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**Bijlage(n)**
1

Datum 9 april 2019
Betreft Berichtgeving over bijenrichtsnoer

Geachte Voorzitter,

Vorige week zaterdag 4 april 2019 publiceerde Follow The Money (FTM) een artikel waarin enkele uitspraken stonden over de inbreng van de Nederlandse delegatie in EU-overleg (SCoPAFF gewasbescherming) inzake een bijenrichtsnoer, aan de hand waarvan de risico's voor bijen bij een aanvraag voor goedkeuring (of verlenging van bestaande goedkeuring) van werkzame stoffen kunnen worden beoordeeld. De vaste commissie voor Landbouw, Natuur en Voedselkwaliteit heeft verzocht om een reactie op de berichtgeving van FTM (kenmerk 2019Z06961/2019D14475). Hierbij geef ik invulling aan dit verzoek.

Het gebruik van gewasbeschermingsmiddelen is nodig om ziektes en plagen in de plantaardige sectoren tegen te gaan. Tegelijkertijd is het belangrijk dat dit geen onaanvaardbare risico's heeft voor mens, dier en milieu. Het gebruik van gewasbeschermingsmiddelen is daarom alleen toegestaan als dit veilig is. Het is mijn inzet om de afhankelijkheid van telers van gewasbeschermingsmiddelen te verminderen, zoals ook aangegeven in mijn LNV-visie. Hierbij streef naar onder andere weerbare teelten. Een dergelijke omslag kost tijd en ik zal uw Kamer ook op korte termijn informeren over mijn visie hierop. In de tussenliggende periode is het zaak een balans te vinden tussen enerzijds de teler die gewasbeschermingsmiddelen nodig heeft en anderzijds de omgeving waar mogelijk effecten van de gewasbeschermingsmiddelen zijn. Dat doe ik door mijn besluitvorming te baseren op de meest recente wetenschappelijke inzichten. Dat is de kern van mijn beleid en dus ook van de Nederlandse inzet in EU-verband. Ik vind het belangrijk dat ook de effecten op bijen goed worden meegewogen en ben dan ook voorstander van een nieuw bijenrichtsnoer. Nederland was ook een van de initiatiefnemers voor een expert-workshop over het bijenrichtsnoer in 2013. Het is van belang dat het nieuwe richtsnoer werkbaar is in de praktijk en gebaseerd is op de meest actuele wetenschappelijke inzichten. Die inzet heb ik op 13 maart jl. ook weergegeven in mijn beantwoording van vragen van het lid Ouwehand hierover (Aanhangsel Handelingen 2018/19 no.1865).

Mijn ambtsvoorgangers en ik hebben uw Kamer regelmatig geïnformeerd over de Nederlandse inbreng in de discussie over het nieuwe bijenrichtsnoer. Het meest recent betrof dat de voornoemde antwoorden op vragen van het lid Ouwehand

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(Aanhangsel Handelingen 2018/19 no.1865). Daarvoor waren dat onder meer de brieven over de inperking van het gebruik van drie neonicotinoïden uit 2017 (Kamerstuk 27858, nr. 396) en 2018 (Kamerstuk 27858, nr. 421) met adviezen van het Ctgb als bijlagen. Hierin werd ook ingegaan op aspecten van het bijenrichtsnoer die verbetering behoefden. De Nederlandse inbreng is de afgelopen periode daarop geënt en verder uitgewerkt.

