TECHNICAL REPORT

Inventory of EFSA's activities on bees[1]

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The inventory presented in this report describes the past and current scientific activities of EFSA addressing directly or indirectly bee risk assessment, risk mitigation and monitoring. To perform this work, the Emerging Risks Unit coordinated an internal Task Force including staff from the Pesticides, Animal Health and Welfare, Genetically Modified Organisms, Plant Health, Scientific Assistance Support and Emerging Risks Units and from the Communications Directorate. Up to September 2012, a total of 355 scientific outputs (published/unpublished yet: 344/11), and a number of news stories and a video on bees, were identified from the Pesticides (311/7), Animal Health and Welfare (0/1), Genetically Modified Organisms (29/0) and the Plant Health (2/0) Units and Panels and from the Scientific Assistance Support (2/1) and the Emerging Risks (0/2) Units. However, the majority of these outputs (89.6%) were conclusions on the peer review of pesticide active substances and opinions on applications for the approval of regulated genetically modified products. Among the 355 identified scientific outputs, 14 outputs (0.4%) focused on bees and were predominantly in the areas of pesticide risk assessment and monitoring. In addition, three external scientific activities between EFSA, Anses and OECD on bee issues were identified. The first EFSA scientific outputs on bee issues were published in 2004 and their number has increased progressively over time, but particularly after 2008 (23% published between 2004-2007 and 77% between 2008-2012). The Task Force will use this inventory to conduct a data gap analysis and make further recommendations in terms of research needs and future work at EFSA on bees in a second report.

KEY WORDS

Animal and plant health, bee, genetically modified organisms, inventory, monitoring, pesticides, risk assessment.

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[2] Correspondence: emrisk@efsa.europa.eu

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SUMMARY

The Emerging Risks Unit (EMRISK) was requested by the European Food Safety Authority (EFSA), to set up and coordinate an internal Task Force (TF) to collect, collate and analyse data related to bee risk assessment, risk mitigation and monitoring. The TF was requested to make an inventory of EFSA's outputs and activities on bees. This work will serve as a basis for further analysis during the second term of the TF mandate. In particular, potential cross-cutting areas, data gaps and appropriate research needs in bee risk assessment will be identified.

The TF comprises members of five scientific Units from the Risk Assessment and Scientific Assistance Directorate – Pesticides (PRAS), Animal Health and Welfare (AHAW), Genetically Modified Organisms (GMO), Plant Health (PLH), Scientific Assessment Support (SAS) – as well as members of the Emerging Risks (EMRISK) Unit from the Science Strategy Directorate and members from the Communications Directorate (COMMS).

For each Unit, all scientific outputs (both published and not yet published) related directly or indirectly to bee risk assessment, risk mitigation and monitoring were collected and listed by output category as defined by EFSA (i.e. "opinions of Scientific Committee/Panel'; "other scientific outputs" and "supporting publications"). In addition, external scientific activities of EFSA staff with stakeholders involved in bee risk assessment as well as EFSA's communications on its scientific work and progress on bees were recorded.

For each output, the following information was described: title, abstract, objectives and outcomes, conclusions and recommendations, and in-house collaborations. In addition, for each Unit, an overview table was produced and presented in Appendices to provide information which can be found in the published outputs and/or in the Register of Questions[4] of the EFSA website: subject, keywords, mandate number, question number or project number, starting date, publication date (or deadline for publication in the case of ongoing projects and non yet published outputs), URL to publication, legislation related to the subject matter of the output, and the reference to the publication.

Up to September 2012, a total of 355 scientific outputs were identified of which 344 were already published. Among the published outputs (n=344), the PRAS Unit and PPR Panel, the GMO and PLH Units and Panels and the SAS Unit produced 311, 29, 2 and 2 reports, respectively. Among the non yet published outputs (n=11), the PRAS Unit and PPR Panel, the AHAW Unit and Panel, and the SAS and EMRISK Units are expected to produce 7, 1, 1 and 2 reports, respectively. The majority of the identified outputs (89.6%) were conclusions on the peer review of pesticide active substances (n=306) and opinions on applications for approval of regulated products for authorisations of GMOs (n=12). Among the remaining outputs, 14 (0.04%; 6 published by 20.09.2012) focused on bee issues, predominantly in the area of pesticide risk assessment and monitoring.

Finally, in addition to the above scientific outputs, COMMS published a number of news/press stories and a video to communicate on the recent work coordinated by EMRISK, PRAS and SAS Units. An overview of the scientific outputs over time showed that the first publications involving partly bee risk assessment dealt with conclusions of pesticides peer review, and were issued as early as 2004. In contrast, most of the outputs focused on bees were issued in 2012, and involved the PPR Panel and PRAS Unit. The same trend was observed for media releases produced by COMMS.

A few of EFSA's external activities with stakeholders such as Anses and OECD were identified. The EMRISK Unit collaborated with Anses in the first half of 2012 on the assessment of interactions between pesticides and bee diseases, and the PRAS Unit is currently collaborating with OECD on various aspects of bee risk assessment and bee monitoring such as pollinator incidence, testing methods, risk mitigation and communication on bee research.

[4] http://registerofquestions.efsa.europa.eu/roqFrontend/

The number of scientific areas covered and the number of EFSA Units/Panels involved in bee issues mirrors the multidisciplinary nature of this topic, and demonstrates the breadth of the internal expertise available in this area at EFSA. It also reflects the growing attention on this subject from the scientific community, risk managers and the public. However, to be effective and to make the best use of its limited resources, EFSA needs to integrate its work on bees and expand its activities with stakeholders and other EU bodies involved in bee risk assessment.

In line with the terms of reference (ToR) of the present EFSA mandate, the TF recommends to conduct a scientific assessment of the information presented in this report, in particular to analyse the conclusions and recommendations made for each output to identify potential gaps of knowledge and, where appropriate, to make further recommendations. The TF will perform this analysis in the second term of its mandate interacting with the respective Panels.

With its mandate to improve EU food safety and to ensure a high level of protection of consumers and the environment, the protection of non-target organisms (NTOs) and the ecosystem services they provide is a key activity of EFSA's remit. The TF recognises that besides bees and pollination services, other NTOs contribute to important valued ecosystem services (e.g. pest regulation, decomposition and soil nutrient cycling, water regulation and purification), within an agricultural context and therefore measures aimed at assisting their preservation may benefit from a wider integrated risk assessment approach across EFSA too.

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BACKGROUND AS PROVIDED BY EFSA

Given the significant work already carried out by EFSA in the area of bee risk assessment (i.e. impact on bee health and bee services), the consensus reached by scientists on the multifactorial origin of bee colony losses and the increasing body of scientific evidence showing the way factors may interact to affect bees, it is timely to coordinate work on the risks posed to bees and the services they provide to humans in a more integrated and multidisciplinary manner. In particular, cross-cutting issues, gaps of knowledge, research needs and recommendations need to be identified to reinforce the protection of bees and their ecosystem services.

Bees in general (*Apis* and non-*Apis* bees), but predominantly honey bees, play an important role in the pollination of a wide range of crops and wild plants. The production of about 80% of the 264 crop species cultivated in the EU depends directly on insect pollinators, mostly bees (Williams, 1994) and the global annual monetary value of pollination is estimated to be many hundreds of billions of dollars (MEA, 2005). In addition to pollination services, bees contribute to other ecosystem services such as – to cite the most important - food (i.e. honey, pollen, larvae in some countries, wax for food processing, propolis in food technology, royal jelly as a dietary supplement and ingredient in food) several derived-hive products for various human use (see Krell, 1996 for a comprehensive description), genetic resources (i.e. biodiversity) and cultural services (i.e. education, recreation and aesthetic values) which contribute to human welfare and wellbeing.

Given the importance of bees in the ecosystem and the food chain and given the multiple services they provide to humans, their protection is essential. With its mandate to improve EU food safety and to ensure a high level of consumer protection, the European Food Safety Authority (EFSA) has the responsibility to protect bees and the ecosystem services they provide to humans and this is currently achieved through the activity of the Pesticides Unit (PRAS), the Animal Health and Welfare (AHAW) and GMO Units.

The Pesticides Unit has recently been requested to assess the APENET (2011) project on honey bee mortality and colony losses in Italy[5]. In 2011, the PRAS Unit was requested to deliver a scientific opinion on the science behind the development of a risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) to be published in April 2012. This work will serve as a basis for the drafting of a Guidance document on the risk assessment of plant protection products on bees in the course of 2012. The PRAS Unit has also launched a procurement on literature reviews on topics of relevance to the revision of the Guidance Documents on Aquatic and Terrestrial Ecotoxicology. In respect to bees, an overview of available scientific information on interactions between pesticides and other factors was requested and was published in September 2012. The EMRISK Unit is involved in several of the projects led by Pesticides to provide scientific support on the risk assessment of bees.

The AHAW Panel is requested to deliver a scientific opinion on the risk of introduction and spread of the small hive beetle (*Aethina tumida*) and *Tropilaelaps* in the EU[6], which is known to affect bee colonies. This work will be conducted in collaboration with the Plant Health (PLH) and Emerging Risks (EMRISK) Units.

The EFSA GMO Panel, supported by the GMO Unit, assesses the potential adverse effects that GM plants and their associated farm management practices may have on the environment, and in particular on non-target organisms (including bees and pollinators) and the ecosystem services they provide. The EFSA GMO Panel developed guidelines that provide guidance to assess potential adverse effects of GM plants on human and animal health and the environment, and give the rationales for data requirements required to perform a comprehensive environmental risk assessment.

[5] Request for a scientific opinion on the report "effects of coated maize seed on honeybees" produced in the framework of the Italian monitoring and research project "APENET".
[6] Request for a scientific opinion concerning the risk of entry of the small hive beetle (*Aethina tumida*) and *Tropilaelaps* in the EU.

In addition, the Scientific Assessment Support (SAS) Unit with sought information on the prevalence of honeybee colony losses and the surveillance systems in the 27 EU MS (EFSA, 2009a). More recently, SAS has launched a call on the identification of existing environmental monitoring networks suitable to provide datasets to support post market environmental monitoring of the agricultural environment and EFSA risk assessments (M-2011-0130).

The EMRISK Unit has recently participated in an Anses (Agence Nationale de Sécurité Sanitaire de l'alimentation, de l'environnement et du travail) working group (WG) "GECU - Groupe d'Expertise Collective d'Urgence" on bees, to review a scientific paper on the interaction of pathogens and pesticides on honey bee mortalities (Vidau et al., 2011) and to ensure a tighter scientific collaboration between EFSA and Anses on the risk assessment of bees.

Outside EFSA, several national, European and international organisations carry out work on bees. Among them, Anses and the EURL (European Reference Laboratory) for bee health (Anses – Sophia Antipolis – FR), the European Commission (e.g. current Framework Programme (FP) projects such as COLOSS and STEP and the past FP6 project ALARM - Assessing Large Scale Risks for biodiversity with tested Methods. FP6 project), the EEA (European Environmental Agency) and OECD (Organisation for Economic Co-operation and Development) are actively involved in risk assessment, research and monitoring of bees. The work and progress made by these organisations in the area of bee risk assessments need to be followed closely by EFSA and further collaborations between EFSA and these organisations is requested to avoid duplication and promote a more pro-active and integrated approach for the assessment of risks to bees and the services they provide to humans.

TERMS OF REFERENCE AS PROVIDED BY EFSA

The EMRISK Unit is requested to establish an internal task force with EFSA staff members from the Scientific Committee, PRAS, AHAW, PLH, GMO, SAS and Communications. The task force is requested to liaise with the various organisations involved in the assessment of the risks posed to bees.

The specific tasks would be:

1. To produce a Technical Report, by October 2012, summarising EFSA's outputs dealing with the risks posed to bees and the services they provide to humans

2. To produce a Technical Report, by May 2013:

    a) reviewing the state of the art of the work and research produced outside EFSA in the area of bee risk assessment (e.g. Anses, DG-Research, EEA, OECD, etc.),

    b) performing a gap analysis on the data collected inside and outside EFSA in order to highlight cross-cutting issues, risk assessment and data gaps and research needs,

    c) making recommendations on how to further integrate the work above to provide risk managers with comprehensive advice on which to base their decisions, for example through a working group, a grant, a procurement, recommendations for DG-Research (through the EFSA internal mandate on "research priorities and horizon 2020") and/or through the continuation of an internal task force to keep monitoring this area and ensure coordination of EFSA's activities across Directorates and with engaged stakeholders.

Scope in EFSA's work and outsourcing programme:

This work is in line with the strategy of EFSA to consider risk assessments in a wider integrated manner promoting in-house scientific expertise, tightening horizontal collaborations across units and enhancing the inclusion of environmental aspects in the risk assessment scheme. Finally, it is the role of the Science Strategy and Coordination Directorate (SCISTRAT) to identify and coordinate horizontal scientific issues.

ASSESSMENT

1. Introduction

Bees (*Apis* and non-*Apis* bees) play an important role in the pollination of a wide range of crops and wild plants. In addition to pollination services, honey bees produce food for human consumption such as honey, pollen and royal jelly.

The European Food Safety Authority (EFSA) is the European (EU) reference body for risk assessment on food and feed safety, animal health and welfare, nutrition, plant protection and plant health. With its mandate to improve EU food safety and to ensure a high level of consumer protection (EC, 2002a), EFSA has the responsibility to protect bees and the ecosystem services they provide to humans. This is achieved by several EFSA Units and Panels of experts in the areas of pesticides (i.e. PRAS Unit and PPR Panel), animal health and welfare (i.e. AHAW Unit and Panel) and genetically modified organisms (i.e. GMO Unit and Panel). These Units and Panels receive assistance from the Scientific Assessment Support (SAS) Unit, which has also been involved in bee monitoring projects. The Plant Health (PLH) Unit and Panel, which developed an environmental risk assessment approach for plant pests, is currently supporting the AHAW Unit and Panel to assess the risk posed by two bee pests in the EU. However, the scientific activities of the PLH Unit and Panel remain primarily focused on the risk assessment of plant pests and diseases, not of bee pests and pollinators.

The EFSA Units and Panels involved in the risk assessment and monitoring of bees follow specific regulations or guidelines when performing risk assessments or reviewing applications.

For the risk assessment and peer review of active substances and plant protection products, the PRAS Unit and PPR Panel follow Regulation (EC) 1107/2009 (EC, 2009a), which entered into force on 14 June 2011 and replaced Directive 91/414/EEC (EC, 1991) concerning the placing of plant protection products (both chemicals and micro organisms) on the market. In this area, the protection of honey bees is specifically considered in Regulation 1107/2009, under point 3.8.3. of the Annex II, and the protection of ecosystem services such as pollination is covered under Chapter II, Article 4.3.

In the area of animal health and welfare, consignments of bees traded in the EU must conform to the general animal health conditions laid down in Council Directive 92/65/EC (EC, 1992a). In addition, specific animal health conditions and accompanying health certificates for the import of bees were laid down in Commission Decision 2003/881/EC (EC, 2003a) and repealed by Commission Regulation (EC) No 206/2010 (EC, 2010). This Decision and this Regulation were introduced in response to the threat posed by two exotic pests of bees, the small hive beetle (*Aethina tumida*) and the Tropilaelaps mite (*Tropilaelaps* spp.). According to the Commission Regulation (EC) No 1398/2003, all beekeepers who suspect their colonies are infested by the small hive beetle or the Tropilaelaps mite have to inform the appropriate authorities in their Member State. These European Decisions or Regulations describe the risk management measures in place.

In the EU, depending on their intended use, GMOs are regulated under two distinct legislations, either Directive 2001/18/EC (EC, 2001) or Regulation (EC) No 1829/2003 (EC, 2003c). Living GMOs to be released into the environment for experimental (Part B) or commercial (Part C) purposes are regulated by Directive 2001/18/EC. The GM food and feed Regulation EC No 1829/2003 regulates food and feed products derived from GMOs.

One of the main objectives of Directive 2001/18/EC is to protect human and animal health and the environment from GMOs deliberately released into the environment for any purpose, including the placing on the market of GMOs as, or in, products. Directive 2001/18/EC defines environmental protection goals generically, using terms such as environment, biodiversity and non-target organisms (NTOs) including bees. In addition to these protection goals, the Commission Decision 2002/623/EC (EC, 2002b) supplementing Annex II of Directive 2001/18/EC refers to the functioning of the

ecosystem, and Directive 2004/35/EC (EC, 2004a) on environmental liability defines any damage as representing a measurable adverse change in a natural resource/resource service.

