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Harmonising the process for biocidal products authorisations

In this expert article Indiana de Seze and Darren Abrahams of Steptoe & Johnson LLP examine the recent discussions among the Commission and the Competent Authorities regarding their practices of suspending the evaluation of product authorisation dossiers and the possibility of a harmonised approach.

The Commission and the Competent Authorities (CA) of the Member States are attempting to address the delays observed in the process for the evaluation of biocidal product authorisation applications submitted by industry.

Article 89(3) of the BPR, which concerns transitional measures, states that "Following a decision to approve a particular active substance for a specific product-type, Member States shall ensure that authorisations for biocidal products of that product-type and containing that active substance are granted, modified or cancelled, as appropriate, in accordance with this Regulation within three years of the date of approval". (This period was originally only two years in the first iteration of the BPR before its subsequent amendment.) The evaluation of some applications may consume the entire three-year period foreseen under Article 89(3) of the BPR.

Articles 30(1), 34(4) and 44(1) of the regulation establish the legal deadline (365 days) for the evaluating CA to conclude the assessment of an application. In accordance with Articles 30(2) and 44(2), where the evaluating CA considers that additional information is necessary to carry out the evaluation, it can and shall ask the applicant to submit such information within a specified time limit, during which the 365-day period is suspended. In other words, the evaluating CA may "stop the clock", thereby extending the evaluation period. The interruption shall normally not exceed 180 days, except in "exceptional cases and where justified by the nature of the information requested".

The Commission advocates that the operation of this practice should be harmonised, since the triggering event for the three-year deadline is itself harmonised (i.e. the date of approval of the last active substance contained in the biocidal product).

Identification of the causes of delays

Further to the 66th CA meeting (in September 2016), a number of actions were agreed to tackle the issue. As a result, the Commission, with the help of Echa, is monitoring delays. It has also requested feedback from the CA in order to identify the reasons for such delays. These reasons include:

- the initial quality of the dossier;
- the need to require additional information from the applicant in order to carry out the assessment;
- the delays by applicants when submitting the required information;
- the time needed by the evaluating body to assess the submitted information; and
- the fact that in some cases, the above-mentioned "process" is repeated several times until an acceptable outcome for the assessment is found.

Proposed way forward: one single suspension period

The Commission has issued a proposal (CA-March17-Doc.4.4) to the CA for comments. It is based on the premise that a decision to stop the clock could be seen as a derogation from the general principle according to which the dossier has to be complete and of adequate quality at the time of its submission. According to the Commission, it is an exception to a basic principle, which would have to be interpreted and therefore implemented in a restrictive manner. In other words, this practice should not be interpreted as applying generally but should be applied in limited circumstances.

The Commission recommends that if a suspension is decided, it should be done:

- taking into consideration the time required by the applicant to provide the required additional information, as well the time needed for its evaluation; and

- with a view to ensuring that sufficient time is left for the mutual recognition phase or the peer review by the Biocidal Products Committee (BPC) under Union Authorisation, before the product authorisation(s) can be granted, while remaining within the Article 89(3) three-year period.

The Commission notes that the BPR's "stop of the clock" provision refers to "a suspension" (in the singular form), thus excluding multiple uses.

As a consequence of this interpretation, and since the evaluating CA has the power to reject the application if the information requested has not been submitted, it is proposed that the CA should formally indicate all points to be addressed by the applicant only once.

Concerning the appropriate length of the suspension, the Commission does not exclude that it exceeds 180 days (note: no limit is given) but on the other hand it advocates that it should be limited to what is remaining of the 365-day period (a hard stop).

If the applicant fails to submit the requested information within the deadline set in the suspension decision and depending on whether the required information affects all the intended uses in the application or just some of them, the evaluating CA should decide whether:

- to reject the whole application when no intended use can be authorised and inform the applicant accordingly; or

- to resume and continue with the assessment of the intended uses for which sufficient information is available in order to conclude whether the product authorisation can be granted.

