



**Guidance Document on the Renewal of Authorisations according to  
Article 43 of Regulation (EC) No 1107/2009**

This document has been conceived as a guidance document of the Commission Services. It does not represent the official position of the Commission. It does not intend to produce legally binding effects. Only the European Court of Justice has jurisdiction to give preliminary rulings concerning the validity and interpretation of acts of the institutions of the EU pursuant to Article 267 of the Treaty.

Revision history

When	What
Rev. 12 of 20.03.2015	Update of document to better reflect situation under Regulation (EC) No 1107/2009. Document is limited to renewal of authorisations according to Article 43. Reference is made to a number of recently noted Guidance Documents. Situations for PPPs with more than one active substance are more clearly described.
Rev. 13 of 14.07.2015	Update based on obligations of applicants. Some further clarifications agreed in the Dublin workshop (June 2015).
Rev. 14 of 07.10.2016	Update based on first experience gained : notifications, list of studies relied upon, lists of end-points, data matching and specification checks, Cat. 4 data processes. It should be applied from 1 <sup>st</sup> January 2017 onwards.

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## 1. Background

This guidance document has been developed to elaborate the procedures contained in Regulation (EC) No 1107/2009 (hereinafter called "the Regulation") for the renewal of authorisations according to Article 43 of the Regulation.

It starts from the basic principle that products which will be renewed under the Regulation have already been authorised in accordance with the Regulation or the Directive 91/414/EEC, and therefore comply with the data requirements of that Directive/Regulation and were assessed under the Uniform Principles.

The procedures described in this guidance document only apply to renewals of authorisations<sup>1</sup> based on active substances for which approval is renewed under the Regulation, and where safe uses have been demonstrated.

As the process of renewal of authorisation under Article 43 is only starting, this guidance may need regular updates when experience is gained.

## 2. Legal basis

The procedure to be followed when an application for renewal of an authorisation is submitted is described in Article 43 of the Regulation.

### Main legal provisions:

Article 43(1) provides that a renewal of authorisation shall be made following the submission of an application by the authorisation holder when requirements of Article 29 are still met. The timeframe is not specified, but in paragraph 2 of the same Article an obligation has been included for authorisation holders to **submit an application within 3 months from the date of application (DoA) of the decision on the renewal of the approval of an active substance**. This request should include any new product data with evidence that new data are required as a result of new data requirements/ new or changed endpoints or criteria or are necessary to amend original conditions of approval.

The second subparagraph of Article 43(3) provides that **within a specific zone the compliance check and assessment of the information submitted should be coordinated by a zonal rapporteur Member State (zonal RMS)**<sup>2</sup>. Within 12 months of the renewal of approval of an active substance, Member States (MS) have

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<sup>1</sup> In parallel to the renewal process for a product, an application in some MSs where this or some uses of it are not yet authorised may have been submitted. These MSs may take advantage of the risk assessment performed according to the Article 43, to run a parallel art 33 assessment in which the matching sections of the evaluation can be copied. They should however carefully check that some aspects for an art 33 application may not be covered in the renewal assessment; new data requirements, efficacy, and which data protection applies. By no means may the assessment for the renewal be delayed because of the art 33 assessment.

<sup>2</sup> Or inter-zonal rapporteur Member State in the case of an inter-zonal assessment (e.g. seed treatment). This applies throughout the guidance document.

to decide on renewal of authorisations (Article 43(5)). This gives the zonal RMS the role of a coordinator<sup>3</sup>, but the zonal RMS is not necessarily assessing the information submitted. It is envisaged that the zonal Steering Committee (zonal SC) will play an important role in the allocation of work as regards renewal of authorisation of plant protection products (PPPs).

Article 43(2) focuses on the submission of new data or new information necessary as a result of progress in science or risk management. This may be important in the framework of the renewal of authorisations of mixed products, i.e. products containing more than one active substance, where several subsequent renewals of the authorisation become necessary (see section 3.11).

### **3. Renewal of an authorisation after renewal of approval of an active substance**

#### **3.1 Renewal of approval of the active substance**

In order to prepare an application for the renewal of an authorisation the applicant shall check the following.

The Renewal Assessment Report (RAR), including updates during the peer-review, as published by EFSA is considered helpful to make applicants aware of tests and studies which might fall under the provisions of Article 60(1). For (draft) RARs the reference lists at the end of each section/chapter (sorted by data point) should include the newly submitted data relied upon as well as the original submitted tests and studies that are still considered relevant to support the application for renewal. In addition the active substance Rapporteur Member State (RMS) (for the renewal of the approval of the active substance) should prepare the **list of all necessary studies**<sup>4</sup> (clearly identifying the 'new' and 'old' studies relied upon) as a stand-alone document **once the peer review has been finalised**.

According to Article 60(1), the finalised list shall be available at the time an active substance is renewed. However, to facilitate the re-authorisation process, the RMS should make **available the list of necessary studies by the time the EFSA Conclusion is published**; this list of references relied upon will also be made electronically available on the Commission's [Pesticide Database webpage](#), under each individual substance entry. Further guidance is provided in *Guidance Document on preparing lists of test and study reports according to Article 60 of Regulation (EC) No 1107/2009* (SANCO/12580/2012).