Overall, aspects of the environment to be protected from harm can be divided into two discrete but interconnected categories: (i) the protection of biodiversity (biodiversity conservation) and (ii) the protection of the ecological and anthropocentric functions provided by ecosystems (termed hereafter as ecosystem services). Valued ecosystem services to preserve in an agricultural context are pest regulation, pollination, decomposition of organic matter, soil nutrient cycling, soil structure, water regulation and purification, and cultural services (such as aesthetic value).

In the area of plant health, Directive 2000/29/EC (EC, 2000a) sets protective measures to be taken against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community. These measures aim at protecting crops, fruit, vegetables, flowers and forests from harmful pests and diseases that do not exist in the EU or are not widely spread.

Directive 2000/29/EC allows blocking and regulating the entry, movement and spread of pests to plants and plant products in the EU. It also imposes eradication and containment measures in case of outbreaks. The Directive lists measures including rules on the movement of certain plants, plant products and other objects which may threaten the health of EU plants; rules on trade within the EU and for non-EU imports; rules on production controls, inspections and plant passports and a list of the harmful organisms which may be subject of specific control measures.

Given the global honey bee colony disorders and other threats to insect pollinators (UNEP, 2010) and also because of the significant work achieved at EFSA in the area of bee risk assessment and monitoring, it is time for EFSA to join its efforts in a more integrated way in order to identify cross-cutting issues and priority areas. With its mandate to identify emerging issues and coordinate horizontal scientific issues, the Emerging Risks (EMRISK) Unit of the EFSA Science Strategy and Coordination Directorate (SCISTRAT) has the responsibility to develop and promote such horizontal approaches. For the risk assessment of bees, which encompasses several scientific areas and involves several Units at EFSA, such approaches would be relevant and should be rewarding. In addition, the reinforcement of horizontal collaborations across units and the use of in-house expertise are in line with the new EFSA science strategy for 2012-2016 (EFSA, 2012c).

In April 2012, the EMRISK Unit received a self-task mandate from EFSA to coordinate an internal Task Force (TF) with staff from the various Units involved in bee risk assessment and monitoring (i.e. PRAS, AHAW, GMO, PLH and SAS) and from the Communications Directorate (COMMS). The first step of this TF is to make an inventory of EFSA's activities and outputs on bee issues and the second to list major work and research conducted outside EFSA in the area of bee risk assessment and to conduct an analysis on the data collected inside and outside EFSA in order to identify cross-cutting areas, data gaps and research needs in bee risk assessment. The work presented in this report is the result of the work achieved by the TF during the first step of its mandate (i.e. an inventory of EFSA's activities in bee risk assessment and monitoring).

2. Material and methods

All EFSA scientific activities, including both finalised (published) and on-going (unpublished) activities, related to bee risk assessment and monitoring were listed for each involved EFSA scientific Unit and Panel (i.e. PRAS and PPR in section 3.1, AHAW in section 3.2, GMO in section 3.3, PLH in section 3.4, SAS in section 3.5 and EMRISK in section 3.6), as well as external EFSA scientific activities with stakeholders engaged in bee risk assessment (section 3.7). Some of these scientific outputs were communicated on the EFSA website by COMMS in the form of news stories and press releases (see section 3.7 and Appendix G).

EFSA's scientific outputs can be classified in three broad categories: "Opinions of Scientific Committee/Panel" and "other scientific outputs" and "supporting publications"[7]. The first two are published in the EFSA Journal (http://www.efsa.europa.eu/en/publications/efsajournal.htm).

EFSA can issue Scientific Opinions at the request of the European Commission (EC), European Parliament (EP), European Member States (MS), or on its own initiative or as foreseen in relevant sectoral legislation. Scientific Opinions are prepared by the Scientific Committee or a Scientific Panel. These scientific outputs are adopted by the Scientific Committee or one or more of the Scientific Panels and include the following:

- Opinion of the Scientific Committee/Scientific Panel
- Statement of the Scientific Committee/Scientific Panel
- Guidance of the Scientific Committee/Scientific Panel

EFSA can issue other scientific outputs at the request of the Commission, on its own initiative or as foreseen in relevant sectoral legislation. Requests for these outputs are defined in mandates received by Commission, or internal mandates[8] approved by the Executive Director. The other Scientific Outputs of EFSA are, as a general rule, prepared by an EFSA WG and/or by EFSA scientific staff. Their content and publication are approved by the Executive Director of EFSA. These outputs include the following:

- Statement of EFSA
- Guidance of EFSA
- Conclusion on Pesticides Peer Review
- Reasoned Opinion[9]
- Scientific Report of EFSA

Finally, EFSA can publish supporting publications on its website. These publications are not published in the EFSA Journal and are the following:

- Technical Report[10]
- External Scientific Report
- Event Report

Following the EFSA definitions, the outputs presented in this report were described per broad categories: "Opinions of Scientific Committee/Panel", "Other Scientific Outputs" and "supporting publications".

For each output, the following information was reported:

- Title of the scientific output
- Abstract, when available[11], or short summary
- Objectives and outcomes
- Conclusions and recommendations
- In-house collaborations

[7] http://www.efsa.europa.eu/en/riskassessment/scdocdefinitions.htm.
[8] Internal Mandates are the internal decisions to allocate scientific tasks in order for EFSA to issue an output within its remit.
[9] The Reasoned Opinion is an exception to the rule that the legislation reserves the term "opinion" to output of Scientific Panel/Scientific Committee.
[10] Technical Reports were published in EFSA Journal until 2010
[11] in EFSA scientific outputs published before 2010, abstracts were not requested and therefore, they are not available for these outputs.

Titles and abstracts were copied from the published outputs whereas summaries (provided in the absence of abstracts) were shortened to focus on the main points related to bee topics. The information described in the objectives/outcomes and conclusions/recommendations was summarised from that found in the published output. Finally, collaborations were identified to determine how internal scientific expertise was used across Units and how the different scientific areas cross-fertilised for issues related to bees.

For each Unit and Panel, an overview table was produced and presented in Appendices (i.e. Appendix A for PRAS Unit and PPR Panel; Appendix B for AHAW Unit and Panel; Appendix C for GMO Unit and Panel; Appendix D for PLH Unit and Panel; Appendix E for SAS Unit and Appendix F for EMRISK Unit) to list all scientific outputs with the following additional information:

- **Subject**: it refers to the topic of the question as entered in the Register of Question (RoQ)[4].
- **Keywords**: a list of keywords that refer to the topic presented is described in the published output (except for earlier reports where the inclusion of keywords was not mandatory).
- **Mandate number**: A mandate is defined by an official letter from the EC, EP, EU MS, or EFSA itself, and it contains the reference to the questions that EFSA must reply to. The format of the mandate number starting with the letter "M" followed by the year of acceptance of the request and a number for archiving (i.e. M-<year>-<nnnn>). Each year, the sequential numeration restarts from 0001.
- **Question number and/or Project number**: following the receipt of the mandate, a question is issued by EFSA which corresponds to an internal entity, a task that is part of the mandate. If several Units/Panels work on the same mandate then at least one question will be created for each Unit/Panel; a single question may not be related to more than one Unit/Panel. The format of the question number starts with "EFSA-Q" followed by the year of acceptance of the question and a number for archiving (i.e. EFSA-Q-<year>-<nnnn>). Each year, the sequential numeration restarts from 0001.
- **Question type**: the question type adds information to the question. A total of 13 questions types are available (i.e. Art. 29-Scientific opinion; Application; Art. 31-Scientific and technical assistance, Art. 33-Data collection; Art. 32-Scientific studies; Art. 34-Emerging risks; Art. 35-Rapid alert; Art. 36-Scientific co-operation; Advice; Advisory forum request; Assistance; Procurement; Public consultation).
- **Starting date**: this date corresponds to the date of acceptance of the mandate by the assigned EFSA Unit.
- **Publication date**: this date corresponds to the date of the publication of the output on the EFSA website. If the output has not been published yet, this date corresponds to the anticipated date of publication corresponding to the deadline for publication.
- **URLs to EFSA website**: the URL is the link to access the published output on the EFSA website.
- **Legislation related to the subject**: this column corresponds to the regulations related to the subject. The full references are provided in the list of references.
- **Reference**: each output is linked to the text where it was first cited. The full references are provided in the list of references.

All the above outputs were listed in the appendices by date of publication, from the least to the most recent.

Finally, an overview was made on this inventory to describe the total number of outputs found, their publication over time and the in-house collaboration and relations with stakeholders (see section 4).

3. Results

3.1. Pesticides Unit (PRAS) and Panel on Plant Protection Products and their Residues (PPR)

The PRAS Unit and the Panel on Plant Protection Products and their Residues (PPR) are responsible for the risk assessment of pesticides. They manage the different aspects related to the following scientific areas:

- Scientific advice on the risk assessment of pesticides, including the development of risk assessment methodologies.
- Peer review of the risk assessment of all active substances used in plant protection products in the EU.
- Risk assessment in the framework of setting Maximum Residue Levels (MRLs), the permitted upper legal levels of pesticide residues in food and/or feed at the EU level.
- Preparation of the Annual Report on Pesticides Residues: compilation and analysis of the monitoring information on pesticide residues generated in EU Member States (including some EFTA countries), assessment of the actual consumer exposure to pesticide residues and recommendations for future pesticide monitoring activities at the European level.

3.1.1. Scientific Opinions

1) Development of specific protection goal options for environmental risk assessment of pesticides, in particular in relation to the revision of the Guidance Documents on aquatic and terrestrial ecotoxicology (EFSA, 2010a) - see Table 1 and Appendix A, reference #1

Abstract:

General protection goals are stated in European legislation but specific protection goals (SPGs) are not precisely defined. These are however crucial for designing appropriate risk assessment schemes. Here a process for defining SPG options is presented, which uses the ecosystem services approach as an overarching concept and could be used in consultation processes with risk managers and stakeholders. SPGs are defined in 6 dimensions: biological entity, attribute, magnitude of effect, temporal and geographical scale of the effect, and the degree of certainty that the specified level of effect will not be exceeded. SPG options are presented for 7 key drivers (microbes, algae, non target plants (aquatic and terrestrial), aquatic invertebrates, terrestrial non target arthropods incl uding honeybees, terrestrial non-arthropod invertebrates, and vertebrates), covering all ecosystem services which could potentially be affected by the use of pesticides. To ensure ecosystem services, taxa representative for the key drivers identified need to be protected at the population level or higher. However, for aesthetic reasons (cultural ecosystem services) it may be decided to protect vertebrates at the individual level. To protect biodiversity, impacts at least need to be assessed at the scale of the watershed/landscape. The Panel also emphasizes the importance of a tiered approach for risk assessment, the essential linking of exposure and effect assessments in terms of spatial and temporal scales, and the relevance of ecological scenarios for appropriate pesticide risk assessments. It intends to use the presented concepts as input for the dialogue between risk managers and risk assessors during the next steps of the revision of the Ecotoxicology Guidance Documents.

Objectives and outcomes:

The overall objective was to build a methodology that allows deriving specific protection goals for several organism groups applying the ecosystem service concept as a framework. With regard to bees, the ecosystem services to be protected were identified as provisioning of food (honey and other bee hive products), pollination, genetic resources, education and inspiration, and aesthetic values. In order to protect these services an overall protection at population level as for most organism groups is recommended. Specifically to bees, it was proposed to protect them as outlined in Table 1 (extract of table 3 in the opinion). The aim of the opinion was, however, to develop the framework for developing specific protection goals giving some proposals which were then expected to be further developed and refined throughout the ongoing revision process of the Guidance Documents on Aquatic and Terrestrial Ecotoxicology for pesticide risk assessment (RA).

Table 1: Specific protection goals for honey bees and the ecosystem services they provide that are potentially impacted by the agricultural use of pesticides (extract of Table 3 of EFSA, 2010a).

key driver	ecosystem service	legal requirement	specific protection goal	ecological entity	attribute	scale		
						magnitude of impact	spatial scale of impact	temporal scale of impact
honey bees	food	no unacceptable acute or chronic effects on colony survival and development, taking into account honey bee larvae and honey bee behaviour	no significant effect on colony survival and deve lopment and on production of honey, pollen, etc.	colonies per apiary	survival and function	negligible to small effect	edge of the field and other non-crop areas	no to days
non target arthropods (terrestrial) including honey bees	pollination	no unacceptable lethal and sublethal effects no effects on ongoing behaviour	no to small effect on biodiversity, abundance and behaviour	populations	abundance and foraging behaviour	negligible to small effects (depends on life cycle of species)	in crop to off crop	no to days during the crop flowering period days to weeks in edge of field areas (depends on period of foraging)
		no unacceptable acute or chronic effects on colony survival and development, taking into account honey bee larvae and honey bee behaviour	no significant effect on survival and foraging behaviour on bees foraging in flowering crop	forager populations		negligible to medium effects on forager population within the colonies, no significant impact on foraging behaviour		no to days during the crop flowering period weeks to months in off crop areas (depends on period of bee foraging)

key driver	ecosystem service	legal requirement	specific protection goal	ecological entity	attribute	scale		
						magnitude of impact	spatial scale of impact	temporal scale of impact
non target arthropods (terrestrial) and honeybees	- genetic resources - education an inspiration - aesthetic values	no decrease of biodiversity	no decrease of biodiversity in the landscape, temporary impact on local populations	metapopulation	species diversity, species abundance	Locally small effects but negligible effects in protected areas and landscape	Field to landscape	weeks in field and edge of field no to days in protected areas and landscape
		no unacceptable acute or chronic effects on colony survival and development, taking into account honey bee larvae and honey bee behaviour	no significant effect on colony survival and development	colonies per apiary	survival, foraging behaviour	no decrease of colonies per apiary and negligible to small effects on foraging behaviour	landscape	no to days

Conclusions and recommendations:

The framework for developing specific protection goals (SPGs) in general and also for bees was developed. Concrete proposals for SPGs for bees were included with the recommendation to further refine those in a separate WG with the relevant in depth expertise as for all organism groups.

2) The science behind the development of a risk assessment of Plant Protection Products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) (EFSA, 2012d) - see Appendix A, reference #2

Abstract:

The PPR Panel was asked to deliver a scientific opinion on the science behind the development of a risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). Specific protection goals options were suggested based on the ecosystem services approach. The different routes of exposure were analysed in detail for different categories of bees. The existing test guidelines were evaluated and suggestions for improvement and further research needs were listed. A simple prioritisation tool to assess cumulative effects of single pesticides using mortality data is suggested. Effects from repeated and simultaneous exposure and synergism are discussed. Proposals for separate risk assessment schemes, one for honey bees and one for bumble bees and solitary bees, were developed.

Objectives and outcomes:

EFSA is currently revising the European Guidance Document on terrestrial ecotoxicology elaborated by the Commission and experts from Member States. In the context of this revision, the bees risk assessment is also addressed. Therefore, the objective of this opinion was to produce the scientific basis for the development of a Guidance Document to provide guidance for notifiers and authorities in the context of the review of Plant Protection Products (PPPs) and their active substances under Regulation (EC) 1107/2009 (EC, 2009a).

The outcome of this opinion was the production of 7 chapters tackling the following issues:

- The assessment of the acute and chronic effects of Plant Protection Products on bees, including the colony survival and development.
- The estimation of the long-term effects due to exposure to low concentrations
- The development of a methodology to take into account cumulative and synergistic effects.
- The evaluation of the existing validated test protocols and the possible need to develop new protocols, especially to take into account the exposure of bees to pesticides through nectar and pollen.

In that process, a scheme for the risk assessment of PPPs on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) was proposed.

Conclusions and recommendations:

For the development of robust and efficient environmental risk assessment procedures it is crucial to know what to protect, where to protect it and over what time period. The methodology of definition of specific protection goals follows the approach outlined in the Scientific Opinion of EFSA (2010a). The WG identified pollination, hive products (for honey bees only) and biodiversity (specifically addressed under genetic resources and cultural services) as relevant ecosystem services. It is suggested to define the attributes to protect for the survival and development of colonies and effects on larvae and honey bee behaviour as listed in regulation (EC) No 1107/2009 (EC, 2009a). In addition it is proposed to also include abundance/biomass and reproduction because of their importance for the development and long-term survival of colonies.