The Commission concludes: in case of applications for authorisation of products subject to the provisions in Article 89(3) of the BPR, the periods of grace referred to in Article 89(4) shall apply whenever the whole of the application is rejected or the authorisation is granted for a reduced number of the intended uses.

Feedback from the CAs

The feedback received by the Commission was put on the agenda of the 72nd CA meeting (CA-May17-Doc.4.1.a). It displays a wide array of views.

For instance, **Germany** advocates for several opportunities to stop the clock. "Using "stop the clock" only once, will not be practicable for several applications and would definitely result in a high number of rejected applications or at least serious restrictions of the intended uses". The evaluation is a step-by-step process and the completeness check does not look at the quality or adequacy of the submitted information. Germany adds: "Experience has demonstrated that normally the information, which was sufficient for the validation of the application, was not sufficient to even start with the assessment of the application". Germany also points to the lack of guidance on evaluation and data requirements in certain circumstances, and cites the case of in-situ generated active substances. The same uncertainties the CA are facing are also an issue for the applicants.

Due to such issues, suspensions might become necessary during evaluation. Germany, supported by **Spain, Sweden** and **Italy**, is a proponent of stopping the clock also in the interest of the applicant, to remedy the effect of potential regulatory uncertainty, and not only flaws in the application.

The **Netherlands** do not favour a reoccurring stop-the-clock approach. However, it explains its position by putting forward the different tools developed for applicants to ensure their application is complete and adequate. Such tools are available even before the triggering event, i.e. before the date of approval of the active substance, which follows the adoption of the approval act.

A number of pre-submission meetings (individual or theme-based) are organised with applicants and/or consultants. The Dutch CA also promoted its helpdesk as a means to avoid the need to stop-the-clock. In spite of the above, the Netherlands support the Commission's proposal to limit it to one single occurrence. It adds, however, that "in practice, this is sometimes not always feasible even if you prevent stop the clocks by pre-submission meetings and workshops".

Finally, **France** explained its practice which goes in the direction of the Commission's proposal of one single suspension. France explains that "all sections of a given dossier are assessed in parallel". Thus only one suspension is organised. The evaluation of the application is only resumed after the entirety of the required information is received. "Hence we ask the applicant to reply only when all information is collected by his side, which is usually done after the six month-period", adds the French CA.

Analysis and next steps

From the feedback collected by the Commission, it appears that there is a tension between competing considerations:

- ensuring that dossiers are complete and of good quality;
- managing the resources of the evaluating CA efficiently; and
- applying clear and legally certain evaluation deadlines for the benefit of an applicant's legitimate expectations.

The Commission proposal suggests that meeting the deadlines prescribed by the BPR is the rule and the suspension should be the exception. However, the narrow interpretation it gives to the suspension (once only) does not necessarily assist the substantive evaluation process. Surely the time limit put on the suspension of the administrative process was designed to provide legal certainty to applicants, not to limit their ability to respond to queries from the evaluating CA. Where such suspension is in the interest of the applicant, it could be argued that a suspension should take place every time an applicant agrees to it. This would give applicants some limited control over their fate.

It could also be argued that it is in the interests of the evaluating CA to have more than one opportunity to obtain all the information necessary, as the scope of this information may evolve when the evaluation process develops.

Although there is a clear interest in harmonising the stop-the-clock practices across the EU, it seems even more essential that applicants and market operators in general, are made aware of whichever practice the evaluating CA will apply during the evaluation of their authorisation dossiers. This should be known in advance of a submission being made. The feedback exercise carried out by the Commission has the merit of casting some light on the practices of certain evaluating CAs – reflecting a wide range of perspectives.

Depending on whether a consensus could be found at the 72nd CA meeting (which took place on 11-12 May) the Commission and CAs may start working on a common position on how the stop-the-clock rule must be applied for a legally certain implementation of the BPR throughout the EEA.

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