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<sup>3</sup> This means that a “coordinating MS” should in some way be able to ensure that the cost they have for this work is covered. If the zonal RMS also evaluates the application the application fee can cover the total work for the coordination and assessment.

<sup>4</sup> For the purpose of this guidance, the studies which were used in order “[to fulfil] data requirements or criteria which were not applicable at the time of the last approval of the active or because [the] request is for an amended [renewal of] approval” are named ‘necessary studies’ or ‘studies relied upon’.

It should be clear from the documents accompanying the renewal of approval where critical endpoints<sup>5</sup> have been changed during the active substance renewal procedure<sup>6</sup>. Preferably EFSA will highlight in the EFSA-Conclusions all endpoints which have been changed compared to the endpoints at the time of approval or latest renewal. An amended Review/Renewal<sup>7</sup> Report and Renewal Assessment Report accompanied by a “List of Endpoints” should be prepared according to the *Template to be used for Assessment Reports* (SANCO/12592/2012) and the *Template to be used for the List of Endpoints* (SANCO/12483/2014) taking into account the *Guidance Document on rules for revision of assessment reports* (SANCO/10180/2013). This is one of the crucial elements for the implementation of an efficient and streamlined procedure in MSs to renew authorisations.

### **3.2 Existing vs. pending authorisations**

Art. 43 allows applicants to renew their products in the MS(s) where they hold an national authorisation (existing authorisations).

For authorisations still pending during the last steps of the renewal of the active substance, the zonal RMS should decide on the granting of the authorisation for the new product before the date of application of the renewal of the active substance in order to allow the art. 43 procedure to apply. As this authorisation will be based on the old list of end-points, the applicant should apply within the legal deadlines to renew the product. Concerned MS (cMS) should grant the authorisation in their own territory, following the authorisation by the zonal RMS, within the 120 days and within 3 months of the DoA of the renewal regulation.

The section about delayed renewals (see section 3.10) cannot apply here and pending authorisations should be finalised, granted or refused before the date of renewal.

Where the zonal RMS cannot grant the authorisation before the date of application of the renewal of the active substance, the applicant will need to provide a new application in accordance with Article 33 of the Regulation and only an authorisation according to the conditions of renewal of the active substance may be granted.

### **3.3 Allocation of the zonal RMS**

The assessment of the product shall be coordinated by the zonal RMS. In order to start planning in advance, the zonal RMS should be appointed well before the application for renewal of authorisation is submitted. It is recommended that the zonal RMS allocation is performed before publication of the EFSA conclusions on the active substance. According to the gained experience, allocating zonal RMS by tranches is more efficient (e. g. the AIR3 program is split into 10 batches in which related products were allocated by tranches).

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<sup>5</sup> 'Critical endpoints' are endpoints related to the criteria as laid down in Annex II, point 4 of Regulation (EC) No 1107/2009.

<sup>6</sup> This procedure for emphasising the changes of end-points will be clarified further in an update of the guidance on renewal of active substances.

<sup>7</sup> Reg. (EC) 844/2012, especially its art. 14, states that COM issues a renewal report as a background document for the renewal of active substances.

The Zonal Steering Committees<sup>8</sup>, or MSs on behalf of the zonal SCs, should contact all the authorisation holders for products containing a substance to be renewed, asking whether and in which zonal RMS they intend to seek the renewal of their authorisation.

In the case of multiple applicants for renewal of authorisations of products with the same active substance they shall be encouraged to cooperate as regards their proposal of a common zonal RMS prior to application, where possible. Zonal SCs are also encouraged to assign zonal RMS on an active-substance basis where possible, rather than to only deal with the authorised products in their national territories.

Zonal SCs will have final decision on who will act as zonal RMS and who will inform the applicant about this decision. In most of the cases, it is part of the role of the zonal RMS to confirm this information. There may be several applicants who intend to submit applications for re-authorisation.

### **3.4 Application by authorisation holder**

Within 2 months following the publication of the EFSA-conclusion, the following information<sup>9</sup> should be provided by the authorisation holders to the zonal RMS and copied to the concerned MSs:

- The template<sup>10</sup> to notify intended zonal applications;
- Indication which parts of the risk assessment need updating (preferably agreed in pre-submission meetings with zonal RMS) – see below;
- An indicative "data matching list" regarding references relied upon (where relevant) and where necessary the "data matching program" (see section 3.7.2 and point 4 of section 3.5).
- Indication of agreement on the studies which are needed and where possible an expected timeframe;

Because data protection is decided at national level under Regulation (EC) No 1107/2009 the zonal RMS will not be able to conclude on data protection for all studies to be submitted and for all MSs. The applicant may seek advice from the individual MS about the status of protected /non-protected studies. Please see also 3.8.

Within 3 months of the date of application<sup>11</sup> of the renewal of approval of an active substance all authorisation holders must apply to renew the authorisations of plant protection products containing that active substance in the MS where they have an existing authorisation and wish to renew it. At the same time the applications should

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<sup>8</sup> Or the Inter-zonal Steering Committee (inter-zonal SC), where relevant. See footnote 2.

<sup>9</sup> It should be noted that the zonal RMS should be provided these pieces of information where there is a pre-submission meeting.

