Biocidal active substances: The EU review programme for the approval of the active substances

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The Biocidal Product Regulation

The scope of BPR

- **Harmonising** the market at Union level;
- **Simplifing** the approval of active substances and authorization of biocidal products;
- Introducing **timelines** for Member State evaluations, opinion-forming and decision-making;
- **Promoting** the **reduction of animal testing** by introducing mandatory data sharing obligations; and
- **Encouraging the use of alternative** testing methods.

According to the BPR …

1. Biocidal product requires an **authorisation** before placing on the market
2. Active substances - contained in a biocidal product - must be **approved**

The a.s. approval takes place at **Union level**
while
the b.p. authorization is granted at **Member State level**

The b.p. authorisation can be extended to other Member States by **mutual recognition**

News: BPR introduced the possibility for applicants to apply for a new type of authorization at Union level, named **UNION AUTHORIZATION**

APPROVAL OF ACTIVE SUBSTANCES

BPR - A biocidal product containing an active substance can be authorized only if that active substance has been approved for the relevant product type

A.s. approval – in brief

1. Assessement by an evaluating Competent Authority (eCA) → 1 year
2. Evaluation submitted to ECHA's Biocidal Products Committee for the preparation of an opinion → 270 days
3. Adoption by the European Commission of the a.s. approval

The **approval of an active substance** is granted for a maximum of **10 years**

When the a.s. approval expires an application can be re-submitted and the approval can be renewable

Duration of the a.s. approval depends on whether or not the a.s. meets:

1. the **exclusion criteria** (art. 5 – BPR); or

1. the **substitution criteria** (art. 10 – BPR)

Exclusion criteria (art. 5 – BPR)

BPR - active substance meeting the exclusion criteria cannot be approved

Exclusion criteria includes

- carcinogens, mutagens and reprotoxic substances (CMR) categories 1A or 1B according to the CLP Regulation
- endocrine disruptors
- persistent, bioaccumulative and toxic (PBT) substances
- very persistent and very bioaccumulative (vPvB) substances

Derogations to the non-approval

the a.s. is needed due to the public health or public interest;

no alternatives are available.

Approval of an active substance is granted for a maximum of five years

Substitution criteria (art. 10 – BPR)

Objective is to

- identify a.s. of particular concern to public health or the environment; and
- ensure the phased-out of these a.s. to be replaced by more suitable alternatives over time

Substitution criteria includes substances

(*based on the intrinsic hazardous properties in combination with the intended use*)

- Meeting at least one of the exclusion criteria.
- Classification as a respiratory sensitiser.
- Toxicological reference values significantly lower than those of the majority of approved active substances for the same product-type and use
- Meeting two of the PBT criteria
- Causing concerns for human or animal health and for the environment even with very restrictive risk management measures
- Containing a significant proportion of non-active isomers or impurities.

Substitution criteria (art. 10 – BPR)

Approval process → eCA identifies that the a.s. is a **potential candidate for substitution**, this piece of information is highlighted in the conclusions of the evaluation.

Following to that ECHA launches a **public consultation** in order to prove that no alternatives are available and therefore the a.s. can be approved.

Active substances which are candidates for substitution will not be approved for more than seven years, even in the case of renewal.

If the active substance meets one or more exclusion criteria, it will only be approved for five years.

Substitution criteria (art. 10 – BPR)

Active substance

identified as a candidate for substitution

Biocidal product

containing the active substance

- **to be subject to a comparative assessment at the time of authorization; and**
- **to be authorized if there are no better alternatives**

Substitution criteria (art. 10 – BPR)

ECHA Biocidal Products Committee in cooperation with other Expert Groups

Harmonised classification key element in the exclusion criteria

Biocidal Products Committee (**BPC**) and the Risk Assessment Committee (**RAC**) cooperation is ensured to assess if the a.s. is candidate for substitution

PBT properties

BPC and ECHA **PBT expert group** cooperate to decide if an a.s. is a candidate for substitution

APPROVAL OF ACTIVE SUBSTANCES

Biocidal Products Regulation

Existing active substance

*« a substance which was on the market on **14 May 2000** as an active substance of a biocidal product for purposes other than scientific or product and process-orientated research and development »*

New active substance

*« a substance which was not on the market on **14 May 2000** as an active substance of a biocidal product for purposes other than scientific or product and process-orientated research and development »*

Existing active substance

Review Programme

Review Programme (RP) is a work programme established for the examination of existing biocidal active substances at EU level.

