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Fact sheet BPR

European Biocidal Product Regulation

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Document index:

1. Regulatory framework, ... p2
2. Scope of the BPR, ... p2
3. The systems to submit data, ... p3
4. The guidance documents, ... p3
5. Review program, ... p5
6. Status of our dossiers, ... p5
- Wood preservation = PT 8, …….....p6
- Other application areas: PT 1,2,3,4,10,11,12, ……...p7
7. Type of letters and statements we can make available to our customers, …….p8
8. List of abbreviations used, ……..p9
9. Table 1: Description of the steps / timelines in the peer review process, …….p10
10. Table 2 Product Types supported by, ……..p16
11. Disclaimer,…….p17

1. Regulatory framework

The Biocidal Product Regulation (BPR – EU 528/2012) on the use and placing on the market of biocidal products repealed and replaced the Biocidal Product Directive (BPD) on biocides (98/8/EC) on 1 September 2013. The transition period has been extended up to 2024.
Details on this revision/replacement can be found on:
http://echa.europa.eu/regulations/biocidal-products-regulation

The new regulation should increase the protection of health and environment, and it should be more efficient at the same time, notably through the active involvement of European CHemicals Agency (ECHA - also in charge of REACH). It will retain the two-step authorization process brought in by the Directive, whereby active substances are first tested and approved and included in a Community list (known as the Annex I under the Directive), with subsequent authorization of the products containing the approved active substance.

Under the BPR the RMS's (Rapporteur Member States) are now called eCA's (evaluating Competent Authorities). An eCA does the initial evaluation of an active substance dossier and writes the draft CAR (competent authority report). Draft CAR's can be discussed with applicant and/or individual MS and in working groups to solve open issues before they are brought to BPC (Biocidal Product Committee) for conclusions. According to the Biocidal Products Regulation (BPR) the opinion on the approval of an active substance has to be submitted by ECHA to the Commission within 270 days of the receipt of the conclusions of the evaluating Competent Authority (eCA). An overview of the different steps in this BPR process for authorization of a biocidal active substance of the peer review can be found in table1.

Amendments to the BPR were found to be necessary in an early phase and entered into force on 25 April 2014.

A consolidated version of the BPR can be found via the following link: http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1409322218709&uri=CELEX:02012R0528-20140425

The main consequence of the amended BPR are as follows: The scope of biocidal family increased slightly, formulators can also notify for Article 95 and the authorities can have up to 3 years to finalize the biocidal product evaluations.

2. Scope of the BPR

The scope has been extended to cover articles and materials treated with biocidal products, including furniture and textiles. The regulation will also apply to active substances generated in situ, and to biocidal products used in materials that come into contact with food. But other products that are sufficiently covered by existing legislation (including food and feed, food and feed additives and processing aids) are excluded from the scope of the new regulation. Biocidal products approved under the International Convention for the Control and Management of Ships' Ballast Water and Sediments are considered as authorized.

3. The systems to submit data

The registration system to submit biocides dossiers is part of REACH-IT, the system is paperless and IUCLID based. IUCLID is the data-base system to collect all you data and to prepare your dossier and this is the same system as for REACH dossiers. Via REACH-IT you can generate an own account to submit your dossiers. Early July 2016 the IUCLID software was upgraded to version 6.1. The tool to submit biocides dossiers electronically is called R4BP3. R4BP3 is the communication tool with ECHA for all issues on your biocides dossiers. R4BP was upgraded to version 3.7 on July 6, 2016 and from this date only dossiers in IUCLID 6.1 format can be submitted. Dossiers in older formats will be refused by the system.

The key developments in R4BP 3.7 are:

1) Upgrade to IUCLID 6.1: from now on, only .i6z dossiers are accepted by the REACH IT system. Existing IUCLID 5 dossiers have been migrated to IUCLID 6 format on the ECHA server.