<sup>10</sup> "Template to notify intended zonal applications under Article 33 and Article 43 of Regulation (EC) No 1107/2009 (SANCO/12544/2014)

<sup>11</sup> A regulation renewing the approval of an active substance in general enters into force on the twentieth day following that of its publication in the Official Journal of the European Union. The date that the regulation shall apply is specified ('date of application' – DoA).

be launched in the *EU Plant Protection Product Application management System (PPPAMS)* by the applicants<sup>12</sup>.

As some parts of the dossier will be assessed by the RMS of the active substance (see sections 3.7.2 and 3.7.3), the applicants should submit a copy of the relevant sections to the RMS.

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

- A copy of the authorisation;
- Any new information required as a result of amendments in data requirements, guidance<sup>13</sup> in place by the time of the application date and criteria (changes to endpoints arising from the active substance renewal);
- Evidence/justification that the new data submitted are the result of data requirements, new guidance<sup>13</sup> in place by the time of the application date or criteria which were not in force when the authorisation of the plant protection product was granted or necessary to amend the conditions of approval. A template is provided in Appendix I;
- Any information to demonstrate that the product complies with the requirements (conditions and restrictions) set out in the Regulation on the renewal of the approval of the active substance;
- A report on the monitoring information, where the authorisation was subject to monitoring;
- A comparative assessment dossier should be submitted according to the relevant guidance, where necessary.

Data requirements (DR) that will apply, according to amended Regulation (EU) 283/2013<sup>14</sup> and the guidance document on transitional measures (SANTE 11509/2013 rev. 5.2 or higher)<sup>15</sup>:

- Products containing AIR2<sup>16</sup> active substances only – Old product DRs apply at renewal
- Products containing an AIR2 active substance and an AIR3<sup>17</sup> active substance – Old product DRs at renewal of the AIR2 active substance and new product DRs at renewal of the AIR3 active substance.

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<sup>12</sup> If the existing authorisation to be renewed is not contained within PPPAMS, applicants should in the first instance contact the zRMS and ask for advice on how to submit the application.

<sup>13</sup> MSs should only consider guidance documents for product risk assessment available at the time of application for renewal of the product. Any new Guidance for deriving end-points for active substances should not be taken into account as the risk assessment should rely on the EU agreed end-points at the renewal of the active substance.

<sup>14</sup> Regulation (EU) No 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 and Regulation (EU) No 1136/2014 amending Regulation (EU) No 283/2013 as regards the transitional measures applying to procedures concerning plant protection products

<sup>15</sup> Guidance Document on the Interpretation of the Transitional Measures for the Data Requirements for Chemical Active Substances and Plant Protection Products According to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013

<sup>16</sup> AIR2: second program for the renewal of approval of active substances

- Products containing an AIR2 active substance and an AIR3 active substance which will expire within 12m of one another – Old product DRs
- Products containing AIR3 active substances only – New product DRs apply at renewal
- Products containing AIR3 active substances and other active substances (excluding AIR2 active substances) – New product DRs.

In addition the applicant should provide a list of intended uses including a statement that no significant changes compared to previous authorisations (in the zone) exist. In this list minor uses should be taken up in the Good Agricultural Practices (GAP) separately, according to the EU GAP table format<sup>18</sup>. A significant amendment of the GAP should be accepted only when it is necessary in order to comply with changes in the assessment of the active substance (new endpoints, new guidance applied, conditions or restrictions in the renewal regulation) provided that the applicant can submit all necessary supporting information, including a justification for Category 4 ('Cat. 4') data (see 3.7.3). Only non-significant formulation changes according to the guidance document on formulation changes<sup>19</sup> may be included in applications according to Article 43. In principle all other kinds of applications for amendments or new uses should be dealt with under Article 33, 38 or 40.

A dossier clearly indicating where there is new information, not previously reviewed in the zone, is required (at the latest 3 months after the renewal of the active substance). The assessment of the new information should reflect the guidance applicable at the time of application. This dossier should be product-specific. However applicants can share studies, according to Article 61.

A complete draft registration report, according to *the Guidance document on the presentation and evaluation of dossiers in the format of a (draft) Registration Report (SANCO/6895/2009)*, in which the changes to the risk assessment are highlighted should be submitted, except where Cat. 4 data apply or the product is a mix of active substances renewed within 12 months: see point 4 section 3.5 and Appendix III.

Where an authorisation holder applies for the renewal of the same products containing the same renewed active substance to different zones, information on all the applications should be made available to all the MSs in order to facilitate the exchange of information between them.

In terms of efficacy, applicants should use the template in Appendix I to identify, and justify the submission of new studies according to the above-mentioned provisions. Where a GAP change is triggered e.g. by new endpoints, new guidance<sup>13</sup>, efficacy data addressing the new GAP should be submitted. Otherwise, for renewal applications, only resistance data are required.

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<sup>17</sup> AIR3: third program for the renewal of approval of active substances

<sup>18</sup> This template is laid down in the GD on the Presentation and Evaluation of Dossier according to Annex III of Directive 91/414/EEC in the Format of a (Draft) Registration Report (SANTE/6895/2009, rev. 20 March 2015 or later).

