Note for evaluating Competent Authorities on how to act in case an applicant in the Review Programme does not provide in time information requested during the evaluation phase

Date: 11 July 2019

(1) During the "Active Substance Workshop" of 12–13 February 2019, Member States representatives asked for further guidance on situations in which additional information was requested but the Review Programme participant does not submit the requested information in time. This document aims to provide this guidance.

(2) The relevant provisions are laid down in Regulation (EU) No 1062/2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 (the Review Programme Regulation or RPR).

Article 6 - Evaluation of applications
[…]
(5) Where it appears that additional information is necessary to carry out the evaluation, the evaluating competent authority shall ask the participant to submit such information within a specified time limit, and shall inform the Agency accordingly.

The 365-day period referred to in paragraph 3 shall be suspended from the date of issue of the request until the date the information is received. Unless it is justified by the nature of the data requested or by exceptional circumstances, the suspension shall not exceed the following time-limits:

(a) 365 days in cases where the additional information relates to concerns which were not addressed under Directive 98/8/EC or under the practice established for application of that Directive;

(b) 180 days in other cases.

and

Article 11 - Participants' withdrawal
(1) A participant shall be considered to have withdrawn its support for a substance/product-type combination in the review programme in the following cases:
[…]
(d) where it has failed to provide the additional information within the time limits provided for by Article 6(5);
[…]
(2) A withdrawal shall be considered as timely unless it occurs after the date when the evaluating competent authority submits its competent authority report to the applicant pursuant to Article 6(4) of this Regulation.

(3) If the participant withdraws during the evaluation phase (i.e. before the competent authority report (CAR) is submitted to the applicant), it shall be considered as a timely withdrawal in accordance with Article 11(2) of the RPR.

(4) The applicant should be duly informed of the consequences of not providing the

requested additional information by the specified deadline.

(5) In view of the important consequences of a withdrawal, it appears proportionate to allow additional time provided the evaluating Competent Authority is informed timely that the requested information cannot be provided by the deadline.

(6) It should be noted that a timely withdrawal does not automatically mean that the active substance product type (PT) combination is removed from the Review Programme. Upon withdrawal of all participants for a Review Programme active substance PT combination, the role of participant may be taken over once by other prospective participants. Therefore:

- If all participants have withdrawn and the role of participant in the Review Programme has already been taken over previously, the Agency will inform the Commission that the active substance – PT combination shall be removed from the Review Programme by taking a non-approval decision;

- If all participants have withdrawn and the role of participant in the Review Programme has not been taken over previously, an open invitation to take over the role of participant will be published by the Agency in accordance with Article 14 of the RPR.

(7) Based on these provisions the following procedural guidance is provided:

- In case additional information is requested by the evaluating Competent Authority according to Article 6(5) of the RPR the participant shall be informed via R4BP 3 of the requested information with a deadline by which the information has to be submitted. This deadline should be defined according to the type of information to be provided and should be discussed with the applicant in order to take into account specific elements that may impact the time needed to address the request, such as the type of study and the actual availability of laboratories to perform the study. The deadline for submitting the requested information shall not, in any event, exceed the time limits provided for in points a) and b) of the second subparagraph of Article 6(5) of the RPR, unless justified otherwise in accordance with that provision.

- In this request, the evaluating Competent Authority shall highlight the consequences of failing to provide the requested information within the specified deadline (i.e. failure to provide the additional information within the time limits shall be considered as a withdrawal of the participant in accordance with Article 11(1)(d) of the RPR). The request should also require that the participant informs the evaluating Competent Authority immediately in case of a foreseen delay.

- The evaluating Competent Authority should monitor whether the applicant submits the requested information by the specified deadline.

- If the participant informs the evaluating Competent Authority that it is unable to provide the requested information by the specified deadline, it should provide a justification and indicate the extended timeline needed to address the request. The evaluating Competent Authority will consider the justification provided and the indicative revised timeline and decide whether to modify or keep the deadline for providing the requested information. If the deadline is modified it shall not, in any event, exceed the time limits provided for in points a) and b) of the second subparagraph of Article 6(5) of the RPR, unless justified otherwise in accordance with that provision.

- If the information is not submitted by the specified deadline the evaluating Competent Authority shall inform the participant timely via R4BP 3 – referring to Article 11 of the RPR – that it will consider the participant to have withdrawn, unless the participant

reacts within a given period[1] by submitting the requested information. A period of 15 working days is recommended. The evaluating Competent Authority shall also inform ECHA via R4BP 3.

- If the participant does not react within this period of 15 working days by providing the requested information, the evaluating Competent Authority informs the participant via R4BP 3 and ECHA via the functional mailbox biocides@echa.europa.eu that it considers the participant to have withdrawn.

(8) Templates for letters to be sent by the evaluating Competent Authority are available below.

oOo

[1] Introducing this period to submit the requested information is considered to be good administrative practice as for example the submission by the dead-line may have been prevented by an IT failure.

Template request additional information

Dear […],

We contact you in relation to the application for active substance approval for [insert name active substance] for PT [insert PT(s)] with the following R4BP case number(s) [insert case number(s)].

Following previous consultations with you we request – referring to Article 6(5) of Regulation (EU) No 1062/2014 – the following additional information: [specify requested information].

Please submit the requested information to us via R4BP by the following dead-line: [insert dead-line].

Please note that if the requested information is not submitted by this dead-line we will – referring to Article 11(d) of Regulation (EU) No 1062/2014 – consider that you have withdrawn your support for this application.

If you are not able to submit the information by the dead-line you have to inform us via R4BP well in advance by providing a justification for not meeting the dead-line and suggest a new dead-line. Based on this justification we will consider if we can extend the dead-line set in this letter.

Yours sincerely,

Template letter if the applicant has not submitted the additional information in time

Dear […],

We contact you in relation to the application for active substance approval for [insert name active substance] for PT [insert PT(s)] with the following R4BP case number(s) [insert case number(s)].

In our letter of [insert date and reference] we requested the following additional information: [specify information requested]. The dead-line by which this additional information had to be submitted was [insert date]. We note you have not submitted the requested information by the dead-line set in our letter.

Please be informed that if we do not receive via R4BP the requested additional information by [date applying the 15 days period indicated in the ECHA note] we will – with reference to Article 11(1)(d) of Regulation (EU) No 1062/2014 – consider that you have withdrawn your support for this application and we will take the steps described in Regulation (EU) No 1062/2014 following this consideration.

Yours sincerely,

oOo