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Safety of the Food Chain
Pesticides and Biocides

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Proposed priority list for development and updates of guidance documents (in the context of Regulations (EC) No 1107/2009 and Regulation (EC) No 396/2005)

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Introduction

During the high level meeting (HLM) between MS-Competent Authorities (MS-CA's), the European Food Safety Authority (EFSA) and the European Commission (COM) in December 2020, all participants were in favour of a joint planning and prioritisation of guidance development for implementation of the PPP Regulation and MRL Regulation. This would ensure that:

- there is an overview of Guidance Documents (GDs) under revision or development, as well as a timeline for those GD planned to be developed, and thus increased transparency is guaranteed for all stakeholders;
- work focuses on the GDs with the greatest need;
- the GDs development reinforces and/or complements each other;
- making available MS-CA's capacity and work sharing options can be discussed;
- research can be planned in preparation of upcoming guidance development.

There was no process available to prepare a priority list for guidance development. In a separate document, a process is proposed for future prioritisation.

Based on the agreement in the HLM in December 2020, an ad hoc process has been followed, in order to prepare a first priority list. This ad hoc interim process is described in detail in Annex I.

The Pesticide Steering Network (PSN) and the Post Approval Issues group (PAI) prioritised the technical and procedural guidance documents, respectively, where developments are needed (development of new guidance documents and updates of existing guidance). Following the outcome of the discussion in the HLM of 2021 between MS, EFSA and COM, and the establishment in the Directors Consultation Group (DCG) meeting of 25th February 2022, an overview of GD development with high priority, was compiled in the tables below.

Additionally, COM has ascertained that several other guidance documents need high priority as well, due to e.g. political commitments; these guidances have been added to the list .

It has to be noted that:

- some actions were identified which do not refer to guidance documents, which are however considered important and listed separately
- Some actions related to identified priorities have already been initiated, which is indicated in the tables.

Action points

Nr	Action	MS or agencies who expressed interest in contributing	Remarks:
1	E-learning platform for pesticide risk assessment topics accessible for EFSA and Member State experts.	EFSA, NL	EFSA suggests to take the lead and create a site in Sharepoint and give access to MSs. This site would contain the materials of trainings already organised by EFSA e.g. on nature of residues in plants, residue trials, residue definition, data exposure assessment, residues in livestock. COM suggests to extend it to all kind of available training materials (e.g. recorded BTSF course on ED) in the area of risk assessment, not only to focus on residues.
2	Database for Guidance documents detailing all relevant information (e.g. implementation date, version number, current status, etc.)	HU / EL	ONGOING COM is updating the Communications on data requirements. The proposal is to have a database that includes not only the guidance documents (as per definition agreed by the SCoPAFF) but also other supporting documents. MS are welcome to indicate the COM, if they have capacity to establish such a database that is shared afterwards and kept updated. This work needs to be aligned with EFSA.

Technical guidances

Nr	Guidance document	MS or agencies who expressed interest in contributing	Remarks:
1	Screening of existing regulatory framework in view of new farming techniques/new pesticide application technologies	HU, NL and DE	ONGOING Works is initiated by COM (WG on Environmental Issues) and by Central Zone workshops. This was valued as of high importance by the PSN and by the directors. About the scope: It concerns precision techniques and including this kind of innovations in assessment. What is the impact of new techniques, how can the exposure of these techniques be assessed within the current regulatory framework and guidelines? EFSA could support with an outsource of the work (via e.g. procurement) if the MSs could help draft tender specifications
3	Negligible exposure: draft technical guidance SANCO-2014-12096	BE, DE, EL, HU and IE, DK	ONGOING COM has already re-initiated a WG and proposed an approach for revision of the draft GD available, which was agreed at PAFF (in 2021).
4	Assessment of the relevance of metabolites in groundwater - SANCO/221/2000 rev.10 - February 2003	BE, DE, HU, IE and SI, DK	This work needs to be in line with the other on-going activities on groundwater (e.g. biocides, Recast Drinkwater Directive, WG WFD, SCHEER). Due to regularity complexity, COM would be more appropriate to take the lead. To discuss if prep work could be initiated, rev. 11 was noted at the SCoPAFF. This was just a minor update and a broader revision is still needed.
6	Non-target arthropods (Terrestrial Ecotoxicology - SANCO/10329/2002 rev 2 final - October 2002)	EFSA, DE, EL, NL, FR, Sl, FI	PREP WORK already ongoing (EFSA, COM) This is a top priority and this was already discussed at PAFF (letter from several MS). It is an update, not a new GD. There's an ongoing EFSA procurement for the development of a scientific project on advancing the ERA of non-target arthropods for plant protection products by accounting for the impact on ecosystem services and on the ecological function. The project duration is 4 years, therefore it seems appropriate to start the activity in early 2023, with a discussion with the MSs. Link to SPG definition (COM).