<sup>19</sup> Guidance Document on Significant and Non-Significant Formulation Changes (SANCO/12638/2011, rev. 2 20 November 2012 or later)



### 3.5 Missing data

The following circumstances can result in data being outstanding:

1. Category 1: Data identified by EFSA as data gaps but which are not reflected in the regulation renewing the approval of the active substance;
2. Category 2: Data which are related to a request for confirmatory information as foreseen in Article 6 or in Annex II, point 2.2 of Regulation (EC) No 1107/2009. This will concern at least products that have same or similar uses as the representative uses. In the GD on confirmatory information it is indicated that in this case MSs should not delay the product re-authorisation. So in the framework of the re-authorisation process there should not be a need for an extension of the authorisation period; the assessment of the application should be undertaken without referral to the confirmatory information provided that the requirements of Article 29 are met (see Guidance document on confirmatory information<sup>20</sup>).
3. Category 3: Data which are related to a request for confirmatory information in the case of AIR-2 substances<sup>21</sup> which do not need to comply with the provisions of Regulations (EU) No 283/2013 and 284/2013. Confirmatory information (e.g. exposure via guttation) may be requested in line with the new data requirements according to Article 6(f). In this case also the assessment of the application for renewal of the authorisation should be undertaken without referral to the confirmatory information.
4. Category 4: Data which are directly related to new guidance<sup>13</sup> in place at the time of submission or to a new/revised endpoint decided at the time of the renewal of the approval of the active substance (endpoints as listed in the supporting information to the EFSA conclusions) and for which the time is too short from the publication of the EFSA conclusion to produce the requested study. This can be the case when e.g. a higher tier study (mesocosm) is required based on new endpoints for aquatic toxicity, new residue trials are needed because of a new residue definition or efficacy data are considered necessary because of an amended GAP or for resistance issues.
5. Category 5: Data related to new data requirements or new guidance explicitly mentioned in the renewal regulation, e.g. endocrine disruptor effects for which currently the following statement is included in approval decisions: *“The applicant shall submit confirmatory information as regards the potential for endocrine disruptor effects in birds and fish to the Commission, the Member States and the Authority within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, of Community agreed test guidelines”*. Again this is a request for confirmatory information according to Article 6(f). In this case also the assessment of the application for renewal of the authorisation should be undertaken without referral to the confirmatory information.

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<sup>20</sup> Guidance Document on the procedures for submission and assessment of confirmatory information following approval of an active substance in accordance with Regulation (EC) No 1107/2009 (SANCO/5634/2009 rev. 6.1 or later)

<sup>21</sup> Applications for the renewal of approval of substances following the procedure of Regulation (EU) No 1141/2010.

The applicant must provide an appropriate justification for each situation where data is missing.

In category 1, such a data gap will in most of the cases not have an impact on the re-authorisation procedure. The product can be re-authorised, provided that these data are not necessary to show a safe use of the product.

In categories 2, 3 and 5, the MSs will have to complete the assessment of the product without these data, because it is linked to a request for confirmatory information. As it has been found acceptable to renew the approval of the active substance awaiting the submission and evaluation of confirmatory information at European level, the same logic should be followed when evaluating the application for re-authorisation of the plant protection product on the national and zonal level. This means that the authorisation should be maintained pending the outcome of the evaluation of the confirmatory data, provided that the requirements of Article 29 are fulfilled.

In category 4, the applicant needs to justify the lack of data by the fact that it could not anticipate this request before EFSA conclusions for the substance were available. Proof of, or commitment to, initiation of the study and an expected finalisation date are to be provided. These pieces of information may be related to either active substance or formulated product data requirements. However data falling under the scope of Article 38 (new source of technical material<sup>22</sup>) cannot be considered according to this paragraph. Where the applicant makes a reference to Cat. 4 data, the application should contain a **statement confirming that the product for which the authorisation is to be prolonged and renewed still complies with Article 29** (see section 3.4 and Appendix II) Appendix II

#### **Re-authorisation OF PPPs UNDER REGULATION (EC) No 1107/2009 AFTER RENEWAL OF APPROVAL OF AN ACTIVE SUBSTANCE (ART. 43) – SCHEMATIC IF ALL DATA ARE AVAILABLE AT THE APPLICATION DATE**

). The template in Appendix I should be used. Where the zonal RMS may find it justified to apply Article 43(6), it should extend the expiry date of the authorisations in order to allow sufficient time for the data to be generated, submitted and assessed. See section 3.9 and Appendix III for an explanation of what information is required at which time point.

The applicant should submit a justification for each data point for which not all information as specified in Article 43(2) can be submitted at the three months deadline. The renewal dRR and the Cat. 4 studies should be submitted within 3 months of the final Cat. 4 study being finalised (see section 3.9 and Appendix III).

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<sup>22</sup> Applicants seeking to have a new source assessed should submit their request under Article 38 early enough to have it declared equivalent before Article 43 processes are launched. See section 3.7.1.

The guidance to be used for delayed renewal assessments is still the guidance that was in place at the time of the original application for product renewal.

### **3.6 Non-application for renewal**

If an application to renew the authorisation of a plant protection product, or some of the uses of a product, is not submitted within 3 months of the renewal of an active substance contained in that product, the authorisation will not be extended and will expire in line with Article 32. MSs may grant a grace period in accordance with Article 46.