2) Features to support the Biocides Review Programme related workflows: Some new forms were added to submit active substance information

You can find more information in ECHA's news item, e.g. Q&A on adapting to the new versions of R4BP 3 and IUCLID. A manual to submit national authorisations can be found at the following link: https://echa.europa.eu/documents/10162/14938692/bsm_06_national_authorisation_en.pdf/bc9ad1fd-75e9-4eef-b686-0bb90e83e1e9

IUCLID can be downloaded from ECHA (https://iuclid6.echa.europa.eu/)for free and access to R4BP3 is possible via ECHA when a REACH-IT account is generated. For more information on R4BP: https://echa.europa.eu/support/dossier-submission-tools/r4bp

4. The guidance documents

Several guidance documents on these tools are published on the ECHA website.

Under the BPR there will be a possibility for Union Authorization at the ECHA. The deadlines are laid down in Art 42 of the BPR. To avoid an overload of ECHA a step-wise planning is laid down. Applicants may apply for Union authorization for biocidal products which have similar conditions of use across the Union with the exception of biocidal products that contain active substances that fall under Article 5 and those of Product Types 14, 15, 17, 20 and 21. The Union authorization may be granted:

(a) from 1 September 2013, to biocidal products containing one or more new active substances and biocidal products of product-types 1, 3, 4, 5, 18 and 19;

(b) from 1 January 2017, to biocidal products of product-types 2, 6 and 13; and

(c) from 1 January 2020, to biocidal products of all remaining product-types (besides those excluded).

Active substance suppliers not having own dossier or Letter of Access had to phase out by September 2015. In order to be able to check if suppliers have submitted dossiers under the BPD/BPR a list is prepared by ECHA with approved suppliers and this list is monthly updated. With the amended BPR

there are now also possibilities to apply for listing by formulators of some biocidal products. This possibility is mainly generated for importers of formulations for which the active substance is not supported by the non-EU manufacturers. The latest list of approved suppliers can be found on the ECHA website:
http://echa.europa.eu/web/guest/information-on-chemicals/active-substance-suppliers?_sm_au_=i2HDPpMr46pdW76r

Suppliers participating in the review program had to do an Article 95 notification via R4BP3 to come on this list. Akzo Nobel Surface Chemistry AB has done this Article 95 notification for all our active substance - PT combinations evaluated in the review program. Statements on Article 95 listing can be made available for our customers.
It is very important for formulators of biocidal products to check if their suppliers are included in the Article 95 list for the product types of their interest. The list is legally binding since 1st September 2015. If the active substance supplier is not on the list the formulator is no longer allowed to use the active ingredient from this supplier.

On the following ECHA website you can find more details on Article 95.
http://echa.europa.eu/biocides-2015

The detailed rules for the Review Programme have been adapted to the provisions of the BPR in the new Review Programme Regulation (EU) No 1062/2014, which repeals and replaces Commission Regulation (EC) No 1451/2007. Full details can be found via the following link:
http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/existing-active-substance

In preparation of the legal status of Article 95 several member states have initiated to collect Declarations of Delivery from the registration holders to confirm they are buying from Art 95 listed suppliers. For our customers we make available on request a statement on the Art 95 notification and/or Declarations of Delivery for the active substances supported by Akzo Nobel Surface Chemistry AB.

If a company wants to be able to continue to remain active in the biocides market on the longer term, it will be a legal obligation in all member states of interest to have approval for all the formulations with biocidal claims. In the biocidal product dossier, the access to the active substance dossier will have to be covered with a Letter of Access from the actual supplier of the active ingredient (unless the active substance dossier is also owned by the applicant). Details for the Letter of Access are laid down in Art 61 of the BPR.