Technical guidances

Nr	Guidance document	MS or agencies who expressed interest in contributing	Remarks:
5	Amphibians & Reptiles	DE, NL	Preparatory work is available by EFSA. Link with SPG definition (COM). Priority needs to be discussed also in view of other GD, it seems that at the moment the priority is the update of the NTA GD.
7	Non-target terrestrial plants (Terrestrial Ecotoxicology - SANCO/10329/2002 rev 2 final - October 2002)	DE	Update, not a new GD. Strong link to the SPG project (COM) which is on-going; further steps including priority need to be discussed. Currently EFSA cannot take the lead considering other big files in the ERA area
8	Guidance document for the Authorisation of Plant Protection Products for Seed Treatment – Risk Assessment – (draft available, to be sent to EFSA)	AT, BE, DE, FR, HU, IE, LT, NL, PL, RO, SE, till 31.01.2020 UK	Draft finalized by the WG of MS. Draft to be sent to EFSA for public consultation and finalisation

Technical guidances – micro-organisms

Nr	Guidance document	MS or agencies who expressed interest in contributing: (MS / EFSA)	Remarks:
~~8a~~	~~Guideline developed within the Standing Committee on the Food Chain and Animal Health on the taxonomic level of micro-organisms to be included in Annex I to Directive 91/414/EEC Sanco/10754/2005 rev.5; 15 April 2005~~	-	Old document under 91/414/EEC, not adapted to Reg. 1107/2009 yet. COM and WG BP does not consider this GD as highly relevant, no urgency to update it due to the limited added value in light of the new DR. Link to horizontal review, more procedural than RA. This guidance could be made obsolete by including information on the regulatory process and taxonomic level of microorganisms (single strains or consortia) in other guidance documents. This is currently the case for baculoviruses and should in our view be extended to bacteriophages (and may also be relevant to RNAi). It is not the guidance document as such that is needed, but the possibility for a custom regulatory process for certain groups of biopesticides which ensures a sustainable efficacy of these groups of substances. Proposal to delete this row – this GD will not be updated and becomes obsolete
8	Guidance on risk assessment of microorganisms	DE, EL, IE and NL, and FR, DK	For the new data requirements (DR) to be efficient, guidance is needed on how they should be interpreted. For example, the revised DR aim to only ask for 'need to know' information and MO are very divers. To harmonize between MS (and EFSA) when a conditional requirement is relevant, guidance is needed. Contents still valid from the above document (8a) could be taken over and subsequently declare the latter 'obsolete'. WG BP has so far discussed the need of Q&A or explanatory notes. Need is identified, scope will need discussion also in combination with point 9
9	Guidance on procedure for horizontal review of micro organisms	NL, AT, DK	REFLECTIONS ONGOING COM on the best way to organize this (mandate to EFSA involving BIOHAZ? Procurement? Case study/ pilot case vs all current species in one go?) It is not a GD what is needed, but the horizontal review itself which should also cover related concerns, e.g. metabolites of concern.
10	Guidance Document for the assessment of the equivalence of technical grade active	-	The guidance document is based on the current data requirements and should be updated; for example the definitions used in the document need to be updated (also

Technical guidances – micro-organisms

Nr	Guidance document	MS or agencies who expressed interest in contributing: (MS / EFSA)	Remarks:
	ingredients for identical microbial strains or isolates approved under Regulation (EC) No 1107/2007 SANCO/12823/2012 –rev.4; 12 December 2014		considering the fact that an active substance may consist of a consortium for the revised texts). Also, this guidance document could be used for the custom regulatory approach which is needed for certain groups of microbial active substances (baculoviruses, bacteriophage) Scope will need discussion
11	Guidance on data on genome sequencing	EFSA biohaz panel and WG on biopesticides?	On-going at EFSA (BIOHAZ)
12	Guidance on infectivity and pathogenicity of microorganisms of microorganisms regarding human health risk assessment (new GD including a WoE/weight of evidence approach)	EFSA biohaz panel and WG on biopesticides?	On-going at EFSA (BIOHAZ)

Procedural guidances – micro-organisms

Nr	Guidance document	MS or agencies who expressed interest in contributing: (MS / EFSA)	Remarks:
13	Template draft Registration Report for micro-organisms	FR	URGENT – needed by end of 2022! COM agrees with Priority – FR volunteered – could FR take the lead and make a first draft? New structure of DR, RR, and EFSA Conclusions (on-going) should be considered. BP WG needs to be involved too.