### **3.7 Dossier assessment for the renewal of the authorisation**

#### *3.7.1 Compliance with the conditions of renewal of the active substance*

**Compliance of the authorised products and/or uses** with the conditions and restrictions in the regulation renewing the approval should be verified by each concerned MSs individually.

Applications should include a **separate signed statement** from the authorisation holder indicating that the **existing products, uses and sources of active substances comply with any restrictions or conditions detailed in the renewal regulation**.

Any product (or use) which does not comply with the renewal restrictions by the end of the 3-month period after the renewal of the active substance, is not eligible for authorisation renewal. Their authorisation will expire in line with Article 32, unless the provisions of Article 29 are no longer fulfilled. MSs could grant grace periods according to Art. 46.

#### *3.7.2 Data matching check*

The data matching check should be **performed by the active substance RMS** as soon as possible after the 3 month deadline for application (ideally **within a month**). During data matching, the following information could be used to address the data requirement set in Reg. (EU) 283/2013:

- By providing argumentation from published literature or non-protected data why a study is not required;
- Through a Letter of Access;
- By repeating the study.

The applicant should provide the information requested above using the harmonised template for data matching studies<sup>23</sup>. The RMS should check whether the studies submitted were conducted according to Good Laboratory Practices (GLP), used the

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<sup>23</sup> Templates for Submission Demonstrating Access to a Complete Package According to Regulation (EU) 283/2013 and for the Data Matching Step

same methodology as the data to be matched and that the endpoint was within the same order of magnitude as the reference study.

Under certain circumstances (e.g. change of the EU endpoints – see point 4 in section 3.5), it may be possible that some missing data matching studies could be justified as category 4 data for alternative authorisation holders, unless the changes are provided in the active substance renewal regulation. They should be fully justified according to section 3.5. Along with the conclusion on data matching, the active substance RMS should state within a month whether the justifications for consideration of some missing data matching studies as Cat. 4 data are acceptable or not. Where they are agreed, the RMS should set a deadline for their submission<sup>24</sup>.

Once a Cat. 4 extension for data matching studies is agreed by the RMS for a product authorisation, that authorisation will be allowed to continue until a decision is taken on renewal of the product, provided that the complete dossier (including the Cat. 4 data) is submitted to the RMS by the agreed dossier submission deadline. If no submission is made by this date, or if a submission is made but is considered incomplete by the RMS, then the authorisation will be immediately revoked. MSs could grant grace periods according to Art. 46. The applicant would then need to make an Art 33 application to re-instate their product once the data matching studies were available.

This decision on data matching and Cat. 4 data (scope and date of submission) should be followed by the zonal RMSs and the cMSs in their territory. However the MSs also have the responsibility for ensuring that the protection standards as laid down in the Regulation are respected. See Appendix III for an explanation of what information is required at which time point.

### *3.7.3 Source specification check*

**Where change of the reference minimum specification occurs**, including impurity maximum levels, authorisation renewal dossiers can only rely **on those sources already declared equivalent and compliant with the new criteria**. The applicant may provide a reasoned argument justifying that its source can still be considered equivalent to the EU reference source.

In this case, the RMS should only **check the declared minimum purity and the maximum content for relevant impurities**.

### *3.7.4 Assessment of the justification for Cat. 4 missing (product) data*

When a submitted dossier mentions Cat. 4 product data, the zonal RMS should assess the justification submitted according to paragraph 3.5. This check should be performed **within a 1-month period** after the submission of the dossier to renew the authorisation, in parallel to the data matching step performed by the RMS for the active substance (see section 3.7.2). Where the zonal RMS may find it justified to

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<sup>24</sup> Please note that the deadline for Cat. 4 data matching study submission can be different to the one set for missing cat. 4 product data.

apply Article 43(6), it should extend the expiry date of the authorisations in order to allow sufficient time for the data to be generated, submitted and assessed.

Where the renewal of the same product is sought in different zones, zonal RMSs are encouraged to reach an interzonal decision regarding the use of Art. 43(6).

In case the Cat. 4 data are not sufficiently justified, the dossier should be considered as incomplete and the related authorisations should be withdrawn: Articles 32 and 46 apply.

This decision should be followed by the cMS in their territory. Where the same product is authorised in different zones (see section 3.3), zonal RMSs are encouraged to reach an agreement on Cat. 4 data over the interested zones. However the MSs also have the responsibility for ensuring that the protection standards as laid down in the Regulation are respected. See Appendix III for an explanation of what information is required at which time point.

Once a Cat. 4 extension for product studies is agreed by the zonal RMS for a product authorisation, that existing authorisation will be allowed to continue untouched until a decision is taken on renewal of the product, provided that the complete dossier (including the Cat. 4 data) is submitted to the zonal RMS by the agreed dossier submission deadline. If no submission is made by this date, or if a submission is made but is considered incomplete by the zonal RMS, then the authorisation or the related uses will be immediately revoked. MSs could grant grace periods according to Art. 46. The applicant would then need to make an Art 33 application to re-instate their product once the missing studies were available.