RP was set up by the European Commission under the Biocidal Products Directive (BPD) and continues under the Biocidal Products Regulation (BPR).

The legislations…

BPD – The existing active substances which were accepted to be examined in the RP were those which were identified as such and for which a notification was accepted, as set out in Annex II to Commission Regulation (EC) No 1451/2007

BPR – The detailed rules for the RP, adapted to the provisions of the BPR, have been set up in the **Regulation (EU) No 1062/2014 (Review Programme Regulation, RPR)**

The RPR …

- Defines the **role for ECHA**;

The Review Programme is foreseen to be completed by 2024.

- introduces the possibility to **add substance/PT combinations** to the RP, under certain conditions.

Annex II part 1 of the RPR

ANNEX II

SUBSTANCE/PRODUCT-TYPE COMBINATIONS INCLUDED IN THE REVIEW PROGRAMME ON 4 AUGUST 2014

PART 1

Active substance/product-type combinations supported on 4 August 2014, excluding any other nanomaterial than those explicitly mentioned in entries 1017 and 1019

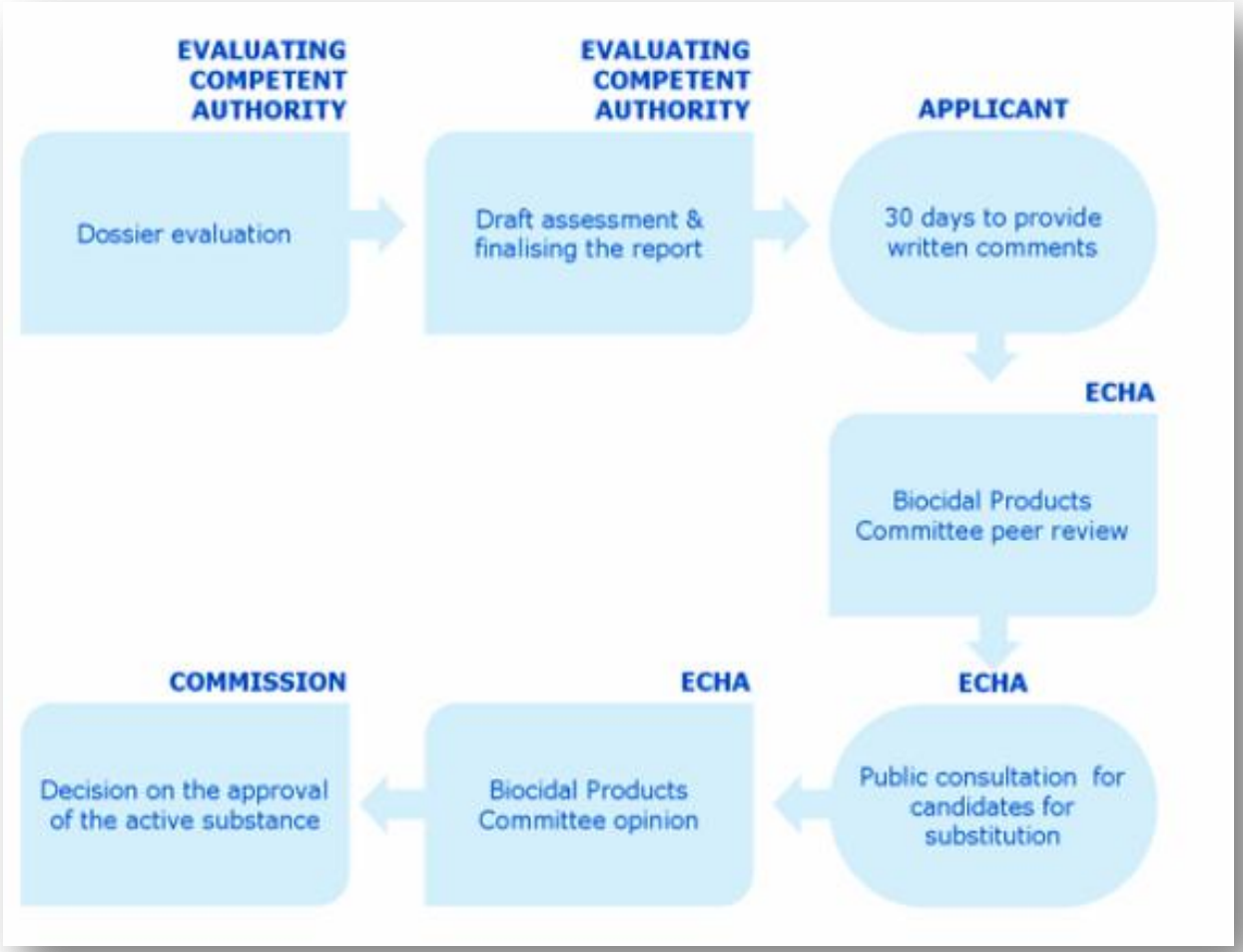
Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
1	Formaldehyde	DE	200-001-8	50-00-0		x	x															x
6	2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether (Piperonyl butoxide/PBO)	EL	200-076-7	51-03-6															x			
9	Bronopol	ES	200-143-0	52-51-7		x				x			x		x	x						x
29	Chlorocresol	FR	200-431-6	59-50-7	x	x	x			x			x				x					
36	Ethanol	EL	200-578-6	64-17-5	x	x		x														
37	Formic acid	BE	200-579-1	64-18-6		x	x	x	x	x					x	x						
40	Propan-2-ol	DE	200-661-7	67-63-0	x	x		x														
43	Salicylic acid	NL	200-712-3	69-72-7		x	x	x														
45	Propan-1-ol	DE	200-746-9	71-23-8	x	x		x														
52	Ethylene oxide	N	200-849-9	75-21-8		x																
60	Citric acid	BE	201-069-1	77-92-9	x																	
69	Glycolic acid	LT	201-180-5	79-14-1		x	x	x														
70	Peracetic acid	FI	201-186-8	79-21-0	x	x	x	x	x	x					x	x						
71	L-(+)-lactic acid	DE	201-196-2	79-33-4		x	x	x		x												

