Datum: 22-02-2017
Opsteller: 5.1.2.e Woo
Vorige bespreking: -

Akkoord secretaris:

C-298.I.3f **Ctgb en RIVM advies aan departementen n.a.v. het aangepaste voorstel voor wetenschappelijke criteria voor hormoonontregelende stoffen**

Inleiding

DOEL

Ter informatie voorgelegd aan het College.

AANLEIDING

In opdracht van IenM en ook EZ hebben RIVM en Ctgb een gezamenlijke reactie opgesteld naar aanleiding van de aangepaste wettekst en annex over criteria voor de identificatie van hormoonontregelende stoffen[1]. Deze reactie is integraal opgenomen in de bijlage. Hierin is de input van RIVM gescheiden die van Ctgb omdat beide vanuit hun eigen, unieke positie commentaar hebben gegeven. Het advies is inmiddels uitgebracht aan EZ en IenM.

CONTEXT

De Europese Commissie is half juni 2016 gekomen met een voorstel voor wetenschappelijke criteria voor de vaststelling van hormoonontregelende eigenschappen. Het voorstel houdt in:

- De WHO-definitie wordt gevolgd: *"an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations*".
- Bij het vaststellen van de causale relatie is plausibiliteit voldoende.

Inmiddels is het initiële voorstel een aantal malen geamendeerd. Begin februari is de laatste revisie gepubliceerd. Deze zal worden voorgelegd aan het Pesticides Standing Committee (PAFF) en aan de Competent Authorities op 28 februari respectievelijk 's ochtends of in de middag. Het advies uit de bijlage wordt door EZ / IenM o.a. gebruikt ter voorbereiding op deze overleggen. Het streven van de Commissie lijkt te zijn om die dag te stemmen over de criteria. Eenmaal vastgesteld zal de Commissie beide teksten tegelijkertijd aan het Europees Parlement en de Raad voorleggen om de samenhang van de twee handelingen te verzekeren.

In beginsel zouden de voorstellen ook toepasbaar zijn in de context van de cosmetica Vo., de Kaderrichtlijn Water en REACh, waarbinnen immers ook hormoonontregelaars worden toegepast. Op deze vlakken wordt het onderwerp voorlopig echter niet opgepakt.

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[1] *De facto deed de Cie 2 voorstellen. De teksten voor biociden blijken in essentie vrijwel gelijk te zijn aan die bij gewasbeschermingsmiddelen (althans de meeste recente versies). Met 'de' criteria of 'het' voorstel wordt zodoende op beide gedoeld tenzij nadrukkelijk anders aangegeven.*

VOORGESCHIEDENIS
Via de verordeningen inzake gewasbeschermingsmiddelen en biociden is de Europese Commissie opgedragen om uiterlijk in december 2013 criteria vast te stellen om hormoonontregelende stoffen te kunnen identificeren. Die deadline is niet gehaald. Zweden, daarin gesteund door EP, Raad en diverse lidstaten waaronder Nederland, heeft de Europese Commissie hierover gedaagd bij het Europese Hof van Justitie. Deze heeft in een uitspraak december 2015 Zweden op alle punten in het gelijk gesteld.

Informatief deel
Zie bijlage.

Advies/ verzoek/ voorstel aan het College en vervolgtraject
Het College zal op de hoogte worden gehouden van de ontwikkelingen.

Bijlage I RIVM/Ctgb advies ED criteria dd. 16-02-2017

First appreciation of the RIVM and Ctgb regarding the new proposed ED criteria
Data: 15-2-2017
Authors: RIVM and Ctgb
Version: 4

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1. INTRODUCTION

On the 28th of February 2017 a new proposal will be discussed on the SCoPAFF and CA meetings regarding the criteria for endocrine disrupting properties (EDs). These criteria are required to identify endocrine disrupting substances in the context of the biocides regulation and the plant protection products regulation.

In this document comments and advice from RIVM and CTGB are formulated. RIVM, in its role as policy advisor, focuses in its comments on the effects of the proposal on methodology and outcome. CTGB focuses its comments from its role as competent authority on procedural and regulatory issues.

As the text of the act and annex for biocides is almost identical to the text for plant protection products, general terms are used to refer to both texts unless explicitly stated otherwise. For instance 'act' refers to both the draft delegated act for biocide as well as the act for PPP.

