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

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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).

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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 Regulation (EC) No 1107/2009.

It starts from the basic principle that products which will be renewed under Regulation (EC) No 1107/2009 have already been authorised in accordance with the Regulation (EC) No 1107/2009 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 based on active substances for which approval is renewed under the Regulation (EC) No 1107/2009, 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 entry into force of the decision on the renewal of the approval of an active substance. This application 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)**[1]. Within 12 months of the renewal of approval of an active substance, Member States (MS) have to decide on renewal of authorisations (Article 43(5)). This gives the zonal RMS the role of a coordinator, but the zonal RMS is not necessarily assessing the information submitted.[2] It is envisaged that the zonal Steering Committee will play an important

[1] Or inter-zonal rapporteur Member State in the case of an inter-zonal assessment (e.g. seed treatment).
[2] 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 ZRMS also evaluates the application the application fee can cover the total work for the coordination and assessment.

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.

3. Renewal of an authorisation after renewal of approval

3.1 Renewal of approval of the active substance

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

The Renewal Assessment Report (RAR) 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. However these studies should be clearly identified in the reference list as well as in the individual study sections. In addition the RMS (for the renewal of the approval of the active substance) should prepare the list of all references relied upon (clearly identifying 'new' and 'old' studies) as a stand-alone document after the peer review has been finalised. The finalised list should be available at the time of voting in the Standing Committee. However, to facilitate the re-authorisation process it is recommended that the RMS makes available the list of test and study reports according to Article 60(1) already at the time the EFSA Conclusion is published (on request by non-notifying companies); this list of references relied upon will also be made available electronically. 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).

It should be clear from the documents accompanying the renewal of approval where critical endpoints[3] have been changed during the active substance renewal procedure. 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 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] 'Critical endpoints' are endpoints related to the criteria as laid down in Annex II, point 4 of Regulation (EC) No 1107/2009.

3.2 Allocation of the zonal RMS

The procedures outlined in the *Guidance Document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009 (SANCO/13169/2010)* should be followed to appoint the zonal RMS. The Zonal RMS should be appointed preferably before publication of the EFSA conclusions on the active substance.

In order to plan the work properly and appoint the zonal RMS in advance to the planned application, information is required from the applicant/authorisation holder of the respective PPP. The information required is summarized in the "*Template to notify intended zonal applications under Article 33 and Article 43 of Regulation (EC) No 1107/2009* (SANCO/12544/2014).
This information should be submitted by the authorisation holder(s) to the concerned MS(s) (national contact points) by the deadline for the submission of the supplementary dossier for the renewal of the active substance.

The assessment for the product should normally be conducted by the zonal RMS. As planning will start in advance the zonal RMS should be appointed well before the application for renewal of authorisation is submitted. In the case of multiple applicants for renewal of authorisations with the same active substance they shall be encouraged to cooperate as regards the selection of a common zonal RMS prior to application, where possible.

Within the zonal Steering Committees it will be finally decided who will act as zonal RMS and who will inform the applicant about this decision. There may be several applicants who intend to submit applications for re-authorisation.

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

- The "updated template" to notify intended zonal applications;
- Indication of agreement on the studies which are needed and where possible an expected timeframe;
- Indication which parts of the risk assessment need updating (preferably agreed in pre-submission meetings with ZRMS);
- A "data matching list" regarding references relied upon (where relevant).

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 MS. 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 reports according to Article 60 of Regulation (EC) No 1107/2009* (SANCO/12580/2012). The applicant may seek advice by the individual MS about the status of protected /non-protected studies.

3.3 Application by authorisation holder

Within 3 month after the *date of application*[4] of the decision on the renewal of an 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 be included into the *EU PPP Application management System* by the applicants.

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, and criteria (changes to endpoints arising from the active substance renewal);
- evidence/justification that the new data submitted are the result of data requirements or criteria which were not in force when the authorisation of the plant protection product was granted or necessary to amend the conditions of approval;
- 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;

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) exists. An amendment of the GAP should be accepted when it is necessary in order to comply with changes in the assessment of the active substance (new endpoints, conditions or restrictions in the renewal regulation) provided that the applicant can submit all necessary supporting information and a justification. In principle all other applications for amendments or new uses should be dealt with under Article 33 or 40. Only non-significant formulation changes according to GD SANCO/12638/2011 may be included in applications according to Article 43.
A dossier clearly indicating where there is new information, not previously reviewed in the zone, is required (3 months after the renewal of the active substance). The assessment of this new information should reflect the guidance applicable at the time of application. A complete draft registration report, according to *the Guidance document on the presentation and evaluation of dossiers according to annex III of Directive 91/414/EEC in the format of a (draft) Registration Report* (SANCO/6895/2009), in which the changes to the risk assessment are highlighted should be submitted.

