necessary due to its specific environmental or agricultural circumstances, that MS shall generate its own national addendum to Part B of the draft Registration Report based on the core assessment. However, all parts of the assessment of the zRMS should be used by other MS in the zone as a basis for national regulatory decisions. It is not the responsibility of the zRMS to evaluate all the national addenda. In addition, the zRMS shall not assess the core dossier on the basis of its own specific agricultural circumstances, or own specific mitigation measures. It has to be done at the cMS level. However there may be opportunities for further work sharing between MS at this stage if some national specific requirements are shared.

66. The Part B core assessments (and national addenda where appropriate) are then used to determine risk mitigation measures and other restrictions or conditions which are due to specific conditions of use in that MS and should be reported in Part A of the Registration Report, that is the reference for the authorisation of the PPP in that MS.

2.2.5.5 *Commenting period*

67. The zRMS' draft Registration Report should be uploaded to the authorisation database[13], for the time being on CIRCABC, for comments by all other MS belonging to the same zone. Further details and guidance on uploading document and naming conventions can be found in the relevant guidance document [14].

68. **Part B and Part C of the registration report should be made available** for comments, and if possible **Part A**. Although if Part A is not available then the preliminary conclusions of the zRMS with regard to whether or not authorisations are likely to be granted, and under which risk mitigation measures, should be included in the aforementioned commenting notification table.

69. A standard format table has been developed to notify other MS that the assessment is available for commenting and the deadline for comments (Appendix 7), as well as a Template for the Reporting Table (Appendix 8).

70. It is recommended that all MS of the zone and more specifically concerned MS (cMS) indicate if they agree in the table provided in Appendix 8 with the evaluation made by the zRMS before the

[13] For the time being documents should be uploaded on CIRCABC as the PPPAMS is still under development.
[14] Guideline for post Annex I uploaders in Member States on managing post Annex I inclusion documents on CIRCA - SANCO/04846/2009 rev. 7 20 February 2009 Document restricted to Member State Competent Authorities, https://circabc.europa.eu/d/a/workspace/SpacesStore/2bf9297a-a70e-4d6b-aacc-39f316a7ab07/Guideline%20post%20Annex%20I%20circa%20rev7.pdf

end of the commenting period mentioned below. It must be emphasised that the zRMS should respond to all comments received on time.

71. A 6-week period should be provided for MS comments using a reporting table format. The final reporting table should be uploaded on CIRCABC by the zRMS (in future: in the PPPAMS). In case of differing opinions on technical issues, the zRMS and the MS concerned shall try to reach a compromise and agreement bilaterally. When there are technical issues affecting the whole zone and more than one cMS, the newsgroup on CIRCABC can be used for the discussion. If a compromise is not possible, this shall be recorded in the Reporting Table. The Reporting Table should therefore be considered as a supplement to the Registration Report, for transparency reasons and its final version therefore sent to the applicant together with the registration report,

72. The Zonal Steering Committees and the Inter-zonal Steering Committee may need to consider the issues where the discrepancies affect the implementation of the zonal system. ZSC and IZSC does not address questions on product specific risk assessments but only on implementation and efficiency of the zonal systems

73. At the same time as uploading to CIRCABC the draft Registration Report should also be sent to the applicant to provide their comments using the reporting table provided in Appendix 8 . It shall be clearly communicated to the applicant, which information is required (factual issues only) and that further information which was not requested would not be considered. In principle, **additional information/studies/data should not be taken into account** once the assessment has been sent for commenting if not specifically asked for by the zRMS.

74. In principle, all applications for new authorisations should be dealt with via the full zonal procedure and thus be subject to commenting from all other MS in the zone. It is clear, however, that certain types of applications (minor pack changes, duplicate authorisation, etc) are dealt with via a more administrative procedure, and are not supported by a technical assessment. Such **applications should be dealt with via a simplified procedure** and should be processed to shorter timelines given the fact that there is no need for commenting. In Appendix 1 the types of applications are listed and it is indicated if commenting is required or not.

75. Other MS should be informed, however, of the amendment that has been made via CIRCABC (in the future via the PPPAMS). Applications requiring technical assessment should follow the zonal procedure.

76. It should be noted that commenting should focus on critical issues that affect the risk assessment and not minor points that do not change its outcome.

2.2.5.6 *Finalisation and Decisions*

2.2.5.6.1 Decisions by zonal RMS

77. Once the comments have been received and addressed, the zRMS should finalise their assessment and make their decision on authorisation in accordance with Article 37.1. It is still possible to seek further clarifications from the applicant at this stage within the overall six month period for requests for further information, although further data/studies should not be taken into account at this stage. **The zRMS may grant or refuse the authorisation**. Either way, the conclusions of the assessment of the zRMS should still be used by the cMS as the basis for their

decisions. Therefore, if the zRMS 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 to this territory, this conclusion should be considered a positive assessment by the zRMS. 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.

78. The final Registration report (RR), including the reporting table and the decision of the zRMS should be uploaded into the PPPAMS[13] without delay**, replacing previous versions**. The zRMS should inform the cMS via email accordingly, a template for this email is included in Appendix 7

2.2.5.6.2 Authorisation by other MS in the zone

79. The cMS have to issue an authorisation or refuse the authorisation within 120 days of receipt of the zRMS assessment and a copy of the authorisation. The date of the upload of the RR should be considered as the date of receipt mentioned above.

80. **Other MS must not re-evaluate the application** but should restrict their complementary assessment to their national requirements described under Article 36.3 and to data protection. In particular, formulation comparability assessments conducted by the zRMS with respect to zonal applications for generic products should be accepted by the other MS, not re-assessed, provided the reference products in both MS are the same.

2.2.5.6.3 Harmonisation of authorisation format

81. The basic information contained in an authorisation as well as the format for information to be kept available for public access should be harmonised to facilitate information sharing and to this end an application and authorisation management system (PPPAMS) has been developed which in the future will also include a public database for information on authorisations. In the meantime obligatory information is clearly described in Article 31 and in Article 57 of Regulation (EC) No 1107/2009.

2.2.5.7 *Publication*

82. As a minimum MS should publish the information referred in Article 57.1. In principle final Registration Reports could also be published to increase transparency and openness if legal provisions in the individual MS allow. Removing confidential information (see Article 63 of Regulation (EC) No 1107/2009 amended by Regulation (EU) No 2019/1381[15]) and appropriate redaction would be required. Appendix 10 includes a template to be used by applicants to request for certain information to be kept confidential (Article 63.2) of Regulation (EC) No 1107/2009) amended by Regulation (EU) No 2019/1381).

[15] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC

3. Mutual recognition

3.1 Legal basis

83. The principle of mutual recognition itself is embedded in Articles 34 and 36 of the Treaty on the Functioning of the European Union (TFEU), and its further elaboration resulted from established case law.

84. Regulation (EC) No 1107/2009 provides for a specific mutual recognition procedure. The holder of an authorisation may apply for an authorisation for the same product, the same use and under comparable agricultural practices in other Member States.

85. As of 14 June 2011, mutual recognition in the sense of Article 40 applies to authorisations granted by MS in accordance with Article 29 of Regulation (EC) No 1107/2009.

86. The procedure to be followed when an application for mutual recognition of an authorisation is submitted is described in Articles 40-42 of the Regulation (EC) No 1107/2009 while the extension of authorisations for minor uses is included in Article 51 in general and more specifically in Article 51.7. Article 42 of the Regulation (EC) No 1107/2009 describes the information that shall be submitted together with the application for mutual recognition.

    - a copy of the authorisation granted by the reference Member State as well as a translation of the authorisation into an official language of the Member State receiving the application (depending on the Member State a translation into English could be sufficient);
    - a formal statement that the plant protection product is identical to that authorised by the reference Member State;
    - a complete or summary dossier as required in Article 33.3 when requested by the Member State;
    - an assessment report (Registration Report or other) of the reference Member State containing information on the evaluation and decision on the plant protection product.

87. If any of these elements are missing then the application should not be accepted

88. Specific provisions have also been included for some special cases:

    - for low-risk products: Article 47.1 and 2 apply in addition to the ones for mutual recognition (see chapter 8.3),
    - PPP containing substances that are included in the list of “candidates for substitution”: provisions of Article 41 and 50 apply in addition to the ones for mutual recognition.
    - for PPP where an application of general interest is submitted for mutual recognition (Article 40.2).
    - (d) it contains a substance approved in accordance with Article 4.7.