Ik constateer dat de discussie in de EU over het nieuwe bijenrichtsnoer al jaren loopt en nog niet tot een uitkomst heeft geleid. In 2016 heeft Nederland al gepleit om de onderdelen te implementeren waarover overeenstemming bestaat en EFSA mandaat te verstrekken voor herziening van de overige onderdelen. Zelf lever ik actief een bijdrage om de discussie in de EU vlot te trekken en zo te komen tot een gedegen en wetenschappelijk goed onderbouwd richtsnoer. In november 2018 heeft Nederland aangedrongen op harde deadlines voor de implementatie en herziening. In de bijlage zijn de Nederlandse reacties aan de Europese Commissie weergegeven op een conceptversie van het implementatieplan van de Europese Commissie (verstuurd op 18 september 2018 en 21 november 2018). De Commissie heeft in het SCoPAFF van 21-22 maart 2019 gemeld dat het mandaat aan EFSA voor de herziening inmiddels is verleend, met een deadline van twee jaar.

Ik heb zowel inhoudelijke als procedurele voorstellen gedaan om tot een goed en geharmoniseerd bijenrichtsnoer te komen. Inhoudelijk kan het bijenrichtsnoer op het gebied van toxiciteit op de lange termijn (chronische toxiciteit) en eisen aan veldstudies verbeterd worden. Nederland heeft daarbij onder meer naar voren gebracht dat Nederlands onderzoek op het gebied van chronische toxiciteit, waarvan de resultaten naar verwachting in de eerste helft van 2019 gepubliceerd kunnen worden, daar aan kan bijdragen. Dit kan tevens bijdragen aan de praktische uitvoerbaarheid van het richtsnoer. Procedureel heeft Nederland voorstellen gedaan en ondersteund die enerzijds een implementatie mogelijk maken van de onderdelen waarover overeenstemming bestaat en anderzijds zorgen voor een concreet mandaat aan EFSA om het richtsnoer te actualiseren op basis van nieuwe wetenschappelijke inzichten.

De Nederlandse inbreng is gebaseerd op de adviezen van het Ctgb. Het Ctgb adviseert in het geval van richtsnoeren en beoordelingscriteria op basis van zijn technisch-wetenschappelijke deskundigheid over de kwaliteit en de praktische uitvoerbaarheid ervan. Aan de hand van het advies wordt de Nederlandse inbreng in een ambtelijk interdepartementaal overleg vastgesteld, waarna ik uw Kamer informeer. Dit advies heeft uw Kamer, zoals hiervoor aangegeven, ook van mij ontvangen. Dat neemt niet weg dat maatschappelijke organisaties, belangenorganisaties en burgers de overheid en het Ctgb kunnen benaderen met hun zienswijzen. Deze zienswijzen worden ter kennisgeving aangenomen.

Ik hecht zeer aan een goede informatievoorziening richting uw Kamer en tracht zo transparant mogelijk te handelen in mijn beleid voor gewasbescherming. Om die reden heb ik eerder aangegeven dat ik uw Kamer voorafgaand aan elke vergadering van SCoPAFF gewasbescherming informeer over de Nederlandse standpunten bij de onderwerpen waarover besluitvorming plaatsvindt. Mijn

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standpunten baseer ik op de adviezen van EFSA en Ctgb. Ik zal dienovereenkomstig blijven handelen, ook waar het nieuwe bijenrichtsnoer betreft.

Carola Schouten
Minister van Landbouw, Natuur en Voedselkwaliteit

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**NL comments on the proposal for implementation of the EFSA 2013 (revision 2014) Guidance document for RA of bees and the proposal for revision of the Uniform Principles**
*(verzonden per mail aan de Europese Commissie, 18 september 2018)*

The NL supports the adoption of the EFSA Guidance (2013, revision 2014) and a two-step schedule, provided that some adjustments are implemented to make the guidance more workable. Please see our comments on the Commission's proposal below.

Main points:

Commission Notice, Part A:

1) The Guidance Document (GD) does not contain an adequate Tiered approach, as almost all substances fail the first Tier, even for honeybees. This can be rectified if the conservative chronic oral trigger is revised based on the latest scientific insights (e.g. background mortality and bee colony modelling). We ask the Commission to provide EFSA with a mandate to revise this trigger as soon as possible, so that the revised trigger is available before implementation (i.e. before 30 June 2019) and can then be included in the revision of the Uniform Principles.

