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Process for prioritisation of 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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This guidance has been developed in co-operation with the Member States. It does not intend to produce legally binding effects and by its nature does not prejudice any measure taken by a Member State within the implementation prerogatives under Regulation (EC) No 1107/2009, nor any case law developed with regard to this provision. This document also does not preclude the possibility that the European Court of Justice may give one or another provision direct effect in Member States.

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Introduction

In this document a process is proposed for the prioritisation of the development and updates of guidance documents (GDs), supporting the implementation of the PPP and MRL Regulations. The role of each actor in this process is defined and the collaboration between the actors within that process. This process aims to add to current processes within the context of the existing governance between COM and EFSA and the existing terms of reference of PSN (Pesticide Steering Network) and PAI (Post Approval Issues Working Group).

What is a GD and its role in risk assessment

Guidance documents are stand-alone documents that have been developed under the auspices of an official body (e.g. EFSA, the European Commission, in some cases national authorities) with the aim to address a certain area of risk assessment, or procedural issues, which were consulted with relevant stakeholders, and endorsed by SCoPAFF.

GDs play an important role in harmonising the process of assessments; in this way ensuring that active substances, PPPs or MRLs are assessed based on the same principles and processes. GDs also provide a certain level of predictability and transparency to applicants, i.e. if a GD is followed there is an expectation that the risk assessment submitted will be considered as valid.

However, GDs are not legally binding and will probably not be able to accommodate all possible cases i.e. they are not fully exhaustive. Furthermore, scientific and technical knowledge evolves over time. This implies that a certain number of cases which were not (yet) considered in a GD remain possible or that certain cases may change over time. Therefore, it needs to be kept in mind that

1) GDs may need to be updated, and

2) applicants and/or evaluating/rapporteur Member States may apply different approaches for issues not falling under a GD, which would then need to be assessed via ad-hoc procedures.

Out of scope

EFSA also develops technical and procedural GDs that are relevant for all work areas within EFSA's remit, not only for pesticides. As the development of these overarching EFSA GDs is managed through different bodies, the development of these GDs is out of scope for this prioritisation process.

Process description prioritisation of guidance document development

New scientific and technical knowledge, policies and legislation require continuous development and updates of GDs. As a result, the prioritisation of the GD development is a continuous process. The process is coordinated by COM in consultation with the ScoPAFF and EFSA.

Criteria for priority setting

The setting of priority should be a transparent process and based on clear criteria. When setting the priority, the following broad criteria can be used:

- regulatory need;

- integration of scientific new information and new improved techniques (e.g. for risk assessment, or application of products)

- potential risk to human and animal health and/or the environment (e.g. based on new scientific knowledge);

- political sensitivity.

The rationale for prioritisation should always be given right at the start of the process. It should be based on the above broad criteria and, where relevant, also consider additional factors. It should go into more detail for each specific GD.

Prioritisation process

Step 1: Identify list of existing GD

A complete list of existing GDs (procedural and technical GDs) on active substance approval/renewal, product authorisation and pesticides residues, and their status, is compiled by COM and made publicly available.

Overarching EFSA GDs and zonal level GDs or any other supporting documents can be included in the list by COM, EFSA and MS-CA's for information purposes and not for priority setting in order to have the complete overview.

Step 2: Identify need for GD development through Member State and stakeholder consultation

The need for a new GD or an update of existing GD needs to be transparently assessed, e.g. via a consultation (IT survey).

Such IT survey should be based on agreed criteria for prioritisation, for instance it could ask details on: the content of the proposed GD, the rationale for the request to produce a GD in view of the broad criteria for prioritisation, the nature of the GD (update of an existing GD or a new GD), the added value (expected impact and relevance of prioritisation criteria) of the development.