The magnitude of effects was defined as negligible if the natural background mortality, compared to controls, is not exceeded. An effect is defined as small if the natural background mortality is increased for example by a factor of 2. Further work is needed to give recommendations on the deviation from the controls up to which an effect is still considered negligible. The current methods of field testing would need major improvements in order to detect for example an increase in daily mortality of foragers by 10% with high statistical power. Based on expert judgement it was considered that a small effect could be tolerated for some days without putting the survival of a hive at risk. However, it is not clear up to what extent the strength of the colony would be affected. Further research (modelling) is proposed to clarify this question and to revise the proposal for the magnitude and temporal scale of effects.

The final decision on protection goals needs to be taken by risk managers. There is a trade-off between plant protection and the protection of bees. The effects on pollinators need to be weighed against increase in crop yields due to better protection of crops against pests. The overall level of protection also includes the exposure assessment goals. Decisions need to be taken on how conservative the exposure estimate should be and what percentage of exposure situations should be covered in the risk assessment.

Residues in different environmental matrices and bee products were combined with estimates of exposure of different categories of bees. Worker bees, queens and larvae of bumble bees and adult females and larvae of solitary bees were considered the most exposed bee categories via oral uptake. Larvae of solitary and bumble bees consume large mass provisions with unprocessed pollen thus, compared with honey bee larvae, they are more exposed to residues in pollen. Moreover, bumble bee and solitary bees may be exposed to a larger extent via contact to nesting material (soil or plants) compared to honey bees suggesting the need for a separate risk assessment for bumble bees and solitary bees.

It was therefore recommended that the categories of bees which represent the worst-case exposure scenarios through multiple exposures are further assessed (e.g. honey bee nurses) and that those categories which highlighted potential but unknown exposures through consumption of water and inhalation of vapour in/out field are further analysed with more studies. Further research is recommended on the testing of the presence and fate of residues (e.g. in bee relevant matrices and in-hive following spray and dust applications) and on the development of reliable exposure models.

An overview of the acute and chronic effects of Plant Protection Products on bees, including the colony survival and development and the estimation of the long-term effects due to exposure to

low concentrations has been performed. Conclusions, recommendations and data gaps and research needs have been formulated in the following areas:

- Further research to improve laboratory, semi-field and field tests (e.g. extrapolation of the endpoints in first tier to the colony/forager effects, extrapolation of the toxicity between dust and spray, extrapolation of laboratory based *Bombus* micro colonies to *Apis* and solitary bees) is recommended.

- Toxicological studies to be performed in bees for a wider range of pesticides on both adults and larvae including sub-lethal endpoints, and contact and inhalation routes of exposure which are not currently covered in the conventional standard tests based on acute toxicity (48 to 96 h) and are likely to be unsuited to assess the long-term risks of exposures to pesticides.

- Because of the specific toxicokinetic profile of bees compared with other insects, it has been recognised that toxicokinetic data can provide useful information on the potential biological persistence of a pesticide which, in some cases, could have effects after continuous exposure that maybe more marked compared with their short-term effects.

- All together the integration of toxicokinetic knowledge and sub-lethal dose effects generated from laboratory and field studies in the hazard identification and hazard characterisation of pesticides in *Apis* and *non-Apis* bees can provide a better understanding of short-term and long-term effects.

Regarding the development of a methodology to take into account cumulative and synergistic effects, two analyses have been performed:

For cumulative effects, a testing protocol and mathematic model, based on Haber's law, have been developed as a simple prioritisation tool to investigate the potential effects after repeated exposure to single pesticides using mortality data. However, assumptions inherent to the model have raised uncertainties and it was concluded that the protocol and model needs further validation in the laboratory and to be tested for sub-lethal endpoints in adult and bee larvae. Finally, combining basic toxicokinetic data for an active substance and its metabolites, such as the half life, will also provide more precise estimates on the potential of bioaccumulation. In the case of potential persistence of the active ingredient, half life of the parent compound and its metabolites should be determined in larvae, newly emerged bees and foragers.

For synergistic effects, since pesticides are often applied in tank mixes (2 to 9 active ingredients at the same time), bees will be exposed to mixtures of compounds following sequential applications to crops. A review of the literature has identified a number of cases involving metabolic interactions for which synergistic effects of pesticides and active substances applied in hives as medical treatments against *Varroa* mites in honey bees have been shown. The use of full dose responses for mixtures between potential inhibitors and different classes of pesticides for either lethal effects or sub-lethal effects in bees is recommended so that predictions of the magnitude of these interactions at realistic exposure levels cannot be performed. When synergistic effects can be predicted based on the mode of action of the chemical classes involved (e.g. EBI fungicides and insecticides), and in the absence of existing data on toxicity of the mixture, it is also recommended to design full dose-response studies in adult bees and larvae for mixtures of potential synergists at environmentally realistic exposure to pesticides. The evidence for synergistic effects between honey bee diseases (fungi, bacteria and viruses) and pesticides

have also been reviewed and further work to investigate whether and how these may be included in risk assessment has been recommended.

The evaluation of the existing validated test protocols and the possible need to develop new protocols, especially to take into account the exposure of bees to pesticides through nectar and pollen:

Separate risk assessment schemes were proposed for honey bees, bumble bees and solitary bees. In the first Tier, including toxicity testing to cover a longer period of exposure (7 to 10 days) for adult bees as well as larval bees has been suggested since both life stages can be exposed for more than one day and this is currently not covered by the standard OECD tests (213 and 214) for oral and contact exposure. Insufficient evidence was available to conclude that acute oral LD50 data can reliably predict toxicity following extended exposures. The scheme also includes the investigation of the indications of cumulative toxicity for each compound and a new method based on Haber`s law has been proposed. It is concluded that if there is an indication that a compound is a cumulative toxin then it would need further evaluation since the potential effects of prolonged or repeated exposure to low doses may be underestimated. It has been recommended that further research on exposure routes and toxicity (sub-lethal effects, mixture toxicity) are needed to integrate the results of these studies in the risk assessment scheme.

In-house collaborations:

For this output, the PRAS Unit received support from the EMRISK Unit.

3.1.2. Other scientific outputs

1) Findings in recent studies investigating sub-lethal effects in bees of some neonicotinoids in consideration of the uses currently authorised in Europe (EFSA, 2012e) - see Appendix A, reference #3

Abstract:

The European Food Safety Authority was requested to perform a comparison between the doses of several neonicotinoids tested in the studies from Henry et al. (honeybees, thiamethoxam) and Whitehorn et al. (bumblebees, imidacloprid) published in Science (2012) with exposure of bees, following the actual use of these neonicotinoids. A third study investigating sub-lethal effects on honeybees for clothianidin and imidacloprid was also considered (Schneider et al., 2012). Data of uses authorised in EU and data on residues in pollen and nectar were collected to compare the actual exposure of bees with the investigated doses. The residue data were limited and available only for some crops; therefore, the extrapolation to other crops was not considered appropriate. In the studies on honeybees, the highest residue levels of thiamethoxam, clothianidin and imidacloprid in nectar were compared with the actual concentrations tested. The results indicated that the tested concentrations were higher than the concentrations found in nectar. The residue intake was estimated using different exposure scenarios. The results indicated that the doses tested in these publications were lower for clothianidin and for thiamethoxam than the estimated exposure. For imidacloprid the doses tested were higher in all the scenarios. In the studies on honeybees, the total amount of active substance was consumed by honeybees within a relatively short period instead of being not administrated over a longer period i.e a day. In the study on bumblebees the tested concentrations were in the range of the highest residues of imidacloprid in pollen and nectar. However, the relevance of the exposure period in the study is unknown. The

comparison between the doses tested in the studies with the actual doses with the exposure of bees was considered feasible only for the seed treatment uses to maize, sunflower, oilseed rape and alfalfa. Further data would be necessary before drawing a definite conclusion on the behavioural effects regarding sub-lethal exposure of foragers exposed to actual doses of neonicotinoids.

Objectives and outcomes:

Following a request from the European Commission, EFSA performed a comparison between the doses of some neonicotinoids tested in the studies from Henry et al. and Whitehorn et al. (2012) with potential exposure of bees following actual use of neonicotinoids. Additionally, a third study (Schneider et al., 2012) investigating also the effects of neonicotinoids on honeybees was considered, as well.

Launch of a statement of EFSA (EFSA, 2012e): Statement on the findings in recent studies investigating sub-lethal effects in bees of some neonicotinoids in consideration of the uses currently authorised in Europe.

Conclusions and recommendations:

The assessment made on the study design presented in the paper of Henry et al. (2012) showed that for the estimated hourly residue intake, bees will likely not be exposed to higher doses than those used in the studies, with the exception of some scenarios for clothianidin. The estimated daily intake indicated that, for thiamethoxam and clothianidin the exposure can be higher than the tested doses. However, neither the energy expenditure nor the kinetics of the adsorption of the toxicants in the studies is reliably known.

The assessment made on the study design presented in the paper of Whitehorn et al. (2012) showed that the concentrations tested were in the range of the maximum residues of imidacloprid measured in pollen and nectar. However, it is uncertain as to what extent exposure situation in the study is representative of field conditions, since bumblebees would need to forage for two weeks exclusively on imidacloprid-treated crops in order to be exposed to the same extent as in the study. Further consideration would be necessary to understand whether this situation may occur in intensive monoculture landscapes.

In-house collaborations:

For this output, the PRAS Unit received support from the EMRISK Unit.

2) Assessment of the scientific information from the Italian project "APENET" investigating effects on honeybees of coated maize seeds with some neonicotinoids and fipronil (EFSA, 2012f) - see Appendix A, reference #4

Abstract:

The European Food Safety Authority was asked by the European Commission to assess the scientific information on some neonicotinoids (i.e. thiamethoxam, clothianidin and imidacloprid) and fipronil gathered by the Italian authorities with a funded project named "APENET" and to identify whether this new scientific information might require a change in the assessment of these substances as regards their effects on bees. APENET is a multidisciplinary monitoring and

research project, mainly aimed at evaluating the bee health status, the dust dispersal during the sowing of maize coated seeds with thiamethoxam, clothianidin, imidacloprid and fipronil, the lethal effects on bees exposed to this dust, and homing behaviour and orientation effects. Potential synergism between clothianidin and bee pathology was also considered. EFSA evaluated in particular the scientific information as reported in the project report from 2011 (APENET, 2011), which was brought to the attention of the European Commission. Overall, due to some deficiencies in the study designs, weakness in the statistical analysis as documented and incompleteness in the reporting of results, it was not possible to draw a definitive conclusion on all the scientific information. However, within this project some potential concerns such as lethal effects on bees exposed to dust, sub-lethal effects and interactions between clothianidin and pathogens were identified suggesting that a change in the assessment of the substances thiamethoxam, clothianidin, imidacloprid and fipronil as regards their effects on bees might be required.

Objectives and outcomes:

Following a request from the European Commission, EFSA assessed the scientific information on some neonicotinoids and fipronil, which the Italian authorities gathered with a project named "APENET".

Launch of a statement of EFSA (EFSA, 2012f): Assessment of the scientific information from the Italian project "APENET" investigating effects on honeybees of coated maize seeds with some neonicotinoids and fipronil.

Conclusions and recommendations:

Overall, it was not possible to draw a firm conclusion on all the scientific information in the APENET report, due to some deficiencies in the study designs and weakness in the statistical analysis and conclusions drawn as reported, or due to the incompleteness in the reporting of the results. However, within this project some potential concerns such as lethal effects on bees exposed to dust, sub-lethal effects and interactions between clothianidin and pathogens were identified suggesting that a change in the assessment of the substances thiamethoxam, clothianidin, imidacloprid and fipronil as regards their effects on bees might be required.

In-house collaborations:

For this output, the PRAS Unit received support from AHAW, EMRISK and SAS Units.

3) Peer review of the pesticide risk assessment of the active substances - see Table 2 and Appendix A, reference #7

Abstract:

The EFSA conclusions summarise the identity, physical-chemical properties and methods of analysis; mammalian toxicology; residues and consumer risk assessment; fate and behaviour in the environment and exposure assessment; and ecotoxicological risk assessment of the active substances with all the relevant endpoints and the followed procedures.

Objectives and outcomes:

Council Directive 91/414/EEC (EC, 1991) and the Regulation 1107/2009 (EC, 2009a) of the European Parliament and of the Council regulates for the European Food Safety Authority (EFSA) procedures for organising, upon request of the European Commission, a peer review of the initial evaluation of active substances, i.e. the Draft Assessment Report (DAR), provided by the designated rapporteur Member State. The outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative use(s) is summarised in the EFSA conclusion. The outcome of the peer review for each active substance is provided in an individual EFSA conclusion. EFSA conclusions are performed in the context of the registration procedure of pesticides under the Regulation 1107/2009 (EC, 2009a). Therefore, it is a continuous process for EFSA.

Active substances are approved by MSs at the Standing Committee on the Food Chain and Animal Health (SCoFCAH) by voting on a proposal of the EC, based on the conclusion provided by EFSA as well as socio-economic aspects relevant for food and feed production. Following the approval of the active substance, previously listing in Annex I of the 91/414/EEC (EC, 1991), currently listing in the Commission implementing Regulation (EU) No 540/2011 (EC, 2011b) the applicant is requested to submit a dossier for national evaluation and authorisation of the formulated Plant Protection Product containing the active substance.

Since EFSA became responsible for the EU peer review in August 2002, 311 conclusions have been issued from this date until 20 September 2012. Out of the 311 conclusions, 306 include risk assessment for honeybees for active substances and the representative formulations for the applied for representative uses. These 306 conclusions belong to 280 active substances. A list of pesticide active substances for which EFSA has issued a conclusion comprising risk assessments for bees, is included in **Table 2**.

Table 2: List of pesticide active substances for which an EFSA conclusions were issued (updated 20 September 2012)

A	Cydia pomonella GV	Fluometuron	O	Tebuconazole
Abamectin	Cyflufenamid	Fluopicolide (AE C638206)	Oryzalin	Tebufenozide
	Cyflumetofen	Fluoxastrobin	Oxadiazon	Tebufenpyrad
Adoxophyes orana Granulovirus	Cymoxanil	Fluquinconazole	Oxamyl	Teflubenzuron
Acequinocyl	Cyproconazole	Flurochloridone	Oxydemeton-methyl	Tefluthrin
Acetochlor	Cyprodinil	Fluroxypyr	Oxyfluorfen	Terbuthylazine
Aclonifen	Cyromazine	Flurprimidol	P	Tetraconazole
Acrinathrin	D	Flutolanil	Paclobutrazol	Thiamethoxama
Aluminium ammonium sulfate	Dazomet	Flutriafol	Paecilomyces fumosoroseus	Thiodicarb
Aluminium phosphide	Denathonium benzoate	Folpet	Paecilomyces lilacinus 251	Tolclofos-methyl
Aluminium silicate (Kaolin)	Diazinon	Formetanate	Paraffin oil - Neudorff	Tolylfluanid

			CAS 8042-47-5	
Aluminium sulphate	Dicamba	Fosetyl-AL	Paraffin oil - Staehler CAS 8042-47-5	Tralkoxydim
Amidosulfuron	Dichlobenil	Fuberidazole	Paraffin oils CAS 64742-46-7 CAS 72623-86-0 CAS 97862-82-3	Triadimenol
Ammonium acetate	Dichlorobenzoic acid methylester	G	Penconazole	Tri-allate
Asulam	Dichlorprop-P	Garlic extract	Pencycuron	Triazoxide
Azadirachtin	Dichlorvos	Gibberellic acid	Penflufen	Tribenuron
Azimsulfuron	Diclofop	Gibberellins	Penoxsulam	Trichlorfon
Azoxystrobin	Dicloran	Glufosinate	Pepper dust	Trichoderma asperellum strain T34
B	Didecyl-dimethylammonium chloride	Guazatine	Phosalone	
Bacillus thuringiensis kurstaki (ABTS-351 and PB-54 and SA-11, SA-12, EG-2348	Diethofencarb	H	Phosmet	Trichoderma atroviride I-1237
Bacillus firmus I-1582	Difenacoum	Haloxyfop-P	Phosphane (phosphine)	Triclopyr
BAS 700 F (fluxapyroxad)		Helicoverpa armigera NPV	Picloram	Triflumizole
Benalaxyl-M	Difenoconazole	Heptamaloxyloglucan	Pirimicarb	Triflumuron
Benfluralin	Diflubenzuron	Hexythiazox	Pirimiphos-methyl	Trifluralin
Benfuracarb	Diflufenican	Hydrolysed proteins	Potassium hydrogen carbonate	Triflusulfuron
	Dimethachlor	Hymexazol	Prochloraz	Trimethylamine hydrochloride
Bensulfuron	Dimethenamid	I	Prohexadione-calcium	Trinexapac
Benthiavalicarb	Dimethoate	Imazalil	Propamocarb	Triticonazole
Bifenox	Dimethomorph	Imazaquin	Propanil	U
Bifenthrin	Dimoxystrobin	Imidacloprid	Propaquizafop	urea
Bispyribac-sodium	Diphenylamine	Indolylbutyric acid	Propargite	Z
Bitertanol	Dithianon	Iron sulfate	Propisochlor	Zeta-Cypermethrin
Blood meal	Diuron	Isopyrazam	Proquinazid	Zinc phosphide
Bromadiolone	Dodemorph	Isoxaben	Prosulfocarb	ZYMV-WK
Bromuconazole	Dodine	K	Prothioconazole	Others
Bupirimate	E	Kieselgur	Pyridaben	1,3-dichloropropene
Buprofezin	Epoxiconazole	Kresoxim-methyl	Pyrimethanil	1,3-dichloropropene
C	Ethanol	L	Pyriproxyfen	1,4-Diaminobutane (Putrescine)