2. CHANGES COMPARED TO THE COMMISSION'S PROPOSED VERSION NOVEMBER 2016

2.1 Act

Main differences between the previous version:

- The Commission includes a new Article 3 where it is proposed to evaluate the experiences gained from the application of the scientific criteria within seven years.
- The Commission includes an addition to Article 4, where a transitional period of 6 months is proposed.
- Preamble 4: The Commission includes to take into account the current scientific and technical knowledge, specific scientific criteria should also be specified in order to identify substances having endocrine disrupting properties that may cause adverse effects on non-target organisms. The second part of preamble 4 excludes the mode of action of active substances whose intended mode of action is to control target harmful organisms via their endocrine system from ED identification.
  The text in preamble 4 differs from the text regulating this point in the Annex, Section B(2)(e).
- Finally, the Commission has removed text from an earlier version that proposed changing the (PPP) Regulation wording from "*negligible exposure*" to "*negligible risk*", concerning an exemption for active substances with ED properties.

2.2 <u>Annex</u>

2.2.1 Human Health

For human health only few changes are made in the EU Commission's new version of the draft proposal compared to the version proposed in the December 2016 meeting.

- The passage 2d has been deleted as this part was also represented under Section A 1 (A substance is considered and ED if it meets the criteria unless evidence demonstrates that the effects are not relevant for humans).
- Secondly the passage *"in vivo studies or adequately validated alternative test systems predictive of adverse effects in humans or animals; as well as in vivo, in vitro, or, if applicable, in silico studies informing about endocrine modes of action"* is more emphasised because it is placed higher in the text, however the same wording is used as in previous versions of the proposed criteria.

2.2.2 Environment

2.2.2.1 Section A(1)(a), (b) and (c) and Section B(1)(a), (b) and (c)

The sections in Annex A(1)(a), (b) and (c) and B(1)(a), (b) and (c) are a merger of the WHO/IPCS definitions of endocrine disruptor and adverse effect, respectively. These texts are not in line with the WHO/IPCS definitions, which results in an inconsistency with the preamble.
In addition, the text in Section B(1)(a) is not in line with that in Section A(1)(a) at crucial points (intact organism, progeny).

2.2.2.2 Section B(2)(e)

It is proposed to leave an entire phylum out of scope of ED identification if the mode of action of the active substance is designed to be of an endocrine disrupting nature.

3 POLICY ADVICE RIVM

3.1 Act

RIVM agrees with the proposed evaluation within 7 years as well as the transitional period of 6 months. It should be noted however that the EFSA/ECHA ED Guidance will be available at the end of 2017.
RIVM is not in favour of the removal of the "negligible risk" text in the PPP Regulation, as harmonisation between BPR and the PPPR as well as a risk based approach for ED's is preferred.
RIVM does not agree with the text in Preamble 4 and Section B(2)(e), see below for detailed comments.

3.2 Annex

3.2.1 Human health

RIVM agrees with both proposed changes in the proposed criteria.

3.2.2 Environment

3.2.2.1 Section A(1)(a), (b) and (c) and Section B(1)(a), (b) and (c)

RIVM proposes to take the following action: 'Non target organisms' Section B(1)(a), (b) and (c)
Cite the WHO/IPCS definition correctly and completely.

The first line of B(1)(a) should be adapted as follows (additions given in red / underlined):
(a) *it shows an adverse effect in* an intact ~~*non-target*~~ *organism*~~*s*~~, or its progeny, or (sub)populations, *which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences*

- Intact should be added because adverse effects can only be considered in intact animals
- non-target should be deleted because ED effects observed in target organisms need to also be considered in the identification process (see also explanation below)
- progeny should be added because effects may be become apparent in later generations
- (sub)population should be added because it is part of the WHO/IPCS ED definition
- Each of these additions/deletions are crucial elements of the WHO/IPCS definition that should not be disregarded.

3.2.2.2 Section B(2)(e)

The implication of the suggested text is not acceptable. In both Regulations, the legislator has set out to exclude all substances being ED from the market, by hazard assessment (unless clauses art 5.2 BPR possible). Given this point of departure, it cannot be understood, nor accepted that if a substance is an intended ED, the exclusion criterion would not apply.

With the current text proposal, a rodenticide (BPR PT14) that has an intended ED mode of action would not be considered for the identification as ED. For those substances, all Chordata are left out of the ED hazard assessment, which includes amongst others all vertebrates, e.g. birds, reptiles, amphibians and mammals, including humans. This implies that this substance cannot be identified as ED for human health.

Similarly, if the substance would be e.g. an insect growth regulator, all non-targets insects and other non-target insect families may be targeted, which is undesirable, but the phylum Arthropoda (in which the insects) also contains crustaceans (including lobsters, crabs, shrimps), spiders, myriapods (millipedes, centipedes), etc., which are then neglected from the departure point of ED exclusion. As the endocrine system of invertebrates is not yet well understood, we do not know whether chemicals designed to target only one species group, will not also affect other taxa. The current proposal is therefore unacceptable.