2) Because of the strict requirements in the GD very few to none of the current field and semi-field tests for honeybees will be acceptable for use in risk assessment. The important refinement option of semi-field and field tests for honeybees will then become unavailable. We propose revision of these protocols before implementation of the guidance (i.e. before 30 June 2019).

Commission Notice, Part B:

3) Many of the actions listed in Annex B are dependent upon the development of "internationally agreed protocols". As a result, adequate implementation of the Guidance will require that this work be given high priority and a concrete planning schedule, especially if these topics are to be assessed by Member States in a harmonized way. What is the Commission's view on how to monitor and ascertain progress in this area?
   Furthermore, a lack of international agreed protocols and guidance on higher tier refinements for bumble bees and honeybees keeps applicants and assessors in the dark on how to perform and assess (semi-)field studies. We therefore recommend that an expert working group be established as soon as possible, in which risk assessors from the member states and EFSA discuss and agree how to interpret and use studies, and which protocols (including drafts) might be used in the event that no "internationally agreed protocol" is available. In view of the conservative first tier risk assessment, these studies will be necessary for many dossiers. Discussion of and agreement on protocols could prevent many future harmonization issues.

4) The implementation date for "Exposure from guttation fluid" should be made dependent on the information needed, as mentioned in the table.

Commission Notice , Part C:

5) The protection goals for bumble and solitary bees are currently based upon those for honey bees. If risk assessments for bumble and solitary bees proceed under this assumption, as is proposed in the current draft of the implementation timeline, most applications for plant protection products will be rejected, potentially unnecessarily. As a result, we consider developing protection goals for bumble and solitary bees to be an extremely important action for which concrete deadlines should be set, at the latest before the implementation date of Part B of the Commission Notice.

Uniform principles:

- We propose to revise the Uniform Principles only after the chronic oral trigger is revised.

In summary, we propose the following actions to be included in the implementation schedule:

- A Commission mandate to EFSA to set-up an expert group of risk assessors and scientific experts to review the trigger values (especially the chronic oral trigger) for honeybees and to review the protocols for field and semi-field studies taking into account the latest scientific insights, to be finalised before the proposed implementation date of Part A.
- A Commission mandate to EFSA to:
    - review the safety factors for the bumble bee and solitary bee endpoints,
    - develop detailed protection goals for bumble bees and solitary bees

  to be finalised before the implementation date of Part B.
- The setting-up of a working group of risk assessors from member states and EFSA to discuss and agree how to interpret and use (semi-) field studies, and which protocols (including drafts) might be used in the event that no "internationally agreed protocol" is yet available to foster a harmonized approach in such interim period.

More in-depth comments and explanation of our position can be found below.

Regarding Annex Part A:

1) Almost all substances (including herbicides and fungicides) fail the first Tier risk assessment. Thus, the Tiered approach of the GD is not adequate. A Tiered approach should filter out a number of lower risk substances so that only those substances for which an actual risk is expected go to the higher Tier. The problem is caused by the trigger for the chronic oral risk assessment, which is so low that even when substances show no effect at limit doses, they do not usually pass the honeybee chronic oral assessment. New information suggests that the chronic oral trigger is set too conservatively.

The trigger is based on an assumption of background mortality which is debatable and being tested in the Netherlands at this moment[1], and on model calculations with an unsuitable model[2] (moreover using a background mortality in the model calculations of 15% per day whereas the trigger is based on the assumed background mortality of 5.3% per day, introducing further conservativeness). Furthermore the trigger is based on a linear relationship between the exposure and the mortality which is an unnecessarily conservative assumption. We ask the Commission to provide EFSA with a mandate to revise this trigger as soon as possible, so that the revised trigger is available before implementation (i.e. before 30 June 2019).

