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	General comment			Need to keep consistency in wording : • Renewal is linked to Active Substance (AS), • Reauthorisation is linked to PPP.
	3 §2		Article 43(6) is a provision allowing the Member States with to extend the existing authorisation where a decision cannot be made due to circumstances beyond the applicant's control. This may be important in the framework of the renewal of authorisations where new endpoints from the AS renewal and/or the impact of guidance not implemented at the previous product authorisation result in the need for additional data that cannot be provided in time for the product application	There is a need to include a paragraph on Art 43(6) as this provision may have to be used by the Member States authorities.
	4	this list of references relied upon will also be made electronically available on the Commission's Pesticide Database webpage, under each individual substance entry.	this list of references relied upon ~~**will also be**~~ **is at the same time** made available electronically on the Commission's Pesticide Database webpage.	The list of studies is of utmost importance, especially in attempt to limit Cat4 studies. Therefore the list should be made electronically available at the COM database at soon as it is established. That will greatly help timely preparation of Article 43 dossiers.
	5 §3.2	Where the zonal RMS cannot grant the authorisation before the date of application of the renewal of active substance, only a new authorisation under art 33 of the regulation and according to the conditions of renewal may be granted.	Where the zonal RMS cannot grant the authorisation before the date of application of the renewal of active substance: • If the new list of endpoints does not affect the application already under evaluation, the evaluation should not be stopped and must continue. • If the new list of endpoints does affect the application already under	To clarify if applicants have to submit a new dossier or if they can just update their dossier with new endpoints and thus save time compared to a brand new dossier as they stay in the queue. The conditions for an authorization should be those under which a dossier was submitted. If the ZRMS (or cMS) is delayed due to reasons beyond the control of the applicant, the timelines in Art 37 should apply. It should not be

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			evaluation, the applicant should be given the opportunity and time to update the dossier, in order to allow finalisation of the evaluation within the same procedure, avoiding a new submission and new timelines of evaluation. **However zonal and concerned member states should endeavour to respect timelines for Article 33 applications. Where the timelines for Art 33 application is exceeded for pending authorisations MSs should consider prioritising evaluations or possibility of workshare with cMSs to ensure finalisation ongoing reviews.**	possible to cancel an application that was submitted well in time and request a re-submission, due to work load delays at the ZRMS or cMS. This generates severe unpredictability for the applicant, and prevents new products to enter the market.
	5 §3.3	The assessment of the product shall be coordinated by the zonal RMS.	The assessment of the product shall be coordinated by the zonal RMS **(in any case the zRMS should ensure that the evaluation to meet all MS renewals is fully addressed).**	Under 3.3 Allocation of zonal RMS; comment that zRMS is responsible for ensuring a complete evaluation is available
	5 §3.3	It is recommended that the zonal RMS allocation is performed before publication of the EFSA conclusions on the active substance.	~~**It is recommended that**~~ The zonal RMS allocation **has to be** performed before publication of the EFSA conclusions on the active substance.	A deadline should be set and the zRMS must be announced before EFSA conclusion as applicants are supposed to discuss the cat4 studies with the zRMS.
	5 § 3.3	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).	To be elaborated	The Excel sheets filled by applicants on the request of the zonal steering committees should be used for planning purposes. These can be updated at any time.
	6 §1	The Zonal Steering Committees8, 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	The Zonal Steering Committees8, 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	Provide a timeline by when applicants should have confirmation of zRMS allocation to enable setting of pre-submission meetings.

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		zonal RMS they intend to seek the renewal of their authorisation.	zonal RMS they intend to seek the renewal of their authorisation. **Applicants should be informed of the allocated zRMS 3 months before expected EFSA conclusions to allow setting pre-submission meetings with zRMS.**	
	6 § 3.4	Within 2 months following the publication of the EFSA-conclusion, the following information9 should be provided by the authorisation holders to the zonal RMS and copied to the concerned MSs: - The template10 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;		The current version of the notification form is not suitable to comply with these specific instructions. ECPA has developed and use an updated version of the notification form. This updated version follows all notifications prescriptions and is very helpful to make that step of the process more practical. We hope that this new version will be adopted in the near future by authorities.
	6	An indicative data matching list regarding references relied upon (where relevant)	An indicative data matching list regarding references relied upon (where relevant), **as far as it has been made available on time by the RMS**.	For feasibility
	7 1st line	At the same time the applications should be launched into the EU PPP Application management System by the applicants.	**When guidance on implementation, including roles and responsibilities for use of the EU PPP Application management System is available, ~~At the same time the~~** applications should	Under 3.4 Application by authorisation holder; currently supporting information is not available

