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REVIEW PROGRAMME OF ACTIVE SUBSTANCES: ESTABLISHMENT OF A WORK PROGRAMME TO MEET THE 2024 DEADLINE

1. PURPOSE OF THE DOCUMENT

During the 50th and 51st CA meetings, the Commission services presented documents in order to discuss the progression of the review programme of existing active substances, proposed some priorities and a way forward for setting deadlines and some principles to be followed[1].

Some discussions took also place during the two Meetings of the Biocidal Product Committee (BPC).

The objective of the present document is to come to a final agreement concerning the general organisation of the review programme, and the general principles to run it.

2. DISCUSSIONS

At the request of Commission, most Member States submitted their own current plans for the submission of their draft CARs (see Appendix 1 to this document). According to these estimations, a lot the remaining draft CARs in the review programme would be submitted by Member States within the next 2 years (i.e. by the end of 2015).

It will be impossible to manage all these draft CARs as from the date of their submission to ECHA considering the related workload, unless resources are drastically increased in the BPC secretariat, Member States (which are members of the BPC), and the Commission services. In addition, properties of some substances related to exclusion or substitution criteria need to be clarified before an opinion can be given, and a decision taken. It shall also be taken into account that the review programme of active substances is running in parallel to product authorisation procedures, which also create an important

[1] See documents *CA-Feb13-Doc.8.3 - Review programme of AS.doc*, and *CA-May13-Doc.8.3 - Review programme of AS.doc*

workload for Member States.

As such a drastic increase of resources is currently not foreseen for the next coming years, a more realistic deadline for ending the review programme has been decided, and the overall objective is now to finish it by the end of 2024 at the latest.

The Commission services presented some proposals at the occasion of past meetings to organise the review programme. Some Member States expressed some concerns in relation with these proposals, mainly:

- the impossibility to submit a draft CAR if the RAC is over loaded and has not given its opinion on the harmonised C&L, or if the P/B/T status is not yet clarified, when needed, with a consequential slowdown of the progression of the biocides review programme;

- the postponement of discussions on some reports for a few years with a possible loss of expertise in the Member States responsible of the reports, generating additional costs.

The Commission services have prepared a revised proposal, which aims at tackling these concerns, keeping the objective of ensuring the most efficient implementation of the biocides framework.

3. ORGANISATION OF THE REVIEW PROGRAMME OF ACTIVE SUBSTANCES

To ensure the most efficient implementation of the biocides framework, for both the active substance review and the biocidal product authorisations scheme, the Commission services are convinced that there is need to set a frame, stepwise objectives, and general principles, with flexibility in the detailed organisation and plans of discussion in the BPC.

For the various reasons summarised in section 2 of the document *CA-May13-Doc.8.3 - Review programme of AS.doc* discussed at the 51st CA meeting, the Commission services are still convinced that it is needed to set legally binding deadlines to ensure that all draft CARs for a PT will have been submitted to ECHA by a certain date, and that all related opinions of the BPC will have been submitted to the Commission by a certain date. For instance, it would be unacceptable to still receive a draft CAR on a PT18 active substance in 2020, and a decision taken at that time, although the original dossier was submitted in 2006 and that most decisions on PT18 substances would have been taken years before.

The following deadlines are therefore proposed:

Priority	Existing active substances for product types	All draft CARs have to be submitted to ECHA by	The BPC have to submit all its opinions by
1st priority list	8, 14, 16, 18, 19, 21	31/12/2015	31/12/2016
2nd priority list	3, 4, 5	31/12/2016	31/12/2017
3rd priority list	1, 2	31/12/2018	31/12/2019
4th priority list	6, 13	31/12/2019	31/12/2020

5th priority list	7, 9, 10	31/12/2020	31/12/2021
6th priority list	11, 12,15,17, 22, 23 (new PT20 under BPR)	31/12/2022	31/06/2024

These timings will be set in the new review regulation that will replace Regulation (EC) No 1451/2007.

It is important to note that these dates are deadlines: MS shall continue to submit their draft CARs as they progress on them, taking into account these priorities and the general principles presented in section 4.

These deadlines shall therefore not prevent MS to send their CAR, nor the BPC to deliver its opinions before: they give a direction on the priorities to be followed in the management of the common workload and the decision-making, and give more certainty for stakeholders who need to anticipate and plan the preparation and submission of their applications for product authorisation.

After a few years, these priorities and deadlines could be revised in the light of the experience and the progress that would have been achieved, if appropriate.