2) If the requirements for higher tier testing in the GD are strictly followed, very few to none of the current field and semi-field tests for honeybees will be acceptable for use in risk assessment, resulting in the possible rejection of many products, potentially unnecessarily. The requirements for (semi) field testing, as outlined in the GD, are so demanding that it is not currently feasible to undertake field testing. This means that this refinement option, which is regularly used under the current assessment framework, will not be possible. Two other refinement options are given: risk mitigation and exposure refinement (i.e. residue measurements in nectar and pollen). However, risk mitigation cannot reduce all potential risks coming from the first Tier, and there is little experience with exposure refinement, making the usefulness of this refinement option uncertain. We recommend that the protocols be revised as soon as possible, taking into account all new information on background mortality (see A.1) and residue measurements (collected by EFSA) and making use of all expertise available in the field.
3) Currently the FOCUS run-off scenario is used for the aquatic risk assessment but not for the assessment of the puddle concentrations. It is no problem to perform the scenario calculations and to extract the concentrations but the Commission is asked to ensure that the environmental Fate sections come to a harmonized agreement on formats for outputs before June 2019.

Regarding Annex Part B:

1) A "re-consideration of the safety factor", as stated in the draft implementation timeline for chronic and larval bumble bee, should be expedited if the implementation deadline of 30 June 2021 is to be met. If the risk assessment is performed using the current safety factors it will fail in most cases and many applications will have to be rejected. The same holds true for the solitary bee risk assessments. This comment goes hand in hand with the development of a protection goal for non-*Apis* bees (see main comment 5 and comment C.1).
2) For guttation, scientific studies are needed to assess the probability of occurrence of guttation water in combination with the probability of use of guttation water by the bees (as is correctly pointed out in this annex). To the best of our knowledge no one is working on these matters so it is very unlikely

[1] governmental project BO-20-002-011
[2] EFSA, 2015. Statement on the suitability of the BEEHAVE model for its potential use in a regulatory context and for the risk assessment of multiple stressors in honeybees at the landscape level. EFSA Journal 2015;13(6):4125, 91 pp. doi:10.2903/j.efsa.2015.4125

that these studies are finalized before the proposed implementation deadline of 30 June 2021. We recommend a concrete timeline be established to address the remaining questions surrounding guttation in order to ensure that implementation will be possible in the near future. Since adequate risk assessment is not possible without this information, we recommend to change the implementation date of the guttation risk assessment to 'once the necessary scientific information has been gathered and incorporated into a risk assessment methodology'.

3) The extrapolation of residue trials is a topic for which more guidance is needed and we therefore recommend it be moved to Part C.
4) A screening step for honeydew might not necessarily require "protocols", but would require a risk assessment framework. The potential toxicity is covered by the existing tests and only a framework for estimating exposure should be produced. The text in part B should be updated to reflect this. Also, we note that since honeydew is not included in the current (2014) version of the Guidance, it is unclear what to do if a screening step does not pass. Would the next step be risk mitigation? Is there some refinement? If refinements or mitigations are possible/the next step, this would presumably also have to be placed here in Annex B.
5) Many of the actions listed in B are dependent upon the development of "internationally agreed protocols". To ensure that the use of protocols is harmonized among Member States, we recommend that an expert working group be established as soon as possible, in which risk assessors agree on which (draft) protocols can be used from which time point, and what conclusions can be drawn from studies performed according to old protocols. Unless such a working group is made, interpretation of higher tier studies is unlikely to be adequately harmonized, while these studies will be necessary in many cases as the first tier will often fail.
6) The statement on the repeated exposure test beyond pupation can be removed from part B, as the OECD GD 239 includes emergence of pupae.