The following circumstances can result in data being outstanding:

1. Data identified by EFSA as data gaps but which are not reflected in the regulation renewing the approval of the active substance;

[4] 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'*).

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 (see *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)).

3. Data which are related to a request for confirmatory information in the case of AIR-2 substances[5] 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. Data which are directly related to a (new) endpoint decided at the time of the renewal of the approval of the active substance (endpoints as listed in the EFSA conclusions) and for which the time is too short from the publication of the EFSA conclusion (because it is a re-authorisation of a PPP) 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. Proof of (commitment to) initiation of the study and an expected finalisation date are to be provided.

5. Data related to new data requirements or new guidance, 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.

The applicant must provide an appropriate justification for each situation where data is missing.
In category 1, such a data gap will not have an impact on the re-authorisation procedure and the product can be re-authorised.
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

[5] Applications for the renewal of approval of substances following the procedure of Regulation (EU) No 1141/2010.

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 all other protection standards are respected.
In category 4, the applicant may justify the lack of data by the fact that it could not anticipate this request before EFSA conclusions for the substance were available and a MS may find it justified to apply Article 43(6) and extend the authorisation and delay the re-authorisation- but the MS also has the responsibility for ensuring that the protection standards as laid down in Regulation (EC) No 1107/2009 are respected. (See Appendix II 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.

3.4 Non-application for renewal

If no application to renew the authorisation of a plant protection product is submitted within 3 month after the date of application of the renewal regulation 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.

3.5 Assessment by zonal RMS

Compliance with the conditions and restrictions in the regulation renewing the approval should be verified by each concerned MSs individually. The data matching check should be performed by the active substance RMS as soon as possible after the 3 month deadline for application. The zonal RMS assesses 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..’).

3.6 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.

Comparative assessment for products containing candidates for substitution will need to be conducted in all cases by all MSs individually where an application for renewal of authorisation is made. Such assessments should address the criteria foreseen in Article 50(1).
The applicant should add to his application a section presenting the benefits of the products to be considered by authorities when conducting comparative assessment

with alternative control solutions preferably according to 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 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). 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.

3.7 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 receipt of the information (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 I). After every step in the procedure the *EU PPP Application management System* should be updated respectively by the applicant or by the concerned MS.

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 3.3) or where the MS is not able to complete the examination and to adopt a renewal decision within the prescribed timeframe.

3.8 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 3.5 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 3.3. 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 II.

The data related to circumstances as listed under point 4 in chapter 3.3 should be submitted as soon as possible taking into account the time necessary to conduct the studies (generally within 2 years) to the ZRMS 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.

3.9 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). As a consequence the PPP authorisation must 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[6] of the first one, zRMS 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. 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 II, ex. PPP containing 2 AS's for explanation of what information is required at which time point).