ECHA regularly publishes new guidance on BPR. Practical guides on various topics relevant to the BPR can be found on:
http://echa.europa.eu/practical-guides/bpr-practical-guides

5. Review program

Under the BPR, the application areas are called Product Types (PT). The different PT's we support for our active substances are given in Table 2. A detailed description of the PT's can be found on: http://echa.europa.eu/regulations/biocidal-products-regulation/product-types

As AkzoNobel Surface Chemistry AB we support three quaternary ammonium compounds:
-Didecyldimethylammonium chloride (CAS number 7173-51-5) in case of the DDAC dossier,
-C_{12-16}-alkyldimethylbenzylammonium chloride (CAS number 68424-85-1) in case of the BKC dossier
-Cocoalkyltrimethylammonium chloride (CAS number 61789-18-2) in case of the TMAC dossier.
For simplicity we will remain calling these single substances in this factsheet BKC, DDAC and TMAC.

The three quaternary ammonium compounds are being evaluated by Italy. Italy has informed us that they intend to follow the priority setting made by ECHA to meet the 2024 deadline (see listing below).

Next to the 3 quaternary ammonium compounds we support Triameen Y12D (dodecyldipropylene triamine - CAS no 2372-82-9) sometimes abbreviated in the review program as Diamine. The evaluation of Triameen Y12D is done by Portugal. Portugal informed us that they intend to come with Competent Authority Reports for all Product Types supported in one go, but they could not give an indication when the draft CAR's will be made available.

Although a proposal for a decision on inclusion officially had to be taken by the RMS within 1 year after accepting dossiers as complete, unfortunately this did not happen in practice.

To be able to meet the new deadline for the review program of 2024 ECHA has set priorities for the different application areas (PT's) in the new review program.

Priority	Existing active substances for product types	Deadline for submission of all draft CARs by eCA to ECHA	Deadline for ECHA to deliver its opinions
1st priority list	8, 14, 16, 18, 19, 21	31/12/2014	30/09/2015
2nd priority list	3, 4, 5	31/12/2016	30/09/2017
3rd priority list	1, 2	31/12/2018	30/09/2019
4th priority list	6, 13	31/12/2019	30/09/2020
5th priority list	7, 9, 10	31/12/2020	30/09/2021
6th priority list	11	31/12/2022	30/09/2023
7th priority list	12,15,17,22 and 23 (new PT20 under BPR)	31/12/2023	30/09/2024

6. Status of our dossiers:

In the overview below all the different steps (actions) in the evaluation process under the BPR are listed. The implementation of the BPR has slightly changed the evaluation process and the system of TM meetings and CA meetings is replaced by a system of WG (Working Group) and BPC (Biocidal Product Committee) meetings at ECHA. It is planned that the frequency of meetings will increase to speed up the process. In the new process the BPC meets about 5 times per year (instead of 3 times for the previous TM meetings) to discuss the technical issues and decide on a final version of the CAR (= AR and Conclusions).

- **Wood preservation = PT 8:**

For BKC and DDAC there are 2 consortia involved, an US consortium (USQC) and the European QUAT Consortium (EQC). We as Akzo Nobel Surface Chemistry AB are member and chair of the EQC.

In February 2013 the decisions on Annex I inclusion of CAS number 68424-85-1 (BKC) and CAS number 7173-51-5 (DDAC) for PT 8 became final and the deadline for product dossier submission for PT8 for all existing biocidal products on the market using the approved CAS numbers (independent of the supplier) was February 1st 2015. When an extra active ingredient, which is not yet approved, is included in a biocidal product, then the deadline for BPR dossiers is related to the official approval of the last active substance. When the formulation is used for several PT's the deadline for BPR submission is after the approval of the active substance for the last PT. (See p39 of the ECHA guidance: http://echa.europa.eu/documents/10162/21742587/pg_on_bpr_6_national_authorisation_en.pdf) . In the meantime of course the national rules have to be followed.

