

BTO – Meeting with representatives of BASF to discuss issues related to their pending applications**9 March 2018**Participants:

[REDACTED] (BASF)

DG SANTE [REDACTED] – only for the point on cholecalciferol)

The meeting was organised on request of BASF.

BASF criticised various issues regarding the process for renewal of approval of active substances, in particular the refusal by EFSA for direct interactions with applicatns, the use of updated guidance documents by EFSA despite its claim that it was using version that were in force when dossiers were submitted, the lack of participation of experts from the Member States in the peer-review process and EFSA conclusions that do not actually represent the outcome of the peer review process but rather the particular (and often overly conservative views) of EFSA alone. BASF also considered that the Commission was not using its discretion as risk manager by following completely the EFSA conclusions, thus disregarding the views of the rapporteur Member States and those of other Member States.

DG SANTE rejected the latter and explained that the Commission carefully considered the merits of every case, pointing to the fact that the approval of many substances had been renewed – although often with restrictions – despite critical EFSA conclusions, as long as the examination of the merits and discussions with Member States allowed to conclude that there were safe uses. Nevertheless, EFSA's conclusions remain the main basis for the Commission, even though this is often criticised by industry (e.g. for the neonicotinoids) or by NGOs (e.g. for glyphosate). DG SANTE also mentioned recent activities of EFSA and the Pesticides Steering Network (i.e. experts from Member States) to improve transparency of the process, e.g. through reflecting in more detail the positions of the experts and minority views in the conclusions. EFSA has also recently indicated its willingness to engage with rapporteur Member States earlier on in the process, if so requested, and already for pre-submission meetings, in order to increase certainty and predictability for applicants.

BASF reported very positively on a recent experience with a new active substance (mefentrifluconazole) which has been designed specifically for safety. It had chosen to work with three Member States as rapporteurs (UK, FR, AT), which had led to a fast and clear peer-review process where no problems had been identified. BASF in particular appreciated the possibility to have been present at one expert-meeting during the peer review. EFSA's conclusions are very positive and so are those of ECHA as regards classification (i.e. no classification for reprotoxicity). BASF called on the Commission to treat the case with priority to ensure swift approval once the EFSA conclusions will be available. DG SANTE confirmed its established policy to give priority to new substances with non-problematic EFSA conclusions.

BASF criticised the criteria for the identification of endocrine disruptors for biocides as they identify one of its substances (cholecalciferol – Vitamin B) as ED with ensuing ban for sale to consumers, although the substance is sold as food supplement and anyway present in food. DG SANTE clarified that the ban for sale to consumers in Article 19 (4) (d) of the Biocidal Products Regulation applied to biocidal products – not active substances per se. It would be up to Member States to decide whether they consider a formulated product with a certain concentration of cholecalciferol as ED or not. BASF could discuss this with the rapporteur Member State (SE).

Upon request of BASF, DG SANTE confirmed that the proposal to amend the General Food Law (and certain articles in the Pesticides Regulation) to increase transparency in the assessment process for active substances was planned to be adopted by April/May 2018 as announced in the response to

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the European Citizens Initiative on glyphosate. Among others, the proposal would foresee that full study reports instead of only summaries of all industry studies would be published in the future.

BASF inquired about the latest developments as regards the setting of import tolerances for substances falling under the cut-off criteria. DG SANTE informed that discussions on its initial proposals (i.e. that Member States should reject such requests) had revealed some reservations by Member States and further reflections were ongoing.