

Helsinki, 23 February 2017

RAC/40/2017/07

40TH MEETING OF THE COMMITTEE FOR RISK ASSESSMENT

6-10 MARCH & 14-15 MARCH 2017

HELSINKI, FINLAND

Concerns: Updated working procedure for authorisation process

Agenda Point: 9.1.a

Action requested: For information

Application for Authorisation process - New approach for the Conformity Check

1. Purpose

This note documents a new approach to the conformity check part of the Working Procedure for RAC and SEAC for developing opinions on the applications for authorisation and outlines how it is to be implemented in practice.

2. Background

The Application for Authorisation (AfA) process was implemented in 2012, including how conformity of the applications would be checked. At that time, the ECHA's procedure stated that after the submission of the application the ECHA secretariat would verify that all the information mentioned in Article 62(4) had been provided by applicants. This was done at the same time as the invoice was prepared for the applicant. Should any information appear to be missing, the ECHA secretariat informed the rapporteurs so that they could take this into account. Upon payment of the invoice, the application was considered "received" and the public consultation was started. At the same time, the rapporteurs formally checked that the application conformed with the requirements of Article 62(4) taking into account the information provided by the ECHA secretariat. If an application was found not to be in conformity, then the Committees would could require the applicants to bring it into conformity within the 10 month deadline.

From the experienced gained from the evaluation of many applications by RAC and SEAC, the input from stakeholders and advice from the Commission, ECHA saw the need to make adjustments to the conformity check procedure. The outlines of the adjusted procedure are described below.

3. Procedure

1. ECHA checks whether all administrative data and assessment reports are included in the application when it is received from the applicant.
2. The RAC and SEAC rapporteurs check if the application conforms with the requirements of Article 62(4) with the help of ECHA secretariat. However, RAC and SEAC will not conclude on conformity at this stage. The rapporteurs will identify any issues relating to conformity that can then be raised and documented in the questions form the Committees that will be sent to the applicant. No other communication relating to conformity will be sent to the applicant during the process.
3. When the RAC and SEAC rapporteurs ask questions/clarifications of the applicants, they will indicate when these relate to conformity. However, in all cases, irrespective of such conformity indications, applications may not conform with the requirements

of Article 62(4) if the applicants fail to provide the information requested by the Committees.

4. RAC and SEAC concludes on the conformity at the same time when they agree on the draft opinions, or earlier, if it is considered that the information provided is sufficient and no conformity issues have been raised by the rapporteurs.

4. Documentation and communication

1. ECHA will amend the working procedures of the committees and the internal secretariat working instructions according to this approach.
2. ECHA will update other relevant documents, such as the opinion format, internal and external user manuals, Working Instructions (WINS), Practical Guide and documentation in the pre-submission information sessions.
3. ECHA will prepare and publish a Q&A on its website to reflect the adjustments made to the conformity check procedure.
4. As this is a change in administrative policy related to REACH implementation, it will not be consulted with, or tabled for agreement by the Committees
5. ECHA will inform stakeholders in relevant fora.

5. Practical implications

1. ECHA does no longer send letters to the applicants confirming the conformity of their applications. ECHA has already ceased sending these letters from November 2016 onwards.
2. This approach may incite 'less cooperative' applicants to provide earlier in the process the necessary information for RAC and SEAC in order to draft their opinion.
3. If the Committees, while issuing the draft opinion, conclude the AfA not being in conformity, the applicants may still provide additional information to bring the AfA into conformity when they are commenting on the draft opinion.