The official decisions for PT8 can be found here:

BKC:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:049:0066:0069:EN:PDF

DDAC:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:044:0010:0013:EN:PDF

Akzo Nobel Surface Chemistry AB dossiers for BKC and DDAC were discussed and technically approved during the TM meeting of June 2013. For these 2 substances there are two official applicants with approved dossiers (EQC and USQC). In this situation of multiple applicants the official guidance documents for multiple dossiers have to be followed. This guidance tells that a combined assessment report and a combined Listing of Endpoints have to be developed before the inclusion decision is made. Officially these combined documents should be used for the risk assessment calculations of the biocidal products. This guidance was not followed by eCA Italy. Unfortunately these combined documents were not available before the PT 8 product deadline. Finally the proposed combined Listing of Endpoints of BKC and DDAC were discussed and agreed in the BPC-11 meeting of 15-18 June 2015. The official decision will remain the same but the previous Assessment Report is now replaced with the Combined Assessment Reports as they were finalized by Italy in July 2015. The eCA's (that have received PT8 product dossiers) have to check all the submitted PT8 product dossiers and have to correct them when differences are found between the submitted information and the results given in the combined Listing of Endpoints. The combined List of Endpoints (given in the combined Assessment Report) contains the results to be taken into account by all parties (independent of the source material) when preparing risk assessments for product dossiers.

For access to the latest public combined assessment reports of DDAC and BKC for PT8 you can use the following link:

http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances

You can find the official information on BKC when entering the CAS number (68424-85-1) in the table found when you click on the link above. Please enter the CAS number and accept the legal notice and then click on search. You then come in an overview of the review status of the substance. For the combined Assessment report you click (at the row for PT 8) on the link under the column Data. You then come in an overview of disseminated data for the specific substance and half way the information

you can click on the Assessment Report of July 2015 and at the end of the AR you find the combined Listing of Endpoints.

For DDAC you have to use the CAS number 7173-51-5 to start the search.

For TMAC for PT8 a draft CAR was received in 2010 and comments were submitted in 2010. For TMAC also a multiple dossier situation exists. The TMAC dossier was discussed during the WG meeting in March 2015 (together with the dossier of the other applicant). Some additional information had to be collected from both applicants during the coming period and some open issues have been solved via Ad-hoc discussions. The BPC decision for approval for PT8 was taken in the meeting of April 2016. The BPC decision for Coco alkyltrimethylammonium chloride (ATMAC/TMAC) is published on the ECHA website:
http://echa.europa.eu/web/guest/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval
For TMAC for PT8 in November 2016 the COMMISSION IMPLEMENTING REGULATION (EU) 2016/1934 was published laying down as deadline for product dossier submission for PT8 products based on TMAC 1st of May 2018.

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R1934&from=EN

- **Other application areas: PT 1,2,3,4,10,11,12:**

In March 2012 we received the initial draft CAR for PT 1,2,3,4 (disinfection areas) for DDAC for commenting on availability of confidential information within one month.
In beginning of May 2012 we received the commenting tables for DDAC for PT 1, 2, 3, 4, and we have delivered our comments within the 90-days commenting period of the BPD. This means for DDAC for PT1,2,3,4 we are now in step 8 of the BPR process (see below tables for process details).

For BKC for PT1,2,3,4 (disinfection areas) we received the commenting table half September 2012 and the 90 days commenting period of the BPD started and deadline for submission of comments was set on December 10th 2012. The commenting tables for BKC for PT1,2,3 and 4 were submitted in time. This means we are for BKC for PT 1, 2, 3, 4 in step 8 of the BPR process.

For the other PT's for BKC (10,11,12) and DDAC (10,11,12) we are still waiting for step 1.

Italy has informed us that they intend to follow the priority setting made by ECHA to meet the 2024 deadline. In the current ECHA agenda of Working Group and BPC meetings a WG meeting for PT 3 and 4 dossiers for DDAC and BKC is booked for November 2017.
(https://echa.europa.eu/documents/10162/17287015/wp_active_substance_approvals_2016_17_en.pdf/fe3698a4-c6c5-4e41-bbfc-06ba64f283db)

According to informal information Italy has the intention to discuss PT 1 and 2 in the WG meeting of September 2018.

