



Outline of the revision of the Guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) (EFSA, 2013)



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1. Introduction

EFSA adopted and published in 2013 a guidance document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) (EFSA, 2013), which was republished in 2014 following feedback from Member States collected during a workshop organised by the European Commission (EC).

Although the EFSA 2013 guidance has been used for the assessment of neonicotinoids and its use was recommended by risk assessors in a general ecotoxicology expert meeting (EFSA, 2015), the guidance has not been fully implemented in the process for the approval of the active substances. This is due to insufficient support from Member States represented in the Standing Committee on Plants, Animals, Food and Feed (PAFF). Many Member States have expressed their preference for an update of several aspects of the guidance document. As a follow up, in March 2019, the EC mandated EFSA to revise the guidance (EFSA, 2013).

According to the mandate, EFSA was asked to provide within three months an outline document describing procedural aspects, such as stakeholder consultation, timelines and deliverables. The scope of this document is to describe those aspects and to develop a roadmap for the revision of the guidance.

2. Workplan

The revision of the guidance will be carried out by an EFSA working group (WG) set according to the EFSA rules and standards. EFSA staff and external experts, e.g. from MS organisations and other organisations, will be involved in the WG. The external experts will be selected for their specific experience and expertise relevant to the mandate.

The European Chemicals Agency (ECHA) and EFSA will cooperate to harmonise approaches for assessing risks to bees under the biocides and pesticides regulations. This cooperation includes the possibility for ECHA to comment on documents and be involved in the WG as an observer. This would allow ECHA to follow the work in progress for pesticides and to reflect on commonalities in its activity on the same topic for biocides. Reciprocally, to ensure consistency, EFSA will be consulted on the preparation of the biocides guidance on this topic and may involve the WG.

The time plan for the drafting process, consultations steps and finalisation of the draft for public consultation is presented in **Figure 2**. The time plan takes into consideration the need for EFSA to receive input from risk managers on the definition of specific protection goals in order to review the guidance document. In addition, the revision of parts of the guidance i.e. the exposure via dust drift for seed treatment uses depends on the finalisation of the draft guidance on seed treatment (SANCO/10553/2012, July 2018_rev 16).

A revised guidance document will be published within 24 months from receipt of the mandate, pending the input from the risk managers (RM) needed prior to a public consultation, as explained in section 3.3 and in **Figure 1** and **Figure 2**.

3. Consultation of stakeholders, Member States and other scientific bodies

According to the mandate, during the process of revising the guidance document, EFSA should consult relevant stakeholders, Member State risk assessors and risk managers. EFSA will address this request by organising several consultations as described in the following sections. In brief, the drafting process will include targeted consultations with an *ad-hoc* stakeholder consultation group, with Member States and with the public.

All comments and relevant feedback received will be considered during the revision of the guidance.

3.1. *Ad hoc* Stakeholder Consultation Group

An *ad hoc* Stakeholder Consultation Group has been created to support the drafting of the revision of the guidance document.



EFSA will consult the *ad hoc* Stakeholder Consultation Group on the current guidance (EFSA 2013) to collect feedback to be considered by the WG. Furthermore, the WG will consult the group on initial versions of (or parts of) the revised draft guidance document. No meetings of the *ad hoc* Stakeholder Consultation Group are planned; written comments from group members will be considered by the WG. However, no responses to the individual comments will be made.

3.2. Member States/risk assessors

EFSA will consult the Member States through the Pesticides Steering Network (PSN) on the current guidance (EFSA 2013) to collect feedback to be considered by the WG. Furthermore, the WG will consult Member States on initial versions of (or parts of) the revised draft guidance document. The consultation will be performed in writing and comments from Member States will be considered by the WG. However, no responses to the individual comments will be made.

3.3. Member States/risk managers

According to the mandate, EFSA is asked to provide as a separate output a review and summary of the evidence as regards bee background mortality, in particular considering realistic beekeeping management and natural background mortality.

EFSA will deliver a technical report, which will be considered in the context of the on-going process for setting specific protection goals (SPGs) led by DG SANTE. Once the risk managers have provided their input on SPGs, EFSA will finalise the revision of the guidance document by setting the lower tier assessment factors (e.g. trigger values) relevant to meet the desired level of protection and by revising the requirements for the higher tier tests. This process is shown in **Figure 1** below while the timelines are presented in **Figure 2**.

In addition to the above consultations, risk managers will be informed on the progress of the drafting at the regular meetings organised by the EC, in particular, the PAFF meetings.

A draft revised guidance will be developed for a public consultation, once the final agreement has been achieved as shown in **Figure 1**.

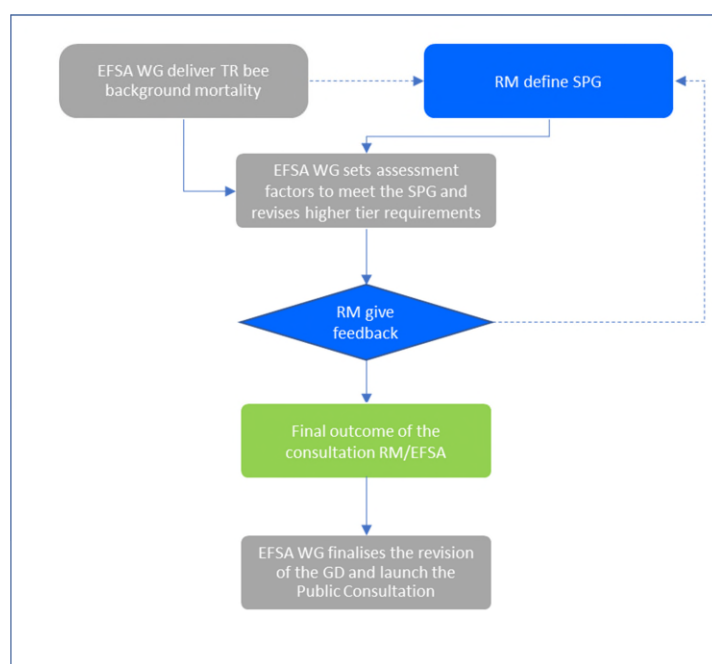


Figure 1: Description on the EFSA deliverable and RM input needed to finalise the guidance document



3.4. Other scientific bodies

The WG may also consult other scientific bodies, such as the EFSA Scientific Committee or the Plant Protection Products and their Residues (PPR) Panel and their working groups (WGs), on specific issues.

