High level meeting with delegation from Ctgb – Board for the Authorisation of Plant Protection Products and Biocides

Meeting date: 14 September 2020, 09:30-12:30 (virtual meeting)

List of participants:

European Food Safety Authority (EFSA)

Bernhard Url	EFSA Executive Director
5.1.2.e Woo	Head of Scientific Evaluation of Regulated Products (REPRO) Department
5.1.2.e Woo	Head of Pesticide Peer Review (PREV) Unit
5.1.2.e Woo5.1.2.e Woo	Head of Pesticide Residues (PRES) Unit *(a.i.)*
5.1.2.e Woo	Scientific Officer – Scientific Coordination Team (PREV) Unit

Dutch Board for the authorisation of PPP and biocides (Ctgb)

Mr Johan de Leeuw	Chair of the Board
Mrs Ingrid Becks	Director
Mrs 5.1.2.e Woo	Deputy-director
Mrs 5.1.2.e Woo	Policy advisor

Topic	Discussion	Actions
1) Welcome and introduction	A short introduction was given including the scope and main agenda topics of the meeting and a tour de table of the participants. This has been the 5th high level meeting with the delegation from the CTGB, which was considered a good practice in line with EFSA's aim to consolidate collaboration with MSs and to identify constant opportunities to improve interaction. The pesticides area and the upcoming changes in the field of food safety (GFL, Green Deal and REFIT) provide further opportunities for collaboration to achieve common goals. CTGB is one of the MS organisations leading for new initiatives and playing a key role in this area for the upcoming years.	-
2) Farm to Fork/REFIT/NL Vision Agriculture 2030 and Action plan Plant Protection	CTGB gave an update on the high level strategy on a vision for crop protection in the NL by 2030 (`**Dutch Vision Agriculture 2030')** and its implementation programme, aiming at the protection of natural resources and the reduction of the environmental impact. In particular, 3 main goals are proposed as follows: • more resilient plants and crops to reduce dependence on pesticides • integrating agriculture with nature • reduction of emission to the environment and achieving almost zero residues An action programme (`**Action plan Plant Protection')** has been developed with involvement of stakeholders to achieve these goals within 10 years, which is expected to have major impact on the Dutch agriculture. A key element of the plan is the introduction of precision farming practices as a way to mitigate emission to the environment through the decreased use of pesticides, which may then be used in a more targeted way. An exchange of views took place on these developments, goals and improvements included in this ambitious action plan in order to create the necessary conditions for the transition to a circular agriculture, in line with the new perspective of the EC Farm to Fork strategy. A key issue is the need for a sustainable agriculture with a reasonable and intelligent use of pesticides, as outlined in the Dutch programme that promotes the preference of low-risk substances and new technologies to minimize the use of pesticides. The cost/price aspects of the programme was also touched upon.	-

	Concerning the challenges, there is an urgent need to reduce the large increase in emergency authorizations granted by MSs. At EU level, Commission has announced their intention to mandate EFSA to provide support and investigate the justifications for certain emergency authorizations granted by MSs. In the NL, it is proposed to allow granting of emergency authorizations in the transitional period only in exceptional cases, provided that applicants would develop alternatives. The NL is committed to encourage the development of low risk alternatives in the coming years. In fact, the vast majority of the pesticide applications, where NL is acting as rapporteur, are microorganisms and plant extracts to facilitate the availability of low risk substances. As another challenge, the reduced capacity of MSs to process dossiers together with the increased complexity of the renewal process was indicted in addition to the work undertaken for granting product authorizations. The timelines provided for in the legislation are not considered by CTGB to comply with the work that needs to be undertaken in practice. It was agreed that urgent actions would be needed from Commission to take structural measures. At EFSA, one of the main focus is to improve and increase engagement and collaboration with MSs in the coming years. EFSA is therefore investigating options and looking to establish long term partnerships with different partners across the EU. As an example, potential collaboration with EUROSTAT and MSs was mentioned to create a platform for exchange of data related to agriculture.	
3) High level meeting COM, EFSA and CA's	CTGB will chair the upcoming high level meeting between Commission, EFSA and MS competent authorities that will take place later in 2020. An exchange of views between EFSA-CTGB took place on the proposed scope and agenda of the upcoming meeting. A draft agenda has already been prepared that includes e.g. implications and capacity needs at Commission, EFSA and MSs arisen from the upcoming changes in relation to REFIT and the Farm to Fork Strategy, and related amendments of the active substance approval process. Risk mitigation measures were also highlighted that are growing importance and need to be taken more into account at the time of the active substance approval at EU level. Commission already started an initiative on this topic, however further discussions would be needed to have a better understanding and agreed definition for risk mitigation measures. Prioritization of GD documents and update on the GFL developments are also planned to be discussed. Whilst a formal communication on the status of the implementation of the GFL measures for stakeholders will take place in Nov 2020, this is planned to be at a high level, and therefore an update with more focus on pesticides area would be desirable.	EFSA to ensure support for the high level meeting between COM, EFSA and CA's