For the evaluation of Triameen Y12D (dodecyldipropylene triamine) CAS no 2372-82-9 we are still waiting for step 1 for all PT's applied for. The draft CAR reports for Triameen Y12D for PT 2,3,4,11,12 are not yet received from Portugal. Portugal informed us years ago that they intend to come with Competent Authority Reports for all Product Types supported in one go, but they could not give an indication when the draft CAR's will be made available.

For Triameen Y12D for PT 6 and 13 a submission for inclusion in Art 95 was made via R4BP in summer 2015 and we are now also included in Art 95 for these two PT's .

Since the deadlines are not followed by the authorities, it is difficult / not possible for us to predict dates for final Union listing for the remaining PT's supported.

7. Type of letters and statements we can make available to our customers:

1. **Letter of Access** = LoA to the active substance under the national system (needed for national approvals as long as the active substance/PT combination is not approved yet under the BPR and a national approval system exists)
2. **Letter of Access** = LoA to the active substance under the BPR (needed for PT8 biocidal products based on BKC and/or DDAC for which all other actives are already approved and no other PT's are involved)
3. **Statement on Art 95** (needed to proof that you are using an approved supplier of the active substance)
4. **Declaration of Delivery** (required by some national authorities to proof the supplier used is on Art. 95)
5. **Listing of Endpoints** = LoE (needed to do the risk assessments of the biocidal products to be registered under the BPR, but might also be needed/used when a national registration scheme exists)

Please contact your local sales manager in case you need such statements/letters. They can also give you more information on the terms involved.

8. List of abbreviations used

AR	Assessment Report
ASO	Accredited Stakeholder Organizations
BPC	Biocidal Product Committee (selected experts of the MS's that meet about 5 times per year at ECHA to propose active substance decisions)
BPD	Biocidal Product Directive
BPR	Biocidal Product Regulation
CA	Competent Authority
CAR	Competent Authority Report
CIRCA-BC	a portal of collaborative workspace for partners of the European Institutions.
COM	Commission (In the overview COM is used but where relevant to be more specific also COM-ENV (Directorate General Environment) and COM-JRC (Joint Research Centre) are used.
eCA	evaluating Competent Authority
ECHA	European Chemicals Agency
EQC	European QUAT consortium
LOE	Listing of Endpoints
MS	Member State
MSCA	Member State Competent Authority
n.a.	not applicable
PT	Product Type (application area)
RCOM	response to commenting table (consolidated commenting table)
RMS	Rapporteur Member State
SECR	ECHA secretariat
TM	Technical Meeting (representatives present of all MS)
USQC	United States based QUAT Consortium
WG	Working Group meeting (selected technical experts of the MS's that meet about 5 times per year at ECHA to discuss technical issues)

Due to the implementation of the BPR there is now again a kind of "transition state". New active substance dossiers (not falling under the review program) will be under the responsibility of ECHA. The existing active substances already under evaluation according to the BPD continue to be evaluated by those RMS's / eCA's that were already responsible for the substances. They do the evaluation up to the level of draft CAR publication. Instead of moving it then to TM level it is now moved via the WG meeting to BPC meeting level at ECHA.

For the CAR's submitted before 1 September 2013 the situation is as follows: A number of evaluations have been submitted by RMS's under the BPD. The peer review of these CARs can be at any stage of the process, as e.g. some of them have gone through the commenting stage and others have been finalized at the Technical Meetings under the BPD. The decisions on these active substances will be made according to the BPD, while the decisions on active substances for which the CAR is submitted after 1 September 2013 will be made according to the BPR.