### **3.7.5 Product risk assessment**

The zonal RMS assesses all the new information as provided in the dRR, which includes the conditions or restrictions of the approval (e.g. ‘MS shall pay particular attention to..’) and the fulfilment of requirements of Article 29. It takes into account all the relevant GAPs notified within the zone. Where different zonal RMS are assigned products containing the same active substance within a zone, exchange of information is recommended, even if no commenting period is provided or possible.

Where a GAP change is necessary, efficacy data addressing the revised GAP should be assessed. If not, only information about resistance should be assessed in the efficacy section.

Where Cat. 4 product data have been accepted and submitted on time, the assessment should be undertaken by the zonal RMS within 6 months after the submission of the dRR.

When necessary, and **only where no new data are needed**, the zonal RMS may consider **requesting further information or clarification from the applicant**. As there is no legal provision to stop the clock pending the submission of additional information, requesting further information may affect the ability of the zonal RMS to

deliver to target. They should quickly update cMSs of any impact on the assessment timelines.

Aside the final RR, the zonal RMS should provide **the list of studies relied upon for the product renewal**.

It should be noted that when a zonal RMS assesses a product or a use not authorised in its national territory, the assessment should be limited to evaluating the core dossier. The release of the final RR (i.e. the upload of the final RR on CIRCABC<sup>25</sup>) should then trigger the evaluation in the cMSs.

### **3.8 Assessment by other Member States**

The task of MSs within the 12-month period or a longer period in case an extension is granted under Article 43(6), referred to in Article 43(5) is to take a decision on whether or not to renew the authorisation in their MS. See Appendix II.

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

The applicant should add a section to the application presenting the benefits of the products to be considered by authorities when conducting comparative assessment with alternative control solutions. This should be presented in the format of the template provided in the appendix to the *Guidance document on Comparative Assessment and Substitution of Plant Protection Products in accordance with Regulation (EC) No 1107/2009* (SANCO/11507/2013).

Further guidance on the procedures and various elements of comparative assessment are also provided in the aforementioned Guidance Document on comparative assessment.

The list of all references relied upon as prepared by the zonal or inter-zonal RMS is considered a useful tool in deciding on data protection. The precise data protection position will have to be determined by each MS individually. Article 59(1) of Regulation (EC) No 1107/2009 provides for 30 months period of data protection if the data were necessary and never previously protected<sup>26</sup> for the renewal of an authorisation. The duration of this period should start at the moment of the applicability of the decision on the renewal of the authorisation (also in cases the submission of information takes place in two phases). Further guidance on the procedures and policies surrounding various elements of data protection is provided in the *Guidance Document on data protection* (SANCO/12576/2012) and the *Guidance Document on preparing lists of test and study* (see section 3.1).

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<sup>25</sup> See Guideline for Post Annex I uploaders in Member States on managing Post Annex I inclusion documents on CIRCA BC (SANCO/04846/2009 rev. 7)

<sup>26</sup> The Guidance on Data Protection contains all the information regarding rules and cases where and how long studies may be protected. For the interplay between data protection for new authorisations or renewal data protection, please refer to section 1.

Authorisations of products for which a full data package or access to a full data package is not available at that point shall not be renewed and will expire in line with Article 32. A grace period may be granted in accordance with Article 46 by that MS.

### 3.9 Timelines

**The zonal RMS should complete its assessment of the new information and provide the results to other MSs in the same zone electronically (via CIRCABC) 6 months after the submission deadline for the renewal application (this period includes a 3 week commenting time for the applicant and the MSs of the relevant zone(s)). At the same time the results of its assessment should be communicated to the applicant. This allows three months for the other MSs to conduct comparative assessment (if necessary) and to decide on the renewal of their authorisations (see Appendix II Appendix II**

### **RE-AUTHORISATION OF PPPs UNDER REGULATION (EC) NO 1107/2009 AFTER RENEWAL OF APPROVAL OF AN ACTIVE SUBSTANCE (ART. 43) – SCHEMATIC IF ALL DATA ARE AVAILABLE AT THE APPLICATION DATE**

). After every step in the procedure the *EU PPP Application management System* should be updated respectively by the applicant or by the concerned MS to ensure all parties are aware of the status of applications during the complete process.

According to Article 32(1) the duration of an authorisation of a product shall not exceed one year from the date of the expiry of the approval of the active substance. For products with more than one active substance this will be the expiry date of the approval that expires the earliest.

If in circumstances **beyond the control of the applicant** more time is required, MS should extend the authorisation as provided for by Article 43(6) for the period necessary to complete the examination and to adopt a renewal decision. Circumstances 'beyond the control of the applicant' are circumstances where the applicant has not been able to complete the dossier (circumstances as listed under point 4 in chapter 3.5) or where the MS is not able to complete the examination and to adopt a renewal decision within the prescribed timeframe. zonal RMSs are encouraged to agree on common deadlines for products containing the same active substances, when applying art. 43(6). These deadlines, where possible, should reflect the various justifications for prolonging the existing authorisations, so the authorisation is prolonged only once before a decision on renewal is made. **cMSs should follow the decision made by the (zonal) RMS** according to art. 43(6) (see sections 3.7.2 and 3.7.3).