	EFSA offered its support for the meeting, in particular as follows: • providing information as regards the current state of the active substance approval process including possibilities for improvements and actions already implemented (e.g. consideration of risk mitigation measures and less critical scenarios in the assessment beyond the risk envelope approach in case the worst case assessment might be expected to fail); • working at the programme agreed with SANTE on revision of GD documents and related work planning; • for GD development, exploring further the option to finalize guidance documents by EFSA following ongoing preparatory work undertaken by MSs at zonal level; • update on GFL with focus on pesticides and impact on MSs. As a specific event regarding pesticides, a dedicated PSN meeting will be organized on 6 October relating to the developments on IUCLID.	
4) Promotion of low risk solutions (REFIT area of improvement 11)	CTGB welcomes the ongoing process on the amendment of the data requirements and adaptation of the Uniform Principles for microorganisms lead by the Commission in the context of the REFIT / Farm to Fork Strategy. Although the WG Biopesticides offers good forum for discussions, based on the current experience it appears often difficult to be able to reach agreements or conclusions. In fact, the NL is highly committed to accelerate the availability of low risk substances and therefore they would be in favour of simplifying the approval process by taking some data requirements out, in particular in the areas of efficacy and environmental fate. Overall, CTGB raised concerns that the current situation does not lead to the simplification and speed up of the authorisation procedure for microorganisms and further actions would be needed in order to be able to meet the policy objectives of the Farm to Fork Strategy. EFSA is also involved in the discussions of the WG Biopesticides and shared the view about the difficulties to make progress, which could deserve discussion with Commission. It was confirmed that for the time being no request has been received from Commission as regards EFSA's view on the data requirements. Overall, EFSA shares the view that further actions and collaboration with Commission would be needed and would be willing to take on board an eventual mandate in case needed. EFSA will feed back the concerns raised by NL regarding the scope and current progress of the revision of the data requirements to the WG Biopesticides. EFSA also welcomed the update by CTGB on their involvement in the training on microorganisms in the context of the BTSF for MSs organized by Commission.	EFSA to feed back the concerns raised by NL regarding the scope and current progress of the revision of the data requirements for microorganisms to the WG Biopesticides.

5) 'One substance one assessment' approach	CTGB welcomes the initiative advocated by ECHA on the "one substance - one assessment" concept and shared their experience gained so far with a pilot project (on sodium hypochlorite approved as biocide but not approved as pesticide yet) to facilitate biocide applicants to apply for pesticide approval/authorization. The "one substance - one assessment" approach has in particular high relevance for the assessment of chemicals that may be used across different legislative fields such as biocides/pesticides. A joint ECHA-EFSA Position Paper on 'EU Chemicals Strategy, one substance - one assessment' has been prepared and submitted recently to the Commission. In the concept paper the following main ideas have been identified: - Coordinating tasks: need for better governance to tackle the different regulatory framework, different data requirements and timelines; - Need for integrated workplan for common substances under the different legislative processes, possibility for addressing chemicals in groups; - Sharing IT tools and data, common methodology for efficient use of data, harmonized templates. EFSA gave an update on the cooperation between EFSA-ECHA currently in place to ensure harmonization of the scientific assessments in both agencies. There is already an established procedure since 2017 for the alignment of the EFSA a.s. approval process with the ECHA classification and labeling (CLH) process which works successfully on the basis of common templates and procedures and by sharing information and exchange of data. EFSA-ECHA also started to establish a practical approach for alignment of the ED assessments between pesticides/biocides, in particular since the same scientific criteria and the joint ED GD are applicable for both processes. So far less experience has been gained in this area due to the limited number of common substances with similar timeline in the pipeline for both processes (CO2, tebuconazole). As regards limitations, currently there are doubts whether a 'mutual recognition' would be legally acceptable considering the legal uncertainties due to the 2 different legislative frameworks. Overall, all actors are supportive of the "one substance - one assessment" concept which would avoid duplication of work while ensuring regulatory consistency across different legislations. As a pilot exercise, Commission has mandated EFSA for the re-assessment of phthalates (industrial chemical) in collaboration with ECHA.	-

