Courtesy translation of Ctgb's letter to the President of the Dutch House of Representatives responding to the Scientist's impact assessment of EU-proposal 'Food and animal safety simplification package (focused on plant protection products)'
May 6th 2026

Dear Mr President,

During the parliamentary debate on the Agriculture and Fisheries Council held on 23 April, your House requested a response from the Ctgb regarding the scientist's impact assessment of the Food and Feed Safety Simplification Package (focusing on plant protection products). This letter contains that response. Earlier this year, the Ctgb advised the ministers of Agriculture, Fisheries, Food Security and Nature (LVVN) and Infrastructure and Water Management (IenW) on this Simplification Package. In its advice, the Ctgb stated that it welcomed the European Commission's (EC) proposal, but that it needed to be amended on key points. You can find this advice here.

Ctgb response to the scientist's impact assessment

The Ctgb appreciates the attention given to the Simplification Package proposed by the European Commission. A thorough discussion on the proposal is important to ensure that European regulations governing the placing on the market and use of plant protection products are simplified, whilst maintaining the level of protection for humans, animals and the environment.

The Ctgb considers it important that this discussion is conducted on the basis of accurate facts. In this light, it is notable that the scientist's impact assessment contains several inaccuracies regarding the EC proposal. Furthermore, in our view, a scientific assessment would be strengthened if it were based on scientific research and referred to the findings thereof. This is largely absent from the present assessment. The Ctgb also finds that a proper comparison with the current system and its shortcomings is lacking. This is important because the competent authorities in Europe (such as the Ctgb) and EFSA have become overburdened in their implementation of the current system.

In summary, the review examines two topics (the risk-based reassessment of approved active substances and the acceleration of biocontrol) from various perspectives. The review makes a number of recommendations on these matters. Below, we provide a response to the authors' findings and recommendations for each topic.

1. Risk-based reassessment of approved active substances

Process: responsibility, mandate, criteria

The EC proposes replacing the system of periodic reassessment for part of the approved active substances with a risk-based system, based on which substances are reassessed as part of a targeted work programme. The authors consider it unclear how the process works, what criteria are applied and who is given what mandate in the decision-making on this matter. The authors also find it unclear when a reassessment is triggered and by whom.

In its opinion, the Ctgb has also called for more safeguards to be built in to ensure that a risk-based system functions effectively and responsibly. The Ctgb does, however, point out that a number of elements mentioned by the authors have already been included in the EC's proposal. The proposal

clearly states that the EC is obliged to adopt a work programme for the reassessment of active substances. The work programme is adopted in accordance with the comitology procedure for implementing regulations (just like the current periodic work programmes). This means that the EC presents a proposal to the Standing Committee (SCoPAFF), on which the Member States vote, after which the EC adopts the work programme.

The proposal sets out clear triggers for when the EC must adopt a work programme, namely no later than three years after any amendment to the substance approval criteria, data requirements or guidance documents. The EC must consult EFSA to identify relevant substances to be included in the work programme for reassessment. When identifying substances, the EC must also take into account safety concerns and new scientific insights. The EC may also take requests from Member States into account. The work programme must also specify which Member State will carry out the reassessment (rapporteur), which data the manufacturer must submit and by when, and the expiry dates of the substance authorisations. The latter is important: if a manufacturer fails to submit the data on time, the substance approval will automatically expire.

The Ctgb agrees with the authors that it is not immediately clear from the proposal exactly what the content of such a work programme will be. Will the relevant substances be included? For this reason, the Ctgb has also recommended advocating for a European vigilance system that provides the EC and the Member States with timely and systematic information on new scientific insights regarding the risks of active substances. This system is to form a transparent basis for the design of the work programme, so that active substances are reassessed at the right time (in a timely manner) and on the right points (risk-based). Another way to strengthen the EC proposal on this point would be for EFSA to open its advice to the EC on the identification of relevant substances to public consultation.

The authors also point out that an underlying programme involving, among other things, risk monitoring is essential for the effective implementation of a risk-based reassessment system. The Ctgb endorses the importance of monitoring data, but notes that this applies to both the current periodic re-evaluation system and a risk-based system. Furthermore, it is important to realise that the selection of substances for inclusion in work programmes will not be based solely on monitoring data. In the technical briefing, the authors indicated that the proposal would mean that other parties (such as water boards, local authorities, health institutions) would be made responsible to provide information in order to select an active substance for re-evaluation. That is not the case. The proposal states that the EC must identify relevant substances for inclusion in a work programme, advised by EFSA. This may be based on monitoring data but need not be. For example: in the case of a new guidance document on the assessment of the risk to bees, insecticides are in any case relevant substances to be included in a work programme. No monitoring data is required to reach that conclusion.

A level playing field and innovative capacity

According to the authors, the proposal leads to an uneven playing field and hinders innovation, as new substances are assessed against new frameworks whilst older substances are not. This is, in itself, a valid observation. However, this effect also occurs under the current periodic re-evaluation system, where, due to all the delays, it can sometimes take 20 years for a substance to be reassessed. The Ctgb expects that the risk-based system will not exacerbate this problem. After all, within a risk-based system, substances that give cause for concern can actually be reassessed more quickly against new, stricter frameworks.