3.2 Different cases for mutual recognition

89. The situations under which mutual recognition can be applied for are very clearly described in Article 40.1, with the prerequisite that the reference authorisation needs to have been granted in accordance with Article 29. The interpretation of this is that also products evaluated and authorised according to Directive 91/414/EEC fulfil the criteria in Article 29:

    - authorisations between MSs belonging to the same zone;
    - authorisations between MSs belonging to different zones with the provision that this authorisation is not used for mutual recognition in another MS within the same zone e.g. Belgium authorisation (central zone) can be mutually recognised by Sweden (northern zone) however Denmark (also northern zone) may only mutually recognise the same product from the Belgium and not from Sweden to avoid the 'domino effect'.
    - authorisations between any MS (regardless the zone it belongs to) where the application concerns use in greenhouses or post-harvest treatment, or for treatment of empty rooms or containers used for storing plant or plant products or for seed treatment.

90. There are a number of cases for which mutual recognition is optional. These are namely the following (Article 41.2):

    - an application has been submitted for an authorisation that has been granted in accordance with second bullet of paragraph 89 above (voluntary mutual recognition between countries that belong to different zones);
    - the product contains a substance that is included in the list of candidates for substitution;
    - the application concerns a product that contains a substance that has been approved under the derogation of Article 4.7 (substances for which there are no alternatives);
    - the application is submitted for mutual recognition (Article 40.2) by somebody else than the authorisation holder.

91. Mutual recognition according to Article 40.1 and 41 is also applicable to minor uses. In this specific case, an applicant applies for the mutual recognition of the authorisation of a minor use from one MS to another MS under the precondition that the product has a regular authorisation in both MS.

3.3 Timelines, procedures and communication

92. For mutual recognition the principles applied are the same as those outlined above for zonal authorisations in cMS. However, in this circumstance it is necessary to underline an important difference between the zonal evaluation and the mutual recognition. According to Article 40 Regulation (EC) No 1107/2009, mutual recognition can only be based on an existing authorisation. Therefore, the statement of the zonal Rapporteur Member State (zRMS) in the registration report according to which the use would be acceptable in the concerned MS in the zone in principle, but not under the special conditions of its own territory, precludes the

application under Article 40 of the Regulation to the assessment of the application refused by the zRMS.

93. Additional information cannot be submitted within the procedure for mutual recognition unless it is to demonstrate comparable agricultural, plant /crop protection[16] and environmental (including climatic) conditions or national requirements which are fully justified. In these limited cases, data requirements and guidance available at the time of the application for mutual recognition may apply.

94. Intra-zonal mutual recognition cannot be refused on the basis of national specific requirements if these requirements are not linked to human or animal health, agricultural, plant /crop protection and environmental (including climatic) conditions as provided in Article 36.3.

95. Authorisations given on the basis of mutual recognition must be clearly identified to avoid the 'domino effect'. The central database on applications, and in the future the PPPAMS should help MS receiving the application. MS should also state in their authorisation certificate that this authorisation is based on mutual recognition under Regulation (EC) No 1107/2009.

96. MS have 120 days to decide on authorisation or refusal of a mutual recognition application. They shall avoid re-evaluation of the application other than to fulfil the requirements of Article 36.3. In principle, this timeline applies to applications for mutual recognition of the same product and same use under comparable agricultural conditions. Whilst there may be some flexibility to accept slight changes within an application for mutual recognition (e.g. where no technical assessment would be required to support the differences i.e. no new assessment to be performed), **more significant changes would be dealt with as new zonal applications**. In order to prevent systematic refusal of applications for mutual recognition because of national requirements, MS should consider making them publicly available, so that they can be taken into account by the applicant in the submission for the application for mutual recognition (in the national addenda to the dRR).

97. Where the product contains a candidate for substitution, MS should decide on the outcome of the mutual recognition application prior to undertaking the comparative assessment. In these cases, the MS will decide on the application of mutual recognition and the comparative assessment within the 120 days established by the Article 42.

98. Where the applicant for mutual recognition is not the authorisation holder in the reference Member State, the applicant should justify the general interest of such a product in the MS of introduction in addition to the information listed in Article 42.1. Information about the agreement of the authorisation holder in the reference Member State should also be submitted. If the authorisation holder in the reference Member State does not consent, the competent authority to which the application is submitted may still accept the application. Once the application is accepted, the general provisions for mutual recognition apply. The applicant should be reminded of their obligation with regards to labelling and liability, especially provisions in Article 56, Chapters VII and VIII of Regulation (EC) No 1107/2009.

[16] https://ec.europa.eu/food/plant/plant_health_biosecurity/legislation_en

4. MRL setting in the context of zonal evaluation

4.1 Legal provisions

99. Two legal provisions on the authorisation of PPPs in Regulation (EC) No 1107/2009 refer to the MRL setting under Regulation (EC) No 396/2005:

- Article 33.3 (e) of Regulation (EC) No 1107/2009: "the application shall include the following: (…) where relevant a copy of the application for a maximum residue level as referred to in Article 7 of Regulation (EC) No 396/2005 or a justification for not supplying such information";

- Article 29.1 (i): "… a plant protection product shall only be authorised where (…) it complies with the following criteria: (…) for plants or plant products to be used as feed or food, where appropriate, the maximum residue levels for the agricultural products affected by the use referred to in the authorisation have been set or modified in accordance with Regulation (EC) No 396/2005".

100. In addition the following legal provisions of Regulation (EC) No 396/2005 are relevant in this context:

- Articles 6 to 9: where there is a need to set or modify an MRL in the context of an application for authorisation, the evaluating MS should draft an evaluation report and submit it to the Commission and EFSA; there is no time limit for the evaluating MS to do so, however indicative timelines of the MRL setting procedure have been summarized in SANTE/2015/10595 rev.5.4[17];

- Article 11: EFSA has 3 months to draft a reasoned opinion on the MRL; where more detailed evaluations are needed, this time period may be extended to 6 months; where supplementary information is needed, the time limit shall be suspended;

- Article 14: upon receipt of the reasoned opinion, the Commission shall prepare within 3 months a regulation on the setting or modification of the MRL, for submission to the Standing Committee.

4.2 Coherence of zonal application and MRL setting or modification

101. Considering the timelines set out in chapter 2.2.5.2 (see also Appendix 6) and the time lines under Regulation (EC) No 396/2005 (or the absence of a time limit for the evaluating MS to draft the evaluation report), it is obvious that it might be very difficult to achieve a MRL setting or modification within 12 months as of the application.

102. Several elements can contribute to achieving the goal of an MRL setting or modification within 12 months after the PPP application. It should be avoided that detailed evaluations are needed by EFSA, leading to a time line of 6 instead of 3 months for the finalisation of the reasoned opinion. Such detailed evaluations can be needed for instance where new metabolism studies need to be evaluated, where there are new methods of analysis, etc. It is therefore

[17] Technical guidelines on MRL setting procedure in accordance with Articles 6 to 11 of Regulation (EC) No 396/2005 and Article 8 of Regulation (EC) No 1107/2009 (SANTE/2015/10595 Rev. 5.4)

recommended that applicants submit, as far as possible, all available information that may be needed for future MRLs with the application for the active substance approval (or the renewal of the approval, see the relevant piece of guidance[18]), even if this information is not essential for the representative uses.

103. Even when these recommendations are implemented, there may still be a need to set or modify MRLs in the context of new PPP authorisation applications. And even if the time limit of 3 months for EFSA to draft a reasoned opinion can be applied, it might be difficult to fit the MRL setting/modification procedure within the 12 months period. In order to streamline the procedure as much as possible, consideration also needs to be given to the two aspects in chapters 4.3 and 4.4.

104. Where the conclusion on the evaluation for authorisation is favourable, but a proposed MRL, required for a positive decision, is still under evaluation at the time of decision, the decision on authorisation should be suspended until the MRL is adopted and published.

