EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Safety of the Food Chain
Pesticides and Biocides

Request for an ECHA opinion under Article 75(1)(g) of the BPR - Mandate

"Evaluation of the Endocrine disrupting properties of certain biocidal actives substances according to the scientific criteria"

1. Background

(1) The scientific criteria for the determination of endocrine-disrupting properties ("the scientific ED criteria) pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council ("the BPR") are established under Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017.

(2) Pursuant to Article 2 to that Regulation, these criteria shall apply as of 7 June 2018, except for procedures where the Standing Committee on Biocidal Products has voted on a draft Regulation.

(3) Over the past months, ECHA has formulated its opinions on the approval of several active substances for use in biocidal products. For some of the active substances related to these opinions, it will not be possible to consult the Standing Committee on Biocidal Products before 7 June 2018 on a draft Regulation and obtain the opinion. These are:

(a) substances for which the opinion was submitted to the Commission very recently;

(b) substances which were identified in the opinion of ECHA as having endocrine-disrupting properties according to the interim criteria pursuant to Article 5(3) of the BPR. However, the Standing Committee on Biocidal Products considered that an evaluation according to the scientific ED criteria is needed to ensure legal certainty for all parties, in the view of the regulatory consequences of the identification as ED for the approval and authorisation processes;

(c) substances which are meeting other exclusion criteria set out in Article 5(1) of the BPR but which may eventually be approved by the Commission after the consultation Standing Committee, in particular in case it is considered that the conditions for derogation to exclusion set out in Article 5(2) to the BPR are met. It has indeed been clarified that an

evaluation according to the scientific ED criteria is also needed for such substances in this particular situation[1].

2. The question referred to ECHA

(4) Pursuant to Article 75(1)(g) of the BPR, ECHA is therefore requested to formulate revised opinions concerning the approval of the active substances listed in section 4 to the present mandate. These revised opinions must contain an assessment of the endocrine-disrupting properties of these active substances according to the scientific ED criteria.

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

(5) For determining the ED properties of an active substance ECHA shall use any information already available in the application and consider whether additional information should be requested to the applicant(s) in accordance with the principles agreed in document CA-March18-Doc.7.3a-final- EDs-active substances under assessment.docx.

(6) The previous opinions should in most cases be updated only on the part in relation to the assessment of the ED properties, unless the conclusion of this assessment affects the results of the risk assessment already performed as well as the recommendations for approval. In the latter case, such assessment and recommendations should also be updated.

4. List of actives substances and opinions of ECHA concerned by the present mandate

(7) Revised opinions are requested on :

(a) Cyanamide :

1. Opinion on the application for approval of the active substance: Cyanamide, Product type: 3, ECHA/BPC/116/2016, Adopted on 16 June 2016

2. Opinion on the application for approval of the active substance: Cyanamide, Product type: 18, ECHA/BPC/117/2016, Adopted on 16 June 2016

(b) Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1):

1. Opinion on the application for approval of the active substance: Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1), Product type: 2, ECHA/BPC/161/2017, Adopted on 29 June 2017

[1] CA-March18-Doc.7.3a-final- EDs- active substances under assessment.docx agreed at the 77th CA meeting of May 2018, in particular footnote 19

2. Opinion on the application for approval of the active substance: Reaction products of paraformaldehyde and 2-hydroxypropylamine, (ratio 1:1), Product type: 6, ECHA/BPC/162/2017, Adopted on 29 June 2017

3. Opinion on the application for approval of the active substance: Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1), Product type: 11, ECHA/BPC/163/2017, Adopted on 29 June 2017

4. Opinion on the application for approval of the active substance: Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1), Product type: 13, ECHA/BPC/164/2017, Adopted on 29 June 2017

(c) Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2):

1. Opinion on the application for approval of the active substance: Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2), Product type: 2, ECHA/BPC/156/2017, Adopted on 29 June 2017

2. Opinion on the application for approval of the active substance: Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2), Product type: 6, ECHA/BPC/157/2017, Adopted on 29 June 2017

3. Opinion on the application for approval of the active substance: Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2), Product type: 11, ECHA/BPC/158/2017, Adopted on 29 June 2017

4. Opinion on the application for approval of the active substance: Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2), Product type: 12, ECHA/BPC/159/2017, Adopted on 29 June 2017

5. Opinion on the application for approval of the active substance: Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2), Product type: 13, ECHA/BPC/160/2017, Adopted on 29 June 2017

(d) Chlorophene:

1. Opinion on the application for approval of the active substance: Chlorophene, Product type: 2, ECHA/BPC/165/2017, Adopted on 3 October 2017

(e) 2-Phenoxyethanol:

1. Opinion on the application for approval of the active substance: 2-Phenoxyethanol, Product type: 1, ECHA/BPC/190/2018, Adopted on 6 March 2018

2. Opinion on the application for approval of the active substance: 2-Phenoxyethanol, Product type: 2, ECHA/BPC/191/2018, Adopted on 6 March 2018

3. Opinion on the application for approval of the active substance: 2-Phenoxyethanol, Product type: 4, ECHA/BPC/192/2018, Adopted on 6 March 2018

(f) Salicylic acid:

1. Opinion on the application for approval of the active substance: Salicylic acid, Product type: 2, ECHA/BPC/187/2018, Adopted on 6 March 2018

2. Opinion on the application for approval of the active substance: Salicylic acid, Product type: 3, ECHA/BPC/188/2018, Adopted on 6 March 2018

3. Opinion on the application for approval of the active substance: Salicylic acid, Product type: 4, ECHA/BPC/189/2018, Adopted on 6 March 2018

(g) Formaldehyde:

1. Opinion on the application for approval of the active substance: Formaldehyde, Product type: 2, ECHA/BPC/181/2017, Adopted on 13 December 2017

2. Opinion on the application for approval of the active substance: Formaldehyde, Product type: 3, ECHA/BPC/086/2015, Adopted on 10 December 2015

5. Deadline for the ECHA opinion

(8) ECHA shall formulate the revised opinions as soon as possible. ECHA shall inform DG SANTE on the expected date by when the opinions on each substance could be expected.