The working procedure for active substances has been updated in February 2015. The full details of the Standard Operating Working Procedures for the Biocidal Product committees can be found on the ECHA website:
http://echa.europa.eu/documents/10162/4221979/bpc_working_procedure_active_substance_en.pdf

9. Table 1: Description of the steps / timelines in the peer review process.

	1. Submission of CAR	Responsible actor (Approximate time limit)
1	**Submission.** The eCA submits the results of the evaluation in the form of a CAR together with either an annotated IUCLID dossier or study summaries (Doc III).	eCA (365 days after validation of application)
2	**Accordance check**. SECR performs a check to verify that the CAR fulfils the requirements as indicated under 5.24.	SECR (14 days after the end of a submission window)
	a) Accordance check: pass. The submission is accepted and the evaluation will proceed to the commenting stage (see *3. Commenting phase*) and to public consultation if relevant (see 2. *Public consultation*). The eCA is informed of the result of the accordance check via R4BP v3.	SECR
	b) Accordance check: fail. The CAR and the IUCLID dossier are returned to the eCA for modifications. The eCA is informed of the result of the accordance check via R4BP v3.	SECR
3	**Rapporteur**. SECR appoints the BPC rapporteur according to Article 17(2) of the BPC RoPs unless this has already been done.	SECR

2. Public consultation	Responsible actor (Approximate time limit)
These steps are performed only if the eCA proposes the active substance to be a potential candidate for substitution. For CARs already submitted, public consultation will be performed before scheduling discussions in WGs.	
See for full details the working procedure for step 4-6	

	3. Commenting phase	Responsible actor (Approximate time limit)
7	**Distribution of CAR**. SECR distributes the CAR and a template for commenting to the MSCAs *via* CIRCABC and to the applicant via R4BP v3.	SECR (Without delay)
	Applicant: The applicant will receive the CAR from the eCA and the template for commenting from SECR via R4BP 3.	eCA, SECR (Without delay)
8	**Commenting phase**. SECR launches the commenting phase by sending an e-mail to all BPC and WG members. The MSCAs use the template for commenting and upload their comments directly to the appropriate CIRCABC newsgroup indicated by the SECR in the launching message.	SECR (Without delay) MSCAs; applicant (42 days)
	Applicant: The applicant may provide comments using the template for commenting and send these to SECR via R4BP 3. SECR uploads these comments to the appropriate CIRCABC newsgroup.	Applicant (42 days)
9	**Response to comments table (RCOM)**. As soon as the MSCAs, SECR and applicant provide their comments, the eCA will start providing responses to the comments with the aim of reaching an agreement bilaterally with the commenting body. The eCA prepares a consolidated table including all comments received together with the eCA responses. Where possible, during this time the eCA will verify whether the commenting MSCA/applicant agrees with the response, and include information on this in the table. The eCA sends this RCOM to SECR *via* CIRCABC and to the applicant via R4BP 3. The eCA prepares a separate confidential RCOM if there are comments on confidential information.	eCA, MSCA, applicants (28 days)
	Applicant: The applicant receives the RCOM from the eCA and will discuss bilaterally with the eCA on the eCA responses.	
10	**Distribution of RCOM**. SECR makes the RCOM available to the MSCAs *via* CIRCABC.	SECR (Without delay)

4. Working Group meeting and preparations	Responsible actor (Approximate time limit)
WG meets about 5 times a year to discuss open issues – See for full details the working procedure for step 11-24	

5. Ad hoc **follow-up**	**Responsible actor (Approximate time**

	limit)
These steps are performed only if there are open points following from the WG meeting.	
See for full details the working procedure for step 25-29	

6. Minutes of Working Group meeting	**Responsible actor** (Approximate time limit)
See for full details the working procedure for step 30-33	

7. CAR's coming from Technical meetings	**Responsible actor** (Approximate time limit)
These additional steps are necessary when the technical discussions were finalized in the TMs and not in WGs.	
See for full details the working procedure for step 34-37	