4.3 Member State performing the evaluation

105. Two scenarios should be considered:

106. Product applications limited to one zone: The zRMS shall perform the evaluation for the MRL setting/modification.

107. Product applications are made in 2 or 3 zones: Following the chapters above, in this case 2 or 3 zonal RMSs would normally evaluate the application. Any MS should be able (from the technical/scientific point of view) to evaluate the studies needed for the setting/modification of MRLs, even if the MRL applied for is not relevant for the zone to which it belongs. It is therefore recommended that all MRL related studies are evaluated by one zRMS for all three zones. It would be logical to allocate this task to the MS which will be responsible for the evaluation of data which are not related to the environmental and agricultural conditions, or for the zRMS of that zone, to which the new MRL belongs to act as the evaluating MS considering the MRL setting according to Regulation (EC) No 396/2005. This approach will have the further advantage that this zRMS will have the complete overview of all GAPs and will be able to identify the critical GAP for a certain crop. This will help avoiding that divergent MRLs are being proposed by the 3 zRMSs for the same commodity.

4.4 Timelines

108. According to Article 8.1 of Regulation (CE) No 396/2005, the EMS has an obligation to draw up an Evaluation Report without undue delay. The timeline for evaluation is reported in SANTE/2015/10595 Rev. 5.4, the timelines as outlined in Article 37 of Regulation (EC) No 1107/2009 for product authorisations should be considered (i.e. 12 months plus 6 months in case the applicant is to submit additional data) for the assessment of MRL application. However since the time needed between the submission of the evaluation report and the publication of the regulation setting/modifying the MRL is about 12 months (and more where EFSA needs to perform more detailed evaluations). When the application for setting MRL is included with the

[18] Guidance Document on the renewal of approval of active substances to be assessed in compliance with Regulation (EU) No 844/2012 (SANCO/2012/11251 rev. 4, 12 December 2014) https://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_en

zonal dossier and in order to meet the time limit of 12 months for the granting of the authorisation by the zRMSs, it should be recommended that the evaluating **zRMS submits the evaluation MRL report to EFSA within 3 months after the receipt of the application**.

109. It is recommended that the applicant submits the application for MRL setting in advance of the application for authorisation of a plant protection product to the relevant evaluating MS/zRMS.

5. Withdrawal and amendment of authorisations according to Article 44

110. Article 44 of Regulation (EC) No 1107/2009 lays down detailed provisions on withdrawal and amendment of an authorisation. In Article 44.1 it is indicated that **Member States may review an authorisation at any time** where there are indications that a requirement referred to in Article 29 is no longer satisfied. Furthermore Article 44.3 describes other cases for which Member States shall withdraw or amend the authorisation. Article 44.4 indicates that where a Member State withdraws or amends an authorisation in accordance with Article 44.3 **it shall immediately inform the authorisation holder, the other Member States, the Commission and EFSA**. The other Member States of the same zone shall withdraw or amend the authorisation accordingly taking into account the national conditions of use and risk mitigation measures.

111. When a withdrawal or amendment according to Article 44 is intended the authorisation holder should be informed in advance stating the reasons and terms of the withdrawal or the amendment. The applicant will have the possibility to submit comments or further information within an appropriate timeframe.

112. However there are cases in which a requirement referred to in Article 29 is no longer satisfied due to a change of an endpoint of the approval of the active substance (e.g. in the framework of an assessment according to Article 56 and Article 21 Reg. 1107/2009) and/or the amendment of residue definition (in the framework of an assessment according to Article 12 of Reg. 396/2005), the cases described exclude the situations covered by the routine Article 43 of Reg. 1107/2009. In those cases in which the new endpoints are established in the framework of an assessment according to Article 56 and Article 21 Reg. 1107/2009, a zonal procedure for the revision of the authorizations of the plant protection products shall be initiated. Appendix 9 includes a more detailed process. When such a change has been noted **a clear time schedule for the amendment of existing authorisations should be reported in the amended review or renewal report and agreed in the Standing Committee**, including the date of implementation of the new end-point by Member States and the **date of revision of authorisations in place.** Sufficient time should be allowed to zRMS for the assessment of additional data/information, a commenting period and decisions by zRMS and cMS. This is especially the case when the procedure for the amendment of existing authorisations does not coincide with the renewal process.

113. In principle, at the time of publication of the updated review or renewal report or the implementing regulation, if necessary, in the EU - Pesticides database, registration holders shall demonstrate that the requirements provided for in points (a) to (h) of paragraph 1 of Article 29 are met. MS can ask for additional data/information from all the registration holders of PPP

containing the active substance, with an indication of the zRMS. Unless otherwise indicated, **an amended dRR, with the changes highlighted**, must be submitted by registration holders to the zRMS and the cMS within 3 months of the publication of the updated review or renewal report, or by the applicability date provided for in the implementing regulation. If additional information and/or an updated dRR is not submitted by the applicant, the authorization of the PPP might be amended or withdrawn, applying a grace period.

114. In principle, zRMS will perform the evaluation of the additional information/data within 5 months. The amended draft registration report should be uploaded to the PPPAMS (for the time being CIRCABC) for comments by all other MS belonging to the same zone. A 6-week period should be provided for MS comments using a reporting table format, and the comments should be submitted to the zRMS. It is recommended that cMS indicate if they agree with the evaluation made by the zRMS. The zRMS should respond to all comments received. The final reporting table should be uploaded to the PPPAMS, for the time being CIRCABC by the zRMS.

115. At the same time as uploading to PPPAMS[13], the amended draft Registration Report should also be sent to the applicant to provide comments in the same format. In principle, additional data/information shall not be accepted during and after the commenting period.

116. Once the comments have been received the zRMS should finalise their assessment and make their decision on the amendment of the authorisation in accordance with Article 44.3 available to the other MS of the zone. Where zRMS withdraws or amends the authorisation, **it shall immediately inform the holder of the authorisation, the other Member States, the Commission and EFSA** through an efficient electronic communication system.

117. The conclusions of the assessment of the zRMS should be used by the cMS as the basis for their decisions, taking into account national conditions and risk mitigation measures. For those cases in which zRMS 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 to that territory, this conclusion should be considered as a positive assessment by the zRMS (Article 36.3).

118. Other MS must not re-evaluate the submitted data but shall restrict the assessment to their national requirements described under Article 36.3 and national data protection.

119. The finalised Registration Report (including the reporting table) should be sent to the applicant and uploaded on CIRCABC, replacing previous versions.

120. An appropriate period of grace can be granted on a case-by-case basis in accordance with Article 46.

121. An electronic ‘rapid alert’ system in order to exchange information between MS about safety concerns and harmonisation of the grace period could be considered and alerts could be co-ordinated by the zonal steering groups.

6. Withdrawal and amendment of authorisations according to Article 45

122. Article 45 lays down the possibility for withdrawal or amendment of an authorisation at the request of an authorisation holder. Other than specifying that the authorisation holder shall state the reason for his request no further provisions are made with regard to application modalities, procedures, timelines etc.

123. Requests for amendment of existing authorisations can be made for a number of reasons, e.g.:

- Change in the chemical composition regarding co-formulants;
- New source of the technical active substance;
- Amendment of the GAP e.g. because of an Article 12 review according to Regulation (EC) No 396/2005 (without being an application for a new product);
- Change in packaging size and material (within evaluated range for the authorisation);
- Change of the name of the authorised products;
- Change of authorisation holder or marketing company.

124. Amendments of authorisation may generally be divided in two groups: those which require an assessment and therefore fall under the zonal system and those which do not.

125. The latter are amendments of a purely administrative nature. In those cases, the request (the application) should be made to those MS where the amendment is applicable. The concerned MS will inform the other MS, where appropriate, via an electronic communication system (email; CIRCABC or PPPAMS when available) on the amendment made.

126. **A zonal assessment is NOT required** for the following amendments of authorizations

- Change of the name of the authorised products;
- Change of authorisation holder (transfer of authorisation), or change of the name or address of the authorisation holder;
- Change in packaging size and material (within existing range);
- Amendments according to previously agreed standards or criteria, e.g. change of source of the technical active substance to an equivalent declared source; non-significant change of formulation (see Guidance Document on significant and non-significant changes[4]);
- Extension of use (via extrapolation/risk envelope without assessing any data);
- See also Appendix 1 of this Guidance Document

127. The provisions of Article 45 shall not be used in cases where the amendments are linked to **new information on potentially harmful or unacceptable effects** from the use of the product. In these cases, **the procedure from Article 56 shall be considered first**.