The IT survey will address all relevant parties: stakeholder associations (Adv Group SANTE, Adv. Group EFSA, industry), risk assessors (EFSA, MS-CA's), risk managers (COM, MS-CA's and MS), and other targeted agencies/bodies (e.g. JRC, ECHA, OECD). Also PSN and PAI can provide input for prioritisation.

Step 3: Prioritisation, identify available resources (at MS-CA's, EFSA) and workplan

COM in collaboration with EFSA and MS-CA's will draft a proposal for prioritisation based on the identification of needs and the rationale given (see Step 2). This proposal will comprise of a list of GD to be developed, the priority and rationale for the priority to develop a certain GD, the nature of the GD (new GD vs update of existing GD) , timelines/workplan and commitment of MS-CA with expertise in the respective area to contribute to a certain GD. The ongoing work on GDs also needs to be considered in this planning as this also takes up available capacity at EFSA and the MS-CA's.

COM will make an initial proposal for the prioritisation for both the technical and procedural GD development based on the outcome of the IT survey and the input from PSN and PAI. It will take into account the broad criteria for prioritisation and the specific rationales provided for each GD.

The allocation of resources to work on development and updates of GDs is agreed among COM, EFSA, MS (e.g. at the High Level Meeting (HLM)), as well as a first outline of the update or new GDs.

Step 4: Prioritisation presentation and endorsement

The prioritisation will be presented to SCoPAFF by COM.

The prioritisation of technical and procedural GD development will be discussed and endorsed by SCoPAFF and made public.

In general, an update of the prioritisation should not be needed on a yearly basis as in most case the GD will be medium term projects. Such a periodic review could take place every three years in general but flexibility should be provided in case an earlier update would be needed, in particular in the case of new regulatory needs becoming applicable. This periodic review process should take place according to the above described process and should take into account new information or scientific developments and/or new needs. This periodical review will start from the existing list of GD developed and agreed in the previous cycle and updated/completed, where necessary.

If necessary, measures can be taken to address unforeseen situations risking to cause delays. Adapting the prioritisation, especially the priorities of the GDs under development, should in general not be done in the regular update. GD development takes several years and it is undesirable to stop already ongoing work. However, incidental urgent developments that require instant adaptation of the prioritisation will be discussed between COM, EFSA and/or the chair of the PAI, depending on the guidance that needs drafted or updated. In that discussion consideration of the impact on the ongoing or planned work should be included. If necessary, a proposal for adaptation of the prioritisation of development of GDs will be discussed and endorsed by SCoPAFF and made public.

Roles of actors

European Commission (COM)

- The Commission may adopt or amend technical and other GDs regarding active substance approval, MRL setting and product authorisation for the implementation of the PPP Regulation and the MRL Regulation.
- The Commission may initiate and take the lead on the development or update of GDs or may mandate EFSA and/or other EU agencies to prepare or contribute to GDs.

Standing Committee (SCoPAFF)

- At SCoPAFF, section Phytopharmaceuticals- Legislation and section Phytopharmaceuticals-Pesticide Residues, which is chaired by the Commission, Member States discuss and endorse GDs.

European Food Safety Authority (EFSA)

- EFSA prepares or contributes to technical and other GDs regarding active substance approval/renewal and pesticides residues at the request of the Commission or at their own initiative.
- At the PSN, which is chaired by EFSA, discussion takes place between COM, EFSA and MS-CA's on drafting or updating technical GDs used for approval/renewal of active substances and pesticides residues.

MS-Competent Authorities (MS-CA's)

- MS-CA's prepare and/or contribute to GD development regarding active substance approval/renewal, pesticides residues and product authorisations for PPPs, under consideration of discussions and actions agreed among COM, EFSA, MS (e.g. at the High Level Meeting (HLM)).
- At PAI, which is chaired by MS-CA's, discussion takes place between COM, EFSA and MS-CA's on drafting or updating procedural GD.

Member States at SCoPAFF level (MS)

- MS endorse GDs at SCoPAFF regarding active substance approval/renewal, pesticides residues and product authorisation.