The detailed rules for the functioning of the BPC are developed in section 5 of this document.

4. GENERAL PRINCIPLES FOR THE REVIEW OF EXISTING OR NEW ACTIVE SUBSTANCES AND FOR THE SUBMISSION OF DRAFT CARS

The Commission proposes that the following general principles shall now apply:

(1) Deadlines :

Deadlines in the various procedures shall be applied more strictly by each party. In particular, appropriate deadlines shall be given to applicants when they are requested to submit additional information, and in case no good justification is given concerning delays of submission, the RMS shall continue the evaluation on the basis of the current data, or apply more strictly the provisions of article 14(3) 2nd subparagraph of Regulation (EC) n°1451/2007[2], which might eventually lead to a non-approval of the active substance.

(2) Assessment of multiple dossiers:

[2] Article 14(3) 2nd subparagraph of Regulation (EC) No 1451/2007: […] *All participants shall be deemed to have withdrawn [their application] and Articles 11(2) and 12 shall apply mutatis mutandis if: (a) the additional information is not received by the deadline; (b) the participant fails to provide adequate justification for further postponing the deadline; (c) no other dossier concerns the same existing active substance/product type combination*. A similar provision will also be established in the new review regulation.

On multiple dossiers[3], only combined draft CARs shall from **now on** be submitted by RMSs, in order to avoid several discussions on the same AS/PT, and in order for ECHA's BPC to deliver an opinion on an assessment taking into consideration all data available. In case separate CARs are submitted, no discussion would take on an AS/PT combination if all related CARs are not available.

(3) Establishment of the harmonised C&L, P/B/T status, when needed :

a) The harmonised C&L dossier, or request for the advice on the PBT/vPvB status to the PBT Expert Group (including whether 2 out of 3 of the PBT criteria are met), **shall be submitted as soon as possible** when the hazard evaluation of a substance has been done, and **at the latest** at the same time when the draft CAR is sent to ECHA. **No draft CAR will be accepted anymore by ECHA if this has not been done.**

b) In case where it is suspected that the active substance might fulfil the exclusion/substitution criteria (for the moment on CMR, P/B/T), **it is highly preferable and therefore strongly recommended that Member States submit their draft CAR only when the RAC has given its opinion on the CMR status, or PBT subgroup has given its opinion**, in order to take into account these opinions in their draft CAR before submitting them.

c) For draft CARs from the backlog[4], Member States shall send the appropriate dossiers (harmonised classifications, PBT status) **as soon as possible** to ECHA.

Considering that, according to the own plans of Member States, a lot of CARs are currently expected to be ready by the end of 2015, the application of these principles should not present an issue in relation with deadlines for sending draft CARs as proposed in section 2. In addition, in relation to C&L and P/B/T status, ECHA has clarified during the 2nd BPC meeting that it is not requested to fill each section of an IUCLID template, nor of a PBT factsheet, to make a request for opinion. So, for substances currently concerned by the earliest deadline (1st priority list on 31/12/2015) and for which a CMR/PBT status needed to be clarified, it leaves currently more than 2 years for the Member State to submit the dossier, and possibly obtain an opinion. On a case-by-case, it can be asked to the RAC to prioritize some dossiers.

On the other hand, the application of these principles will help to ensure that the assessment on a substance is as finalised as possible, in order that the BPC have the most appropriate material to deliver an opinion and a finalised assessment report, in particular with regards to the exclusion or substitution criteria.

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[3] The document *CA-Dec09-Doc.8.3 - Note on multiple dossiers.doc* (https://circabc.europa.eu/w/browse/386abfea-55ce-4764-8a31-f9d4f6ceaf0a) will need to be reviewed

[4] Draft CAR submitted before 1st September 2013 but for which the technical peer review has not been finalised. This will represent around 160 draft CARs.

These principles will be set in the new review regulation that will replace Regulation (EC) No 1451/2007.

5. WORK PROGRAMME IN THE BPC

A detailed work programme should be established by the BPC with at least a minimum of a rolling one-year visibility, and reviewed by the BPC secretariat at each BPC meeting in order to adjust it with regards to the priorities and new draft CARs that are submitted on a day-to-day basis.