128. If an assessment is required, the amendment should be dealt with according to Article 33. This is the case for:

- 'Significant' change in composition: This is in line with the Guidance document on significant and non-significant changes[4] on changes to chemical compositions (SANCO/12638/2011) in which is stated that for changes which go beyond changing a co-formulant a new application for authorisation must be submitted according to Article 33. To allow time-efficient assessment the application, the same zRMS as for the original application should be nominated;
- Additional uses;
- GAP changes for uses: If it is necessary to amend the GAP because of the assessment of the active substance and the applicant can submit all necessary supporting data and a justification for the GAP change is provided, this should be acceptable;
- Changes of risk mitigation measures included in the label.

129. For those amendments which fall under the zonal system procedures aligned with those described in chapter 2 of this Guidance Document should be applied, e.g. the principles of:

- application at the zRMS;
- information to all other MSs having an authorisation of the same product at the same time with the indication that the zRMS is asked for assessment;
- assessment by the zRMS;
- and commenting procedure for the assessment.

130. The time allowed for the evaluation after submission should be appropriate to the kind of amendment being assessed. Results of these amendments should be made available as early as possible for other MS to consider further action. This would be best done through an efficient electronic communication system/PPPAMS (for the time being CIRCABC). The other MS should bring in line their authorisations within 120 days at the latest, preferably shorter depending on the kind of amendment.

131. Also for applications under Article 33+34 or Article 33+45, for authorisations of the same product by using different trade names and registration numbers (back-to-back authorisations, new authorisations but same product and GAP as already authorised) the evaluation time after submission should be appropriate to the assessment that has to be performed which for these types of applications implies no evaluation except of checking access to protected data.

7. Grace period according to Article 46

132. Article 46 of Regulation (EC) No 1107/2009 establishes the provisions applicable to the grace period to be applied by MS when withdrawing or amending an authorisation or when an authorisation is not renewed. The grace period is granted for disposal, storage, placing on the market and use of existing stocks. Where the reasons for withdrawal, amendment or non-renewal of the authorisation are not related to the protection of human and animal health or the environment, the grace period shall be limited and shall not exceed 6 months for the sale and the distribution and an additional period of a maximum of 1 year for the disposal, storage, and use of existing stocks of the plant protection products concerned.

133. Minor changes to the authorisation which were requested by the authorisation holder or Member State should not be considered as amendments to an authorisation in the sense of Articles 44 and 45 of the Regulation since they do not have any impact on the safe use of the product. Therefore, the provisions of Article 46 concerning the grace period do not apply to them i.e. the grace periods may be longer so long as this would not cause them to extend beyond the expiry of the earliest active substance (plus Article 46 grace period).

8. Low-risk plant protection products (Article 47)

134. This chapter describes the specific requirements for the authorisation of low-risk plant protection products. Unless otherwise specified, the other parts of this guidance apply fully to low-risk products.

8.1 Legal provisions

135. Regulation (EC) No 1107/2009 favours the inclusion of low-risk substances in plant protection products and facilitates their placing on the market by providing several incentives for low-risk plant protection products.

136. According to Article 47.1 a plant protection product shall be authorised as a low-risk plant protection product when all the active substances contained in the PPP are low-risk active substances as referred to in Article 22 of Regulation (EC) No 1107/2009 (amended by Regulation (EU) No 2017/1432), provided no specific risk mitigation measures are needed following a risk assessment. It shall also meet the requirements listed under (a) – (e) of Article 47.1. The application of these requirements on the low-risk criteria will be further elaborated.

137. The authorisation procedure for low-risk PPPs is the same as for conventional PPPs, but with different timelines. Article 47.4 provides that unless otherwise specified, all provisions relating to authorisations under Regulation (EC) No 1107/2009 shall apply. Hence, the provisions on zonal evaluation apply to low-risk products and the "Member State" referred to in Article 47 is the zRMS.

8.2 Zonal Authorisation procedure for low-risk products

8.2.1 Before industry submits an application (notification)

138. Applicants shall state in their notification form that they intend to seek authorisation for a low-risk product. For reasons of efficiency and feasibility of meeting the reduced timelines for low-risk PPP authorisations, it is recommended that the applicant proposes, where possible, the

RMS as zRMS for the low-risk active substance. For the same reason, it is especially important that applicants use, where appropriate, the risk envelope approach as described in paragraph 29, when building their dossiers.

8.2.2 Industry application

139. The applicant shall submit with the application a complete and a summary dossier for each point of the data requirements of the active substance and the plant protection product. The applicant shall demonstrate that all intended uses for the product meet all the requirements for low-risk PPPs set in Article 47.1 and in particular for each intended use that no specific risk mitigation measures are needed following a risk assessment. The applicant shall include a specific conclusion on the low-risk requirements in each section of the dossier, where relevant. Applicants are recommended to consult related information when this is available.

8.2.3 Zonal RMS evaluation

8.2.3.1 *Completeness check*

140. The zRMS shall conduct a completeness check as described in paragraph 50 and following, paying particular attention to the information provided to demonstrate that the requirements set out in Article 47.1 are met. If any of the elements set out in Articles 33, 34 or 47 are missing, the application should not be accepted.

141. When, during the completeness check it becomes apparent that the product applied for cannot be a low-risk product in the zone (e.g. when the active substance is not approved as a low-risk substance or when the product contains known substances of concern) the zRMS should not accept the application. The zRMS shall update the zonal database/application spreadsheet and inform the other MS accordingly.

142. The completeness check should be completed within 3 weeks after submission of the application.

8.2.3.2 *Timelines*

143. The zRMS shall decide whether the requirements for authorisation are met within 120 days from receiving the application for authorisation of a low-risk product. This period may be extended by a maximum of 6 months if further information is requested. In addition, the timelines can be suspended if the procedure in Article 38 (assessment of equivalence) is necessary. As Article 47 does not include specific timelines for the decision by the concerned member states, Article 37.4 applies in those cases. Accordingly, concerned member states shall at the latest within 120 days of the receipt of the assessment report and the copy of the authorisation of the Member State examining the application decide on the application.

144. Special effort is required by the applicant for the zRMS to be expected to meet the reduced timelines for low-risk product authorisations. The applicant shall provide clear justification in the dossier that the product meets all conditions set in Article 47.1. The applicant shall respect the schedule agreed during the pre-submission meeting and submit the dossier timely.

145. In cases where MRLs need to be set, a decision on the authorisation can only be made after the MRLs have been set. The time needed between the submission of the evaluation report and the publication of the regulation setting/modifying the MRL is about 12 months (and more where

EFSA needs to perform more detailed evaluations). Considering these timelines it is unrealistic to expect that the 120 day timeline for low-risk products can be respected, unless the applicant submits the dossier for MRL setting in advance.

146. In order to allow for the commenting phase envisaged in Article 36.1 the initial assessment should be completed within 11 weeks of the date of submission of the application.

147. With regard to Article 37.3, an applicant should be able to submit an application for authorisation of a low-risk PPP before the date of application of the approval regulation of the low-risk active substance, but the timelines of Article 47 shall apply and they will then apply from the date of entry into force of the approval regulation. In case where the substance is approved as a regular active substance (not low-risk), the zRMS shall treat it as an application for a regular PPP in accordance with Article 33, apply the timelines of Article 37 and inform the applicant of this.

8.2.3.3 *Comments on zonal RMS draft*

148. A 3 week period should be provided for comments by all MS in the zone. cMS shall pay particular attention to the preliminary conclusions with regard to whether or not authorisation as low-risk is likely to be granted.

149. To avoid unnecessary delays, cMS shall immediately notify the zRMS when they decide not to comment.

8.2.3.4 *Finalisation and decision*

150. A plant protection product shall be authorised as a low-risk plant protection product when it meets the requirements of Article 47.1. Member States shall state in their national authorisation decision specifically that the product is authorised as a "low-risk plant protection product".

151. In addition to paragraph 77, if the zRMS has come to the unambiguous conclusion that a plant protection product can be authorised as a low-risk plant protection product in the zone in principle this conclusion should be considered a positive assessment by the zRMS with regard to the low-risk status and reported as such in Part A of the registration report. Where the zRMS cannot grant the low-risk status in its own territory for conditions specific to that territory they should report in the national addendum and in the Part A of the dRR in addition to the conclusion mentioned above in this paragraph.

152. The zRMS shall finalise the assessment and complete the decision-making within the timelines stipulated in Article 47.3.