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			be included into the EU PPP Application management System by the applicants.	
	7 § 3.4	A report on the monitoring information, where the authorisation was subject to monitoring;	A report on the monitoring information, where the authorisation was subject to monitoring **(such as water monitoring, resistance monitoring)**	Clarification
	7	A comparative assessment dossier should be submitted according to the relevant guidance, where necessary.	A comparative assessment dossier should be submitted according to the ***Guidance document on Comparative Assessment and Substitution of Plant Protection Products in accordance with Regulation (EC) No 1107/2009*** **(SANCO/11507/2013)** where necessary.	Clarification
	8	…(at the latest 3 months after the renewal of the active substance)	at the latest 3 months **after the date of application of the renewal** of the active substance	Clarification
	8 §2	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.	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 **expired** within 12 months: see point 4 section 3.5 and Appendix III.	It is supposed to be the expiry dates which have to be taken into consideration as it is mentioned in §3.11, not the renewal which cannot be properly scheduled! Furthermore, the considered expiry date should be clarified as these could change (original, extended 1, extended 2).
	8 §4	…efficacy data addressing the new GAP should be submitted. Otherwise, for renewal applications, only resistance data are required.	…efficacy data addressing the new GAP **may** be submitted, **or required as post authorisation request**. Otherwise, for renewal applications, only resistance data are required.	As there are diverging point of view amongst MS, it seems appropriate to give the flexibility of the MS to require or not the efficacy data at a later stage than PPP submission (thus avoiding Category 4 data related to efficacy only).
	10 §4, line 7	Where the applicant makes a reference to Cat. 4 data, the application should	Text to be deleted	There is not link between Art. 43(6) and Art. 43(1) in the regulation, Member states should

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		contain a **statement confirming that the product for which the authorisation is to be prolonged and renewed still complies with Article 29**		be responsible for making sure that products meets the requirements in Art 29 for receiving authorizations. The applicant can only confirm that the AS complies with the renewal regulation, and that the product previously was authorized in line with the requirements at the time of authorization. The applicant should not be requested such statement. It has been understood at the ECPA-ECCA conference in March that this statement is no longer required, and ECPA welcomes this fact.
	10	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).	The renewal dRR should be submitted within **the 6 months** of the missing cat. 4 studies being finalised (see 3.8 and Appendix III).	6 months is a more realistic time period. Depending on the complexity of the risk assessment 3 months is a real stretch. After the study completion the risk assessment has to be written, potentially impacting several sections of the dossier. Thereafter the dossier has to be formatted, printed and distributed to the countries.
	10	Where the zRMS 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.		It is important to have the decision from zRMS long before the submission of the dossier of the PPP re-authorisation.
	12 §2	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.	Delete	Data matching studies should not be considered Cat 4 data. This gives an unfair competitive advantage to alternative authorisation holders.
	12	§ 3.7.3 Source specification check		The AS specifications should not be changed except for truly “good reasons” i.e. change in the **specification of the relevant impurities**.

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				A sole increase in the purity of the active substance should not lead to immediate ban of authorised products. It is **impossible** for any applicant other than the original one **to be aware of the change of specifications** until the renewal is voted.
	12	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**	The **product** 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**	We believe that this requirement is not applicable to the applicant(s) supporting the AS approval. If so it should be clarified in the guidance document.
	13 §2	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.	In case the Cat. 4 data are not sufficiently justified, **the applicant should have the opportunity to submit within a specified timeframe the dRR supporting product renewals.**	The result of the non-acceptance of the cat. 4 data justifications is too severe.
	13	Where different zRMS are assigned products containing the same active substance, exchange of information is recommended, even if no commenting period is provided or possible.	Where different zRMS are assigned products containing the same active substance, exchange of information is recommended, **during the commenting period as a minimum.** ~~**even if no commenting period is provided or possible.**~~	Under 3.9 Timelines; a 3-week commenting period is included in the evaluation timing.
	14 §3.8 Last §	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).	The duration of this period should **only** 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)	Clarification

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	15 §3.9	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)).	The zonal RMS should **perform a completeness check within a month and** 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)).	Need for completeness check
	15 §3.9	After every step in the procedure the EU PPP Application management System should be updated respectively by the applicant or by the concerned MS.	**When guidance on implementation, including roles and responsibilities for use of the EU PPP Application management System is available,** after every step in the procedure the EU PPP Application management System should be updated respectively by the applicant or by the concerned MS.	Currently supporting information is not available
	15 §3.9	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.	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, **unless the expiry date of the active substances within the product are within 1 year, in which case this will be the expiry date of the approval that expires the latest within 1 year.**	Include description for products containing ASs that expire within 12 months
	16 §3.10	The zonal RMS should determine if all the new information is submitted only with the exception of the data related to	The zonal RMS should determine if all the new information is submitted only with the exception of the data related to	Important for zRMS to communicate decision on acceptance of Cat 4 data to allow prolongation of existing authorisations while Cat