Cadusafos	Ethephon	Lecanicillium muscarium (Verticillium lecanii)	Q	1-decanol
Calcium carbide	Ethoprophos	Lenacil	Quartz sand	1-methylcyclopropene
Calcium carbonate	Ethoxyquin	Lime sulphur (Calcium polysulphide)	Quinmerac	1-Naphthylacetamide
Calcium phosphide	Ethylene	Limestone	Quinoclamine	1-Naphthylacetic acid
Captan	Etofenprox	Lufenuron	Quizalofop-P-ethyl / tefuryl	2-Naphthyloxyacetic acid
Carbaryl	Etridiazole	M	R	2-phenylphenol
Carbendazimb	F	Magnesium phosphide	Rimsulfuron	5-Nitroguaiacolate, o-nitrophenolate, p-nitrophenolate (sodium nitrocompounds)
Carbetamide	Fat distillation residues	Malathion	S	
Carbofuran	Fenamiphos	Mepiquat	Sea-algae extract	6-benzyladenine
Carbosulfan	Fenazaquin	Metaldehyde	Sedaxane	8-Hydroxyquinoline
Carboxin	Fenbuconazole	Metam	Sheep fat	
Chloridazon	Fenbutatin oxide	Metamitron	Sintofen	
Chlormequat	Fenitrothion	Metarhizium anisopliae	Sodium aluminium silicate	
Chloropicrin	Fenoxaprop-P	Metazachlor	Sodium hypochlorite	
Chlorpyrifosb	Fenoxycarb	Metconazole	Spearmint oil	
Chlorsulfuron	Fenpropidin	Methiocarb	Spirodiclofen	
Chlorthal-dimethyl	Fenpropimorph	Methomyl	Spiromesifen	
Citronella oil	Fenpyrazamine	Methyl bromide	Spiroxamine	
Clethodim	Fenpyroximate	Methyl nonyl ketone	Spodoptera littoralis NPV	
Clodinafop	Fenugreek seed powder (FEN 560)		Sulcotrione	
Clofentezine	Fipronil	Metosulam	Sulfuryl fluoride	
Clomazone	Fish oil	Metrafenone	Sulphur	
Clopyralid	Flonicamid	Metribuzin	T	
Clove oil	Fluazifop-P	Myclobutanil	Tall oil - crude (CAS 8002-26-4)	
Copper-compounds	Fluazinam	N	Tall oil - pitch (CAS 8016-81-7)	
Cyanamide	Fludioxonil	Napropamide	tau-Fluvalinate	
Cycloxydim	Flufenoxuron	Nicosulfuron	Tea tree oil	

[a]: only risk assessment for bees was considered in this conclusion
[b]: no full evaluation was addressed in this conclusion

Conclusions and recommendations:

EFSA conclusion summarises the final outcome of the risk assessment for each active substance; it lists the agreed toxicity endpoints and the data gaps; it identifies particular conditions that may need to be considered in relation to the risk and the critical areas of concern. EFSA conclusions support the decision-makers (EU Commission and MSs) to finalise the registration process of active substances and to make recommendations on risk management.

4) Risk assessment of Plant Protection Products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) (EFSA, in preparation) - see Appendix A, reference #8

Abstract:

Not yet available. The guidance document will be published in December 2012.

Objectives and outcomes:

EFSA was asked by the European Commission to develop a Guidance Document on the risk assessment of Plant Protection Products on bees. The Guidance Document is intended to provide guidance for notifiers and authorities in the context of the review of Plant Protection Products (PPPs) and their active substances under Regulation (EC) 1107/2009 (EC, 2009a). The scientific Opinion on the science behind the development of a risk assessment of Plant Protection Products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) (EFSA, 2012d) provided the scientific basis for the development of the Guidance Document.

The process of the development of the Guidance Document follows the methodology of definition of Specific Protection Goals (SPG) as outlined in the Scientific Opinion of EFSA's PPR Panel (EFSA, 2010a). The SCoFCAH was consulted for the appropriate levels of protection (e.g. to make choices on the magnitude of effects, duration of effects and exposure percentiles).

The Guidance Document suggests proposed the implementation of a tiered risk assessment scheme with a simple and cost effective First Tier to more complex Higher Tier studies under semi-field and field conditions. Each of the tiers will have to ensure that the appropriate level of protection is achieved.

Conclusions and recommendations:

Not yet available. The Guidance Document will be published in December 2012.

5) EFSA Conclusions in accordance with Article 21 of Regulation (EC) No 1107/2009 to perform an evaluation of neonicotinoids as regards the risk to bees (EFSA, in preparation) - see Appendix A, references #9, 10 & 11

Abstract:

Not yet available. The scientific opinion will be published in February 2013.

Objectives and outcomes:

To provide EFSA Conclusions for imidacloprid, thiamethoxam and clothianidin in relation to the risk assessment for bees, with particular attention to uses as seed treatment and granules and to the following critical issues: dusts from seeds and granules, residues in nectar and pollen and sub-lethal effects on bees and bee colonies survival, guttation.

6) EFSA Conclusions in accordance with Article 21 of Regulation (EC) No 1107/2009 to perform an evaluation of fipronil as regards the risk to bees (EFSA, in preparation) - see Appendix A, reference #13

Abstract:

Not yet available. The scientific opinion will be published in February 2013.

Objectives and outcomes:

To provide EFSA Conclusion for fipronil in relation to the risk assessment for bees for the seed treatment use, in particular with regard to the acute and chronic effects on colony survival and development, taking into account effects on bee larvae and bee behaviour, and the effects of sub-lethal doses on bee survival and behaviour.

3.1.3. Supporting publications

1) Completion of data entry of pesticide ecotoxicology Tier 1 study endpoints in a XML schema – database (EFSA, in preparation) - see Appendix A, references #5 & 12

Abstract:

The work developed under the present contract (CT/EFSA/PPR/2010/03) should be considered as an integration of the work done under the specific contract NP/EFSA/PPR/2009/04 under multiple framework contract CT/EFSA/AMU/2009/01. The main goal under these contracts was the completion of a database in IUCLID 5.2 on the ecotoxicological endpoints of the active substances and plant protection products (PPPs).The completion of data entry has been outsourced in 2010 according to EFSA procurement procedures and fully carried out at EFSA premises by ChemService S.r.l.

Objectives and outcomes:

The deliverable of specific contract NP/EFSA/PPR/2009/04, concluded on the 22nd of March 2011, was a database on ecotoxicological properties of pesticides including all Tier 1 ecotoxicology studies of dossiers where ecotoxicology higher tier studies were available in the context of Directive 91/414/EEC (EC, 1991). The second part of the project included further ecotoxicological endpoints for additional substances and the respective agreed Risk Assessment endpoints as reported in the EFSA Conclusions on Pesticides.

For NT arthropods (including bees), 305 endpoints were extracted. Endpoints (LD50, NOAEL etc) were extracted from 180 studies. Data were inserted in an IUCLID 5.2 database which is based on OECD harmonised template format.

Conclusions and recommendations:

The database compiled is a valuable collection of pesticide effects on non target organisms including a large dataset for bees. It will be useful for comparison of sensitivities, validation of assessment factors and for many other purposes. The database could be further extended covering other plant protection products and other properties of the inserted compounds (such as physicochemical properties and environmental fate properties) in order to allow other calculations.

2) Interaction between pesticides and other factors in effects on bees (EFSA, 2012g) - see Appendix A, reference #6

Abstract:

Bees are important pollinators of both managed crops and wild flora. An overview of the interactions between pesticides and other factors in effects on bees considered: 1) The importance of the different exposure routes in relation to the overall exposure of bees to pesticides; 2) Multiple exposure to pesticides (including substances used in bee medication) and potential additive and cumulative effects; and 3) Interactions between diseases and susceptibility of bees to pesticides. Nectar foraging bees are likely to experienced highest exposure to both sprayed and systemic seed and soil treatments compounds followed by nurse and brood-attending bees. In both cases the major contribution to exposure was contaminated nectar with direct overspray playing a significant role in exposure. However, there are a variety of other routes (and other bee species) where there is currently insufficient data to fully total exposure: There are a large number of studies that have investigated the interactions between pesticides in bees. By far the majority have related to the interactions involving EBI fungicides and can be related to their inhibition of P450. The scale of the synergy is shown to be dose and season-dependent in acute exposures but there are few data relating to the effect of time between exposures, the effect of route of exposure or on chronic exposure effects at realistic exposure levels. There are a wide range of factors which affect the immunocompetence of bees including diet quality, pest and diseases. Although there are a limited number of laboratory based studies which suggest effects of a pesticide on disease susceptibility there is no clear evidence from field-based studies that exposure of colonies to pesticides results in increased susceptibility to disease or that there is a link between colony loss due to disease and pesticide residues in monitoring studies.

Objectives and outcomes:

The objectives of this review was to summarise the state-of-the-knowledge through search of information on the interactions between pesticides and other factors in effects on bees from scientific literature, study reports and other documents.

The outcome of this overview was the production of a database of 148 references containing data directly relevant to routes of exposure in bees, 103 references for mixtures of which 84 were specific to honeybees and 19 related to other insects and 112 references for pesticide interactions with disease of which 71 were specific to honeybees, 7 to bumble bees and 34 other insects. Residues per unit dose (RUD) were identified for directly over-sprayed honeybees, pollen and nectar, and stored pollen and nectar.

Conclusions and recommendations:

There are a variety of other routes of exposure where there is currently insufficient data to fully quantify their contribution to total exposure and further research is required:

If dusts are produced during sowing of treated seeds this may be a significant source of exposure and may result in residues in pollen and nectar of nearby flowering weeds or crops further work is required to develop robust methods to fully quantify this.

Inhalation may be a significant route of exposure for compounds with high vapour pressure and present in stored pollen or collected in water and further data are required.

Beeswax may be a significant route of exposure for highly lipophilic chemicals and more information is required to evaluate transfer to brood.

Water may be sourced from puddles or guttation droplets which may contain high residues for periods of days-weeks and further data is required on the relative importance of these routes.

There was insufficient data available to assess the exposure of bumble bees or solitary bee species. More data are required to fully evaluate the importance of differing routes of exposure for bumble bees and other non-*Apis* bees.

Other bees may be exposed to mixtures of pesticides through multiple applications, overspray of residues already present, e.g. systemic pesticides, collection of pollen and nectar from a variety of sources and stored within the nest. As previously there is a need to quantify this for non-*Apis* bees.

There is evidence in the literature of multiple residues of pesticides detected in honeybees, honey and pollen and wax within the hive but this is limited by the direction of the analysis to chemicals of interest to the researchers, and rarely are levels of individual components reported. More data are required on realistic levels and combinations of pesticides at the individual colony level within the EU to more fully evaluate the effects of multiple pesticide exposure.

There are a large number of studies that have investigated the interactions between pesticides in honeybees. By far the majority have related to the interactions involving EBI fungicides and can be related to their inhibition of P450. The scale of the synergy is shown to be dose and season-dependent in acute exposures but there are few data relating to the effect of time between exposures or on chronic exposure effects at realistic exposure levels.

The vast majority of the studies have concentrated on the contact toxicity of the combinations. However the exposure section shows that a significant proportion of the exposure may be through ingestion of contaminated nectar. It appears that pesticides which induce P450s in other insects do not induce these enzymes in honeybees but natural chemicals, such as quercetin present in honey and propolis do induce P450s and reduce the toxicity of some pesticides. Given the role of the midgut enzymes in the metabolism of xenobiotics the shortage of data following oral exposure of mixtures is a major gap in our understanding of the potential interactions between chemicals, particularly those present in pollen and nectar, and the effects of diet quality in maintaining xenobiotic metabolising capacity within the gut.

Greater synergy is observed in the laboratory between EBI fungicides at field rates application rates and pyrethroids used as varroacides (flumethrin and fluvalinate) and between coumaphos and fluvalinate varroacides. Given the persistence of residues of varroacides detected in monitoring studies further evaluation of the combined effects of these with agricultural pesticides is warranted.

As effects are dose-dependent synergism between pesticides may be an area where modelling is applicable both from toxicokinetic/toxicodynamic and QSAR approaches but also needs to take into account formulation differences in affecting rate of uptake.

More recently data has shown that antibiotics used in hives may increase the susceptibility of bees to organophosphorus, pyrethroid and neonicotinoid insecticides through interaction with the membrane bound transporter proteins and further work is required to more fully understand the implications of these findings. It is therefore important that all treatments used on colonies used in studies are reported.

The exposure data demonstrate that bees are often exposed directly through applications of multiple active ingredients or indirectly through consumption of stored pollen and nectar to several pesticides over a period of time. Data are required to determine the effects of such long term low level exposure to multiple pesticides on the health and functioning of honeybee colonies foraging in agricultural environments.

There are data that may demonstrate increased spore counts of *N.ceranae* in bees previously chronically exposed to pesticides but there are also reports that spore count decreased following exposure to some pesticides. However, spore count may not be a reliable indicator of the impact of *N ceranae* infection in bees. There is a need for improved methods of assessment for some pathogens, e.g. *N. ceranae* which more clearly link to the impact of the disease on the individual and the colony.

There are a wide range of factors which affect the immunocompetence of bees including the quality of the pollen diet, the presence of other diseases, such as *N ceranae*, or pests, e.g. *Varroa*, and in-hive treatments, such as antibiotics. In addition, the confinement of colonies or individuals may result in stress leading to immunosuppression. It is important that these factors are taken into account in studies determining the effects of pesticides on both individual and social immunity.

The effect of the diet on both the immunocompetence and the xenobiotic metabolising enzymes within the gut are important and impact on both the effects on the toxicity of other pesticides and the impacts on disease susceptibility. Pathogens may also impact on some measures of sub-lethal effects of pesticides. It is therefore important that the realistic routes of exposure are used in mixture studies, i.e. oral for contaminated pollen and nectar, and that the disease status of bees used in pesticide studies is fully understood.

3.2. Animal Health and Welfare Unit and Panel (AHAW)

The Panel on AHAW provides independent scientific advice on all aspects of animal diseases and animal welfare. Its work essentially concerns food producing animals, including fish. The Panel carries out mainly risk assessments in order to produce scientific opinions and advice for risk managers. Its risk assessment approach is based on reviewing scientific information and data in order to evaluate the risks as consequence of a given animal health or welfare hazard. This helps to provide a science-based foundation for European policies and legislation and supports risk

managers in taking balanced and timely decisions. The AHAW Panel has adopted several guidelines on how to develop risk assessments both for animal health[12] and animal welfare[13].

The AHAW Unit provides administrative and scientific support to the work of the AHAW Panel and its working groups, and may carry out other projects in EFSA's remit. The unit may also produce scientific outputs on behalf of EFSA, for instance in response to urgent requests for scientific advice.

3.2.1. Scientific Opinion

1) Risk of entry of the small hive beetle (*Aethina tumida*) and *Tropilaelaps* in the EU (EFSA, in preparation) see Appendix B, reference #1

Abstract:

Not yet available. The scientific opinion will be published in February 2013.

Objectives and outcomes:

The objective of this work is to assess the risk of introduction of *Aethina tumida* (small hive beetle) and the mite *Tropilaelaps* into the EU through importation from third countries via bees, via bee products destined to be used in apiculture, via products other than bee products (e.g. fruits, vegetables, other possible vectors and fomites, etc.) or via the natural movement of live bees and the small hive beetle. The risk reduction factors that have proven to be or that could potentially be effective in reducing the risk of introduction will be identified and evaluated.

Conclusions and recommendations:

Not yet available. The scientific opinion will be published in February 2013.