153. Low-risk plant protection products shall be authorised by cMS under the same conditions of the zRMS, except where Article 36.3 applies. If the original authorisation is for a low-risk plant protection product it will be authorised as such, unless national requirements lead to the setting of specific risk mitigation measures in such a way that the conditions of Article 47.1 are no longer met.

154. If the zRMS has come to the unambiguous conclusion that a plant protection product cannot be considered as a low-risk PPP in the zone, then after informing the applicant the zRMS shall treat it as an application for a regular PPP in accordance with Article 33 and decide within the

timelines of Article 37 whether the requirements for authorisation as a regular PPP are met. This may have implications for the fees applied by the Member State. Where the low-risk status cannot be granted because of some uses, discussion between the zRMS and the applicant should address this issue.

155. The zRMS shall alert other MS of the change of applied timelines and update the zonal database/application spreadsheet accordingly.

156. The final Registration report (RR), including the reporting table and the decision of the zRMS should be uploaded into the PPPAMS[13] without delay**, replacing previous versions**. The zRMS should inform the cMS via email accordingly, a template for this email is included in Appendix 7

8.3 Mutual recognition

157. Mutual recognition applies similarly to low-risk PPPs. Article 41.1 states that a PPP shall be authorised under the same conditions, except where Article 36.3 applies. If the original authorisation is for a low-risk PPP then under mutual recognition it will be authorised as low-risk product, unless national requirements lead to the setting of specific risk mitigation measures in such a way that the conditions of Article 47.1 are no longer met.

158. This also applies the other way around for products that were not originally authorised as low-risk solely because of specific risk mitigation measures related to national requirements of the reference MS, but can be authorised as low-risk in the MS where the application for mutual recognition is done because the national requirements of that MS do not require specific risk mitigation measures (or it does not have national requirements).

8.4 Amendment of authorisations

159. When authorised, the same provisions on amendment apply to low-risk products as for regular products. Hence, Article 37 and section 5 and 6 apply.

160. If the zRMS has concluded that the amendment of the authorisation challenges the low-risk status of the plant protection product, they should consult the applicant. The zRMS shall then decide and report in the dRR if the authorisation is amended and turned into a non-low-risk one or if the amendment is refused.

9. Harmonisation

161. Harmonisation of risk assessments is a medium term aim. A number of steps were proposed during the workshop in Braunschweig in January 2010 and were followed up in the Dublin workshop on Zonal Evaluation, Mutual recognition and Re-authorisation of Plant protection Products in June 2015. Any new developments will be added in an amendment to this guidance document or other guidance documents as they are formalised.

10. Transitional measures (Article 80)

162. Re-registration applications will be processed in accordance with the timelines set out under Directive 91/414/EEC and using the voluntary re-registration work-sharing guidance if appropriate.[19]

163. If an application relates to a PPP which is a new product in one MS (12 month zonal deadline applies) but an existing PPP in another MS (2 year re-registration deadline applies), the timing of evaluations will depend on the choice of zRMS and this should be discussed at the pre-submission phase.

[19] SANCO/6896/2009 Guidance document on a process for intra & inter-zonal work-sharing to facilitate the registration and re-registration of plant protection products following inclusion of an active substance in annex I of council Directive 91/414/EEC
https://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_en

Appendix 1 - Types of applications and commenting requirements

	Type of application	**Description**	**Requirement for commenting Y/N**
1a	Duplicate authorisation (from data owner). No technical assessment (Articles 33 & 45)	Identical product (same formulation manufacturer and source of a.s.)– same authorisation holder: • Administrative changes may be acceptable, such as commercial name, marketing company. • Same or reduced label claims **Article 33 & 45**	N
1b	Duplicate authorisation (with access agreement). No technical assessment (Articles 33 & 34)	Identical product – different authorisation holder (will usually require data access agreement): • Identical product (same formulation manufacturer and source of a.s) • In addition to the authorisation holder administrative changes may be acceptable, such as commercial name, marketing company. • Same or reduced label claims as original product **Article 33 & 34**	N

	Type of application	Description	Requirement for commenting Y/N
2a	Authorisation of a PPP exempted from supplying the test and study reports referred to in Article 33.3 – no technical assessment (Articles 33 & 34)	• New product referencing an existing authorisation but with different source of active substances (previously found technically equivalent according to Article 38[11,12]) and different manufacturing company. • Same or reduced GAP and label claims as reference product. • Formulation differences from the reference product are non-significant **with no data provided for the areas of the assessment**[4] Reference product data are unprotected[20] in the evaluating MS or relevant data access agreement is in place. **Articles 33 & 34**	Y Assessments of formulation comparison should be accepted by other MS. Concerned MS will need to consider data protection / data access in their MS and whether the reference product is authorised in their MS. If the authorization of the reference product was withdrawn the new product may not be authorised.

[20] COMMISSION NOTICE Technical Guidelines on Data Protection according to Regulation (EC) No 1107/2009 (2019/C 229/01)

	Type of application	Description	Requirement for commenting Y/N
2b	Authorisation of a PPP exempted from supplying the test and study reports referred to in Article 33.3 – with technical assessment (Articles 33 & 34)	• New product referencing an existing authorisation but with different source of active substances (previously found technically equivalent according to Article 38[11,12]) and different manufacturing company. • Same or reduced GAP and label claims as reference product. • Formulation differences from the reference product are usually significant with specific formulation **data provided for some areas of the assessment**[21]. Organised as standard format of DRR. • Additional data may be required to cover differences from the reference product • Reference product data are unprotected[22] in the evaluating MS or relevant data access agreement is in place or relevant data are submitted. **Article 33 & 34**	Y Concerned MS will need to consider data protection / data access in their MS and whether the reference product is authorised in their MS.
3a	Minor change of existing authorisation (no data required)	Change of authorisation within existing risk envelope. E.g. non-significant formulation change[4] / packaging change **Article 45**	N
3b	Change of existing authorisation (new data are required)	More significant changes[21] to e.g. formulation / packaging where new data or risk assessment is required. **Article 33**	Y

[21] Guidance Document on significant and non-significant changes of the chemical composition of authorised plant protection products under Regulation (EC) No 1107/2009 – SANCO 12638/2011, https://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_en)

[22] COMMISSION NOTICE Technical Guidelines on Data Protection according to Regulation (EC) No 1107/2009 (2019/C 229/01)

	Type of application	Description	Requirement for commenting Y/N
4a	Additional crop or pest control claim (no data required)	When extrapolation from assessment for existing crop/pest is acceptable (MRL check required) **Article 45**	N
4b	Additional Crop	Technical assessment required **Article 33 & 45**	Y
5	New product with complete data package	**Article 33**	Y
6	Concerned MS application	Concerned MSs national 120-day assessment **Article 36.2**	N
7	Mutual recognition	National 120-day assessment submitted after zRMS assessment is complete **Article 40**	N
8	Application to address product data gap	Where authorisation previously granted with minor data gap (most commonly shelf life data) Ideally this would be assessed by original zRMS at the next significant application.	N (unless a concern has been identified)
9	Technical equivalence	Assessment of a new source of active substance[11,12] **Article 38**	Y

	Type of application	Description	Requirement for commenting Y/N
10	New crop (minor use)	New use on minor crop based on new data and or/risk assessment (see case 4a if no new data is submitted or no risk assessment triggered) **Article 51**	Y
11	Parallel permit	**Article 52**	N
12	Emergency authorisation for 120 days	**Article 53**	N (must inform COM)
13	Product containing a GMO	**Article 48**	Y
14	Permit for trials purposes	**Article 54**	N
15	Low-risk PPP	Considering the reduced timelines for authorisations of low-risk PPP the commenting period is reduced to **3 weeks** (instead of 6 weeks). **Article 47**	Y

Appendix 2 - The Inter-zonal Steering Committee

Remit of the inter-zonal Steering Committee (izSC)

- The izSC is a co-ordination body dealing with issues of work-sharing. In this respect the izSC will address and co-ordinate issues between the zones.
- The izSC takes over the role of the zSC for applications for use in greenhouses, post-harvest treatment, treatment of empty storage rooms and for seed treatment. In this respect the izSC may take a role in the allocation of the Member State who will undertake the core evaluation of a particular product on behalf of the other MS – the inter-zonal Rapporteur Member State (izRMS).
- The izSC facilitates the harmonisation of risk assessment relevant between the zones, i.e. by initiating the development of respective harmonised guidance by a particular expert group.
- The izSC contributes to relevant guidance documents.
- The izSC discusses any general issues relating to the efficiency of the system.
- The izSC ensures transparency and gives a formal feedback of its work to all MS and also communicates to Stakeholders.