### 3.10 Delayed renewal authorisation

Where the authorisation is extended as provided for by Article 43(6) each concerned MS must verify that the existing authorisation complies with the conditions and restrictions in the regulation renewing the approval as indicated in chapter 3.7.1 above. The zonal RMS should determine if all the new information is submitted only with the exception of the data related to circumstances as listed under point 4 in chapter 3.5. In the case of extension no draft Registration Report for the product has to be submitted by the applicant at the three months deadline. For detailed examples (“what is to be submitted when”) see Appendix III.

The data related to circumstances as listed under point 4 in chapter 3.5 should be submitted as soon as possible taking into account the time necessary to conduct the studies (generally within 2 years) to the zonal RMS who will evaluate within 6 months after submission. All MS should then take a decision within 3 months. Only in exceptional cases and in agreement with the zonal RMS a different time period for submission can be decided upon.

### **3.11 Products containing more than one active substance**

For products containing two or more active substances the applicant shall apply for a renewal of authorisation after the renewal of each active substance contained in the PPP. This should be followed by an evaluation/assessment of the PPP authorisation by the MS(s) to ensure that the product still complies with the requirements set by Article 29 of Regulation. As a consequence the PPP authorisation needs to be renewed after the renewal of the approval of each active substance contained in the product, respectively.

However, if the PPP contains two or more active substances and the approval of the second active substance expires within 12 months<sup>27</sup> of the first one, the zonal RMS and MSs should evaluate the data submitted for both active substances after the data for the second active substance are submitted. In this case the renewal decision for the PPP shall be issued within 12 months from the renewal of the second active substance. Where such an agreement has been reached, it is assumed on a general basis that there is no need to reconsider the question where the expiry dates of the active substances are changed.

In this case, while an application is required after each active substance renewal, MS and applicant should jointly agree that a dRR does not have to be submitted following the first active substance renewal (See Appendix III, ex. PPP containing 2 AS's for explanation of what information is required at which time point). Therefore the dossier should address the guidance in place at the time of the second submission date. This implies that where two different zonal RMS are assigned for a two-active-substance product, they should liaise to agree which one will act as zonal RMS.

Articles 32 and 43 of the Regulation do not specify how the duration of the authorisation should be set in the case of PPPs containing multiple active substances. In order to comply with the provisions of Article 32, the renewed –or “extended”-

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<sup>27</sup> A period of 12 months is appropriate because Article 43(5) stipulates that MSs shall decide on the renewal of an authorisation within 12 months.



authorisation should not exceed one year of the duration of the approval of the next active substance to expire.

For products containing two or more active substances -and when the 1<sup>st</sup> substance is renewed- there is no need to evaluate data related to the 2<sup>nd</sup> substance. For products containing two or more active substances -and once the 2<sup>nd</sup> substance is renewed- there is no need to evaluate data related to the 1<sup>st</sup> substance because this has already been performed in the frame of the re-authorisation of the PPP following the renewal of the 1<sup>st</sup> active substance. Where necessary a combitox assessment should be performed.

For PPPs containing more than one active substance where an assessment of the application for renewal of the authorisation will be carried out after the renewal of the approval of each active substance, each of these renewals of authorisation may trigger data protection. In case the renewal of the authorisation will take place only after the renewal of the second active substance, then the data protection will cover all the data submitted at different time points but will only start from the date of the renewal of the authorisation.

