21 November 2019

Active Substances Action Plan

Introduction

After 15 years of the Review Programme, and only 6 years left until 2024, decisions have been taken for about only one third of the active substance/product type (AS/PT) combinations. After a promising period between 2014 and 2016, the submission of draft Competent Authority Reports (CARs) has almost dried out in 2018 and 2019.

In 2018, ECHA conducted the "Grip on the Review Programme" survey, addressed to the Member States' Competent Authorities for biocidal products (MSCAs). The aim of the survey was to collect information on the status of the Review Programme dossiers, identify the causes for delays and propose solutions.

In February 2019, ECHA organised the second Workshop on the Active Substance process, to have an open discussion with Member States (MSs), European Commission (EU COM) and Accredited Stakeholders Associations (ASOs) on how to improve the active substance approval process, with a special focus on the Review Programme.

The focus is on the Review Programme because the evaluation and peer review is finalised for only 293 Active substance/Product type combination, out of a total of 727 , possible unacceptable risk are not managed, thousands of biocidal products not being evaluated are still on the market. In essence, the expected high level of safety for human and environment is not achieved. In addition, future resources in the biocides authorities are dependent on the progress on the active substances and the subsequent fee income at product authorisation phase. Finally, companies' situations varies dependently on the status of their active substance dossier under the Review Programme, and a level playing field is not ensured.

A joint commitment is crucial to make progress. Within its capacity, ECHA will reinforce the support and coordination actions in place since 2018, and will undertake the agreed actions from this document; nevertheless a clear and strong engagement is required from the Member States on which, ultimately, lies the capability to progress further with the Review Programme. The EU COM will contribute within its role and remit in this integrate effort. The applicants are also invited to cooperate with the eCAs and to maintain transparent and constructive communications.

In the light of the results of the Grip on the Review Programme survey and the active substance workshop, ECHA is proposing the following action plan to the CAs for biocides and the European Commission to unblock the submission of the draft CARs.

The CA meeting members are requested to discuss and agree on the action plan.

Action Plan

ECHA analysed the information collected at the Workshop and through the regular contacts with the eCAs and identified five main areas that the MSs reported as blocking factors: insufficient resources, unclear priorities, incomplete and low quality dossiers, high complexity of the process and of the assessment (e.g. in situ generated active substances, endocrine disruption properties), and absence of pragmatic approaches.

From the identified areas, ECHA has had internal discussions in order to define in which aspects could the Agency, within its remits and availability of resources, provide meaningful support. ECHA has elaborated the actions described below:

- prioritisation of dossiers;
- support to the evaluating Competent Authorities (eCAs) to overcome resource or capacity issues;
- streamlining the peer review phase;
- reduction of the complexity in the assessment;
- facilitate and harmonise the assessment of confidentiality claims.

Prioritisation of dossiers

In general, the Review Programme including backlog substances competes in the MSCAs planning with other activities such as new active substances and product authorisations under the BPR and under national transitional legislation. The timelines set in the Review Programme regulation are not always considered by the MSCAs among the criteria for prioritisation. This results in diverging priorities between MSCAs.

Description of the action:

ECHA national contact points [1]have been following the eCAs portfolio regularly. In the exchanges with the eCAs, ECHA has reminded the eCAs of the priorities as stated in CA-Nov18-Doc.5.1: dossiers submitted before 1 September 2013 (backlog dossiers) and the Review Programme priority lists. Among these dossiers, further priority could be given to substances meeting the exclusion or substitution criteria according to Art 5 and 10 of the BPR, and AS/PT combinations for which and unacceptable risk is identified and accordingly, the eCA concludes on non-approval proposal.

In addition, ECHA proposed to prioritise:

- active substance dossiers for which the finalisation of the draft CAR is blocked only by the determination of endocrine-disrupting properties (EDs) pursuant to Delegated Regulation (EU) 2017/2100;

- active substance dossiers for which a limited effort is required to complete the draft CAR (e.g. substances blocked by only one blocking factor or several but easy to solve).