In-house collaborations:

For this output, the AHAW Unit is receiving support from EMRISK and PLH Units.

3.3. Genetically Modified Organisms Unit and Panel (GMO)

The GMO Panel provides independent scientific advice on the safety of GMOs such as plants, animals and micro-organisms and GM food and feed. The Panel carries out risk assessments in order to produce scientific opinions and advice for risk managers. Its risk assessment work is based on reviewing scientific information and data in order to evaluate the safety of a given GMO. This helps to provide a sound foundation for European policies and legislation and supports risk managers in taking effective and timely decisions on GMO market registration applications. The Panel carries out much of its work in the context of authorisation applications, since all GM food and feed products must be evaluated by EFSA before they can be authorised in the EU (EFSA, 2011f).

[12] Guidance on Good Practice in Conducting Scientific Assessments in Animal Health using Modelling, EFSA Journal 2009; 7(12):1419 [38 pp.]. doi:10.2903/j.efsa.2009.1419

[13] Guidance on Risk Assessment for Animal Welfare, EFSA Journal 2012;10(1):2513 [30 pp.]. doi:10.2903/j.efsa.2012.2513

The GMO Unit provides administrative and scientific support to the work of the GMO Panel and may carry out other projects in EFSA's remit. The unit may also produce scientific outputs on behalf of EFSA, for instance in response to urgent requests for scientific advice.

GMOs and derived food and feed products are subject to a risk analysis before they can be placed on the EU market. In this process, the role of EFSA and its GMO Panel is to give scientific advice to risk managers on any risks that GMOs may pose to human and animal health and the environment in the following four areas:

- GM plant market approval applications,
- Guidelines for the safety assessment of GM plants,
- Guidelines for post-market environmental monitoring of GM plants,
- National safeguard clause measures.

The scientific outputs produced in each of the four areas are further described below.

3.3.1. GM plant market registration applications:

Objectives and outcomes:

Approximately 120 GM plant market registration applications have been submitted to EFSA under Directive 2001/18/EC or Regulation (EC) 1829/2003. These applications cover a diversity of crops (mostly maize, followed by soybean, cotton, oilseed rape, potato, sugar beet and rice) and traits (mostly herbicide tolerance, insect resistance, or both). Other traits include: drought tolerance in maize; altered oleic acid content in soybean; or reduced amylose content in potato. Most GM plant market registration applications are for import and processing for food and feed uses, meaning that GM plants are cultivated outside the EU, and subsequently imported and processed, mainly for feed uses within the EU. At present, 19 GM plant market registration applications submitted under Regulation (EC) 1829/2003 cover cultivation in the EU.

GM plant market registration applications submitted under Regulation (EC) No 1829/2003 or Directive 2001/18/EC have to include an environmental risk assessment. This assessment covers several specific aspects of risk, one of which is the possible risk to NT organisms such as bees and other pollinators. Given the low level of environmental (e.g., through occasional feral GM plants) under import and processing conditions[14] for food and feed uses, only GM plant market registration applications for cultivation are considered here.

The GMO Panel has issued 12 scientific outputs pertaining to the cultivation of GM plants. Most outputs do not display an abstract. The objectives and outcomes of all scientific outputs on GM plant market registration applications have common objectives and outcomes.

The objectives are as follows:

[14] Considering the scope of these applications, which excludes cultivation, and the low level of exposure to the environment, potential interactions of these GM crops with non-target organisms were not considered an issue by the EFSA GMO Panel.

- To evaluate the scientific quality of environmental risk assessments supplied by applicants

- To assess the potential risk that the cultivation of GM plants and their associated farm management practices may have on NT organisms (including bees and other pollinators) and the ecosystem services they provide

- To provide recommendations to risk managers on how to manage identified risks and to resolve remaining scientific uncertainty through monitoring

The outcome is to produce scientific outputs on the environmental safety of GM plants for cultivation. Based on the available data provided by the applicant and a review of the scientific literature, the GMO Panel concluded, in most cases, that the likelihood of adverse effects on honeybees and the ecosystem services they provide arising from the exposure to the GM plants (under consideration) and the newly expressed proteins are expected to be very low.

3.3.1.1. Scientific Opinions

1) Opinion of the Scientific Panel on genetically modified organisms [GMO] related to the notification (Reference C/ES/01/01) for the placing on the market of insect-tolerant genetically modified maize 1507 for import, feed and industrial processing and cultivation, under Part C of Directive 2001/18/EC from Pioneer Hi-Bred International/Mycogen Seeds (EFSA, 2005a) - see Appendix C, reference #1

Abstract:

No abstract available (shortened summary)

Notification C/ES/01/01 concerns cultivation, import, processing and use as any other maize, excluding food uses. 1507 maize is comparable with maize bred traditionally, except for the expression of tolerance to glufosinate herbicide and certain lepidopterans. Maize does not colonise and rarely survives outside the cultivated environment. It is winter-hardy only in parts of Southern Europe, and it has no cross-compatible wild relatives in Europe. Therefore, no unintended environmental effects due to the establishment and spread are anticipated. The likelihood of adverse effects on non-target organisms or on soil functions due to the expression of the *cry* gene or the *pat* gene is considered to be very low. The possible development of resistance of target organisms to *Bt* toxin has been identified as a potential risk due to large scale cultivation and/or long term exposure. Thus, an appropriate case-specific monitoring plan to record the development of resistance has been provided. In addition, the GMO Panel agrees in principle with the approach proposed by the applicant in the general surveillance plan. In conclusion, the Panel considers that the information available for 1507 maize addresses the outstanding questions raised by the Member States and considers that 1507 maize will not have an adverse effect on human and animal health or the environment in the context of its proposed use.

2) Opinion of the Scientific Panel on genetically modified organisms [GMO] related to the notification for the placing on the market of insect resistant genetically modified maize Bt11, for cultivation, feed and industrial processing (EFSA, 2005b) - see Appendix C, reference #2

Abstract:

No abstract available (shortened summary)

This document provides an opinion of the Scientific Panel on Genetically Modified Organisms (GMO Panel) of the European Food Safety Authority (EFSA) on Bt11 maize, genetically modified to provide protection against specific lepidopteran pests. The maize also contains a gene providing tolerance to the herbicide glufosinate. Notification C/F/96/05.10 concerns cultivation, import, processing and use as any other maize, excluding food uses. Bt11 maize is comparable with maize bred traditionally, except for the expression of tolerance to glufosinate herbicide and resistance to certain lepidopterans. Maize does not colonise and rarely survives outside the cultivated environment. It is winter-hardy only in parts of Southern Europe, and it has no cross-compatible wild relatives in Europe. Therefore, no unintended environmental effects due to the establishment and spread are anticipated. The likelihood of adverse effects on non-target organisms or on soil functions due to the expression of the *cry*1Ab gene or the *pat* gene is considered to be very low. The presence of the *pat* gene and the use of glufosinate ammonium are not likely to give an additional botanical diversity effect compared to other herbicides. The possible development of resistance of target organisms to Bt toxin has been identified as a potential risk due to large scale cultivation and/or long term exposure. Thus, an appropriate case-specific monitoring plan to record the development of resistance has been provided. In addition, the GMO Panel agrees in principle with the approach proposed by the applicant in the general surveillance plan.

3) Clarifications of the Scientific Panel on Genetically Modified Organisms following a request from the Commission related to the opinions on insect resistant genetically modified Bt11 (Reference C/F/96/05.10) and 1507 (Reference C/ES/01/01) maize (EFSA, 2006a) - see Appendix C, reference #6

Abstract:

No abstract and no summary available.

4) Opinion of the Scientific Panel on genetically modified organisms [GMO] related to the notification (Reference C/SE/96/3501) for the placing on the market of genetically modified potato EH92-527-1 with altered starch composition, for cultivation and production of starch, under Part C of Directive 2001/18/EC from BASF Plant Science (EFSA, 2006b) - see Appendix C, reference #3

Abstract:

No abstract available (shortened summary)

This document provides an opinion of the Scientific Panel on Genetically Modified Organisms (GMO Panel) of the European Food Safety Authority (EFSA) on genetically modified potato EH92-527-1 Unique identifier BPS-25271-9), with an altered starch composition (higher amylopectin:amylose ratio). Amylopectin starch potatoes are mainly used for the production of starch for industrial purposes. The GM potato tubers are not intended for direct human consumption. The potatoes will be cultivated within a closed loop system that is on a contractual basis. Notification C/SE/96/3501 concerns cultivation of potato EH92-527-1 for the production of starch. Potato rarely survives outside the cultivated environment and there is no indication of

enhanced weediness or invasiveness of potato EH92-527-1. Potato has no cross-compatible wild relatives in Europe. Since it is vegetatively propagated and the natural exchange of genetic material is only possible with other varieties of potato, there is negligible risk to the environment of any transgene flow. Therefore, no unintended environmental effects due to the establishment and spread are anticipated. In the unlikely event that horizontal transfer of gene sequences would occur between the GM potato and bacteria, the bacteria would not pose any additional risk to human health or the environment. No adverse effects on plant-associated organisms and soil function have been observed or would be likely from cultivation of the potato EH92-527-1. In addition, the GMO Panel agrees with the approach proposed by the applicant in the environmental monitoring plan. In conclusion, the GMO Panel considers that the information available for the potato EH92-527-1 addresses the outstanding questions raised by the Member States and considers that the potato EH92-527-1 is unlikely to have an adverse effect on human health or the environment in the context of its proposed uses.

5) Request from the European Commission to review scientific studies related to the impact on the environment of the cultivation of maize Bt11 and 1507 **(**EFSA, 2008a) - see Appendix C, reference #9

Abstract:

No abstract available (shortened summary)

On 19 January 2005 and 20 April 2005, the Panel on Genetically Modified Organisms (GMO Panel) of the European Food Safety Authority (EFSA) issued scientific opinions on genetically modified maize Bt11 and 1507, both including the scope of cultivation. At a meeting of the European Commission with national competent authorities on 19 June 2006, some Member States raised objections to the original opinions of the GMO Panel. Most of these objections related to potential effects of maize Bt11 and 1507 on nontarget organisms and in particular lepidopteran species and to post-market environmental monitoring. Following the meeting with competent authorities and upon request of the European Commission, the GMO Panel amended its previous scientific opinions on 7 November 2006 by adopting an Annex of clarifications. In the Annex, the GMO Panel concluded that the information available for maize Bt11 and 1507 addresses objections and questions raised by Member States, and confirmed that maize Bt11 and 1507 are unlikely to have adverse effects on human and animal health or the environment in the context of their proposed uses. On 24 July 2008, the GMO Panel received a new request from the European Commission to review the previous scientific opinions of maize Bt11 and 1507 in the light of 11 scientific publications, published after the adoption of the complemented scientific opinions of the GMO Panel, as well as any other relevant study. The GMO Panel concludes that neither the 11 scientific publications selected and provided by the European Commission, nor recent peer-reviewed papers identified as relevant by the GMO Panel, invalidate the former risk assessments of maize Bt11 and 1507 performed by the GMO Panel.

6) Applications (references EFSA-GMO-NL-2005-22, EFSA-GMO-RX-NK603) for the placing on the market of the genetically modified glyphosate tolerant maize NK603 for cultivation, food and feed uses, import and processing and for renewal of the authorisation of maize NK603 as existing products, both under Regulation (EC) No 1829/2003 from Monsanto (EFSA, 2009b) - see Appendix C, reference #12

Abstract:

No abstract available (shortened summary)

The EFSA GMO Panel considers that maize NK603 has no altered survival, multiplication or dissemination characteristics and interacts with other organisms as conventional maize. The likelihood of unintended environmental effects due to the establishment and spread of maize NK603 will be no different from that of traditionally bred maize. The EFSA GMO Panel considers that the potential environmental impacts of the specific cultivation, management and harvesting techniques of maize NK603 are indirect effects entirely associated with the use of the complimentary herbicide regimes. Thus the EFSA GMO Panel concludes that maize NK603 plants are unlikely to cause any direct adverse effects, but that potential adverse environmental effects of the cultivation of maize NK603 associated with the use of the complimentary glyphosate herbicide have been identified. This conclusion is in line with the conclusions of the Spanish Competent Authority and its Biosafety Commission. The EFSA GMO Panel recommends that the potential adverse effects of the glyphosate should be evaluated for the specific use on maize NK603 during the national registration by Member States under the pesticide Directive 91/414/EEC. In addition, the EFSA GMO Panel recommends that the occurrence of weed resistance and appropriate management strategies should be addressed as part of the registration of glyphosate under Directive 91/414/EEC. In line with its interplay working document (EFSA, 2008) and the requirements of Directive 2001/18/EC (EC, 2001), the EFSA GMO Panel also recommends glyphosate use on maize NK603 in regimes that have similar or reduced environmental impacts compared with conventional maize cultivation. The Spanish Competent Authority and its Biosafety Commission propose that monitoring should be conducted under Directive 2001/18/EC and recommend to "consider deeper studies on the following potential adverse effects: the potential indirect effects on non-target organisms due to the weed management, the development of weed resistance to glyphosate and the evolution of the flora associated to management of the cultivation of NK603 maize and their potential impacts on biodiversity". However, the EFSA GMO Panel is of the opinion that an alternative option would be the use of herbicide management measures in conjunction with the monitoring for weed resistance evolution under Directive 91/414/EEC (as proposed by the Spanish Competent Authority and its Biosafety Commission) and general surveillance of maize NK603 under Directive 2001/18/EC to detect unanticipated adverse effects.

7) Applications (EFSA-GMO-RX-MON 810) for renewal of authorisation for the continued marketing of (1) existing food and food ingredients produced from genetically modified insect resistant maize MON 810; (2) feed consisting of and/or containing maize MON 810, including the use of seed for cultivation; and of (3) food and feed additives, and feed materials produced from maize MON 810, all under Regulation (EC) No 1829/2003 from Monsanto (EFSA, 2009c) - see Appendix C, reference #13

Abstract:

No abstract available (shortened summary)

On the basis of the data provided by the applicant and obtained from a literature survey and a modelling exercise on the effect of the cultivation of maize MON810 on non-target lepidopteran species in representative maize cultivation regions in the European Union (EU), the EFSA GMO Panel concludes that the likelihood of adverse effects on non-target organisms or on ecological functions is very low, especially if appropriate mitigation

measures are adopted. In agreement with the environmental risk assessment by the applicant and the assessment conducted by the Spanish Competent Authority and its Biosafety Commission, the EFSA GMO Panel identifies the possible evolution of resistance in target species, as a potential risk linked to the cultivation of maize MON810. In conclusion, the EFSA GMO Panel considers that the information available for maize MON810 addresses the scientific comments raised by Member States and that maize MON810 is as safe as its conventional counterpart with respect to potential effects on human and animal health. The EFSA GMO Panel also concludes that maize MON810 is unlikely to have any adverse effect on the environment in the context of its intended uses, especially if appropriate management measures are put in place in order to mitigate possible exposure of non-target Lepidoptera. Moreover, the EFSA GMO Panel advises that pest resistance management strategies continue to be employed.

8) Scientific Opinion on application (EFSA-GMO-CZ-2008-54) for placing on the market of genetically modified insect resistant and herbicide tolerant maize MON 88017 for cultivation under Regulation (EC) No 1829/2003 from Monsanto (EFSA, 2011a) - see Appendix C, reference #19

Abstract:

This Scientific Opinion reports on an evaluation of a risk assessment for placing on the market of genetically modified maize MON 88017 for cultivation. The EFSA GMO Panel considers that maize MON 88017 is unlikely to have any adverse effect on the environment, except for the possible resistance evolution to the Cry3Bb1 protein in coleopteran target pests; resistance evolution may lead to altered pest control practices that may cause adverse environmental effects. The cultivation management of maize MON 88017 could result in environmental harm. The EFSA GMO Panel therefore recommends managing the use of glyphosate on maize MON 88017 within diversified cropping regimes that have similar or reduced environmental impacts compared with conventional maize cultivation. The EFSA GMO Panel recommends the deployment of insect resistance management strategies and case-specific monitoring to address (1) the possible resistance evolution to the Cry3Bb1 protein in coleopteran target pests, (2) changes in botanical diversity within fields due to novel herbicide regimes, and (3) resistance evolution to glyphosate in weeds due to novel herbicide regimes. The EFSA GMO Panel agrees with the general surveillance plan of the applicant, but requests that the proposals made to strengthen general surveillance are implemented. Whilst the scope of this application only covers the cultivation of maize MON 88017, this Scientific Opinion also updates the previous EFSA GMO Panel safety evaluation of the food and feed uses, import and processing of maize MON 88017 and derived products. The EFSA GMO Panel concludes that the information available for maize MON 88017 addresses the scientific comments raised by Member States and that maize MON 88017, as described in this application, is as safe as its conventional counterpart and commercial maize varieties with respect to potential adverse effects on human and animal health. If subjected to appropriate management measures, the cultivation management of maize MON 88017 is unlikely to raise safety concerns for the environment.

