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EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Director

Brussels,
SANTE/E4/SK/mb(2018) 5781116

Dear Mr de Seze,

Subject: EFSA's planning for publishing two technical reports on cumulative exposure assessment

I would like to inform you that, during the Standing Committee on Plants, Animals, Food and Feed, section pesticides residues (SC PAFF phytopharmaceuticals – section residues) of 18-19 September 2018, the Member States agreed on certain assumptions concerning risk management aspects of the assessment of cumulative exposure in a retrospective scenario (related to monitoring data in food). These aspects were included in chapters 3.2, 3.5.1.2, 3.5.3.1, 3.5.33, 3.5.3.4, 3.5.4, 3.5.1.1, 3.5.2.1 of the Commission working document SANTE/10216/2015 in its revision 7. They are compiled in Annex I to this letter.

At the end of 2017 and as a result of the Framework Partnership Agreement between EFSA and the Dutch National Institute for Public Health and the Environment (RIVM), the latter prepared the following two technical reports:

a) Cumulative exposure assessment to pesticide residues regarding two acute effects on the nervous system conducted with Monte Carlo Risk Assessment (MCRA) tool 8.2

b) Cumulative exposure assessment to pesticide residues regarding two chronic effects on the thyroid conducted with MCRA tool 8.2

At the time, EFSA had planned to repeat those exposure assessments internally using SAS® Software and to publish the assessments of RIVM and EFSA by the end of 2018. However, with the agreements reached in the September SC PAFF on the assumptions that should be used in the retrospective scenario, the assessments would need to be adapted to these changes. I would therefore like to ask you to make sure that these agreed parameters will be used by both EFSA and RIVM when calculating cumulative exposure in the retrospective scenario before publishing the assessments, even if this may delay publication.

Mr Guilhem de Seze
Head of Department Scientific Evaluation of Regulated Products (REPRO)
European Food Safety Authority
Via Carlo Magno 1A
I-43126 Parma

With this important first step done, the discussions among risk managers will now continue for the prospective scenario (MRL setting scenario) which we plan to approach in a stepwise procedure. To assist the Commission in the development of this scenario, I would like to request EFSA to arrange for further specific calculations comparing deterministic and probabilistic outcomes, after finalisation of the above mentioned retrospective assessments. This was already discussed between SANTE and EFSA staff and with Member States in a working group meeting on Cumulative Risk Assessment that took place in June 2018.

I am very grateful for the support and the constructive collaboration with EFSA colleagues in this important area and looking forward to the challenging discussions ahead.

Yours sincerely,

Sabine Jülicher

Encl.

Cc: Mr J. Tarazona, Mr L. Mohimont, Mr B. Dujardin, Ms H. Reich (EFSA)
Mr P. Bokor, Mr K. Berend, Ms A. Bitterhof, Mr S. Kirkagaslis, Ms L. Fabrizi (SANTE)

ANNEX I: Table of agreed assumptions required to be included in the two technical reports

WDv7§	Assumption	Calculations
3.2	>Margin Of Exposure >Percentile of exposure distribution	MOE=100 P99.9 (whole population approach, §3.5.2.1)
3.5.3.1 3.5.1.2	Non-Quantified Residues	Tier 1: For datasets with at least one finding, replace NQs with ½ LOQ, regardless of authorizations and also take into account Processing Factors. Ideally make use of the full distribution of values, if available, else medians. Include information from EFSA & BfR data. Tier 2: Calculations based on Option 5 of the Commission working document.
3.5.3.3	Processing Factors (PF)	Tiers 1 & 2 use PF distribution all sources, otherwise medians (see above)
3.5.3.4	Pesticide Residues in Water	Tier 1: 0.1µg/L for the 5 most potent substances of the CAG. Tier 2: 0.05µg/L for the 5 most potent substances of the CAG.
3.5.4	Variability Factor (VF)	Acute Exposure/Tier 1: b-distribution, VFs from PRIMO model. Acute Exposure/Tier 2: b-distribution, VF= 3.6
3.5.1.1	MRL exceedances	Agreement that samples exceeding MRLs should be taken into account resulting into a more realistic approach
3.5.2.1	Consumers-Only or Whole-Population	Whole Population approach (as indicated for §3.2)