BTO meeting with BASF 11 July 2017

Participants: (BASF); (SANTE)

BASF raised their concerns about the general functioning of the system under Regulation (EC) 1107/2009 which in BASF's view is generally disfunctional, brings too many uncertainties about timelines and is not predictable enough. BASF claim that regulatory systems in several countries outside the EU are doing much better. BASF is particularly concerned about the lack of expertise and resources available in some smaller Member States.

BASF asked for more information about the setting of import tolerances for substances meeting the cut-off criteria and referred to the position paper provided by ECPA. COM clarified that, as an outcome of the internal discussions so far, it does not seem likely that import tolerances would be granted for substances that are not approved because of health related cut-offs.

BASF would be keen to see the initiative taken by President Juncker concerning an amendment of the comitology procedure progressing.

BASF inquire about the impacts of BREXIT. COM informed that it is preparing communication material for economic operators as EMA has already done in the pharmaceuticals sector. COM will also start discussions with Member States about re-distribution of workload so far attributed to the UK and invited BASF to reflect on which MS could usefully take over their substances.

BASF criticised again that substance approval and MRL setting happen sequentially instead of in parallel. COM explained that MRLs will be set very quickly after a substance approval, if all necessary information is available. BASF informed about some new active substances currently being in development with extraordinarily positive properties. BASF at the same time feared that such substances might not make it to the EU market due to the restrictive legislation (i.e. they might be caught by the forthcoming ED criteria).

BASF reiterated their support for not following the ECHA approach in the assessment of the “persistence”-criterion. COM referred to the ongoing discussions between EFSA and ECHA on this topic and for the willingness of EFSA to harmonise their approach with ECHA.