Regarding Annex Part C:

1) As mentioned above, we consider the development of detailed protection goals for bumble and solitary bees to be vitally important. Both the effect and exposure goals in the GD are not considered fully fit for purpose. For example, the GD proposes that the assessment goal for solitary bees be based upon protection of populations of solitary bees living at the edges of treated fields, and indicated that this is quite conservative, because only a small proportion of all solitary bees are expected to be living at the edges of treated fields (see p. 61 of the GD). Less conservative protection goals are also possible: E.g. the least conservative option could be all populations of solitary bees in a Member State; an intermediate option could be all populations of solitary bees in areas with high intensity of pesticide use, etc.. A suite of options could be developed to address the protection goals that are considered relevant by bee population experts. It would, in principle, be possible to develop a tiered scheme starting with a non-conservative option and move stepwise to more conservative options. A similar approach could be followed for bumble bees. Considering the potential difficulties in developing such new options, we propose that a

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working group be established as soon as possible, making use of existing expertise (e.g. IPBES, SETAC).

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**NL Comments on Commission's amended proposal on implementation plan Bee Guidance Document**
*(verzonden per mail aan de Europese Commissie, 21 november 2018)*

In the PAFF Committee the Commission tabled a proposal to adopt the EFSA (2014) guidance document on the bee risk assessment together with an amended implementation plan (chronic toxicity parts moved from part A to part B) and a mandate to EFSA for the update of the GD. The proposal would include an amended proposal for revision of the uniform principles, including only the acute toxicity trigger values for honey bees.

The Commission circulated the updated implementation plan. The amended proposal for the uniform principles and a proposal for the EFSA mandate are not yet available, so it is not yet possible for us to fully respond to the Commission's proposal and provide you with a final position. We do however want to communicate our concerns at this stage and propose two essential modifications to strengthen the proposal and a list of items to be included in the EFSA mandate.

The NL appreciates that the amended implementation plan now allows for implementation of the less disputed parts of the new GD and an update of problematic parts of the GD based on the latest scientific information, such as honey bee background mortality. However, this does not address all of our previous concerns. We note that the Commission's proposal still includes the implementation of the strict requirements for field and semi-field studies in the current version of the EFSA GD. Since these requirements are dependent on parts of the GD included in the update and thus themselves will be updated, we consider it necessary that these requirements are also moved to part B of the implementation plan. This then follows a clear reasoning: parts of the GD included in the update need to be implemented after the updated GD is adopted and thus included in part B.

To ascertain that the guidance is updated in time for the implementation of Part B, the mandate to EFSA should include a hard deadline. Furthermore, to prevent the implementation of elements of part B in case of delay of completion and adoption of the updated GD, we stress the importance of changing the proposed implementation date of these elements from "30 June 2021" to "one year after adoption of the updated EFSA bee GD". Otherwise we may in two years be faced with the same problems we are trying to avoid by postponing implementation of those elements to allow their update. This also allows applicants sufficient time to ensure their dossiers are in line with the updated GD at the moment of implementation. We note that this is similar to other parts where international protocols still need to be developed.

Our other previously communicated concerns with regard to part B and C of the implementation plan still stand. They can be addressed in the update process of the GD, provided that they are included as specific requirements in the COM mandate to EFSA. See below a list of elements that we feel need to be included in the mandate, based on our previous comments.

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List of elements to be included in the COM mandate to EFSA for the update of the bee GD, based on our previous comments:

- Chronic trigger values for honey bees should be updated to reflect the most recent data on background mortality, more complex modelling options, and the conservativeness of the linear extrapolation. The NL is able to contribute with the results of two research projects whose results are expected to be published in the first half of 2019.
- The statistical power requirements for semi- field and field tests should be revisited, considering the data mentioned above.
- Development of detailed protection goals for bumble bees and solitary bees (or provide data to support honey bee assessment/protection goals as sufficiently protective so safety factors can be reconsidered).
- Update of trigger values for bumble bees and solitary bees, considering protection goals.
- Inclusion of scientific information on the occurrence of use of guttation water by honey bees.
- Risk assessment framework for exposure to honey dew. The NL can contribute to this by providing information on the framework currently applied in the NL.

We thank the Commission for taking our comments into consideration.