Organisation of the inter-zonal Steering Committee

- Representatives for izSC are experts from Member States and the European Commission (DG SANTE).
- Meetings will be held on a quarterly basis, usually in March, June, September and December, generally as a half-day face-to-face meeting in Brussels, adjacent to the PAI. Additional teleconference may be arranged
- There should be a face-to-face meeting at least once a year, which should in principle take place in Brussels.
- The chair is appointed for 1 year amongst the participants to the iZSC.
- The responsibilities of the chair are
    - organisation of teleconferences and at least one face to face meeting,
    - preparing the necessary agenda,
    - ensuring that feedback is provided to the Standing Committee,
    - managing the updating of the overview table on inter-zonal applications,
    - managing the contribution to relevant guidance documents.
- Preparation of the minutes of the teleconferences/meetings (preferably within 2 weeks) will be shared amongst the attendees of the izSC (until question of secretariat solved) and circulated to all MS via CIRCABC.

- An additional summary of the minutes, excluding confidential information, will also be prepared by the same MS preparing the minutes, which is foreseen to be made publically available.

Appendix 3 - The zonal Steering Committees

Remit of the Zonal Steering Committees (zSC)

- The zSC co-ordinates work sharing activities within zones, which is seen to be the **key function** of the group.
- The zSC is a co-ordination body dealing with issues of work-sharing; it does not address questions on product specific risk assessments.
- The zSC takes a role in the allocation of the Member State who will undertake the core evaluation of a particular product on behalf of the other MS in the zone – the zRMS. In principle the applicant's choice is followed. But in case of unbalanced distribution, the zSC should be involved at a very early stage (preferably before detailed pre-submission meetings) to look for an alternative zRMS. The zRMS should be known at the time of detailed pre-submission meetings, in order to respect the deadlines and avoid duplication of work.
- The zSC ensures that all MS are involved in the evaluation of PPP applications. In doing so the zSC will take into account the capacity of the MS to act as zRMS. MS should inform the zSC of their capacity in general, and of their capacity to take additional applications on board.
- The zSC discusses any general issues relating to the efficiency of the system.
- The zSC contributes to relevant guidance documents.
- The zSC does not get involved in disagreements between zRMS and a commenting MS regarding an assessment (this should be dealt at expert level). The zSC can recommend an expert meeting to solve the disagreements or to consider the issues in the Director´s Meeting or similar group.
- The zSC facilitates the harmonisation of national risk assessments relevant within the zone, i.e. by initiating the development of respective harmonised guidance by a particular expert group.
- The zSC ensures transparency and gives a formal feedback of its work to all MS in the zone.

Organisation of the zonal Steering Committees

- Each MS in the zone should participate in the zSC.
- Within each MS two zonal contact points should be nominated. They are
    - contact point for mutual communication and information,
    - contact point for the commenting procedures on dRRs,

- the representatives of each Member State to zSC meeting (other experts can also join the zSC).

- Meetings of the zSC should preferably take place every 2 months by teleconference / remote meeting tool. They should take place in uneven months.
- There should be a face-to-face meeting at least once a year, which should in principle take place in the MS of the chair (decision up to the chair).
- In principle every MS should be willing to be the chair. Two MSs could co-chair at the same time. With this option small member states which may not have the resources to chair but who wish to do so can coordinate with another small MS or even with one of the larger MSs and they can chair concurrently.
- The chair is appointed for a 1 year.
- The responsibilities of the chair are
    - organisation of teleconferences and at least one face to face meeting,
    - preparing the necessary agenda,
    - preparation the minutes of the teleconferences/meetings (preferably within 2 weeks) and to circulate them to the other MS of the zone,
    - attendance of the inter-zonal Steering Committee,
    - manage the updating of the overview table on zonal applications,
    - collecting remarks and comments from MS and industry on relevant guidance documents and discuss them in the zSC,
    - To prepare and distribute position papers of the zSC

- The minutes/conclusions (non-confidential part) should be made publically available in order to improve transparency.
- A meeting with stakeholders (industry) at least once a year [preferable after the face-to-face meeting] should be held.

Appendix 4 - Recommendations for applications for extension of uses

Draft Registration Reports for label extensions/amendments should be restricted to only those parts relevant to the application, in case the existing authorisation has a RR (under 1107/2009). For authorisations without a Registration Report (under 91/414/EC), it is up to the MS how the draft Registration Report should be drafted. The relevant parts are described in the table below:

Sections of the draft Registration Report required for label extensions/amendments on authorisations with Registration Report:
Part C – Confidential information not necessary since this covered by the original authorisation
Part A – Risk Management should be submitted, covering: - only summaries of the risk assessment for the extension - gap table including only the extended uses (new uses) - new (complete) label text - copy of authorisation document for the extension
Part B0-General Information Background information of the active substance and the plant protection product shall be included. The Good Agricultural Practice table (GAP table) for which authorisation is applied for should be included and the justification for the risk envelope approach shall be included
Part B1 B2– B4 Identity, physical and chemical properties, further information Should be submitted, covering: - GAP table including only the extended uses - if the application rate (dilution) of the new uses is outside the range of the existing uses, relevant technical properties (e.g. foaming, suspensibility) should be re-evaluated, where appropriate - no further details needed, make reference to original RR
Part B3 – Efficacy Should be submitted, covering: - all aspects, either by a new data, or by a reasoned case or data showing that the aspect is covered by the Registration Report for the original authorisation - bridging studies, if necessary

- summaries of studies submitted in connection to the new uses
Part B5 – Analytical Methods Should only be submitted in case: - new analytical methods may need to be provided concerning the new uses (additional exposure scenarios or different crop groups) - no further details needed, make reference to original Registration Report
Part B6 – Mammalian Toxicology Should be submitted, covering: - all aspects, either by a new risk assessment, or by a reasoned case or data showing that the risk of the new uses is covered by the RR for the original authorisation[23]
Part B7 – Metabolism and Residues Should be submitted, covering: - all aspects, either by a new risk assessment, or by a reasoned case or data showing that the risk of the new uses is covered by the RR for the original authorisation[23] - residue trials and MRLs for the new uses - bridging studies, if necessary - summaries of studies submitted in connection to the new uses
Part B8 – Environmental Fate Should be submitted, covering: - all aspects, either by a new risk assessment, or by a reasoned case or data showing that the risk of the new uses is covered by the Registration Report for the original authorisation[23] - summaries of studies submitted in connection to the new uses
Part B9 - Ecotoxicology Should be submitted, covering: - all aspects, either by a new risk assessment, or by a reasoned case or data showing that the risk of the new uses is covered by the Registration Report for the original authorisation[23] - bridging studies, if necessary - summaries of studies submitted in connection to the new uses
Part B10 – Groundwater metabolites Should only be submitted in case: - new uses give rise to assessment of relevant metabolites[23]

[23] New Guidance Documents adopted after the original authorisation should be taken into account. The latest model versions should be used

Appendix 5 - Mixed applications (indoor /outdoor)

Requirements for mixed applications: 2 draft Registration Reports and 2 dossiers

In each zone where authorisation is sought, 2 draft Registration Reports and 2 dossiers should be submitted. In this way, the 'mixed 'application is split into 2 (not mixed) dRRs and dossiers:

Please note that Part C and zone independent aspects should be evaluated by only one zRMS if the field uses are applied for in at least 2 different zones. The applicant should indicate which zRMS is asked to do this. The zRMS and applicant should cooperate in organising the zone independent aspects.

dRR1 and dossier 1:

dRR1 (**for outdoor uses, for only the zone concerned**), with

- Part A (outdoor uses only or combined with indoor uses; to be discussed with zRMS)
- Part B (outdoor uses, all sections)
- Part C (same as for dRR2))

Dossier 1: Part K (study reports for outdoor uses)

dRR2 and dossier 2:

dRR2 (**for indoor uses, inter-zonal**), with:

- Part A (indoor uses only or combined with outdoor uses; to be discussed with zRMS)
- Part B (indoor uses, all sections)
- Part C (same as for dRR1)

Dossier 2: Part K (study reports for indoor uses; often different from dossier 1)

Options for mixed applications (to be decided at MS level)

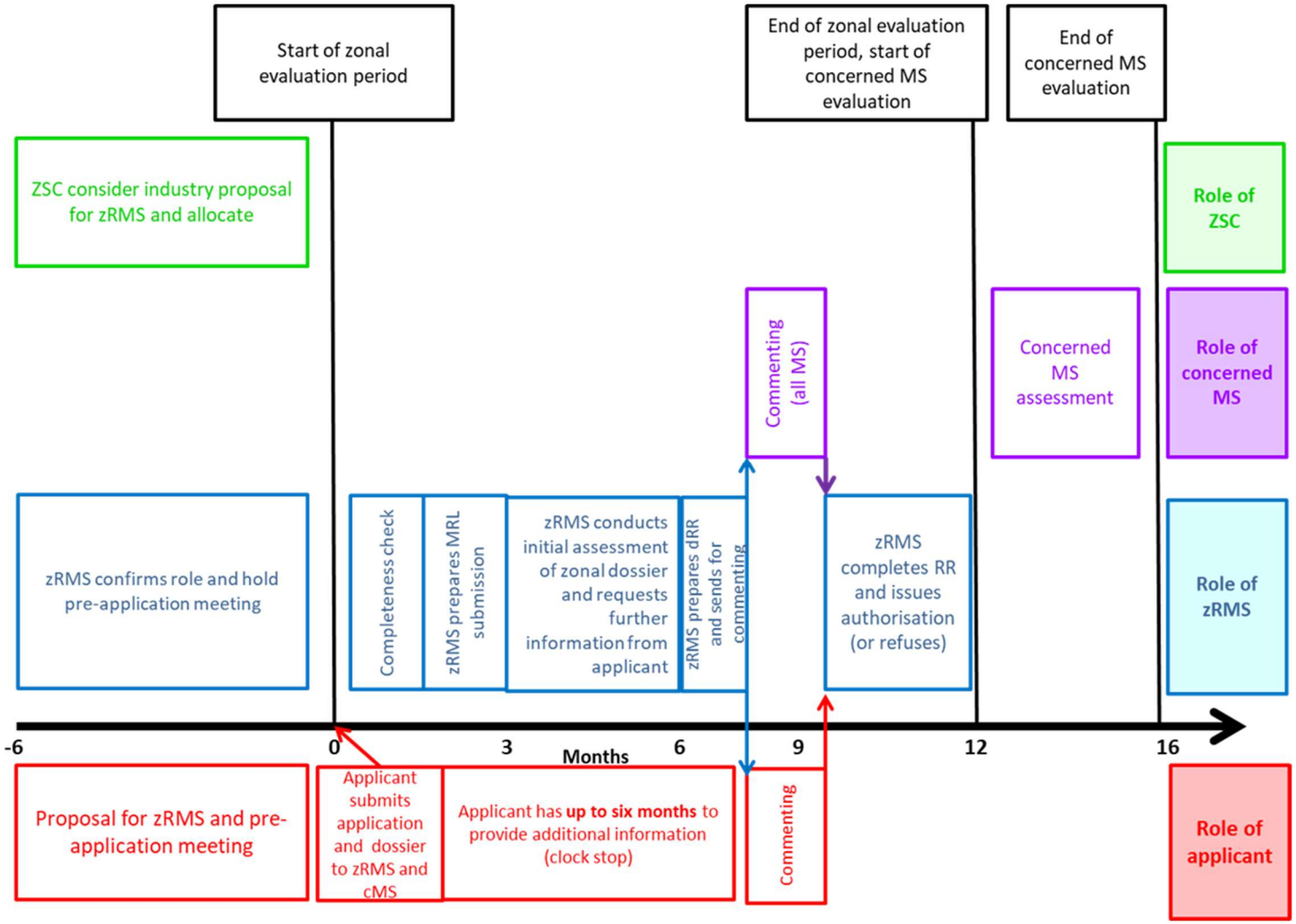
MS can ask for 2 applications, 1 for indoor uses, 1 for outdoor uses. 1 or 2 fees possible, for example:

- In case a MS is both zRMS (for field uses) and cMS (for indoor uses), process and timelines for the field uses (max 12+6 months) differ from process and timelines for indoor uses (max 120 days after indoor uses are announced as registered by

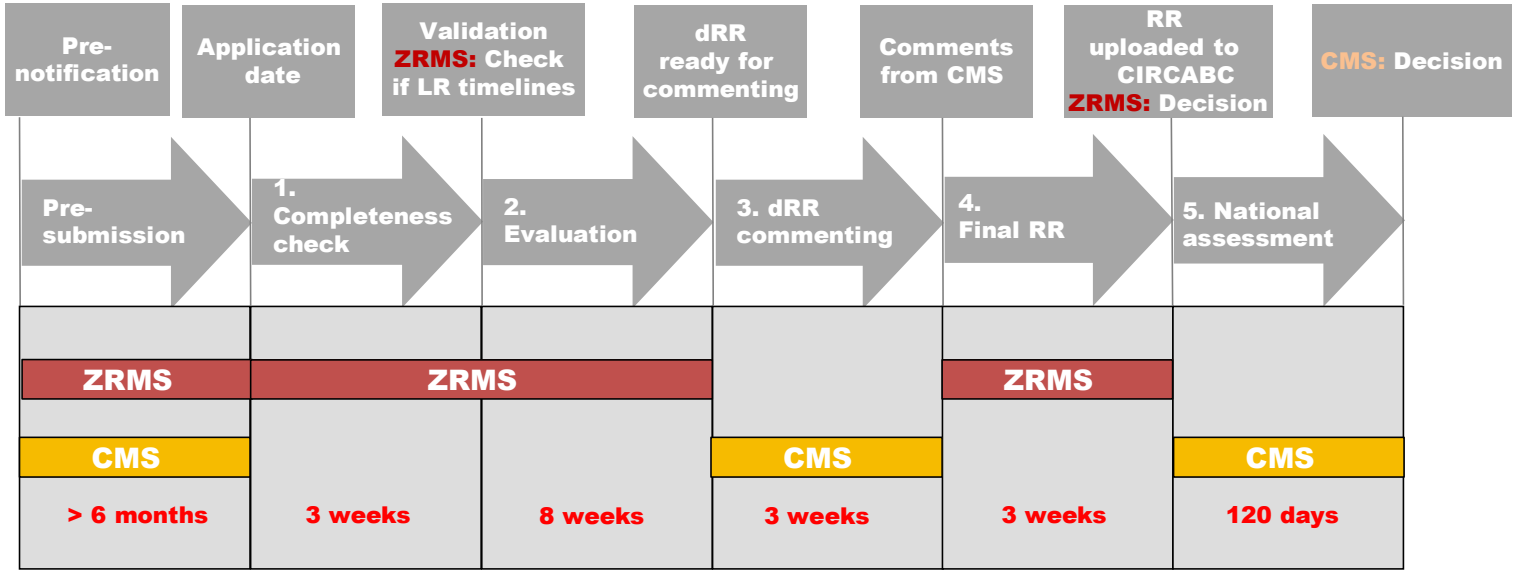
the zRMS for indoor uses). In this case MS will often ask for 2 applications (1 zRMS and 1 cMS application)

- Also in case a MS is cMS for both field and indoor uses (with 2 different zRMS), MS will often ask for 2 cMS applications (since the process is done twice, and timelines might differ for the 2 zRMS applications)

Appendix 6 - Timelines zonal evaluation under Regulation (EC) No 1107/2009 (Articles 33 – 42)



Timelines zonal evaluation of low-risk PPP's (Art. 47)



Phase 1-4 is 120 days; up to 6 months clock stop may be added when relevant to request additional information.
Phase 5 is 120 days for CMS only.