9) Scientific Opinion updating the evaluation of the environmental risk assessment and risk management recommendations on insect resistant genetically modified maize 1507 for cultivation (EFSA, 2011b) - see Appendix C, reference #20

Abstract:

In this Scientific Opinion, the EFSA GMO Panel supplements its previous evaluations of the potential impact of maize 1507 cultivation on a range of non-target lepidopteran species using existing data on species susceptibility and considering various scenarios of exposure which may occur across Europe. The mathematical model, developed for maize MON 810, was recalibrated and extended to estimate the efficacy of certain mitigation measures. In situations where highly sensitive non-target Lepidoptera populations might be at risk, the EFSA GMO Panel recommends that mitigation measures are adopted to reduce exposure. Risk managers are provided with tools to estimate global and, where needed local, mortality of exposed non-target Lepidoptera, both before and after different mitigation measures are put in place, and for different host-plant densities. Mitigation measures are only needed when the proportion of maize and uptake of maize 1507 are sufficiently high, regardless of the other parameters. If maize 1507 cultivation remains below 5% of the Utilized Agricultural Area, then risk mitigation measures are not required. In addition, the EFSA GMO Panel recommends case-specific monitoring to assess the efficacy of risk mitigation measures put in place to reduce levels of risk and scientific uncertainty for (1) the possible resistance evolution to the Cry1F protein in target pests, and (2) the risk to sensitive non-target Lepidoptera from maize 1507 pollen. The EFSA GMO Panel also considers that the plan for general surveillance, and in particular the methodology, needs further details according to the requirements of its 2011 Guidance Document on post-market environmental monitoring of generically modified plants, as well as its Scientific Opinion on the annual 2009 monitoring report on maize MON 810. The EFSA GMO Panel concludes that, subject to appropriate management measures, maize 1507 cultivation is unlikely to raise safety concerns for the environment.

10) Scientific Opinion on application (EFSA-GMO-UK-2008-60) for placing on the market of genetically modified herbicide tolerant maize GA21 for food and feed uses, import, processing and cultivation under Regulation (EC) No 1829/2003 from Syngenta Seeds (EFSA, 2011c) - see Appendix C, reference #21

Abstract:

This Scientific Opinion reports on an evaluation of a risk assessment for placing on the market of genetically modified maize GA21 for food and feed uses, import, processing and cultivation. Maize GA21 was developed through particle bombardment and contains a single insertion locus consisting of modified maize *epsps* (m*epsps*) gene, conferring tolerance to glyphosate-based herbicides. Bioinformatic analyses and levels of the mEPSPS protein were considered sufficient. The comparative analysis of compositional, agronomic and phenotypic characteristics indicated that maize GA21 is not different from the conventional counterpart and its composition fell within the range observed among non-GM maize varieties, except for the presence of the mEPSPS protein in maize GA21. The safety assessment of maize GA21 identified no concerns regarding potential toxicity and allergenicity. A feeding study with broiler chickens confirmed that maize GA21 is as nutritious as its conventional counterpart. The EFSA GMO Panel considers that maize GA21 is unlikely to raise additional environmental safety concerns compared to conventional maize, but that its cultivation management could result in environmental harm under certain conditions. The EFSA GMO Panel therefore recommends managing the use of glyphosate on maize GA21 within diversified cropping regimes that have similar or reduced environmental impacts compared with conventional maize cultivation. The EFSA GMO Panel recommends the deployment of case-specific monitoring to address (1) changes in botanical diversity within fields due to novel herbicide regimes, and (2) resistance evolution to glyphosate in weeds due to novel

herbicide regimes. The EFSA GMO Panel agrees with the general surveillance plan of the applicant, but requests that its proposals to strengthen general surveillance are implemented. The EFSA GMO Panel concludes that the information available for maize GA21 addresses the scientific comments raised by Member States and that maize GA21, as described in this application, is as safe as its conventional counterpart and commercial maize varieties with respect to potential adverse effects on human and animal health. If subjected to appropriate management measures, the cultivation management of maize GA21 is unlikely to raise safety concerns for the environment.

11) Statement supplementing the evaluation of the environmental risk assessment and risk management recommendations on insect resistant genetically modified maize Bt11 for cultivation (EFSA, 2012h) - see Appendix C, reference #24

Abstract:

In this Statement, the EFSA GMO Panel supplements its previous evaluations of the potential impact of maize Bt11 cultivation on a range of NT lepidopteran species using existing data on species sensitivity and considering various scenarios of exposure which may occur across Europe. The mathematical model, initially developed for maize MON 810 and recently recalibrated for maize 1507, was used to estimate the efficacy of risk mitigation measures. In situations where "extremely sensitive" non-target Lepidoptera populations might be at risk, the EFSA GMO Panel recommends that risk mitigation measures are adopted to reduce exposure. Risk managers are provided with tools to estimate global and, where needed local, mortality of exposed non-target Lepidoptera, both before and after different risk mitigation measures are put in place, and for different host-plant densities. Risk mitigation measures are only needed when the proportion of maize and uptake of maize Bt11 (and/or maize MON 810) are sufficiently high, regardless of the other parameters. If maize Bt11 (and/or maize MON 810) cultivation remains below 7.5% of the regional Utilized Agricultural Area, then risk mitigation measures are not required. In addition, the EFSA GMO Panel recommends that appropriate insect resistance management (IRM) strategies for maize Bt11, which should be integrated with those of other Cry1Ab-expressing maize events currently grown commercially in the EU, are implemented in order to delay the possible resistance evolution to the Cry1Ab protein in target pests. The EFSA GMO Panel also considers that post-market environmental monitoring and IRM need to be revised. The EFSA GMO Panel concludes that, subject to appropriate management measures, maize Bt11 cultivation is unlikely to raise additional safety concerns for the environment compared to conventional maize. The EFSA GMO Panel considers that the conclusions on the risk to non-target Lepidoptera from maize Bt11 apply equally to maize MON 810.

12) Scientific Opinion on an application (EFSA-GMO-NL-2005-24) for the placing on the market of the herbicide tolerant genetically modified soybean 40-3-2 for cultivation under Regulation (EC) No 1829/2003 from Monsanto (EFSA, 2012i) - see Appendix C, reference #28

Abstract:

This Scientific Opinion reports on an evaluation of a risk assessment for the placing on the market for cultivation of genetically modified soybean 40-3-2, and updates the previous EFSA GMO Panel Scientific Opinion on the renewal applications for the continued marketing of soybean 40-3-2. The EFSA GMO Panel considered that soybean 40-3-2 is unlikely to raise additional environmental safety concerns compared with conventional soybean, but that the

management of its cultivation could result in environmental harm under certain conditions. The Panel therefore recommended managing the use of glyphosate on soybean 40-3-2 in ways that result in similar or reduced environmental impacts compared with conventional soybean cultivation. There is no evidence of adverse effects on non-target organisms (including pollinators) due to the expression of the CP4 EPSPS protein, and there are no indications of the occurrence of adverse effects on non-target predators, herbivores and decomposers due to potential unintended changes in soybean 40-3-2. Owing to the lack of event-specific data on plant-pollinator interactions, scientific uncertainty on the occurrence of adverse effects on pollinators, due to potential unintended changes in soybean 40-3-2, remains, and strategies for resolving this uncertainty are discussed. The Panel recommended the deployment of case-specific monitoring to address: (1) changes in weed community diversity; and (2) the evolution of resistance to glyphosate in weeds due to changes in herbicide and cultivation regimes. The Panel agreed with the general surveillance plan of the applicant, but requested that the Panel's proposals to strengthen general surveillance are implemented. The Panel concluded that the information available for soybean 40-3-2 addresses the scientific comments raised by Member States and that soybean 40-3-2, as described in this application, is as safe as its conventional counterpart and commercial non-GM soybean varieties with respect to potential adverse effects on human and animal health. If subjected to appropriate management measures, the cultivation of soybean 40-3-2 is unlikely to have environmental effects any more adverse than those associated with conventional soybean cultivation.

Conclusions:

In accordance with the EU regulatory framework for the GMOs, the EFSA GMO Panel evaluates the assessment carried out by the applicants of the potential adverse effects that GMOs may have on the environment, and in particular on NTOs (including bees and pollinators). Against this background, the EFSA GMO Panel developed guidelines to applicants in order to assist them in building an application for commercialisation of GMOs and in providing all relevant data to support the safety of their product (see Section 3.3.2, below). EFSA urges the applicants to submit a comprehensive and scientifically-sound ERA.

3.3.2. Guidelines for the safety assessment of GM plants:

Objectives and outcomes:

To assist applicants in the preparation of GM plant market registration applications, the GMO Panel has developed guidelines for the safety assessment of GM plants and derived food and feed. These guidelines provide assistance by describing principles, concepts, data requirements, and issues to be considered in the frame of risk assessment. The GMO Panel has issued several guidelines, but only the ones that are relevant in terms of environmental risk assessment, and which directly consider the protection of non-target organisms (such as bees and other pollinators) and the ecosystem services they provide are considered here.

3.3.2.1. Scientific Opinions

1) Guidelines for the risk assessment of GM plants used for non-food or non-feed purposes (EFSA, 2009d) - see Appendix C, reference #14

Abstract:

This Opinion discusses the risk assessment issues associated with Genetically Modified (GM) plants used for non-food or non-feed purposes (e.g. for the production of industrial or medicinal products, biofuel or for phytoremediation), and outlines the applicable legal framework and the recommended scientific methods for their risk assessment. A comparative approach is advocated but will need to be applied carefully. Consumption is not expected with these GM plants used for non-food or non-feed purposes, but accidental oral, dermal, ocular and inhalatory exposure is possible and assessments of toxicity and allergenicity are discussed. This Opinion recommends that exposure assessments take account of any strategies to reduce exposure or gene flow proposed by the applicant. It is considered that existing guidance on the environmental risk assessment of GM plants is adequate but that additional emphasis should be given to issues such as gene transfer and the exposure of non-target organisms, particularly wildlife feeding on these GM plants. The Opinion further describes the importance of risk management systems, such as post-market environmental monitoring, standard production protocols/stewardship, or confinement strategies to reduce exposure to the GM plant.

2) Guidance on the environmental risk assessment of genetically modified plants (EFSA, 2010b) - see Appendix C, reference #15

Abstract:

This document provides guidance for the environmental risk assessment (ERA) of genetically modified (GM) plants submitted within the framework of Regulation (EC) No. 1829/2003 on GM food and feed or under Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms (GMOs). This document provides guidance for assessing potential effects of GM plants on the environment and the rationales for the data requirements for a comprehensive ERA of GM plants. The ERA should be carried out on a case-by-case basis, following a step-by-step assessment approach. This document describes the six steps for the ERA of GM plants, as indicated in Directive 2001/18/EC, starting with (1) problem formulation including hazard identification; (2) hazard characterisation; (3) exposure characterisation; (4) risk characterisation; (5) risk management strategies; and (6) an overall risk evaluation. The scientific Panel on Genetically Modified Organisms (of the European Food Safety Authority (EFSA GMO Panel) considers seven specific areas of concern to be addressed by applicants and risk assessors during the ERA (1) persistence and invasiveness of the GM plant , or its compatible relatives, including plant-to-plant gene transfer ; (2) plant-to-micro-organism gene transfer; (3) interaction of the GM plant with target organisms and (4) interaction of the GM plant with non-target organisms, including criteria for selection of appropriate species and relevant functional groups for risk assessment; (5) impact of the specific cultivation, management and harvesting techniques; including consideration of the production systems and the receiving environment(s); (6) effects on biogeochemical processes; and (7) effects on human and animal health. Each specific area of concern is considered in a structured and systematic way following the above-mentioned steps (1 to 6). In addition, the guidance document is supplemented with several general cross-cutting considerations (e.g. choice of comparator, receiving environment(s), general statistical principles, long-term effects) that need to be considered in the ERA.

3) Scientific Opinion on the assessment of potential impacts of genetically modified plants on non-target organisms (EFSA, 2010c) - see Appendix C, reference #16

Abstract:

The European Food Safety Authority (EFSA) asked the Panel on Genetically Modified Organisms to establish a self-tasking WG with the aim of (1) producing a scientific review of the current guidance of the GMO Panel for Environmental Risk Assessment (ERA), focusing on the potential impacts of GM plants on Non-Target Organisms (NTOs), (2) proposing criteria for NTOs selection, and (3) providing advise on standardized testing methodology. This initiative was undertaken in response to a need and request from a wide range of stakeholders, including the European Commission and Member States. In first instance, the self-tasking WG on Non-Target Organisms (EFSA NTO WG) mainly considered impacts of GM plants on invertebrate species, but also took account of ecosystem functions that could be altered. The EFSA NTO WG considered the necessity for clear and objective protection goals, for which assessment and measurement endpoints shall be developed; the need to initiate the scientific risk assessment by setting testable hypotheses; criteria for appropriate selection of test species and ecological functional groups; appropriate laboratory and field studies to collect relevant NTO data; and the use of statistical techniques that should be an integral part of experimental design. The EFSA NTO WG considered the range of approaches and methodologies of ERA of NTOs as described in the current literature and proposed risk assessment approaches based on selection of functional groups and individual species within a tiered approach. The present scientific opinion provides guidance to risk assessors for assessing potential effects of GM plants on NTOs, together with rationale for data requirements in order to complete a comprehensive ERA for NTOs. In this respect, guidance to applicants as outlined in the present opinion has been inserted in the updated Guidance Document of the EFSA GMO Panel for the ERA of GM plants.

4) Update of the Guidance document for the risk assessment of food and feed from genetically modified plants (EFSA, 2011a) - see Appendix C, reference #17

Abstract:

This document provides updated guidance for the risk assessment of food and feed containing, consisting or produced from genetically modified (GM) plants, submitted within the framework of Regulation (EC) No 1829/2003 on GM food and feed. The risk assessment strategy for GM plants and derived food and feed proposed seeks to deploy appropriate approaches to compare GM plants and derived food and feed with their respective comparators. The underlying assumption of this comparative approach is that traditionally cultivated crops have gained a history of safe use for consumers and/or domesticated animals. The document provides guidance on how to perform the comparative analysis of the relevant characteristics of the GM plant. The document addresses the details of the different components of the risk assessment: the molecular characterisation, which provides information on the structure and expression of the insert(s) and on the stability of the intended trait(s); the toxicological assessment, which addresses the impact of biologically relevant change(s) in the GM plant and/or derived food and feed resulting from the genetic modification; the assessment of potential allergenicity, of the novel protein(s) as well as of the whole food derived from the GM plant; the nutritional assessment to evaluate whether food and feed derived from a GM plant is not nutritionally disadvantageous to humans and/or animals. In addition every section of the document addresses specifically the requirements for GM plants containing a combination of transformation events, providing guidance on how to establish that the combination is stable and that no interactions occurs between the events that may raise safety concerns. The document does not cover the environmental risk assessment of GM plants which is addressed in a stand-alone environmental risk assessment (ERA) guidance document developed by the EFSA GMO Panel.

Conclusions and recommendations:

In accordance with this 2010 Guidance on the ERA of GM plants, EFSA expects the applicants to comply with

- the specific data requirements (e.g., tier 1b or higher-tier studies with event-specific *in planta* material) and concept (i.e., weight of evidence approach) to assess potential unanticipated unintended adverse effects on non-target organisms including pollinators such as bees (arising from unintended changes in the GM plant due to the genetic modification), as well as with

- the specific data requirements (e.g., lower- and/or higher-tier studies with the newly expressed proteins, or food of vegetal or animal origin containing the newly expressed proteins depending on the case under study and the outcomes of the problem formation) and concept (tiered approach) to assess potential anticipated unintended adverse effects on non-target organisms including pollinators such as bees (arising from intended changes in the GM plant due to the newly expressed protein).