EVALUATION PROCESS

Existing active substance

&

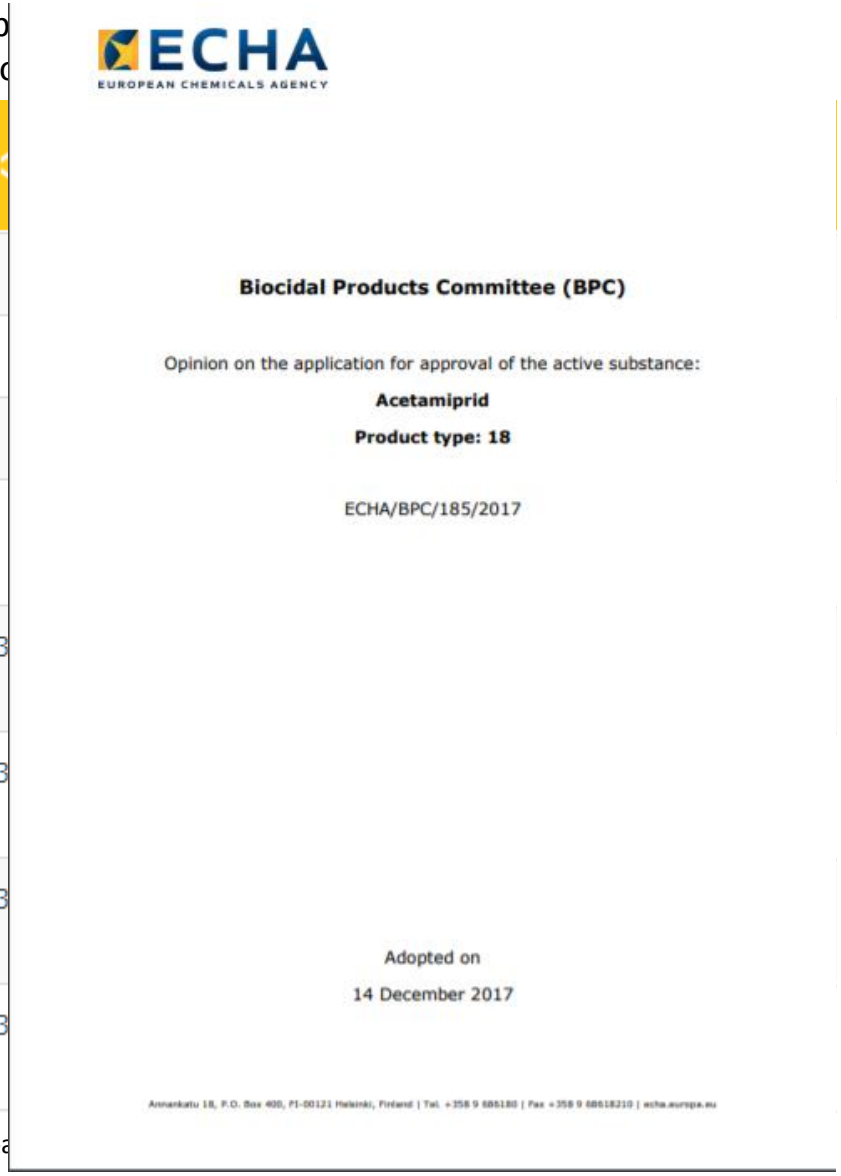
New active substance



Biocidal Products Committee opinions of the approved active substance approval

European Commission includes approved active sub
(formerly Annex I c

Active substance	EC Number	CAS Number
2-Phenoxyethanol	204-589-7	122-99-6
2-Phenoxyethanol	204-589-7	122-99-6
2-Phenoxyethanol	204-589-7	122-99-6
Acetamiprid	-	135410-20-7
Active chlorine released from calcium hypochlorite	231-908-7	7778-54-3
Active chlorine released from calcium hypochlorite	231-908-7	7778-54-3
Active chlorine released from calcium hypochlorite	231-908-7	7778-54-3
Active chlorine released from calcium hypochlorite	231-908-7	7778-54-3



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Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Acetamiprid