6) Tasking grants/collaboration	Collaboration between EFSA-CTGB via various tasking grants (PREV coordination, bees) has been proved as a successful exercise. In particular the recent tasking grant supporting PREV coordination has been highlighted as a very positive experience from both sides, allowing to share knowledge and experience while gaining a mutual understanding of the work and challenges encountered at EU and MS level. A new call for tasking grant is planned to be launched by EFSA by the end of 2020; any input from CTGB based on the previous experiences or proposals for topics would be welcome. Potential areas of collaboration may include the followings: - support in BAU activities related to peer review and MRLs - support in development activities, ERA, microorganisms - REFIT: digital and precision agriculture techniques - Transparency regulation: IUCLID For 2021 CTGB is facing capacity issues, nevertheless they will try to consider the call. Stimulating further simplification of low risk substances/microorganisms was suggested as a possible future area of collaboration. Considering all the successful experience gained in the past, EFSA is considering to investigate longer term plans, for instance to establish a permanent rotation of staff between EFSA-MS authorities which may create a new, enhanced level of collaboration. In addition, further ideas to foster collaboration and optimize resources were proposed (e.g. to involve newcomers at MSs in the EFSA induction trainings, consideration of setting up an online platform for sharing recorded trainings on guidances with MSs). Further ideas and reflections on collaboration would also be welcome.	CTGB to consider providing any input or proposals for topics for future collaboration.
7) General Food Law	EFSA gave a brief update on the progress of the implementation of the General Food Law. In the area of pesticides, frequent updates are provided at the SCoPAFF and a dedicated Pesticide Steering Network meeting on IUCLID will be organized on 6 October 2020. In fact, many activities are ongoing which are yet to be finalized; delays occur due to the large volume of data/information that still need to be agreed with Commission. A formal stakeholder meeting is planned for November 2020 to present the outcome. The Practical Arrangements developed by EFSA will provide clarifications on all new elements but will be rather high level documents. With regard to the implementation in the PPP area, the existing EFSA Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances will be aligned with the new rules and will be extended to cover also MRLs.	EFSA to consider sharing further update on IT developments once more details become available.

	An updated version of the implementing act on renewals (replacement of Commission Implementing Regulation (EU) No 844/2012), including specific details on the new rules as well as clarifications on MS roles as regards the new elements, has been circulated by Commission for stakeholder consultation via the feedback mechanism in mid September 2020. IUCLID will be used as electronic central submission system; it was clarified that for pesticides new submission types have been developed compared to the system in place for biocides, nevertheless lot of elements from biocides area (e.g. existing endpoint summaries, OHTs) have been re-used. Overall, CTGB welcomed the communication activities in relation to the implementation of the GFL, however they raised the need to set up a strategic meeting with IT experts with ECHA-EFSA-MS. For the time being MSs are represented in the IUCLID Technical User Group which is currently focusing on the developments needed for the changes required by the GFL by March 2021. However, a contract with ECHA for 2021 is currently under preparation to tackle more strategic issues on biocides/pesticides in the longer term. EFSA will provide feedback with more details once available. Furthermore, discussions are also starting with ECHA as regards development of an IT infrastructure covering all food sector areas. Consideration should also be given to the integration of existing IT systems developed at MSs level.	
8) AOB: • COVID-19: general exchange on the effect on our daily work and the near future	A brief exchange on the impact of the COVID measures and the experience on the new way of working at EFSA and MS level took place. At EFSA all peer review expert meetings have been switched to 100% telemeetings, which are working well and will continue to be the practice also during 2021. Some requests for extension of deadlines have been received from applicants and rapporteurs in the peer review but the potential impact on the mid/long term planning is not yet clear. Depending on the impact on the overall timelines, Commission may consider to extend the expiry dates of substances where appropriate. There is also a considerable reduction in MRL applications received by EFSA in 2020 but it is unclear if this is due to delays from applicants and/or MS. A similar situation was indicated by CTGB, with delays occurring from applicants to submit additional information or applications due to the current COVID pandemic. Nevertheless, such requests for prolongation of deadlines were received only in a limited number of cases. There is still uncertainty as regards the longer term impact due to potential delays faced by laboratories conducting studies in support of applications.	-
• Advice Dutch Health Council	In the NL there is a high scientific debate concerning residents' exposure from agricultural areas, questioning whether the methodology used for the exposure	-