7. Biocidal Products Committee and preparations		**Responsible actor** (Approximate time limit)
38	**Draft agenda.** The draft agenda for the BPC meeting is published on ECHA website. An invitation is sent to the BPC members and ASOs.	SECR (21 days before the BPC)
	Applicant: The applicant should periodically check the ECHA website for the BPC agenda. The applicant can also anticipate the timing of the discussions based on the Work Programme published at the ECHA website. SECR will inform the applicant(s) of their applications being discussed at the BPC, as far as the appropriate contact information is available.	
39	**Registration.** Registration is open for members, advisers, ASOs and applicants.	SECR (21 days before the BPC)
	Applicant: The applicant may nominate a representative for the agenda item concerning their application. The applicants should contact BPC@echa.europa.eu to receive instructions for registration.	
40	**Registration deadline for the BPC meeting.** The participants will register for the meeting by the deadline.	Members (14 days13 before the BPC)
	Applicant: The same registration deadline concerns the applicant.	Applicant (14 days before the BPC)
41	**SECR-eCA dialogue.** Immediately following the WG meeting (for CARs coming from TM, following the 30-day commenting period), SECR and the eCA will start preparations for the BPC meeting. The aim of the dialogue is to find an agreement on issues related to the BPC opinion**.**	eCA (ending 26 days before the BPC meeting)
42	**Submitting the updated CAR**. The eCA will begin modifying the CAR immediately after the WG discussion, based on the agreements in the RCOM, WG meeting and ad hoc follow-up where relevant. The eCA may consult the SECR, the commenting	eCA (35 days before the BPC meeting)

	MSs and the applicant as relevant. The eCA submits the CAR and the draft BPC opinion to SECR *via* R4BP 3. Where the BPD CAR format is used, the eCA provides a draft BPC opinion using the relevant parts of the AR (Section 3).	
	Applicant: SECR provides the updated CAR to the applicant via R4BP 3**.**	
43	**Distribution.** SECR distributes the Assessment Report or if in the old format used under the BPD the updated Document IIto MSCAs via CIRCABC	SECR (without delay)
	Applicant: SECR provides the AR or if in the old format the updated Document II to the applicant via R4BP 3.	
44	**Checking the updated CAR.** It is up to each commenting MSCA to ensure that all the agreements in the RCOM are carried over to the updated CAR. If an agreement is found to be disregarded in the updated CAR, the MSCA should contact the eCA and SECR without delay.	All MSCAs (22 days before the BPC meeting)
	Applicant: The applicant can ensure that the agreements are carried over to the updated CAR and if relevant should contact the eCA and SECR without delay.	SECR; eCA (20 days before the BPC meeting)
45	**Drafting BPC opinion.** The SECR will prepare the draft BPC opinion in cooperation with the eCA.	
46	**Distribution.** SECR distributes the draft BPC opinion to MSCAs via CIRCABC.	SECR (20 days before the BPC meeting)
	Applicant: SECR provides the draft BPC opinion to the applicant via R4BP 3.	
47	**Other documents.** Any documents intended for discussion at the BPC meeting have to be provided no later than 10 days before the meeting. SECR will make these documents available to the MSCAs via CIRCABC and to the applicant via R4BP 3.	eCA; MSCAs; SECR (10 days before the BPC meeting)
48	**Commenting period.** The MSCAs and SECR may provide written comments on the AR and the draft opinion, especially where issues have not been included as agreed earlier in the process. SECR will open a dedicated newsgroup in CIRCABC for each substance.	MSCAs, SECR (10 days before the BPC meeting)
	Applicant: The applicant may provide written comments to SECR via e-mail.	

49	**Finalisation of the *open issues* document**. The SECR finalises the *open issues* document according to the agreements at the BPC and distributes the document to MSCAs via CIRCABC.	SECR (21 days after the BPC meeting)
50	**BPC opinion finalisation and dissemination**. The SECR, in consultation with the eCA, finalises the BPC opinion according to the agreements at the BPC and forwards it to COM. The finalised opinion is published on the website of the BPC.	SECR (21 days after the BPC meeting)

	Minority positions will have to be submitted to the SECR by the involved member within 7 days after the BPC meeting.	