Product type: 18

ECHA/BPC/185/2017

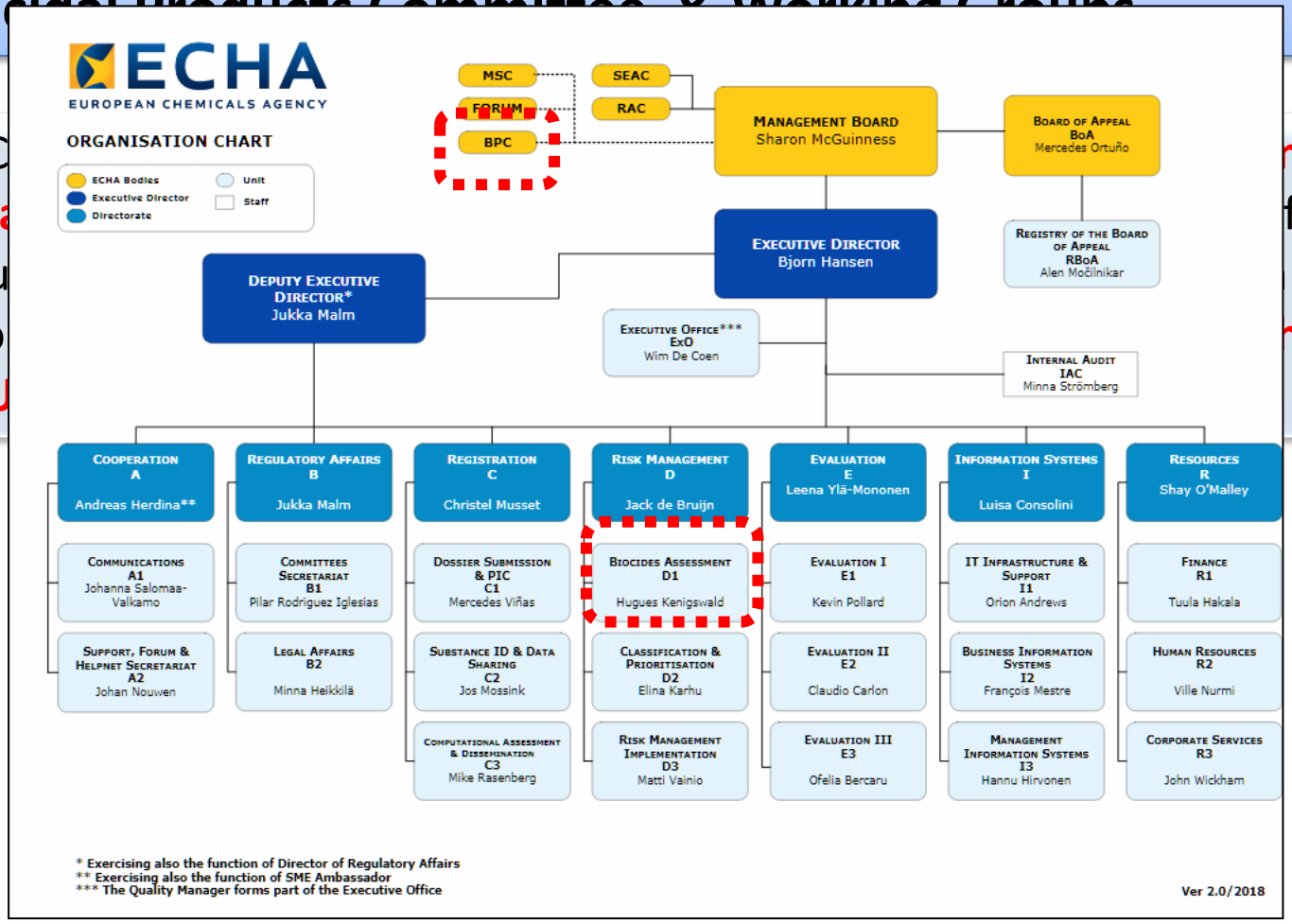
Adopted on

14 December 2017

https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-a

ECHA

Biocidal Products Committee & Working Groups



Biocidal Products Committee

Mission is to prepare opinions on…

- Applications for approval and renewal of active substances;
- Identif…on;
- Applica…dditives, weak acids, p…
- Applica…
- Scienti…
- Any ot… environment, or to technical guidance.

The final decisions are taken by the European Commission

Composition

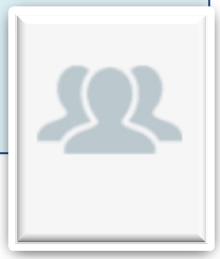
Each Member State is entitled to appoint one member and an alternate member to the BPC for a renewable term of three years. Applicants may participate in BPC discussions.

Working Groups of the Biocidal Products Committee

The **Working Groups** (**WG**) support the BPC with the preparation of its opinions and contribute to the harmonization of risk assessment under the BPR.

Four permanent Working Groups have been established by the BPC, each of them dealing with a specific part of the biocidal risk assessment:

- Working Group - Efficacy
- Working Group - Analytical Methods and Physico-chemical Properties
- Working Group - Human Health
- Working Group - Environment



Composition

WGs consist of **core members** and **flexible members**, advisers may accompany members to meetings.