4 REGULATORY ADVICE CTGB

4.1 Act

Ctgb agrees to the proposed evaluation within 7 years (article 3). We notice that the text for biocides is slightly different compared to the lines for plant protection. We prefer ‘within 7 years’ (over ‘by 7 years’).

As proposed a transitional period, counting from the moment the guidance is taken note or endorsed, is in our view obligatory as provision for the extra time needed to generate, submit and assess data, including studies, for issues related to the ED criteria. An applicant cannot start preparing a dossier when the requirements are not unambiguously set. It is unclear what the Ctgb should decide when requirements are doubted and data for an application inconclusive. The proposed changes do imply that existing approval periods for some active substances may need to be extended.

It remains unclear whether an active, for which an application has already been submitted, is also subject to requests for additional information. As a rule, authorities should not change the rules after submission of a dossier and therefore Ctgb proposes to implement the ED guidance for new notifications or renewals.

Concerning the length of the transitional period: it will not be possible to develop the final guidance within 6 months. Ctgb strongly advises the policy makers to urge upon the Commission not to apply the scientific criteria for ED before an adequate guidance is available. Otherwise many differences in interpretations between member states are to be expected, just as conflicts with applicants. Ideally the ED criteria are applicable only to new applications.

Finally, recital (6) of the act for biocidal ED mentions “voted”. To our understanding the SCoPAFF can vote, but the SCBP will not vote on the ED criteria as the Commission is delegated to amend this act without a voting procedure.

4.2 Annex

4.2.1 Human Health

Regarding the additions to Section A article 2(a) -biocides- or Point 3.6.5 -PPP-, Ctgb advises to remove “*or animals*” as this section only refers to endocrine disruption properties to humans. Endocrine effects which are not relevant to humans should be regarded on the section on non-target organisms.

4.2.2 Environment

Regarding the additions to Section B article 2(a) -biocides- or Point 3.8.2 -PPP-, Ctgb advises to remove “*humans or*” as this section only refers to endocrine disruption properties to organisms in the environment. Endocrine effects that are relevant to humans should not be regarded in the section on non-target organisms.

With regard to separate proposals covering the grounds for derogating from an ED ban, Ctgb noticed that the text for biocides is slightly different when compared to the lines for plant protection. We prefer ‘this mode of action’ (over ‘the effect on organisms’).

Regarding the ‘same taxonomic phylum clause’: Ctgb advises to remove this section. If a chemical is designed to have an effect on a target organism it is either a biocide, plant protection product or (V)MP. As the intention of the legislator is to implement this regulation horizontally, any references to the intended mode of action (or effect) should thus be removed as this is by definition not relevant for REACh, cosmetics or Water Framework Directive.
Having observed this, and despite of the finding that the initial suggested alignment of the PPPR and BPR (i.e. risk-based instead of hazard-based in both regulations) is not included in the current proposal, Ctgb propagates to perform a case-by-case risk evaluation of this type of ED active substances instead of a cut-off without any clauses. Many authorised plant protection products in the Netherlands are insect growth regulators or plant hormones. Although these pesticides act via endocrine disruption, they are generally considered to be of low risk to the user and the environment. Therefore, and also in the light of ensuring a chemical diverse pool of pesticides to minimize the development of resistance, a risk-based approach of this type of ED active substances should be possible.

ANNEX 1. DRAFT COMMISSION REGULATION (EU) AND ANNEX AMENDING ANNEX II TO REGULATION (EC) 1107/2009 BY SETTING OUT SCIENTIFIC CRITERIA FOR THE DETERMINATION OF ENDOCRINE DISRUPTING PROPERTIES [SANTE-2016-12020-REV 2]

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ANNEX 2. DRAFT COMMISSION DELEGATED REGULATION (EU) AND ANNEX SETTING OUT SCIENTIFIC CRITERIA FOR THE DETERMINATION OF ENDOCRINE DISRUPTING PROPERTIES PURSUANT TO REGULATION (EU) NO 528/2012

Draft delegated regulation:
https://circabc.europa.eu/d/d/workspace/SpacesStore/7175d2d8-01e5-49d9-9c3b-bdafa0e65df6/CA-Febr17-Doc.3.1.a draft delegated regulation.docx

Draft annex:
https://circabc.europa.eu/d/d/workspace/SpacesStore/b5232f49-1f94-4179-8d8d-059ab838c877/CA-Febr17-Doc.3.1.b Annex draft delegated regulation.docx.doc