3.5. Public consultation

The draft version of the revised guidance will be subject to public consultation, according to EFSA standards.

3.6. Workshop with stakeholders and Member States

A workshop will be organised by EFSA and DG SANTE at the end of the public consultation to give stakeholders (i.e. *ad hoc* Stakeholder Consultation Group) and Member States (risk assessors and risk managers) the opportunity to discuss the comments and provide additional comments. Member States may be invited to present and discuss case studies by using the draft guidance document. Comments and feedback collected during the workshop will be considered to finalise the guidance document.

4. Deliverables

Technical report (TR) on background mortality

According to the mandate, in a technical report will be reported the review and summary of the evidence on bee background mortality, in particular considering realistic beekeeping management and natural background mortality.

Revised guidance document

A revised guidance document will be delivered and published in the EFSA Journal.

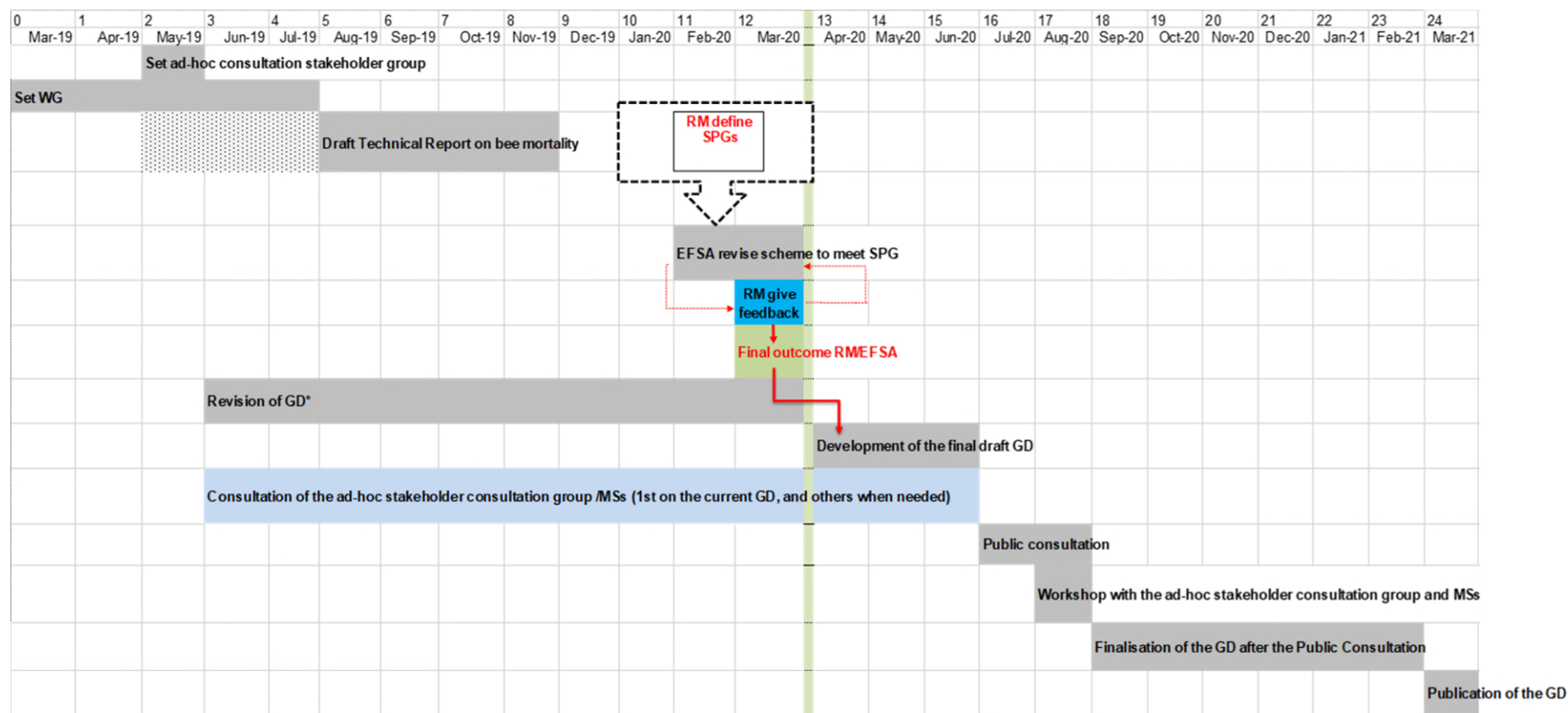
Technical report on the various consultations

The comments received via the stakeholders and Member States (risk assessors and risk managers) will be reported in a technical report that will be published on the EFSA web site. This will include also a report of the workshop.



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Figure 2: Indicative time plan for the revision process, consultations steps and finalisation of the GD



* Revision of dust drift exposure will depend on the finalisation of the draft SANCO/10553/2012 guidance on seed treatment