Ad hoc Working Groups of the Biocidal Products Committee

In addition to the permanent WGs, four **Ad hoc Working Groups** support the **BPC** and its **permanent WGs**

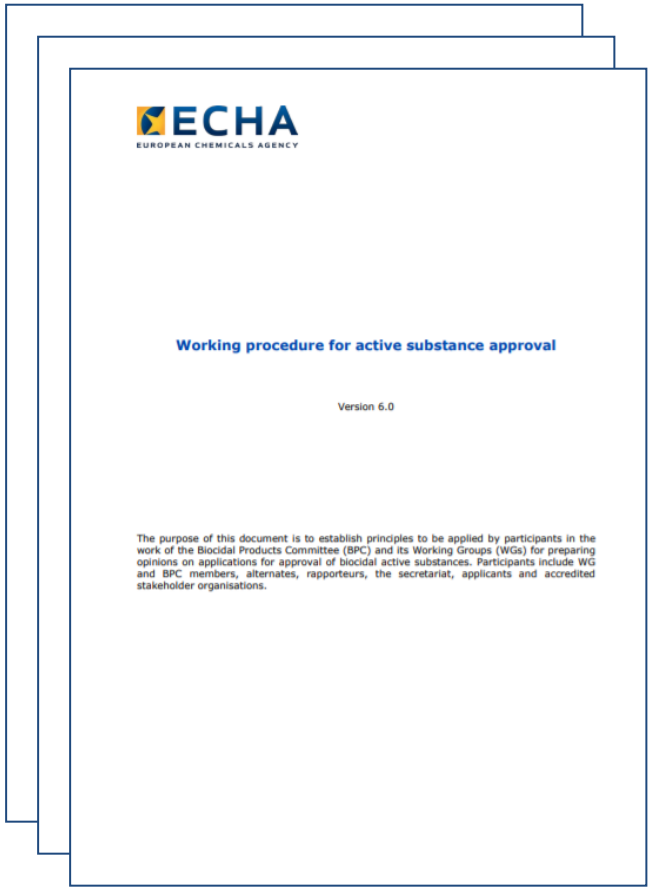
The following Ad hoc WGs have been established:

- Ad hoc Working Group - Human Exposure
- Ad hoc Working Group - Assessment of Residue Transfer to Food
- Ad hoc Working Group - Environmental Exposure
- Ad hoc Working Group – Microorganisms

Composition

Ad hoc WGs do not differentiate between core members and flexible members. In contrast to the WGs, the Ad hoc Working Groups carry out work on a continuous basis throughout the year, mainly by electronic exchanges or virtual meetings.

Working procedure for active substance approval



The document establishes the **standard procedures for the peer review process** of biocidal active substance evaluation

According to the BPR, the opinion on the a.s. approval should be submitted by BPC to the COM **within 270 days** from the submission of the eCA conclusions.

Therefore, WP provides…

- a descriptions of the steps to be taken during these 270 days of the peer review process.

Therefore, the steps considered in the WP start **from** the eCA submitting the Competent Authority Report (CAR) **until** the dissemination of the finalized opinion of the BPC.

https://echa.europa.eu/documents/10162/4221979/bpc_working_procedure_active_substance_en.pdf/3a35e75d-7c08-4c87-b501-8c24f0081dde

Table 1. *Description of the steps in the biocidal active substance 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 including the reference specification and reference source(s) either as an annotated IUCLID dossier or study summaries (Doc III). Please see 3.2 Submitting other documents for information on using the old format (study summaries in Doc [illegible] could be done via R4BP 3 ad hoc	eCA (365 days after validation of application)
[illegible] (see step 2a).	
2. **Accordance check.** Se[illegible] fulfils the requirements	[illegible] 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 SECR informs the eCA of the result of the accordance check via R4BP 3. The eCA closes the evaluation task in R4BP 3 and the case is promoted; the ECHA opinion task is created.	SECR, eCA
b) **Accordance check: fail.** The CAR and the IUCLID dossier are returned to the eCA for modifications. The SECR informs the eCA of the result of the accordance check via R4BP 3, and the eCA will revise and resubmit the CAR, as well as the IUCLID dossier, if necessary.	SECR
3. **Rapporteur.** SECR appoints the BPC rapporteur according to Article 17(2) of the BPC RoPs	SECR

