EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Safety of the Food Chain
Pesticides and Biocides

Mandate requesting ECHA opinions under Article 75(1)(g) of the BPR

"Evaluation of the level of the risks for human health and for the environment of cyanamide used in biocidal products of product types 3 and 18"

1. Background

(1) During the 33rd meeting of the Biocidal Products Committee in December 2019, ECHA adopted its revised opinions[1] on the application for approval of the active substance cyanamide for use in biocidal products of product types 3 and 18.

(2) The review of cyanamide took place in a specific context where the scientific criteria for the determination of endocrine-disrupting (ED) properties came into application while the examination of the active substance was almost finalised. This situation required the Commission to mandate the BPC to update its opinions to assess cyanamide in the light of these new ED criteria.

(3) In its opinions, the BPC concluded that: *"An acceptable risk for both, human health and the environment could be demonstrated for the only applied use (disinfection in empty pig stables by professionals, application by using watering cans or half-automated movable carts). However, the risk for the professional user is only acceptable with adequate PPE. With regards to the fact that cyanamide is considered to have endocrine disrupting properties, there is no currently agreed methodology for undertaking a risk assessment based on such properties and no agreed methodology available on how to consider the data used for the identification of whether this substance is an endocrine disruptor in risk assessment for the environment. Given the exposure of cyanamide to humans and the environment, a risk related to the ED properties cannot be excluded.*"

(4) As cyanamide meets the criteria for the identification of endocrine disruptors for human health, it meets the exclusion criterion set out in Article 5(1) (d) of the BPR. Furthermore it meets the criterion to be identified as a candidate for substitution a set out in Article 10(1)(e) of the BPR.

(5) As the draft assessment reports were submitted by the evaluating Member State (Germany) before 1 September 2013, a decision on the approval may be taken without assessing whether at least one of the conditions for derogation to exclusion referred to in Article 5(2) of the BPR is met. However, as for any active substance, an approval is only possible if it is

[1] The opinions of ECHA are available here

demonstrated that at least a biocidal product containing this active substance may be expected to have no immediate or delayed unacceptable effects to the human health and the environment.

(6) The ECHA opinions referred to in paragraph 3 above do not provide a clear conclusion on the level of the risks of using cyanamide in relation to its ED properties.

(7) A risk assessment can be made either in a quantitative way, or a qualitative way. Quantitative risk assessment builds on the fact that, for a given substance, a biological threshold exists for a given toxicological effect, below which exposure does not exert any adverse effect in organisms. Quantitative risk assessment is feasible when such a threshold can be derived using the (eco)toxicological data available. It is not clear from the opinion whether the existence of a threshold for ED properties was considered by the BPC, and if considered, on which data and scientific considerations it was based and which conclusions were drawn up. An alternative approach to the setting of a threshold would be to perform a qualitative assessment of the risk, with particular focus on whether the exposure can be considered negligible, like for non-threshold carcinogen/mutagen substances or PBTs.

(8) The BPC opinions do not contain any information as to whether a safe threshold may be derived in relation to ED properties and do not conclude clearly whether the risks could be considered acceptable or not acceptable.

2. The questions referred to ECHA

(9) In the light of the background information mentioned above an opinion of ECHA is required on the risks for human health and for the environment that integrate the risks of the ED properties of cyanamide.

(10) As regards to the risks for human health, ECHA is required to :

(a) Based on available information, clarify whether a safe level (threshold) can be determined for the ED properties of cyanamide for human health, and if such threshold can be established, what would be this level.

(b) Clarify the level of the risks for humans by:

1. Assessing the level of risk for human health, either by a quantitative assessment or a qualitative assessment.

2. Providing an opinion whether the risks can be considered acceptable or not.

(11) As regards to the risks for the environment, ECHA is required to:

(a) Based on available information, clarify whether a safe level (threshold) can be determined for the ED properties of cyanamide for the environment, and if such threshold can be established, what would be this level.

(b) Clarify the level of the risks to the environment by:

1. Assessing the level of risk for the environment, either by a quantitative assessment or by a qualitative assessment.

2. Providing its opinion whether the risks can be considered acceptable or not.

(12) Based on the outcomes of this assessment for the human health and the environment, the BPC should revise its current opinions on cyanamide for PT3 and PT18 in order to provide an updated consolidated version of its opinions on cyanamide.

3. Elements to be considered by ECHA when addressing this question

(13) ECHA is invited to take into account in particular:

(a) All the data submitted in the application, as well as the conclusions of the discussions in the BPC and its Working Groups.

(b) Any further information submitted by the applicant or other interested parties within the scope of this request and the timeline specified by the eCA or ECHA as appropriate.

(c) The data submitted during the public consultations on this substance organised by ECHA from 22 February to 21 April 2016 and from 26 June 2019 to 25 August 2019, including those submitted by the applicant.

4. Deadline for the ECHA opinions

(14) ECHA shall adopt its opinions by 31 December 2021 at the latest.