regarding residents	assessment is appropriate. The issue has also raised high media attention. The methodology used for the exposure assessment in the NL is the same as the one applied at EU level and the results show that the exposure level of residents is below the applicable toxicological reference values. Nevertheless, the Dutch Health Council advised to perform a literature review and investigate whether the EU methodology is fit for purpose. In fact, they propose to apply a mixture assessment factor to take into account cumulative, aggregated exposure from pesticides. EFSA confirmed the appropriateness of the EU methodology for non-dietary exposure assessment. Nevertheless, several activities are ongoing currently at EFSA where further work needs to be undertaken (e.g. investigations as regards the link between pesticides and Parkinsons' disease and possible neurodegenerative effects in children[1]). A dedicated workshop on the outcome is planned to take place in Q1 of 2021. EFSA is also working on the revision of the EFSA Guidance on the assessment of the exposure of operators, workers, residents and bystanders in risk assessment of plant protection products, however not touching at this moment bystanders and residents as target populations, since original data produced by companies are not yet available to EFSA. It was also confirmed that based on the Scientific reports of EFSA on cumulative risk assessment of pesticides, a mixture assessment factor proposed by the Dutch Health Council is not deemed necessary.	
• Renewal glyphosate	NL is one of the 4 members of the consortium (Assessment Group of Glyphosate) acting as rapporteur in the upcoming renewal process of glyphosate, and is responsible for undertaking the toxicological assessment. The renewal dossier has been received by CTGB on 9 June 2020. Following request for some additional data, a revised supplementary dossier was submitted by the applicants (Glyphosate Renewal Group) end July 2020. Admissibility of the revised dossier was confirmed on 18 August 2020, nevertheless some additional elements still should be provided during the preparation of the RAR. The evaluations by the rapporteurs are currently ongoing and the first results are planned to be shared between the Assessment Group in October 2020. As preparation for the renewal, CTGB had also a meeting with BfR to share experience gained from the first renewal exercise.	-
• Azole resistance	A recent research on hot spots in the NL revealed azole resistance developed in treated flower bulbs (green part) which necessitates risk management actions. A follow up research is currently ongoing in roots. As a mitigation measure, risk managers in the	-

[1] Scientific Opinion of the PPR Panel for developing Integrated Approaches to Testing and Assessment (IATA) case studies on Developmental Neurotoxicity (DNT) risk assessment (EFSA-Q-2019-00100).

	NL are considering to include relevant communication on the label for the concerned plant protection products. The issue of azole resistance is getting more attention and becomes in the focus also at EU level. Commission is raising awareness of the importance of this issue which should also be duly considered during the renewal of the concerned pesticides. Overall, EFSA agreed that the issue should be tackled at a horizontal level covering the azole pesticides as a group in case of any future mandates.	
• Sequential use of products with the same active substance: not always covered by risk assessment	As an item listed under the Dutch Vision Agriculture 2030, CTGB shared the concerns raised as regards the sequential use of plant protection products containing the same active substance, leading to a potential accumulation in the environment. Indeed in the agricultural practice in the NL it can be the case that in the same year several products with the same active substance may be used subsequently, leading to its consequent accumulation in surface waters, as detected also by monitoring data. To avoid such agricultural situations, that are not covered by the existing risk assessments performed at EU level or at CTGB during the individual product authorizations, the NL developed a guidance on the use of active substances irrespective of the applied formulations, which is also planned to be further considered at zonal level. The aim is to agree on a harmonized way forward on the enforcement actions to be taken.	-
• Ctgb letter to COM regarding flupyradifurone	Flupyradifurone is considered as a 'successor' of the neonicotinoids showing more favorable profile for bees. However, new data made available by the applicant (Bayer) show that solitary bees appear to be more susceptible to this active substance. This also raised the question whether this issue should be considered during the current revision of the EFSA bee guidance, and whether the same protection goals applied for honey bees and bumble bees would also remain valid for solitary bees. CTGB requested the applicant to generate further data which should be submitted after March 2021, to be taken into account as part of the renewal process of the substance. The issue was also flagged to Commission.	-