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		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.	circumstances as listed under point 4 in chapter 3.5 **as part of a completeness check to be communicated to cMSs to allow extension of existing authorisations in all cMSs.** In the case of extension no draft Registration Report for the product has to be submitted by the applicant at the three months deadline.	4 data is generated and evaluated
	16, §3.10	All MS should then take a decision within 3 months.	All MS should then take a decision, **including conducting comparative assessment if required,** within 3 months.	Clarification
	16	However, if the PPP contains two or more active substances and the approval of the second active substance expires within 12 months[8] 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.	However, if the PPP contains two or more active substances and the approval of the second active substance expires within 12 months8 of the first one **(according to the published expiry dates at the time of AIR submission),** zRMS and MSs should evaluate the data submitted for both active substances after the data for the second active substance are submitted.	It is necessary to define which expiry date we consider. Some MS take the extended ones whereas others take the original one before any prolongation. It is our understanding that there is an agreement after the EFSA conclusion of the first AS with the ZRMS about the submission time of the dRR for the product. It may well be that the first AS is so delayed that meanwhile a second AS is in the 1 year period. It can then be agreed to only issue the dRR after a year. On the other hand if it is agreed to only submit a dRR after the renewal of the second AS, this cannot be changed later even if the second AS is delayed. It is really not possible to submit a dRR prematurely then.
	16	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	In this case the renewal decision for the PPP shall be issued within 12 months from the renewal of the second active substance **whatever AIR wave they belong to**. Where such an agreement has been reached, it is assumed on a general basis that there is no need to	In some cases the issue was that authorities were not willing to apply this provision of the guidance document because the 2 AS in question were assessed under 2 distinct AIR processes (AIR 2 and AIR3).

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		expiry dates of the active substances are changed.	reconsider the question where the expiry dates of the active substances are changed.	
	16	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.	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. **Applicant should be informed immediately.**	Clarification
	16 §3.11	Therefore the dossier should address the guidance in place at the time of the second submission date. This implies that where two different zRMS are assigned for a two-active-substance product, they should liaise to agree which one will act as zRMS.	Therefore the dossier should address the guidance in place at the time of the second submission date. This implies that where two different zRMS are assigned for a two-active-substance product, they should liaise to agree which one will act as zRMS. **Agreement should communicated to the applicant no later than the first product application deadline (+ 3 months DoA of the first AS)**	Need to communicate changes in zRMS in timely fashion
	16 §3.10	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.	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.	This limit is no longer relevant
	16	Therefore the dossier should address the guidance in place at the time of the second submission date.	Delete	Sentence to be deleted as it is not in line with GD SANCO/11509/2013
	17 L1	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	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 **last**	Clarify also for cases of a PPP containing 3 or more AS.

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		the next active substance to expire.	active substance to expire.	
	17	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	For products containing two or more active substances -and when the 1st substance is renewed- **data related to the 2nd substance should not be evaluated.** For products containing two or more active substances -and once the 2nd substance is renewed- **data related to the 1st substance should not be evaluated.**	Current phrasing is open to interpretation. "There is no need to evaluate" suggests that it is not necessary to evaluate data related to the 2nd AS. but it could be evaluated. The phrasing should be more firm to avoid such a situation where a MS ask questions related to the re-approval of the 2ndAS. in the frame of the step 2 of the 1st AS. Concrete examples can be listed.
	19	In the chart in Appendix II no timeframe is specified to reach a conclusion on the acceptability of the cat. 4 justifications.	In the chart in Appendix II **1 month** is specified to reach a conclusion on the acceptability of the cat. 4 justifications.	It seems that a time period of 1 month is applicable. CRD issued a national guidance on art. 43 (http://www.hse.gov.uk/pesticides/article-43.pdf). Annex 2a of that document could be used as a basis to incorporate that period in the chart about the re-authorisation timelines.
	20 3rd column, lines with Cat 4 studies	Application, all studies available, study list (including timetable and justification)	Application, study list **(available studies and planned studies** including timetable and justification)	In order to avoid unnecessary submission of study reports which anyway will not be evaluated until full dRR is submitted together with the Cat.4 studies, it is proposed to submit only a list of studies including available and planned studies including timetable and justification. This is already applied by France in its role of zRMS.