2. Public consultation[3]	Responsible actor (Approximate time limit)
These steps are performed only if the eCA proposes the active substance to be a potential candidate for substitution. Where relevant, public consultation is always performed before scheduling discussions in WGs.	
4. **Public consultation.** SECR drafts the text for public consultation and submits it to the applicant via R4BP 3 and to the eCA for consultation before publishing. In addition to the substance identity (name and EC/CAS numbers), the public consultation indicates the PT and eCA, describes the intended uses and indicates the conditions of BPR Art 10(1) that are met.	SECR (14 days after accordance check)
Applicant: The applicant will review the text proposal to check for confidentiality issues and correctness of the information before the consultation is published.	Applicant (Without delay)

[3] Public consultation is parallel to 3. *Commenting phase*.

Task number

Type of task to be accomplished

Responsible of the task & Timing

The fixed timing for each step is provided in the separate document "*Timelines for the peer review of active substance evaluations*".

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9 February 2018

Timelines for the peer review of active substance evaluations

As indicated in section 3 of the Working procedure for active substance approval, the dates given below are the actual dates for each step. The first column 'WP step' refers to the steps given in the working procedure. The numbering for process flows 25 onwards has been reassigned to match the BPC meeting numbering: from PF 29 onwards the PF number is the same as the corresponding BPC meeting number.