The specific situation of the different dossiers under evaluation by a given eCA is taken into account in both prioritisation and support actions.

1 ECHA National contact points have been established by ECHA since 2018 with the main role to monitor the progress of the dossiers within the portfolio of the eCAs; identify issues that prevent the finalisation of the assessment; discuss with the eCA on the setting of priorities for finalising the dossiers; build a communication channel and strong cooperation with the eCA. ECHA has intensified the communications and support since March 2019.

It is planned that ECHA national contact point will follow-up the eCAs' portfolio regularly conducting, with the cooperation of the eCAs, several iterations in order to define dossiers for prioritisation, identification of issues and need for support.

Support to the eCAs

The identification of support needs will be periodically conducted via the regular exchanges between ECHA and the MSCAs.

According to the information collected by ECHA, different type of support may be requested by the eCAs: support of technical/scientific nature, procedural, regulatory, and support to facilitate the relationship with the applicants.

For the selection of the cases for support, ECHA proposes to apply the same criteria as for the prioritisation (Cf. 2.1). ECHA and the eCAs will agree on which draft CARs and which sections will receive support and on the timelines for the finalisation of the evaluation and submission of the draft CAR to ECHA. It is necessary that the MSCAs prioritise the finalisation of these dossiers, allocating sufficient resources to complete the evaluation and support the subsequent steps (peer review) within the agreed timelines.

Direct support from ECHA

Description of the action:

ECHA will provide direct support to the eCAs within the limits of its capacity. The direct support ECHA can provide is dependent on its available resources considering in particular the workload for the peer review of active substances and Union authorisation.

ECHA already selected a first groups of cases, focusing especially on dossiers which are blocked by one specific issue and where solving this issue would enable the eCA to finalise the dossier. A specific action plan outlining resources and timelines has been defined for each case. ECHA can support the eCAs in technical/scientific, procedural and/or regulatory issues. As an example of scientific support, ECHA already performed on the behalf of the eCAs i) the human exposure and risk assessment for one AS, ii) the evaluation of the assessment of the endocrine disrupting properties for two ASs. In agreement with an eCA, ECHA has also provided support to a more

complex backlog dossier, performing a deep evaluation of the deficiencies in order to support the eCA in the identification and implementations of the changes required to finalise the draft CAR.

Eight eCAs have benefitted from different levels of support by ECHA for the assessment of the endocrine disrupting properties of sixteen active substances. Twelve active substances have also been discussed in the Endocrine Disruptor Expert Group, providing advice to the corresponding eCAs.

Scientific/technical support from experts from other MSCAs

The eCAs could more regularly share the work either with other MSCAs, to facilitate ongoing eCA evaluations, increase the number of draft CARs for peer review, increase the consistency of the evaluation and increase the synergies. In addition, this will facilitate the peer review process as it may reduce the number of comments by improving the quality of the assessment.

The following forms of cooperation have been discussed at the February 2019 active substance Workshop:

- Creation of an expert network by specific areas of expertise to be consulted ad hoc (e.g. experts on exposure estimation for disinfectants);
- Creation of specialised taskforce on specific topics (i.e. in situ generated active substances and EDs assessment);
- Creation of teams of eCAs evaluating similar active substances, in line with groups that ECHA already identified based on chemical structure similarity;
- Reorganising the peer review process with the primary role of a co-rapporteur MSCA;
- Developing generic assessments relevant to several active substances for e.g. in situ generated active substances or releasers.

ECHA has already some experience of promotion and coordination of the cooperation among eCAs evaluating similar active substances applications (e.g. coordinating actions for monochloramines applications). ECHA will explore further with MSCAs which form(s) of collaboration would be more beneficial in speeding up the evaluation phase and ease the peer review. The preferred option may be further tested in pilot projects.