The work programme will be established taking into account:

- the objectives set for the BPC to have delivered all its opinion for certain PTs by a certain date,

- a fair balance between draft CARs from the backlog and draft CARs submitted after 1st September 2013,

- the capacity of work of the BPC, with the minimum objective of delivering 50 opinions on existing active substance per year (1 opinion = 1 opinion on an AS/PT combination), to which is added the delivery of opinions on new active substances,

- the status of the harmonised C&L or PBT dossier when the substance is potentially targeted by exclusion or substitution : such a substance shall, *normally*, not be discussed by the BPC until the RAC or PBT Expert group has delivered its opinion,

- to optimize and ensure consistency in the review, several AS for same PT will be put on the agenda of a BPC, for their peer review and preparation of opinions in parallel,

- it will be possible to review an active substance for several PTs at the same in case it is compatible with the workload of the BPC, and if the BPC secretariat anticipates that all appropriate guidance is available and that it won't ask to much work to review them, in order to limit and optimize the work of the RMS (for instance, if one single CAR has been done be the RMS to cover several PTs of the active substance). On the other hand, one or several PTs can also be left aside for future discussion when these conditions are not met.

In addition, it is proposed that:

- draft CARs on an existing active substance can be processed by the BPC later than from its submission and be put on hold by ECHA , in order to leave room for flexibility for the establishment of the above-mentioned rolling work programme,

- when the BPC really starts to work on a draft CAR on an existing active substance, it has 9 months to deliver its opinion,

- new active substances will have to be processed by the BPC 9 months after the submission of the CAR, taking into account the submission window,

- ECHA and the BPC shall continue to work on the development of guidance documents that will be beneficial to solve issues, to help Member States to finalise their draft CARs (ex: Disinfecting by products guidance etc.), and the delivery of opinions by the BPC.

These principles could be set in the new review regulation that will replace Regulation (EC) No 1451/2007.

The 1st work programme will be set in the meeting of the BPC in October, and will concern in a large part draft CARs from the backlog on PTs from the 1st priority list (i.e. PT 08, 18, 19, 21).

6. CONCLUSION

The proposed organisation will have the benefit to leave some flexibility for the adjustment of the organisation of the BPC (i.e. if the BPC can process more opinions per year, if the BPC finalises discussions on substances for a PT well before the deadline etc…), while setting some priorities in the review programme and ensuring that decisions would have been taken on all substances for a PT by a certain date, and that the review programme is finished by the end of 2024 at the latest.

It shall also be noted that the efficiency of the BPC will to a great extent rely on the work that can be achieved by all parties, in particular the members of the BPC, and resources allocated to that work.

7. ACTION

The Commission services would like to endorse the way forward and principles presented in the document.

APPENDIX 1

A- Plan provided by Rapporteur Member States concerning the number of draft CARs on EXISTING AS/PT that they intend to submit each year (information on 28/06/2013)

	Plan provided	2013	2014	2015	2016	Comments
AT	yes	2 to 5	3 to 10	0 to 4		
BE	yes		1			Provided information do not concern all substances
CY	(not concerned)					
CZ						
DE	yes	9	10	12		
DK	yes	6				
EE	(not concerned)					
EL	yes	3				Provided information do not concern all substances
ES	yes		26	8	3	
FI	yes	12				
FR	yes	14	12	6		
HU	yes			2		
IE	yes	3				
IT						
LT						
LV	(not concerned)					
MT	yes					Not possible to give estimations for the moment
N	yes	2		4	3	
NL	yes	5				+ 3 dossiers for which there is no precise information is available on the date of submission
PL	yes		8	1	11	
PT						
SE	yes	11	24	6		
SI	yes		2 to 5	2 to 5		
SK	yes		5			
UK	yes	2	3	6		
TOTAL	-	**69 to 72**	**96 to 104**	**47 to 52**	**17**	

B- Plan provided by Rapporteur Member States concerning the number of draft CARs on NEW AS/PT that they intend to submit each year (information on 28/06/2013)

	Plan provided	2013	2014	2015	2016	Comments
AT	(not concerned)					
BE	(not concerned)					
CY	(not concerned)					
CZ						
DE	(not concerned)					
DK	(not concerned)					
EE	(not concerned)					
EL	(not concerned)					
ES	yes		1			
FI	(not concerned)					
FR	yes		1			
HU	(not concerned)					
IE	(not concerned)					
IT						
LT	(not concerned)					
LV	(not concerned)					
MT	(not concerned)					
N	(not concerned)					
NL	yes	1				+1 substance for which there is no precise information is available on the date of submission
PL	yes	2				
PT	(not concerned)					
SE	yes	8		1		
SI	(not concerned)					
SK	yes					
UK	yes	5	1			
TOTAL	-	**16**	**3**	**1**	**0**	