Type of task to be accomplished

Timing

WP Step	Task		Process flow 19	Process flow 20	Process flow 21	Process flow 22	Process flow 23	Process flow 24	Process flow 29	Process flow 30	Process flow 31	Process flow 32	Process flow 33
1	Submission window	Start	07 Jan 2017	18 Mar 2017	13 Jun 2017	01 Aug 2017	03 Oct 2017	23 Jan 2018	07 Mar 2018	01 Jun 2018	14 Jul 2018	29 Sep 2018	04 Jan 2019
		End	17 Mar 2017	12 Jun 2017	31 Jul 2017	02 Oct 2017	22 Jan 2018	06 Mar 2018	31 May 2018	13 Jul 2018	28 Sep 2018	03 Jan 2019	15 Mar 2019
					31 Jul 2017	02 Oct 2017	22 Jan 2018	06 Mar 2018	31 May 20				Mar 2019
					21 Aug 2017	23 Oct 2017	12 Feb 2018	09 Apr 2018	21 Jun 20				Apr 2019
					04 Sep 2017	06 Nov 2017	26 Feb 2018	23 Apr 2018	05 Jul 201				Apr 2019
					03 Nov 2017	05 Jan 2018	27 Apr 2018	22 Jun 2018	03 Sep 20				Jun 2019
8	Commenting CAR	Start	07 Apr 2017	03 Jul 2017	21 Aug 2017	23 Oct 2017	12 Feb 2018	09 Apr 2018	21 Jun 2018	03 Aug 2018	19 Oct 2018	24 Jan 2019	05 Apr 2019
		End	12 May 2017	14 Aug 2017	25 Sep 2017	27 Nov 2017	19 Mar 2018	14 May 2018	26 Jul 2018	07 Sep 2018	23 Nov 2018	28 Feb 2019	10 May 2019
	updated CAR	End	21 Nov 2017	13 Feb 2018	04 Apr 2018	04 Jun 2018	25 Sep 2018	20 Nov 2018	05 Feb 2019	19 Mar 2019	04 Jun 2019	17 Sep 2019	19 Nov 2019
44	Draft BPC opinion & AR	Start	07 Nov 2017	30 Jan 2018	20 Mar 2018	22 May 2018	11 Sep 2018	06 Nov 2018	21 Jan 2019	04 Mar 2019	20 May 2019	02 Sep 2019	04 Nov 2019
		End	21 Nov 2017	13 Feb 2018	04 Apr 2018	04 Jun 2018	25 Sep 2018	20 Nov 2018	05 Feb 2019	19 Mar 2019	04 Jun 2019	17 Sep 2019	19 Nov 2019
47	Commenting AR & opinion	Start	21 Nov 2017	13 Feb 2018	04 Apr 2018	04 Jun 2018	25 Sep 2018	20 Nov 2018	05 Feb 2019	19 Mar 2019	04 Jun 2019	17 Sep 2019	19 Nov 2019
		End	01 Dec 2017	23 Feb 2018	13 Apr 2018	14 Jun 2018	05 Oct 2018	30 Nov 2018	15 Feb 2019	29 Mar 2019	14 Jun 2019	27 Sep 2019	29 Nov 2019
48	Open issues table	Start	04 Dec 2017	26 Feb 2018	16 Apr 2018	17 Jun 2018	08 Oct 2018	03 Dec 2018	18 Feb 2019	01 Apr 2019	17 Jun 2019	30 Sep 2019	02 Dec 2019
		End	06 Dec 2017	28 Feb 2018	18 Apr 2018	19 Jun 2018	10 Oct 2018	05 Dec 2018	20 Feb 2019	03 Apr 2019	19 Jun 2019	02 Oct 2019	04 Dec 2019