In addition to the proposal for MSCAs agreement and commitment relevant to section 2.2 (Support to eCAs), irrespective of the form in which the support is provided, the following is proposed for the support from other MSCAs.

Scientific/technical support by external experts

ECHA could set-up a framework contract to be able to procure specific contracts to provide scientific support to eCAs. The possibility to fund this activity from 2021 onwards will be explored with the European Commssion, based on the fundamental prerequisite that the eCAs are willing to receive such support and actually use it.

The support from external experts could in particular be relevant for the assessment of ED properties of the active substances, which represents one of the main blocking factor for the eCAs due to lack of experience and expertise. Nonetheless, the support provided will not be limited to the

assessment of EDs, but can also cover other aspects of the evaluation of the dossiers for biocidal active substance approval, depending on the needs of the eCAs.

ECHA will select the external providers with the view to ensure high quality and independence of the assessment, and to avoid any conflict of interests.

Description of the action:

The action would be similar to the one described under 2.2.1 (direct support by ECHA), the difference being that the support would be provided by external experts. This would require that the eCAs indicate the specific issue(s) which are blocking their finalisation of the evaluation of the dossiers and the support would be geared to resolve those specific issues. A framework procurement contract could potentially be active to cover the period 2021-2023 and the role of ECHA would be to coordinate the relationship between the eCAs and the external experts and to monitor the progress made by both parties, ensuring that the agreed timelines for the finalisation of the draft CAR and submission to ECHA are met. This action is subject to funding being made available by COM.

In addition to the proposal for MSCAs agreement and commitment relevant to section 2.2 (Support to eCAs), the following is proposed for the support from external experts.

Advise and support on the relationship with applicants

CAs have indicated that they need support from ECHA to strengthen their role towards the applicants and in adopting a harmonised approach to deal with applicants. ECHA has developed a procedural guidance for eCAs requesting additional information and dealing with applicant not submitting the requested information[2] including templates[3] for letters to be sent to the applicant.

ECHA could support further the relationships between eCAs and-applicants by promoting the exchange of experience and best practices among the eCAs. Nonetheless, it is noted that the two parties, eCA and applicant, retain the responsibility for their relationship, which should be maintained with transparent, constructive and frequent communications on both side. One example of best practice is that ECHA normally suggests the eCAs to inform the applicants of major changes in the evaluation (e.g. when the proposal of the eCA may change from approval to non-approval (or vice versa)) beyond the legal obligation of 30 days applicant's commenting period (Art 8(1) BPR).

2 https://webgate.ec.europa.eu/s-circabc/w/browse/21dfa099-549e-4f7e-b0c0-45319122c7f1

3 https://webgate.ec.europa.eu/s-circabc/w/browse/57b42c0d-d8ee-4592-8ee7-980e10cd6442

On request of eCAs, ECHA may act as facilitator between eCAs and applicants in specific cases, either when supporting the normal process or solving issues that disrupt this process.

Capacity building in the eCAs

The MSCAs indicated at the active substance Workshop a clear need for training to improve the level of knowledge of their experts, especially the new staff, and to cover the specific lack of experience in the assessment of endocrine-disrupting properties according to Delegated Regulation (EU) 2017/2100.

Description of the action:

The European Commission has been organising trainings on ED assessment in the framework of the Better Training for Safer Food (BTSF) programme and will ensure that further training will be provided to the eCAs. On its side, ECHA has set up web streaming for passive participation to the discussions on endocrine-disrupting properties at the relevant Biocidal Products Committee Working Groups (BPC WG).

ECHA has also organised some specific trainings for MSCA experts (e.g. course for the interpretation of fate studies for environment, webinar on endocrine disruptors, IUCLID training).

ECHA will explore more systematically the topics on which MSCAs would like to receive training with the view to organise technical workshops and webinars. ECHA will collect the MSs needs through the BPC WGs and the regular communications with the eCAs.