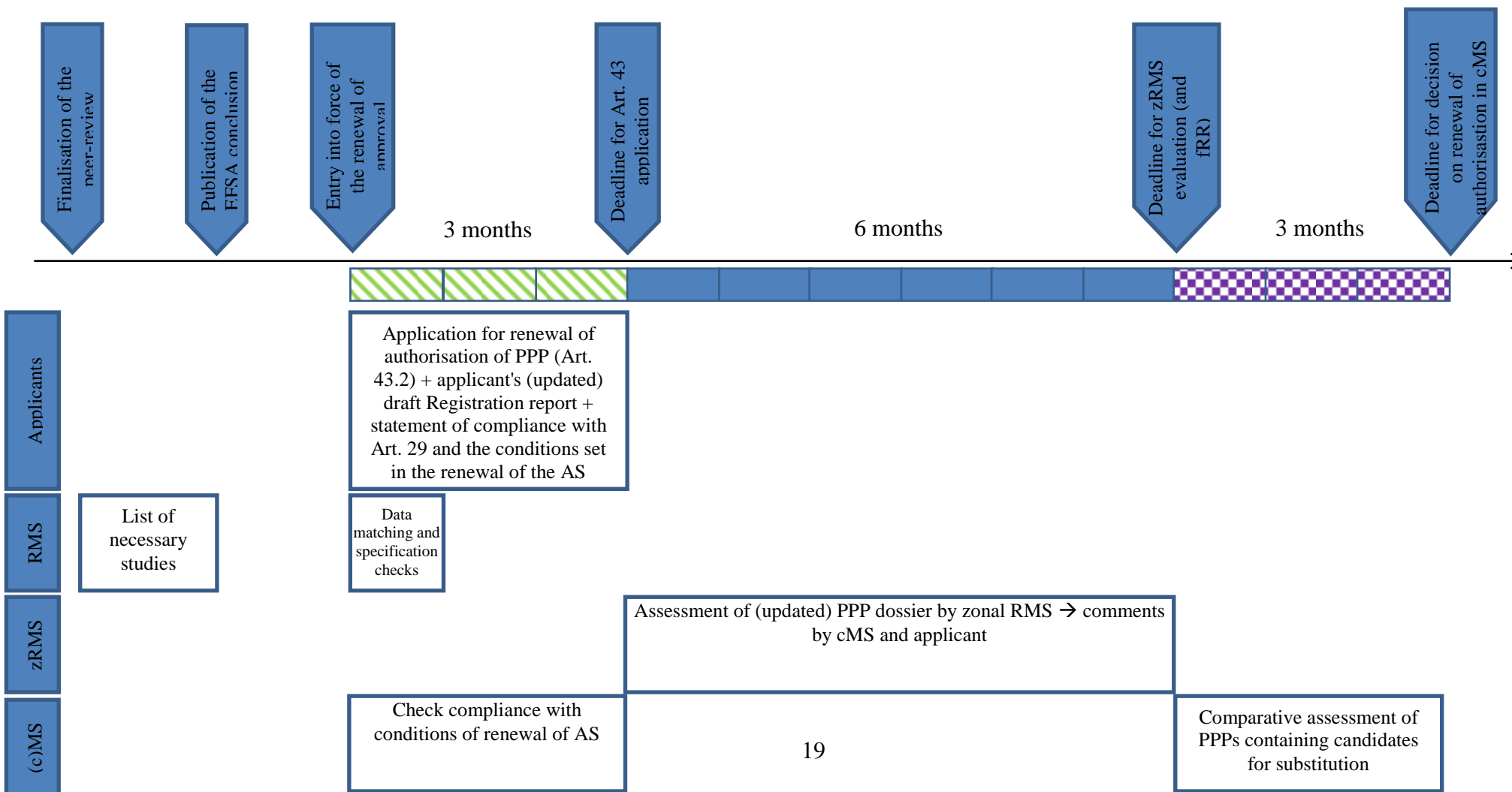
Appendix I

**PROPOSED TEMPLATE FOR THE STUDY LIST IN ARTICLE 43 APPLICATIONS**

<b>Annex Point</b>	<b>Study title (if available ) or study type</b>	<b>Study duration</b>	<b>Completion date/report number (if available)</b>	<b>Justification (including if study is a cat4 study)</b>
XX	Field trials.....		2017-10-15	Efficacy data required following change in endpoint for AI_ Cat 4 study

## Appendix II

### RE-AUTHORISATION OF PPPs UNDER REGULATION (EC) NO 1107/2009 AFTER RENEWAL OF APPROVAL OF AN ACTIVE SUBSTANCE (ART. 43) – SCHEMATIC IF ALL DATA ARE AVAILABLE AT THE APPLICATION DATE



## Appendix III

### EXAMPLES OF “WHAT TO BE PROVIDED WHEN BY THE APPLICANT/AUTHORISATION HOLDER”

PPP containing	Scenario	3 months after DoA <sup>28</sup> of the 1 <sup>st</sup> AS	3 months after DoA of the 2 <sup>nd</sup> AS	2 years <sup>h</sup> after DoA of the 1 <sup>st</sup> AS*	2 years <sup>h</sup> after DoA of the 2 <sup>nd</sup> AS*
<b>1 active substance</b>	All studies necessary available at time of application	Application, all studies necessary, dRR, statement of compliance	-	-	-
	“Cat 4” studies missing at time of application	Application, all studies available, study list (including timetable and justification), statement of compliance	-	“Cat. 4” studies , complete dRR	-
<b>2 active substances (expiry dates within 1 year)**</b>	All studies necessary available at time of application for both active substances	Application, all studies necessary, statement of compliance	Application, all studies necessary, complete dRR, statement of compliance	-	-
	“Cat 4” studies missing at time of application for the 1 <sup>st</sup> active, complete for the 2 <sup>nd</sup> active	Application, all studies available, study list (including timetable and justification), statement of compliance	Application, all studies necessary, statement of compliance	“Cat. 4” studies for the 1 <sup>st</sup> active, complete dRR	-
	“Cat 4” studies missing at time of application for the 2 <sup>nd</sup> active, complete for the 1 <sup>st</sup> active	Application, all studies necessary, statement of compliance	Application, all studies available, study list (including timetable and justification) , statement of compliance	-	“Cat. 4” studies for the 2 <sup>nd</sup> active , complete dRR
	“Cat 4” studies missing at time of application for both actives	Application, all studies available, study list (including timetable and justification), statement of compliance	Application, all studies available, study list (including timetable and justification) , statement of compliance	“Cat. 4” studies for the 1 <sup>st</sup> active	“Cat. 4” studies for the 2 <sup>nd</sup> active , complete dRR

<sup>h</sup> as soon as possible taking into account the time necessary to conduct the studies (e.g. 2 years)

\* unless agreement by RMS and/or zRMS on a different time period for submission

\*\*for actives with an expiry date >1 year: scenarios as for PPP containing 1 active have to be followed

"Cat. 4" studies are data related to circumstances as listed under point 4 in chapter 3.5

<sup>28</sup> DoA refers to the date of application of the renewal regulation