APPENDIX 2

A - Progression of the review programme of existing active substances per PT (the figures might be subject to minor corrections – based on data on 24/04/2013)

		Total number of Active substance (AS) in the review programme	Number of AS still under evaluation by the RMS, (the draft Competent Authority Report (CAR) has not been submitted yet)	*Percentage of AS still under evaluation*	Number of AS currently under peer review (the draft CAR has been sent, and discussions are on-going at TM or CA level)	*Percentage of AS currently under peer review*	Total in still in review (draft CAR not available + CAR under peer review)	*Percentage still in review (draft CAR not available + CAR under peer review)*	Number of AS for which a decision has been or is ready to be taken (voted in SCB, or inclusion or non-inclusion decision adopted after peer review)	*Percentage of AS with a decision taken or ready to be taken*
1st list	PT8	41	0	*0%*	13	*32%*	**13**	**32%**	28	*68%*
	PT14	14	0	*0%*	0	*0%*	**0**	**0%**	14	*100%*
	Total 1st list	**55**	**0**	**0%**	**13**	**24%**	**13**	**24%**	**42**	**76%**
2nd list	PT18	57	10	*18%*	24	*42%*	**34**	**60%**	23	*40%*
	PT19	15	4	*27%*	6	*40%*	**10**	**67%**	5	*33%*
	PT16	0	0	*#DIV/0!*	0	*#DIV/0!*	**0**	**#DIV/0!**	0	*#DIV/0!*
	PT21	10	5	*50%*	5	*50%*	**10**	**100%**	0	*0%*
	Total 2nd list	**82**	**19**	**23%**	**35**	**43%**	**54**	**66%**	**28**	**34%**
3rd list	PT1	37	28	*76%*	9	*24%*	**37**	**100%**	0	*0%*
	PT2	85	59	*69%*	24	*28%*	**83**	**98%**	2	*2%*
	PT3	55	43	*78%*	12	*22%*	**55**	**100%**	0	*0%*
	PT4	55	38	*69%*	17	*31%*	**55**	**100%**	0	*0%*
	PT5	19	14	*74%*	5	*26%*	**19**	**100%**	0	*0%*
	PT6	49	36	*73%*	13	*27%*	**49**	**100%**	0	*0%*
	PT13	30	20	*67%*	10	*33%*	**30**	**100%**	0	*0%*
	Total 3rd list	**330**	**238**	**72%**	**90**	**27%**	**328**	**99%**	**2**	**1%**
4th list	PT7	27	23	*85%*	4	*15%*	**27**	**100%**	0	*0%*
	PT9	38	33	*87%*	5	*13%*	**38**	**100%**	0	*0%*
	PT10	28	26	*93%*	2	*7%*	**28**	**100%**	0	*0%*
	PT11	50	46	*92%*	4	*8%*	**50**	**100%**	0	*0%*
	PT12	39	33	*85%*	6	*15%*	**39**	**100%**	0	*0%*
	PT15	0	0	*#DIV/0!*	0	*#DIV/0!*	**0**	**#DIV/0!**	0	*#DIV/0!*
	PT17	1	1	*100%*	0	*0%*	**1**	**100%**	0	*0%*
	PT20	1	0	*0%*	0	*0%*	**0**	**0%**	1	*100%*
	PT22	8	7	*88%*	1	*13%*	**8**	**100%**	0	*0%*
	PT23	1	0	*0%*	1	*100%*	**1**	**100%**	0	*0%*
	Total 4th list	**193**	**169**	**88%**	**23**	**12%**	**192**	**99%**	**1**	**1%**

Total	660	426	*65%*	161	*24%*	**587**	**89%**	73	*11%*

B - Number of BPC opinions to be processed for AS/PT combinations (the figures might be subject to minor corrections – based on data on 24/04/2013)

PT	Total of AS in still in review (draft CAR yet not available + dCARs under peer review)	Number of dCARs not yet available	Number of dCARs under peer review
8+14+16+18+19+21	67	19	48
3+4+5	129	95	34
1+2	120	87	33
6+13	79	56	23
7+9+10	93	82	11
11+ 12+15+17+22+23	99	87	12
TOTAL	**587**	**426**	**161**

All draft CARs have to be submitted to ECHA by	The BPC have to submit all its opinions by
31/12/2014	**31/12/2015**
31/12/2016	**31/12/2017**
31/12/2018	**31/12/2019**
31/12/2019	**31/12/2020**
31/12/2020	**31/12/2021**
31/12/2022	**31/06/2024**