3.3.3. Guidelines and scientific opinions related to post-market environmental monitoring of GM plants:

Each GM plant market registration application has to include a post-market environmental monitoring plan demonstrating how the applicant will monitor the GM plant for possible adverse environmental effects after it has been placed lawfully on the EU market. The aim of post-market environmental monitoring is two-fold: (1) to monitor the risks identified during the environmental risk assessment (so-called case-specific monitoring); and (2) to identify possible unanticipated adverse effects on the environment which could arise directly or indirectly from the cultivation of GM plants (so-called general surveillance).

In 2006, the GMO Panel provided applicants with guidance for developing post-market environmental monitoring plans, which was updated in 2011.

3.3.3.1. Guidance

Objectives and outcomes:

The objectives of the 2011 Guidance document on PMEM of GM plants are:

- To provide guidance for monitoring potential adverse effects of GM plants on human and animal health and the environment,

- To clarify the objectives, tasks, tools and requirements for post-market environmental monitoring of GM plants.

1) Guidelines on the post-market environmental monitoring of GM plants (EFSA, 2011e) - see Appendix C, reference #18

Abstract:

The European Commission asked the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) to update its 2006 scientific opinion on Post-Market Environmental Monitoring (PMEM) of Genetically Modified Plants (GMPs). For doing so, the EFSA GMO Panel made use of the experience gained from its assessment of applications on GMPs for cultivation and considered different sources of information such as the PMEM reports on cultivated GMPs, relevant scientific literature and stakeholders' comments. This scientific opinion aims to clarify the objectives, tasks, tools and requirements for PMEM. Firstly, the present document explains the scientific rationale for PMEM, including the concept of developing management and monitoring strategies based on the overall conclusions and assumptions of the Environmental Risk Assessment. Secondly, it provides examples and guidance to applicants on how to develop and implement their plans for Case-Specific Monitoring (CSM), taking into account the case-by-case character of CSM. In addition, it provides guidance to applicants on the strategy, methodology and reporting of General Surveillance (GS). Different tools and approaches to implement a plan for GS are considered. The EFSA GMO Panel proposes a holistic and integrative approach for monitoring GMPs in the EU that considers GS within a framework of general environmental protection monitoring. Finally, the EFSA GMO Panel makes proposals to risk managers for the future conduct of PMEM in the EU and suggests that access to PMEM data could be facilitated by setting-up standardised and centralised reporting centres. This scientific opinion repeals the former 2006 scientific opinion of the EFSA GMO Panel on PMEM of GMPs.

In-house collaborations:

For this output, the GMO Unit received support from the SAS Unit.

3.3.3.2. Scientific Opinions

Objectives and outcomes:

The objectives are:

- To assess the scientific quality of annual post-market environmental monitoring reports,
- To provide recommendations to improve the methodology for the post-market environmental monitoring.

The outcomes are:

- Protection of non-target organisms (such as bees and other pollinators) and the ecosystem services they provide are listed as a protection goal that needs to be considered in the process of environmental risk assessment and monitoring,
- Provision of scientific advice to risk managers on the scientific quality of post-market environmental monitoring activities,
- Recommendation to use existing surveillance networks (including those monitoring bee health) for general surveillance.

1) Scientific opinion on the annual monitoring report by Monsanto on the cultivation of GM maize MON 810 in 2009 (EFSA, 2012j) - see Appendix C, reference #22

Abstract:

Following a request from the European Commission, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) was asked to assess the monitoring report for the 2009 cultivation season of maize MON810 provided by Monsanto Europe S.A. The EFSA GMO Panel assessed, in close collaboration with the EFSA Unit for Scientific Assessment Support, the methodology applied by the applicant for the Case-Specific Monitoring and General Surveillance of maize MON810 in 2009. Concerning the Case-Specific monitoring (CSM), the EFSA GMO Panel considered the plan for Insect-Resistant Management mainly based on the 'high dose/refuge strategy', monitoring of target pest resistance and education of farmers. Concerning General Surveillance (GS), the EFSA GMO Panel paid particular attention to the design and analysis of the farmer questionnaires. From the data submitted by the applicant in its 2009 MON810 report, the EFSA GMO Panel did not identify adverse effects on the environment, human and animal health due to maize MON810 cultivation during the 2009 growing season. The outcomes of the 2009 MON810 report do not invalidate the previous risk assessment conclusions on maize MON810. However, the EFSA GMO Panel notes a number of shortcomings in the methodology for CSM and GS. Hence, this scientific opinion gives specific recommendations for improvement of the strategy, methodology and reporting for the post-market environmental monitoring of maize MON810. The applicant should take into account the guidance on Post-Market Environmental Monitoring (PMEM) of genetically modified plants as outlined in the recent scientific opinion of the EFSA GMO Panel. The recommendations of the EFSA GMO Panel in this opinion supplement the previous recommendations on PMEM of maize MON810 in the 2009 scientific opinion for the renewal of the authorisation for continued marketing of maize MON810.

In-house collaborations:

For this output, the GMO Unit received support from the SAS Unit.

2) Scientific Opinion on the annual post-market environmental monitoring (PMEM) report from BASF plant science company GmbH on the cultivation of genetically modified potato EH92-527-1 in 2010 (EFSA, 2012k) - see Appendix C, reference #23

Abstract:

Following a request from the European Commission, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) assessed the monitoring report for the 2010 cultivation season of GM potato EH92-527-1 (variety Amflora) provided by BASF. The EFSA GMO Panel assessed, in close collaboration with the EFSA Unit for Scientific Assessment Support, the methodology applied by the applicant for the four case-specific studies, the General Surveillance (GS) of potato EH92-527-1 and the field study to monitor potential adverse effects on potato-feeding organisms. From the overall dataset submitted by the applicant in its 2010 Amflora monitoring report, the EFSA GMO Panel does not identify adverse effects on the environment, human and animal health due to potato EH92-527-1 cultivation during the 2010 growing season. The outcomes of the 2010 Amflora monitoring report do not invalidate the

previous EFSA GMO Panel's risk assessment conclusions on potato EH92-527-1. Nevertheless, the EFSA GMO Panel notes a number of weaknesses in the methodology for GS and therefore gives specific recommendations for improvement of the strategy, methodology and reporting for GS of potato EH92-527-1. Concerning the field study on potato-feeding organisms as required in the related Commission Decision, the EFSA GMO Panel makes recommendations in order to improve the study. However, the EFSA GMO Panel considers the GS framework as a more proportionate alternative for collecting relevant information on potato-feeding organisms.

In-house collaborations:

For this output, the GMO Unit received support from the SAS Unit.

3) Scientific Opinion on the annual monitoring report by Monsanto on the cultivation of GM maize MON 810 in 2010 (EFSA, 2012l) - see Appendix C, reference #25

Abstract:

Following the request from the European Commission, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) assessed the monitoring report for the 2010 growing season of maize MON810 provided by Monsanto Europe S.A. On 7 September 2011, the EFSA GMO Panel already adopted a scientific opinion on the 2009 monitoring report of maize MON 810. The EFSA GMO Panel followed the same approach as for the assessment of the 2009 monitoring report and assessed, in close collaboration with the EFSA Unit for Scientific Assessment Support, the methodology applied by the applicant for the Case-Specific Monitoring and General Surveillance of maize MON 810 in 2010. Concerning the Case-Specific Monitoring (CSM), the EFSA GMO Panel considered the plan for Insect-Resistant Management mainly based on the "high dose/refuge strategy", monitoring of target pest resistance and education of farmers. Concerning General Surveillance (GS), the EFSA GMO Panel paid particular attention to the design and analysis of the farmer questionnaires. The EFSA GMO Panel notes similar shortcomings in the methodology for CSM and GS as in the 2009 monitoring report. Hence, the EFSA GMO Panel reiterates the same recommendations for improvement of the methodology for the post-market environmental monitoring of maize MON 810 as in its scientific opinion on the 2009 monitoring report of maize MON 810. However, from the data submitted by the applicant in its 2010 monitoring report, the EFSA GMO Panel does not identify adverse effects on the environment, human and animal health due to maize MON810 cultivation during the 2010 growing season. The outcomes of the 2010 monitoring report do not invalidate the previous EFSA GMO Panel's scientific opinions on maize MON 810.

In-house collaborations:

For this output, the GMO Unit received support from the SAS Unit.

Conclusions and recommendations:

In accordance with the EU regulatory framework for the GMOs, the EFSA GMO Panel evaluates the annual PMEM reports submitted by applicants on GM crops cultivated in the EU (see below) from 2010 onwards. These reports should comply with the requirements laid down in the 2011 Guidance Document on PMEM of GM plants. Against this background, EFSA urges the applicants to submit comprehensive and scientifically-sound PMEM reports

Since 2010, the GMO Panel has been responsible for assessing the annual post-market environmental monitoring reports which are submitted by applicants for each GM crop authorised for cultivation in the EU (currently maize MON810 and the Amflora potato).

3.3.4. National safeguard clause measures

Objectives and outcomes:

Based on new scientific evidence related to safety of a GM product, EU Member States can invoke safeguard clause or emergency measures under Article 23 Directive 2001/18/EC (EC, 2001) or Article 34 of Regulation (EC) 1829/2003 (EC, 2003c), to provisionally restrict or prohibit the commercial use of authorised GMOs on their territory. So far, such measures have been invoked by Austria, France, Greece, Germany, Hungary, and Luxemburg for several maize, oilseed rape and potato events, with the majority of safeguard clause or emergency measures being invoked for maize MON 810. For all cases the GMO Panel has been asked by the European Commission to evaluate whether the invocation was justifiable on the basis of new scientific information submitted by an EU Member State in support of a safeguard clause or emergency measure. Only the GMO Panel scientific opinions on safeguard clause or emergency measures that address potential adverse effects on non-target organisms in general and the ecosystem services they provide are considered below; potential effects on bees (and pollinators) were specifically addressed in GMO Panel scientific opinions on safeguard clauses invoked by Greece on maize MON 810.

3.3.4.1. Scientific Opinions[15]

1) Opinion of the Scientific Panel on genetically modified organisms [GMO] related to genetically modified crops (Bt176 maize, MON810 maize, T25 maize, Topas 19/2 oilseed rape and Ms1xRf1 oilseed rape) subject to safeguard clauses invoked according to Article 16 of Directive 90/220/EEC (EFSA, 2006c) - see Appendix C, reference #4

2) Opinion of the Scientific Panel on genetically modified organisms [GMO] related to the safeguard clause invoked by Greece according to Article 23 of Directive 2001/18/EC and to Article 18 of Directive 2002/53/EC (EFSA, 2006d) - see Appendix C, reference #5

3) Request from the European Commission related to the safeguard clause invoked by Greece on maize MON810 according to Article 23 of Directive 2001/18/EC – Scientific opinion of the Panel on genetically modified organisms (EFSA, 2008b) - see Appendix C, reference #7

4) Request from the European Commission related to the safeguard clause invoked by Hungary on maize MON810 according to Article 23 of Directive 2001/18/EC – Scientific opinion of the Panel on genetically modified organisms (EFSA, 2008c) - see Appendix C, reference #8

5) Request from the European Commission related to the safeguard clause invoked by France on maize MON810 according to Article 23 of Directive 2001/18/EC and the

[15] Scientific Opinions on national safeguard clauses or emergency measures address the concerns made by the invoking Member State, not necessarily related to NTO (or bees/pollinators). Therefore, further details of these Scientific Opinions throughout the abstract or a short summary are not provided as of little relevance for impacts on bees/pollinators.

emergency measure according to Article 34 of Regulation(EC) No 1829/2003 (EFSA, 2008d) - see Appendix C, reference #10

6) Request from the European Commission related to the safeguard clause invoked by Austria on maize MON810 and T25 according to Article 23 of Directive 2001/18/EC (EFSA, 2008e) - see Appendix C, reference #11

7) Scientific Opinion on a request from the European Commission related to the emergency measure notified by France on genetically modified maize MON 810 according to Article 34 of Regulation (EC) No 1829/2003 (EFSA, 2012m) - see Appendix C, reference #26

1) Request from the European Commission related to the safeguard clause invoked by Greece on maize MON810 according to Article 23 of Directive 2001/18/EC – Scientific opinion of the Panel on genetically modified organisms (EFSA, 2012o) - see Appendix C, reference #29

Conclusions and recommendations:

The objective is to evaluate whether the invocation of the safeguard clause or emergency measure was justifiable on the basis of new scientific information submitted in support of such measures. For all cases the GMO Panel concluded that, based on the documentation supplied by the EU Member State and a review of recent scientific literature, there is no specific scientific evidence in terms of risk to human and animal health and the environment that would support the notification of a safeguard clause or emergency measure, and that would invalidate its previous risk assessments. Against this background and in order to facilitate a thorough assessment of potential risks, the GMO Panel strongly recommends Member States who invoke safeguard clauses or emergency measures to supply scientific data of a quality which can be subjected to detailed scientific scrutiny.

3.3.5. Fauna database project

3.3.5.1. Supporting publications

1) Establishing a database of bio-ecological information on non-target arthropod species to support the environmental risk assessment of genetically modified crops in the EU (EFSA, 2012n) - see Appendix C, reference #27

Objectives and outcomes

The objectives of the project were two-fold. The first objective was to establish a database that contains relevant information on NT arthropod species found in maize, oilseed rape, potato, sugar/fodder beet, soybean, cotton and rice, and in field margins in Europe. The second objective was to explore how the information contained in the database can inform the environmental risk assessment of GM crops, be it in terms of problem formulation, species selection, environmental risk assessment studies or post-market environmental monitoring. Based on an extensive systematic literature search, data on taxonomy, geography, abundance, habitat, and ecological function were retrieved from over 1000 publications. Species attributes and abundance data have been stored in a SQL-queryable database, which provides ecological information for 3030 arthropod species and 14762 abundance records from 31 European countries. The project started in December 2010 and was finalised in August 2012.

Abstract:

To support environmental risk assessment of GM crops in the European Union, this project provides a detailed overview of the arthropod fauna in arable crops across Europe. In a systematic literature search, relevant publications were identified concerning arthropods in European fields planted with maize, oilseed rape, potato, sugar/fodder beet, soybean, cotton, and rice, and in field margins. Species attributes and abundance data have been stored in a SQL-queryable database, which is available to all on the website of EFSA. This database, which is derived from over 1000 publications, provides ecological information for 3030 species and 14762 abundance records from 31 European countries. The crop with the largest number of identified species and the largest number of records is maize, followed by beet, potato, and oilseed rape. Records from arthropods collected in field margins adjacent to the selected crops are scarce. Arthropods in the database represent 278 families and 30 orders, with beetles (Coleoptera), aphids, bugs, and leafhoppers (Hemiptera), and spiders (Araneae) having the highest number of species and records. Predators (mainly ground beetles, rove beetles, and spiders) and herbivores constitute more than 80% of all species and records in the database, followed by decomposers, parasitoids, non-predatory aquatic species, and pollinators. Herbivores are more crop-specific than the other functional groups. Few data at the species level have been published for soil arthropods. Using eight hypothetical case studies, we demonstrate how the database can facilitate the identification of ecologically and agronomically relevant species for the assessment of potential adverse effects of GM crops on non-target arthropods. Regarding geographical zoning for European GM crop risk assessment, the authors proposed the designation of four climatic zones. Finally, the authors suggested ways in which the database can be improved and maintained for future use.

Conclusions and recommendations:

This NT arthropod fauna database provides risk assessors and applicants with a tool that facilitates:

- the description of the arthropod faunal diversity, abundance and distribution in the EU for the crops under consideration
- the identification of (ecologically and agronomically relevant) species that provide important ecosystem services
- the identification of species that can be used to assist the non-target risk assessment of GM plants (e.g., inform problem formulation, feed the selection of representative species for testing purposes in lower-tier studies, identify those species or groups of arthropods that are abundant, widely distributed, and most relevant in the receiving environment, extrapolate data generated in a specific EU region to other EU regions).

In-house collaboration:

For this output, the GMO Unit received support from the SAS Unit.

3.4. Plant Health Unit and Panel (PLH)

The PLH Panel on Plant Health provides independent scientific advice on the risk posed by plant pests which can cause harm to plants, plant products or biodiversity in the EU. The Panel reviews and assesses those risks with regard to the safety and security of the food chain.

The Plant Health Unit provides administrative and scientific support to the work of the PLH Panel and may carry out other projects in EFSA's remit. The unit may also produce scientific outputs on behalf of EFSA, for instance in response to urgent requests for scientific advice.