Simplification of regulations

The authors argue that the proposal does not lead to simplification, because the periodic reassessment is being replaced by a risk-based system only for active substances, but not for plant protection products based on those substances. The Ctgb agrees with this: the available assessment capacity is used most effectively if the reassessment of a plant protection product follows the reassessment of an active substance. The Ctgb therefore advocates a risk-based system also for the reassessment of products, just as the EC proposes for substances.

Protection of people and the environment

The authors are of the opinion that if the periodic reassessment is discontinued, there is a high risk that substances will remain on the market which, with long-term exposure, have harmful effects on the environment and health. According to the authors, this is due to an assessment method that is insufficiently capable of accurately predicting long-term effects, such as effects on the nervous or immune systems of humans or animals.

The Ctgb cannot follow this reasoning. This instead argues in favour of developing a better assessment methodology. Once this is available, it can be implemented more quickly in a risk-based system for substance reassessment than in a system involving periodic reassessment. After all, in a risk-based system, the EC must then draw up a work programme that includes the substances relevant to that methodology. This therefore argues in favour of a risk-based system and against a system of periodic re-evaluation where no choices are made and it can sometimes take 20 years before a substance is reassessed.

Burden of proof and the precautionary principle

The authors argue that, under the proposed risk-based system, the burden of proof to demonstrate that a substance meets the approval criteria no longer lies with the manufacturer, which would be contrary to the precautionary principle. This is incorrect. Article 18 stipulates that the burden of proof for the reassessment of substances lies with the manufacturer, and the (unamended) Article 43 does the same for plant protection products.

Under the risk-based system, it is true that the authorities (the EC and Member States) must decide on a work programme for the reassessment of substances and, in that sense, therefore assume greater responsibility. That is why the Ctgb considers it very important that the EC and the Member States are informed by a European vigilance system regarding substances.

Impact on workload and feasibility for assessment bodies

The authors point out that the process of deciding whether to carry out a risk-based reassessment of a substance or product will require significant capacity, which can then no longer be devoted to the reassessment itself. Furthermore, the authors suggest that it would be better to focus on expanding capacity within the current system.

The Ctgb notes that the current system is becoming gridlocked and our experience shows that expanding capacity alone, without other measures, does not lead to the desired result. Furthermore, the Ctgb follows the EC's reasoning that, if properly structured, the risk-based system leads to a more effective use of assessment capacity. The drafting of the work programmes and the European

vigilance system advocated by the Ctgb, which should form the its basis , does indeed also require capacity from risk assessors. However, this is not commensurate with the capacity required to carry out the actual reassessments.

2. Fast-track authorisation for biocontrol products

The authors consider the proposed definition of biocontrol substances to be too broad. The Ctgb agrees with this and has also issued advice on the matter. Furthermore, the authors propose the classification of substances/products to enable specific assessment procedures. It is not clear exactly what the authors mean by this.

According to the Ctgb, three aspects are important for accelerating market access for biocontrol products: (1) accelerated procedures in the regulation, (2) an appropriate assessment framework with suitable data requirements, and (3) assessment capacity with the necessary knowledge and expertise. The EC proposal addresses the first point, as the Regulation concerns the procedure, not how biocontrol substances and products should be assessed. That is set out in implementing regulations and guidance documents. The Ctgb therefore agrees with the authors' view that, in addition to improvements to the procedure, other measures are also needed to achieve the intended acceleration.

3. Recommendations

The table below sets out a response to the authors' four recommendations:

Recommendation assessment	**Response Ctgb**
Maintain periodic reassessments for all substances. Smarter assessment methods can reduce the workload.	The Ctgb does not support this recommendation, as it does not offer a solution to the current deadlock in the system. Furthermore, a well-designed risk-based system allows for the faster reassessment of certain active substances than is currently the case, should new scientific insights warrant it. The claim that the workload can be better managed through smarter assessment is unsubstantiated and, in our view, generally unrealistic. There are certainly opportunities here for biocontrol, but for chemical substances the assessment framework is becoming increasingly extensive and complex, meaning that the assessment of an active substance takes ever longer and the workload continues to increase.
Retain the precautionary principle of the current system. The burden of proof must remain with manufacturers, and the precautionary principle of the current regulations must continue to be the guiding principle.	The Ctgb supports the retention of the precautionary principle, but notes that the EC proposal is also based on this principle. Under the EC proposal, the burden of proof also remains with the manufacturer.
Use 'green lanes' for biocontrol substances and products. Developing so-called 'green lanes' for biocontrol agents makes it possible to carry out assessments for specific classes of products. This requires the development of a classification system	The Ctgb shares the desire for 'green lanes' and notes that the EC proposal addresses this by including a classification for biocontrol, certain procedural streamlining measures for such substances and products, and by increasing EFSA's capacity and enabling EFSA to act as rapporteur for biocontrol substances. As stated in the Ctgb's advice, this does, however, require a clear

for biocontrol products, along with corresponding specific assessment procedures for the various classifications.	demarcation of the definition of biocontrol to prevent toxic natural substances from also falling under this category.
Do not allow an extension of 'grace periods'. Extending grace periods will lead to the prolonged use of substances that, in principle, pose unacceptable risks, whilst it remains unclear whether the issue of emergency authorisations will be resolved.	The Ctgb can in principle support this recommendation, but notes that the setting of this grace period falls within the competence of the competent authority (the Ctgb in the Netherlands) and is based on a careful assessment.