In addition, ECHA is open to host for a certain period of time experts from MSCAs for training purposes in the framework of National Expert in professional training. For instance, an expert from a MSCA will join ECHA in November 2019 for one month. Another one is expected in Q1 2020; in this specific case it is foreseen that the expert will work on a case in the portfolio of the respective CA, combining training with actual progress on the dossier. If a longer period of time is envisaged (e.g. one year or at least six months), a secondment to ECHA could be considered.

ECHA may also facilitate the exchange of experts between the MSCAs for the same purpose.

Streamline the peer review

Reduce unnecessary critical discussion in the peer review

Based on ECHA experience the commenting phase of draft CARs during the peer-review may lead to a large number of comments that are difficult to manage by the eCA and afterwards by ECHA when preparing the discussion tables.
ECHA engaged in several actions to reduce the number of the comments in the peer review phase, to ensure that only major comments are discussed at the BPC WGs and to prevent that non-essential issues are discussed in the peer review phase, resulting in most of the cases in the exceedance of the 270 days deadline (BPR, Art 8(4)).

Description of the action:

ECHA has been developing three documents to guide the MSCA experts in identifying, in the evaluation phase, critical issues which may prevent the finalisation of draft CARs; in distinguishing

in which cases active substance specific issues already solved in previous Technical meetings (TM) or BPC WGs can be re-discussed. These documents will be made available by the end of 2019.

In order reduce the number of minor comments, ECHA revised the RCOM template requesting the commenting MS to always indicate whether the comment has a major or minor impact on the conclusion and justifications. The new RCOM template is available to the MSs from April 2019.

Upon request of the eCA, ECHA can provide advice during the peer review phase to answer the comments and facilitate the agreement between the eCAs and the commenting MSs.

Improving the effectiveness of WGs

The effectiveness of WGs depends on the role of the different players at the meetings. The chair has a coordination role with the aim to seek consensus and conclusions, assure consistency and pragmatism in decision making, prevent that already concluded items/same topics are brought up again for discussion, ensure that uncertainties are reported.

The WG members should ensure that risk assessment is performed in line with guidance and previous decisions and conclusions. Core members should actively participate and be well prepared for the discussions. The WG members in general should be prepared for consensus and compromises. Important items should be distinguished from non-important items and expert judgement should be applied when possible instead of asking additional data.

Description of the action:

The following actions have already been initiated in order to increase the WGs effectiveness:

- Regular meetings among the WG chairs have been established to ensure the procedural consistency and support mutual enrichment between WGs;
- Break-out groups/Expert Groups: The use of these groups should facilitate the discussion of difficult points/ general scientific issues upfront;
- Keeping WG members informed on previous WG meeting discussions: Combined minutes (2014-today) will be more regularly provided by ECHA, to be used as knowledge base;
- MSCAs to ensure that WG members have sufficient time for the WG meeting preparation;

– A *tour de table* took place at all WGs to identify blocking issues for meeting preparation/ participation. ECHA will follow-up the identified issues.

Reduction of complexity

Focused assessment of safety and efficacy

The BPR requirements for the approval of an active substance are limited: i.e. that **at least one biocidal product** containing that active substance **may be expected** to meet the criteria laid down in point (b) of Article 19(1) (safety and efficacy), taking into account the factors set out in Article 19(2) and 19(5). However, in practice the approach is not harmonised and a number of different representative uses may be assessed. This is also linked to the actual dossier supporting the assessment, which contain a variable number of representative products and uses.

To address the BPR requirements a focused assessment of safety and efficacy would be sufficient and it is proposed to develop a harmonised approach for performing this assessment.

In parallel, considering the benefit for the authorisation of biocidal products of harmonised exposure assessment and risk mitigation, the possibility to develop in a timely way such approaches separately from the assessment of the active substance should be explored.

Description of the action:

ECHA, in cooperation with a groups of volunteers from MSs, will prepare a proposal for a harmonised and efficient approach for performing a focused assessment. The proposal will be discussed with the CA meeting.