49	BPC	Number	BPC-23	BPC-24	BPC-25	BPC-26	BPC-27	BPC-28	BPC-29	BPC-30	BPC-31	BPC-32	BPC-33
		Start	11 Dec 2017	05 Mar 2018	23 Apr 2018	24 Jun 2018	15 Oct 2018	10 Dec 2018	25 Feb 2019	08 Apr 2019	24 Jun 2019	07 Oct 2019	09 Dec 2019
		End	15 Dec 2017	09 Mar 2018	27 Apr 2018	29 Jun 2018	19 Oct 2018	14 Dec 2018	01 Mar 2019	12 Apr 2019	28 Jun 2019	11 Oct 2019	13 Dec 2019
51	Opinion finalisation	Start	15 Dec 2017	09 Mar 2018	27 Apr 2018	29 Jun 2018	19 Oct 2018	14 Dec 2018	01 Mar 2019	12 Apr 2019	28 Jun 2019	11 Oct 2019	13 Dec 2019
		End	02 Jan 2018	30 Mar 2018	18 May 2018	20 Jul 2018	09 Nov 2018	01 Jan 2019	19 Mar 2019	30 Apr 2019	16 Jul 2019	29 Oct 2019	31 Dec 2019
52	Updating CAR & IUCLID/Doc III	Start	15 Dec 2017	09 Mar 2018	27 Apr 2018	29 Jun 2018	19 Oct 2018	14 Dec 2018	01 Mar 2019	12 Apr 2019	28 Jun 2019	11 Oct 2019	13 Dec 2019
		End	26 Jan 2018	20 Apr 2018	08 Jun 2018	10 Aug 2018	30 Nov 2018	25 Jan 2019	12 Apr 2019	24 May 2019	09 Aug 2019	22 Nov 2019	24 Jan 2020
54	Confidentiality check	Start	15 Dec 2017	09 Mar 2018	27 Apr 2018	29 Jun 2018	19 Oct 2018	14 Dec 2018	01 Mar 2019	12 Apr 2019	28 Jun 2019	11 Oct 2019	13 Dec 2019
		End	25 Feb 2018	20 May 2018	08 Jul 2018	09 Sep 2018	03 Jan 2019	24 Feb 2019	12 May 2019	23 Jun 2019	08 Sep 2019	22 Dec 2019	23 Feb 2020
55	Non-confidential IUCLID/Doc III	Start	25 Feb 2018	20 May 2018	08 Jul 2018	09 Sep 2018	03 Jan 2019	24 Feb 2019	12 May 2019	23 Jun 2019	08 Sep 2019	22 Dec 2019	23 Feb 2020
		End	14 Apr 2018	07 Jul 2018	25 Aug 2018	27 Oct 2018	16 Feb 2019	13 Apr 2019	29 Jun 2019	10 Aug 2019	26 Oct 2019	08 Feb 2020	11 Apr 2020

Note that WG and BPC meetings are subject to changes. Please refer to the ECHA site for updated information:
https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups
https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/meetings-of-the-biocidal-products-committee

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https://echa.europa.eu/documents/10162/4221979/revised_timeline_as_app_en.pdf/ba57583d-b081-4b6e-8632-3d8a5bfe0028

Thank you for the attention!