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

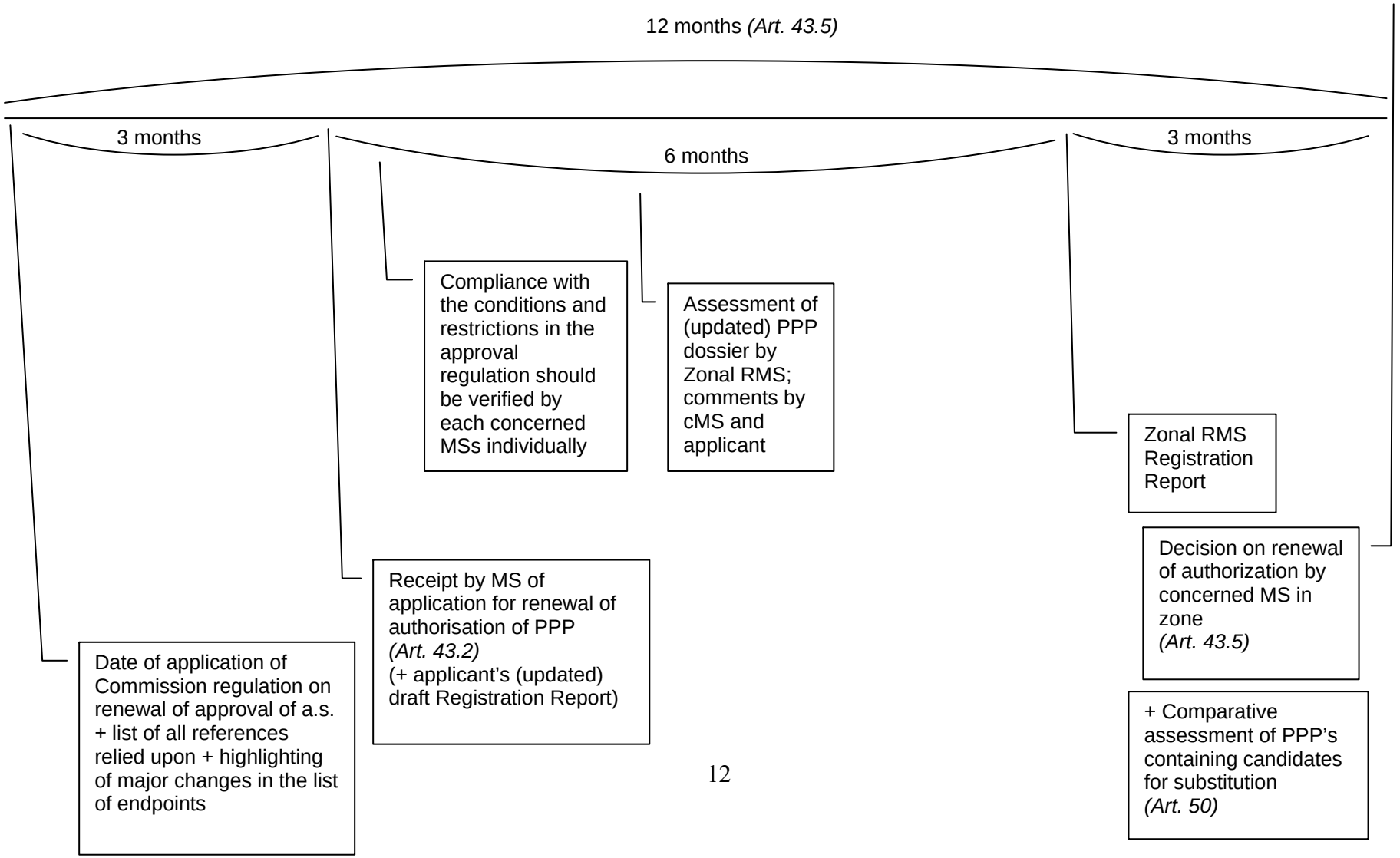
For products containing two or more active substances -and when the 1st substance is renewed- there is no need to evaluate data related to the 2nd substance. For products containing two or more active substances -and once the 2nd substance is renewed- there is no need to evaluate data related to the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

[6] 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.

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

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 II: EXAMPLES OF "WHAT TO BE PROVIDED WHEN BY THE APPLICANT/AUTHORISATION HOLDER"

PPP containing	Scenario	3 months after DoA[7] of the 1st active	3 months after DoA of the 2nd active	2 yearsñ after DoA of the 1st active*	2 yearsñ after DoA of the 2nd active*
1 active substance	All studies necessary available at time of application	Application, all studies necessary, dRR	-	-	-
	"Cat 4" studies missing at time of application	Application, all studies available, study list (including timetable and justification)	-	"Cat 4" studies , dRR	-
2 active substances (expiry dates within 1 year)**	All studies necessary available at time of application for both active substances	Application, all studies necessary	Application, all studies necessary, dRR	-	-
	"Cat 4" studies missing at time of application for the 1st active, complete for the 2nd active	Application, all studies available, study list (including timetable and justification)	Application, all studies necessary	"Cat 4" studies for the 1st active, dRR	-
	"Cat 4" studies missing at time of application for the 2nd active, complete for the 1st active	Application, all studies necessary	Application, all studies available, study list (including timetable and justification)	-	"Cat 4" studies for the 2nd active , dRR
	"Cat 4" studies missing at time of application for both actives	Application, all studies available, study list (including timetable and justification)	Application, all studies available, study list (including timetable and justification)	"Cat 4" studies for the 1st active	"Cat 4" studies for the 2nd active , dRR

[7] DoA refers to the date of application of the renewal regulation

fi as soon as possible taking into account the time necessary to conduct the studies (generally within 2 years)
* unless agreement 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 3.3