ED assessment for substances already meeting exclusion criteria

The BPC agreed that a conclusion on the ED properties is not required if the eCA has already concluded to propose non–approval based on other elements of the evaluation[4], but "*The available information on ED properties, as well as the assessment of this information, should however be included in the CAR*". Some MSCAs have indicated that it is not clear whether this means a detailed assessment or whether a less stringent assessment could be supported. The effort in preparing a detailed assessment may delay the decision on non-approval by years, and it could be argued that it is more important to finalise the assessment in order to reach the decision.

A similar concern has been raised for active substances where a conclusion can already be made that the substance meets the ED criteria for human health, thereby also meeting the exclusion criteria. In some cases it may however not be possible to reach a conclusion on meeting the ED criteria also for non-target organisms, and further vertebrate testing might need to be requested in order to conclude. In such a case, it seems that the need to conclude also for non-target organisms would lead to more vertebrate testing and would unnecessarily delay the assessment. The EU COM is considering how this issue could be best addressed in the applicable legal framework.

4 *Principles for the assessment of endocrine disrupting properties in active substance approval*, agreed at BPC-25

Limit the consideration of new data to revise the assessment to the situations foreseen by the BPR

In recent years there has been a developing trend for the consideration of new data to revise some conclusions of the assessment of approved active substances in light of new data usually submitted in the context of product authorisation applications. This has led to unnecessary and unforeseen additional workload. This has also created uncertainties regarding the active substance reference values to consider for product authorisations. This is also not in line with the legal provisions since the revision of the assessment of an active substance is only foreseen in the BPR through the renewal and review mechanisms.

ECHA proposes to restrict the revision of the assessment of approved active substances to the procedures foreseen in the BPR: renewal (Article 13) and review (Article 15) in case there are significant indications that the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2) are no longer met.

In parallel it would be useful to clarify under which conditions additional data related to the active substance may be used to refine the assessment in the context of specific product authorisation applications.

Facilitate access to key information

The MSCAs remarked that in order to perform their tasks, they need to consult several types of documents: procedural and regulatory documents, practical manuals, templates and scientific guidance and *quasi* guidance[5] documents. Due to the different ownership of these documents and to the predefined ECHA webpage structure, these documents are spread over ECHA web pages, S-CIRCABC and public CIRCABC.

Quasi guidance documents usually do not contain indications of the applicability date, which is considered a key element by the eCA.

Description of the action:

ECHA has already modified the BPR main webpage (https://echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr) including the links to the relevant sources of manuals,

5 Please refer to CA-May18-7.2a for the description of "quasi guidance" documents.

guidance and quasi-guidance documents, forms and templates, practical guides, Coordination Group documents, Competent Authority meeting documents, enforcement.

ECHA is reviewing all generic agreements of Working Groups and *quasi* guidance documents which are in the remit of the Working Groups to ensure that they are adequately included in the Technical Agreements for Biocides (TAB). The applicability date will be included for each item. ECHA will investigate the possibilities to convert the TAB to a new format that would allow easy searching and filtering. The finalisation of the action is expected by Q2 2020.

Harmonised assessment of confidentiality claims

ECHA is preparing guidelines to support MSCAs in assessing confidentiality claims in the application for approval of an active substance or the authorisation of a biocidal product, as part of the evaluation and preparation of the Competent Assessment Report (CAR) and Product Assessment Report (PAR), respectively.

The guidelines focus on the following elements:

- the rules regarding confidentiality in accordance with the provisions of the BPR;
- the roles and responsibilities of MSCAs;
- the assessment of confidentiality requests;
- the details on how to prepare CARs and PARs that are fit-for-purpose for dissemination under the BPR.

Practical examples on the redaction of CARs and PARs will be also provided.

ECHA foresees to prepare the guidelines by the end of Q1 2020.

Action required

The CA meeting members are requested to discuss and agree on the action plan.