Appendix 7 – Standard e-mail

Standard e-mail table to notify MS that an assessment is available for commenting (includes a row detailing the zRMS conclusion)

Product code	
Product name	
Formulation type	
Active substance(s) name(s) and content(s)	
Low-risk substances	Yes/No
Applicant	
Authorisation holder	
Application reference code of zRMS (if available)	
Application for (type of application)	
Application as low-risk PPP	Yes/No
New / old product data requirement used	
Relevant zone and concerned Member States	
Direct link to the completed assessment uploaded to CIRCABC	
Direct link to part C uploaded to CIRCABC	
6 weeks deadline for comments (3 weeks for Article 43 applications or low-risk PPP)	
zRMS conclusion	
Please send comments to:	
Remarks:	

Standard e-mail table to notify MS that the **final RR** is available on CIRCABC:

Product code	
Product name	
Formulation type	
Active substance(s) name(s) and content(s)	
Low-risk substances	Yes/No
Applicant	
Authorisation holder	
Application reference code of zRMS (if available)	
Application for (type of application)	
Application as low-risk PPP	Yes/No
New / old product data requirement used	
Relevant zone and concerned Member States	
Direct link to the completed assessment uploaded to CIRCABC	
Direct link to part C uploaded to CIRCABC	
zRMS conclusion	E.g. An authorisation has been recommended for use on X, Y and Z An authorisation has been recommended for use on X and Y and it is recommended that use on Y is refused due to insufficient *[insert brief details why refusal has been recommended*] No authorisation can be recommended due to insufficient [*insert brief details why refusal has been recommended*]
Date of authorisation	
Contact	

Appendix 8 - *Reporting table*

ZRMS:
cMS:
Active substance(s): *[one line per active substance]*
Trade name:
Formulation code:
Authorisation holder:

Data Req point	Member State / Applicant	Comment	Reply zRMS
dRR - Overall General Comments			
dRR – Part A Risk Management			
dRR – Part B			
Section 0 - Product Background, Regulatory Context and GAP information			
Section 1,2,4 – Identity, Physical and Chemical Properties, Further Information			
Section 3 – Efficacy			
Section 5 – Analytical Methods			
Section 6 – Mammalian Toxicology			

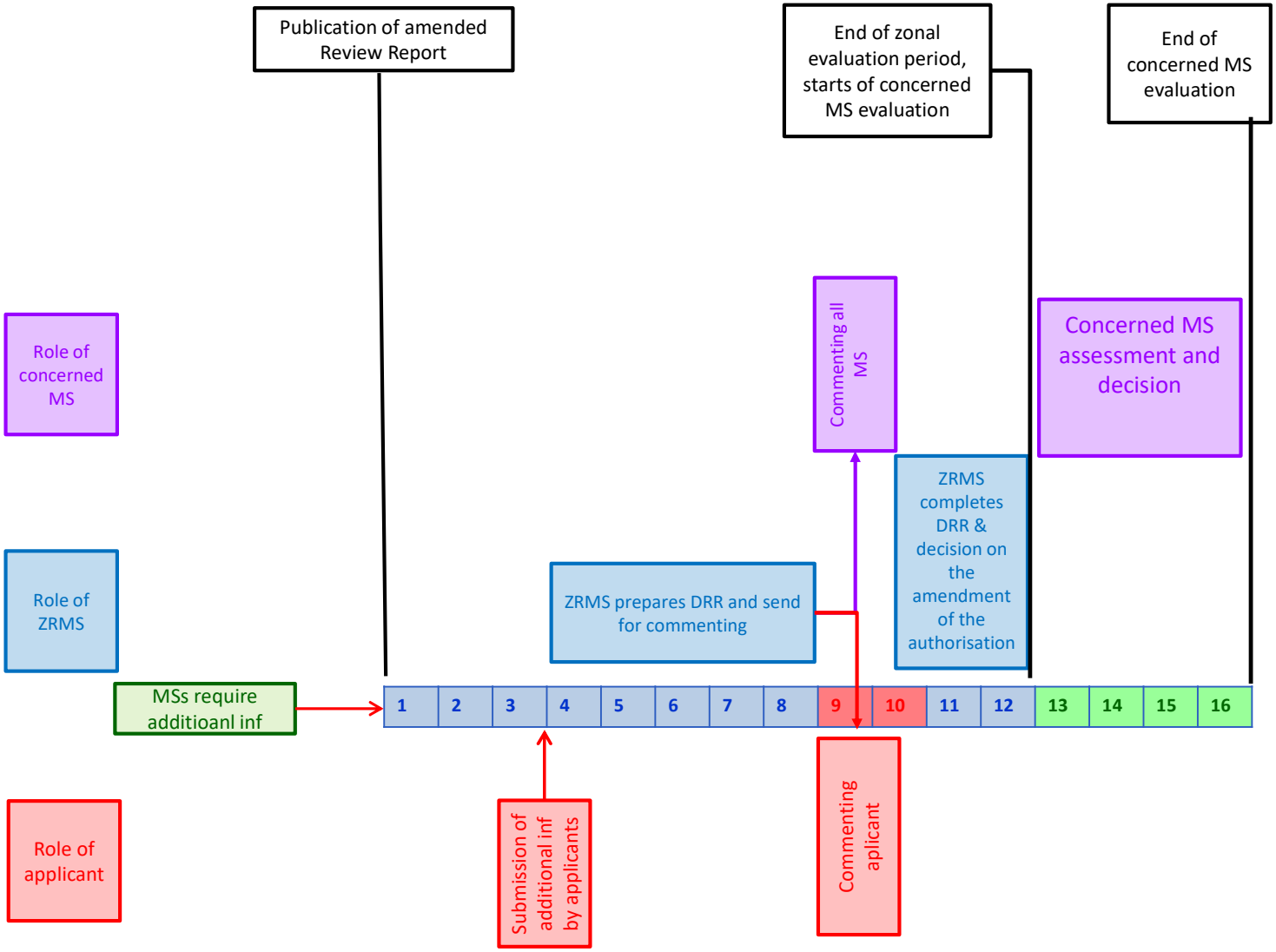
Data Req point	Member State / Applicant	Comment	Reply zRMS
Section 7 – Metabolism and Residues			
Section 8 – Environmental Fate			
Section 9 – Ecotoxicology			
Section 10 - Assessment of the relevance of metabolites in groundwater			

Confidential Commenting table

Active substance:
Trade name/Formulation type:
Rapporteur:
Applicant:

Annex III point	Member State/ Applicant	Comment	Reply ZRMS	Outcome
dRR - overall GENERAL COMMENTS				
dRR – Part C Confidential information				

Appendix 9 - Timelines evaluation and amendment of authorisation according to Article 44 when an endpoint of the active substance is amended



Appendix 10 – Template to request for certain information to be kept confidential (Article 63.2 of Regulation (EC) No 1107/2009 amended by Regulation (EU) No 2019/1381)

Request for certain information to be kept confidential (Article 63 (2) of Regulation (EC) No 1107/2009) amended by Regulation (EU) No 2019/1381

This request pertains to:

☐ **an Application for authorisation or amendment of an authorisation (Art. 33)**
☐ **a Renewal of authorisation (Art. 43)**
☐ **a Mutual Recognition (Art. 40)**
Product name/Product code:
Active substance:
Member State:

Item or Document	Page no	Paragraph	Justification and reference to Article 63.2 of Regulation (EC) No 1107/2009 amended by Regulation (EU) No 2019/1381	Evaluation of the request by the MS
Document …	/	/		
Document	/	/		
Document	/	/		
Summary document Part B Section 1, point …	/	/		
Summary document Part B Section 2, point …	/	/		
Summary document Part B Section 3, point …	/	/		
Summary document Part B Section 4, point …	/	/		
Summary document Part B Section 5, point …	/	/		

Item or Document	Page no	Paragraph	Justification and reference to Article 63.2 of Regulation (EC) No 1107/2009 amended by Regulation (EU) No 2019/1381	Evaluation of the request by the MS
Summary document Part B Section 6, point …	/	/		
Summary document Part B Section 7, point …	/	/		
Data (document K) related to points …	/	/		
Data (document K) related to points …	/	/		
Names and addresses of natural persons involved in testing on vertebrate animals or in obtaining toxicological information	/	/	No justification required	
…	/	/		

Company: ……

Date: ……

Signature: …… (Stamp)

Please send this form:

- **to the Zonal/Interzonal Rapporteur Member State and all cMS together with the application for authorisation or amendment of an authorization (Art. 33)**
- **to the Zonal/Interzonal Rapporteur Member State and all cMS together with the application for renewal of authorization (Art. 43)**
- **to the Member State where the application for mutual recognition is submitted (Art.40)**