Procedural guidances

Nr	Guidance document	MS or agencies who expressed interest in contributing: (MS / EFSA)	Remarks:
15	Guidance Document on preparing lists of test and study reports according to article 60 of Regulation (EC) No 1107/2009 SANCO/12580/2012– rev. 4; 17 March 2019	-	ONGOING COM /EFSA are working on checking which GD are becoming obsolete with IUCLID.

Technical guidances which additionally have high priority, as indicated by COM

Nr	Guidance document	MS or agencies who expressed interest in contributing: (MS / EFSA)	Remarks:
16	GD on baculovirus (SANCO/0253/2008)		BP WG identified need of update. an EU-version of the upcoming OECD guidance on baculoviruses could be considered
17	Cumulative risk assessment		On-going See **SANTE/EFSA Action plan** for further details.
18	Development of a harmonised approach for dietary risk assessment of residues in animal products resulting from different types of uses		EFSA project ongoing under joint mandate with EMA and ECHA
19	PRIMo rev. 4 - New tool for dietary risk assessment		EFSA project ongoing for revising PRIMo, MS will be consulted.
20	GD on residue definitions for risk assessment (OECD guidance)		Drafting group ongoing at OECD level.
21	Drafting group ongoing at OECD level (OECD guidance)		The new OECD GD will deal with residue definitions, MRL setting of pesticide residues in honey as well as test guidelines to perform residue studies.

Technical guidances which additionally have high priority, as indicated by COM			
			Considering that work at OECD level is ongoing, the revision of the existing EU guidance document is of low priority.
22	Assessment of residues in rotational crops (Technical report)		EFSA preparation of Technical Report ongoing.
23	Update GD on bees		Mandated to EFSA in 2019 - ongoing
24	Updated GD on birds and mammals		Mandated to EFSA in 2019 - ongoing
25	New GD on the impact of water treatment processes on residues of active substances or their metabolites in water abstracted for the production of drinking water		Mandated to EFSA in 2019 - ongoing
26	Review of Guidance document on significant and non-significant changes of the chemical composition of authorized plant protection products under Regulation (EC) No 1107/2009 (SANCO/12638/2011)	DE / FR	On-going, once MS (FR/DE) sent the revised draft it will be discussed / endorsed at PAFF

Annex I Ad hoc interim process for compiling this document on prioritisation, which was endorsed by the Standing Committee on Plants, Animals, Food and Feed (phytopharmaceuticals – legislation) on its meeting 25 January 2023

Step 1: Draft proposals for prioritisation and discussion at PSN and PAI meetings
The draft proposals comprised a list with the proposed prioritisation and inventory of MS-CA willingness and expertise to contribute. COM, EFSA and MS-CA participated in PSN and PAI and collaborated in preparing the proposals.
EFSA prepared the prioritisation of technical GD development. This prioritisation was discussed in the PSN meeting held on 13/10/2021.
MS-CA's prepared the prioritisation of procedural GD development. This prioritisation was discussed in the PAI meeting.

Step 2: Discussion on MS-CA's contribution at DCG meeting
Based on the outcome of the PSN and PAI meetings, the MS-CA' discuss the commitment of the MS-CA to contribute to the development of GDs and to prepare for the HLM.

Step 3: Discussion of the proposal at HLM
Based on the draft proposal for prioritisation and on the outcome of the PAI, PSN and DCG meetings, the COM, EFSA and MS-CA, the HLM discussed on 05/11/2021 the commitment of the MS-CA to contribute to the development of GD.

Step 4: Discussion on the allocation of MS-CA's at DCG
The MS-CA's discuss how to allocate the work related to the development of the prioritised GDs, based on the capacity and expertise available at each MS-CA.

Step 5: the draft priority list is discussed with COM and EFSA
COM adds an additional table with priorities and indicated already initiated work.

Step 6: Prioritisation discussion and endorsement at SCoPAFF
The priority list will be presented for discussion to SCoPAFF. Stakeholders will be consulted about the priority list.
The prioritisation of technical and procedural GD development will be discussed and endorsed by SCoPAFF and made public.
In the future prioritisation will be revised.