7. Finalisation and dissemination steps		**Responsible actor** (Approximate time limit)
51	**Finalisation of the open issues document.** The SECR finalises the open issues document according to the agreements at the BPC and distributes the document to MSCAs via CIRCABC.	SECR (18 days after the BPC meeting)
52	**BPC opinion finalisation and dissemination.** The SECR, in consultation with the eCA, finalises the BPC opinion according to the agreements at the BPC and forwards it to COM. The finalised opinion is published on the website of the BPC. Minority positions will have to be submitted to the SECR by the involved member within 7 days after the BPC meeting.	SECR (18 days after the BPC meeting)
	Applicant: SECR provides the final AR to the applicant via R4BP 3.	
53	Updating the CAR and IUCLID file or Doc III. The eCA provides to SECR the updated CAR based on the discussions and agreements. The assessment report should be provided in both a confidential and a non-confidential version as it will be disseminated. The submission is done via R4BP 3. The eCA updates the IUCLID file or Doc III based on the discussions and agreements, and provides them to the applicant for confidentiality check.	eCA (42 days after the BPC meeting)
54	**AR distribution**. SECR sends the final AR to COM and makes it available to the MSCAs *via* CIRCABC.	SECR (Without delay)
	Applicant: SECR provides the final AR to the applicant via R4BP 3.	
55	Confidentiality check for the IUCLID file or study summaries. The applicant will provide to the eCA the files indicating any confidentiality claims to ensure that no confidential information is disclosed to the public.	
56	**Non-confidential IUCLID file or Doc IIIA.** The eCA will assess the confidentiality claims and prepare a non-confidential version of the IUCLID/Doc IIIA and provide them to SECR14 together with any confidential annexes. The submission is done via R4BP 3.	eCA (120 days after the BPC meeting)
57	**Distribution of the IUCLID file or Doc IIIA**. The SECR will make the confidential and non-confidential files available to the MSCAs via R4BP or CIRCABC.	SECR (without delay)
58	**Dissemination.** After the COM approval decision of the active substance, ECHA disseminates the relevant information on the ECHA website: http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances	SECR (without delay)

Biocidal product phase

Action	Deadline
Product authorization: Biocidal product supplier to apply for authorization at country authority level of the country/countries of interest for marketing the biocidal product. Alternatively Union authorization can be applied for at ECHA.	The official approval date (for inclusion in the Union list) of the active substance is in general about 18 months after approval in the BPC meeting. The official approval is generally published 5-6 months (steps 51-58) after agreement in the BPC meeting. Latest at the date of official inclusion of the active substance, biocidal product dossiers have to be submitted. From official publication date, about 18 months are left to submit the biocidal product dossiers. Authorities then have maximum 36 months to finalize the evaluations of the biocidal product dossiers submitted.

10. Table 2 Product Types supported by

AkzoNobel Surface Chemistry AB per active substance: x (on Art 95)

Product Type (PT)	BKC CAS no: 68424-85-1	DDAC CAS no: 7173-51-5	TMAC CAS no: 61789-18-2	TriameenY12D CAS no: 2372-82-9
Main group I: Disinfectants and general biocidal products				
1. Human hygiene	x	x		
2. Disinfectants and algaecide not intended for direct application on humans or animals (previously called Private and public health area)	x	x		x
3. Veterinary hygiene	x	x		x
4. Food and feed area	x	x		x
5. Drinking water				
Main group II: Preservatives				
6. Preservatives for products in storage (previously called: In can preservatives)				x
7. Film preservatives				
8. Wood preservatives	x	x	x	
9. Fiber, leather, rubber and polymerized material preservatives				
10. Construction material preservatives (previously called: Masonry preservatives)	x	x		
11. Preservatives for liquid cooling and processing systems	x	x		x
12. Slimicides	x	x		x
13. Working and cutting fluid preservatives (previously called: Metalworking fluid preservatives)				x
Main group III: Pest control				
14. Rodenticides				
15. Avicides				
16. Molluscicides, vermicides and products to control other invertebrates				
17. Piscides				
18. Insecticides, acaricides and products to control other arthropods				
19.Repellants and attractants				
Main group IV: Other biocidal products				
20. Control of other vertebrates				
21. Antifouling products				
22. Embalming and taxidermist fluids				

11. Disclaimer:

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