3.4.1. Scientific Opinions

1) Assessment of the risk of solanaceous pospiviroids for the EU Territory and the identification and evaluation of risk management options (EFSA, 2011f) - see Appendix D, reference #1

Abstract:

Following a request from the EU Commission, the EFSA PLH Panel conducted a risk assessment for the EU territory of pospiviroids affecting solanaceous crops, identified and evaluated risk reduction options and evaluated the EU provisional emergency measures targeting *Potato spindle tuber viroid* (PSTVd). The risk assessment included PSTVd, *Citrus exocortis viroid*, *Columnea latent viroid*, *Mexican papita viroid*, *Tomato apical stunt viroid*, *Tomato chlorotic dwarf viroid*, *Tomato planta macho viroid*, *Chrysanthemum stunt viroid* and *Pepper chat fruit viroid*. Four entry pathways were identified, three involving plant propagation material, with moderate probability of entry, and one involving plant products for human consumption, with low probability of entry. The probability of establishment was considered very high. Spread was considered likely within a crop and moderately likely between crop species, with exception of spread to potato, rated as unlikely. The probability of long distance spread within vegetatively propagated crops was estimated as likely/very likely. The direct consequences were expected to be major in potato and tomato, moderate in pepper, minimal/minor in other vegetables and minimal in ornamentals. Main risk assessment uncertainties derive from limited knowledge on pospiviroids other than PSTVd, although all pospiviroids are expected to have similar biological properties. Management options to reduce risk of entry, spread and consequences were identified and evaluated. No management options can prevent establishment. Examples of successful PSTVd eradication are linked to timely and strict implementation of measures. Uncertainty exists on the effectiveness of risk reduction strategies targeting only one pathway. The EU provisional emergency measures appeared to have significantly reduced PSTVd incidence in *Solanum jasminoides* and *Brugmansia* sp., even though eradication from the EU is so far incomplete. The low PSTVd incidence in food crops did not permit to conclude whether the reduction in PSTVd prevalence in ornamentals led to a reduction in outbreaks in food crops.

Objectives and outcomes:

In the Terms of Reference of the scientific opinion on the risk assessment of the solanaceous pospiviroids for the EU territory and the identification and evaluation of risk management options, the PLH Panel was not requested to address the bees' situation in particular. However, when performing its analyses, the Panel mentioned the bees in the context of the evaluation of a specific control measure.

Conclusions and recommendations:

Bumblebees (*Bombus ignitus* Smith) have been shown to transmit two different pospiviroids, TASVd (Antignus et al., 2007) and TCDVd (Matsuura et al., 2010) within the same crop (tomato) under greenhouse conditions, but the exact transmission mode remains unknown. In TASVd, pollination by bumblebees has been associated with viroid spread within a greenhouse in which

transmission by human activity was excluded (Antignus et al., 2007). In the context of the evaluation of the effectiveness of risk reduction options with regards to tomato pollination, not using bumblebees may reduce the chance of pospiviroid spread but would simultaneously reduce fruit yield. As an alternative to bumblebee pollination, human-assisted pollination using sticks for vibration of flowers can be applied. It is however less efficient than bumblebees and therefore has negative impact on yield and, in addition, carries a risk of promoting mechanical transmission of pospiviroids.

Not assisting pollination in tomato glasshouse crops cannot be an option due to the consequential yield losses. Human-assisted pollination (e.g. with vibrating sticks) would carry a similar risk of spreading the disease but with higher technical difficulties and would impact yield. Therefore, avoiding bumble bees for pollination should not be considered as a viable management option I.

2) Environmental risk assessment of plant pests (EFSA, 2011g) - see Appendix D, reference #2

Abstract:

The European Food Safety Authority (EFSA) requested the Panel on Plant Health to develop a methodology for assessing the environmental risks posed by harmful organisms that may enter, establish and spread in the European Union. To do so, the Panel first reviewed the methods for assessing the environmental risks of plant pests that have previously been used in pest risk assessment. The limitations identified by the review led the Panel to define the new methodology for environmental risk assessment which is described in this guidance document. The guidance is primarily addressed to the EFSA PLH Panel and has been conceived as an enhancement of the relevant parts of the "Guidance on a harmonised framework for pest risk assessment and the identification and evaluation of pest risk management options by EFSA". Emphasizing the importance of assessing the consequences on both the structural (biodiversity) and the functional (ecosystem services) aspects of the environment, this new approach includes methods for assessing both aspects for the first time in a pest risk assessment scheme. A list of questions has been developed for the assessor to evaluate the consequences for structural biodiversity and for ecosystem services in the current area of invasion and in the risk assessment area. To ensure the consistency and transparency of the assessment, a rating system has also been developed based on a probabilistic approach with an evaluation of the degree of uncertainty. Finally, an overview of the available risk reduction options for pests in natural environments is presented, minimum data requirements are described, and a glossary to support the common understanding of the principles of this opinion is provided.

Objectives and outcomes:

In the Terms of Reference of the guidance document on environmental risk assessment of plant pests, the PLH Panel was not requested to address the bees' situation in particular. However, when performing its analyses, the PLH Panel mentioned the bees in the context of the evaluation of the pollination service.

Conclusions and recommendations:

Among the ecosystem services mentioned in the EFSA PLH ERA guidance document, the pollination service is also considered by the Panel for its assessment.

3.5. Scientific Assessment Support Unit (SAS)

The Scientific Assessment Support Unit provides technical support in the field of statistics, modelling, data management and risk assessment. It contributes in particular to the development and application of new or refined risk assessment approaches in the field of food and feed safety.

On request, the Scientific Assessment Support Unit:

- Contributes to the development and application of new or refined risk assessment approaches
- Collates and summarises data from scientific literature and existing databases
- Evaluates and revises statistical and modelling methods used in risk assessments
- Carries out and supports epidemiological and statistical data analyses
- Develops quantitative risk assessment and quantitative decision support tools for risk managers

This work ultimately supports risk managers in taking effective and timely decisions in the field of food and feed safety.

The Scientific Assessment Support Unit provides expertise to support the production of scientific opinions, reports, guidance documents and publications in response to requests for technical assistance from EFSA's Scientific Committee and Panels, the Advisory Forum, Member States and the European Commission. The unit also carries out its own projects through the application and harmonisation of quantitative or qualitative scientific risk assessment methods and through the development of new risk assessment approaches.

3.5.1. Supporting publications

1) Bee Mortality and Bee Surveillance in Europe - A Report from the Assessment Methodology Unit in Response to Anses (EFSA, 2008f) - see Appendix E, reference #1

Abstract:

All member states have a monitoring programme for residues in honey as required under Directive 96/23/EC. In Directive 86/363/EEC there are no pesticide residue MRLs set for honey so residue monitoring in honey focuses on residues of veterinary medicinal products and environmental contaminants. The following veterinary medicinal products and environmental contaminants that have also been used for plant protection have been detected at non compliant levels in honey; streptomycin, pyrethroides, organochlorine compounds and organophosphates. In September 2008 the Regulation 396/2005, which includes temporary MRLs in honey, will be applicable. Therefore, future monitoring programmes will include data on specific active substances in honey. Five member states reported additional programmes investigating chemical residues. The UK and French surveillance programmes included laboratory testing for pesticide poisoning. The Project "Deutsches Bienenmonitoring" tests for pesticide residues in pollen, the Programa Apícola Nacional includes analysis of honey for pesticides and there is a project in The Netherlands testing for natural plant alkaloids in honey. Responses were received from the EFSA Focal Point Network from twenty-two member states plus Norway and Switzerland. This

identified seventeen bee surveillance programmes in sixteen countries. The surveillance programmes are frequently organised by national associations / federations of beekeepers. Additionally there is collaboration with the international COLOSS Network which aims to explain and prevent large scale losses of honeybee colonies. The honey production figures provided in the questionnaires were frequently higher than those reported in FAOSTAT, EUROSTAT and national residue monitoring plans. Both the FAOSTAT and EUROSTAT datasets suffered from missing data and were not always clear regarding the data sources used to obtain the figures. When honey production figures extracted from EUROSTAT and FAOSTAT were averaged, Spain was the highest producer followed by Germany, Hungary, France, Romania Greece and Poland. A similar pattern was seen for honey production figures from the national residue monitoring plans. The data supplied in the questionnaires identified Hungary and Germany as the largest producers of honey. Luxembourg produced the smallest amount of honey. Greece reported the largest bee population (1,380,000 beehives). Analysis of the bee population figures provided by twenty two countries for 2006-2007 estimates the bee population in Europe at greater than 8 million beehives. This estimate is conservative as data from two of the larger producers of honey Spain and Poland was not available.

Objectives and outcomes:

Objective as to collate of information relating to:

- Monitoring of chemical residue levels in honey within the member states,
- Surveillance programmes monitoring collapse, weakening and mortality in bees active within the EU,
- Data on levels of honey production in the member states.

Chemical residue levels in honey: All member states have a monitoring programme for residues in honey as required under Directive 96/23/EC (EC, 1996). In September 2008 the Regulation 396/2005 (EC, 2005), which includes temporary MRLs in honey, will be applicable. Therefore, future monitoring programmes will include data on specific active substances in honey.

Surveillance programmes: Seventeen bee surveillance programmes in sixteen countries were identified. The surveillance programmes are frequently organised by national associations / federations of beekeepers. Additionally there is collaboration with the international COLOSS Network which aims to explain and prevent large scale losses of honeybee colonies.

Honey production: Honey production figures vary depending on the source but indicate that Spain was the highest producer followed by Germany, Hungary, France, Romania Greece and Poland.

Conclusions and recommendations:

In order to investigate further the phenomena of colony collapse disorder in Europe the following actions should be considered:

- Description of the study design of the surveillance programmes identified to assess the feasibility of combining data for EU level epidemiological analysis

- Collation of historical data on bee mortality rates and colony losses from the member state surveillance programmes identified in this report

- Review of reports referenced in the questionnaire and existing scientific literature on possible causes of colony collapse disorder and bee mortality

An EU-wide review of bee mortality and bee surveillance would facilitate an objective assessment of all possible causes of CCD. Additionally it would prepare the grounds and orientate research towards identified gaps in scientific knowledge.

These recommendations resulted in the launch of the grant CFP/EFSA/AMU/2008/02: Bee Mortality and Bee Surveillance in Europe.

In-house collaborations:

For this output, the SAS Unit received support from AF-SCO, AHAW and PRAS Units.

2) Bee Mortality and Bee Surveillance in Europe (EFSA, 2009h) - see Appendix E, reference #2

Abstract:

The bee surveillance project sought information on both the prevalence of honey bee colony losses, and the surveillance systems found in 27 European countries. Through a standardized questionnaire, data was obtained from 24 countries, relating to 25 systems. Each of the surveillance systems collecting these data was evaluated. In addition, a thorough literature search of the existing databases, as well as relevant grey literature about causes of colony losses was completed, and the literature evaluated. The main conclusions from project activities can be summarized as follows:

- General weakness of most of the surveillance systems in the 24 countries investigated;

- Lack of representative data at country level and comparable data at EU level for colony

- losses;

- General lack of standardisation and harmonisation at EU level (systems, case definitions and data collected);

- Consensus of the scientific community about the multifactorial origin of colony losses in Europe and in the United States and insufficient knowledge of causative and risk factors for colony losses.

The project makes recommendations, in the following areas:

- Establishment of a sustainable European network for coordination and follow-up of surveillance on colony losses to underpin monitoring programmes;

- Strengthen standardization at European level by harmonization of surveillance systems, data collected and by developing common performance indicators;

- Build on the examples of best practice found in existing surveillance systems for communicable and notifiable diseases already present in some countries;

- Undertake specific studies that build on the existing work in progress to improve the knowledge and understanding of factors that affect bee health (for example stress caused by pathogens, pesticides, environmental and technological factors and their interactions) using appropriate epidemiological studies (case control and longitudinal studies);

- The set up of the coordination team at European level. This is a crucial issue and the coordination team should be organized in such a way so as to ensure its sustainability and to enable effective surveillance programme activities at the European level.

Objectives and outcomes:

The objectives are as follows:

- A description of study design for bee surveillance programmes active in Europe;

- The compilation of a dataset of historical nominators and denominators for colony collapse, weakening and colony mortality from the surveillance programmes described;

- A review of relevant published scientific literature and reports from surveillance programmes for possible causative factors of CCD.

Conclusions and recommendations:

This report and a presentation from the consortia to the "Commission Bee Interservices Group" were considered when developing Regulation 87/2011/EC (EC, 2011a). This regulation designated the EU reference laboratory in the field of bee health, for a period of five years from 1 April 2011 to the laboratory of the Agence Nationale de Sécurité Sanitaire de l'alimentation, de l'environnement et du travail (Anses) in Sophia-Antipolis, France. A pilot surveillance project on honey bee colony losses in 2012-2013 was also launched with €3.2 million in EU funding to be shared between 17 participating Member States.

In-house collaborations:

For this output, the SAS Unit received support from AHAW and PRAS Units.

3) Review of statistical methods and data requirements to support post market environmental monitoring of agroecosystems. Mandate for the identification of existing monitoring networks suitable to provide datasets to support post market environmental monitoring (PMEM) of GMOs (EFSA, in preparation) - see Appendix E, reference #3

Abstract:

The abstract of this review is not yet available. The report will be published in October 2014.

Objectives and outcomes:

The objective of this review is to investigate whether data obtained from existing monitoring networks and programmes can effectively contribute to PMEM of new and existing agricultural products authorised for use within Europe.

The specific objectives of the contract resulting from the present procurement procedure are:

- Review of published statistical methods used in the analysis of ecological and environmental datasets to (i) determine whether observed change exceeds existing variability and to (ii) investigate spatial correlation with environmental stressors.

- Review and inventory of the data available as a consequence of EU environment legislation (as listed above) and other national or regional environmental data networks and categorisation in the context of the analysis methodologies data needs

- Recommendations of the most appropriate analysis methodologies for PMEM based on available environmental monitoring data in Europe

The monitoring of pollinators would be considered under this procurement and mandate.

Conclusions and recommendations:

The outcome of this review is not yet available. The report will be published in October 2014.

In-house collaborations:

For this output, the SAS Unit received support from the GMO and PRAS Units.

3.6. Emerging Risks Unit (EMRISK)

Identifying emerging risks in the field of food and feed safety is a key task assigned to EFSA. The EMRISK Unit is responsible for establishing procedures to monitor, collect and analyse information and data in order to identify emerging risks. This includes:

- Collecting data and monitoring relevant information sources such as scientific literature, rapid alert systems for food and feed, trade data and official bulletins.

- Developing procedures for analysing and evaluating collected data.

- Sharing information with stakeholders and Member States.

Each year the EMRISK Unit publishes a report, which details EFSA's strategy and activities on emerging risks in food and feed. Through the early identification of emerging risks in the food chain, the unit's work supports risk managers in anticipating potential risks and taking effective and timely decisions in the field of food and feed safety.

In the context of data analysis, a TF composed of EFSA scientific staff was established at the beginning of 2010. This internal TF is responsible for the initial evaluation of data collected during the monitoring activities. This work feeds into the risk assessment activities of EFSA's Scientific Panels and Scientific Committee.

In addition, the EMRISK Unit works with partner organisations in the EU Member States and third countries. An Emerging Risks Exchange Network was established in May 2010. It includes experts from Member State organisations, the European Commission, relevant EU-agencies and international organisations. It is expected to become the main body for exchanging information on emerging risks to food and feed safety.

A Stakeholder Consultative Group was established in May 2010. It will encourage sharing of data and methodologies. Its experts will have a wide range of experience in the area of emerging risks identification and represent the whole food chain, from primary production to retail.

3.6.1. Supporting publications

1) Inventory of EFSA's activities on bees EFSA (see this report) - see Appendix F, reference #1

Abstract:

See abstract of this report.

Objectives and outcomes:

See objectives and outcomes of this report.

Conclusions and recommendations:

See conclusions and recommendations of this report.

In-house collaborations:

For these outputs, the EMRISK Unit received (and will receive for the second output to be finalised in May 2013) support from AHAW, GMO, PRAS, PLH and SAS Units.

2) Inventory of studies conducted on bees, inside and outside EFSA, to identify cross-cutting issues and further research needs for a more integrated approach on the evaluation of risks to bees and their ecosystem services (outside EFSA inventory and data gap analysis) EFSA's activities on bees with stakeholders (EFSA, in preparation) - see Appendix F, reference #2

Abstract:

Not yet available

Objectives and outcomes:

The objectives are as follows:

a) to review the state of the art of the work and research produced outside EFSA in the area of bee risk assessment (e.g. DG-Research, EEA, OECD),

b) to perform a gap analysis on the data collected inside and outside EFSA in order to highlight cross-cutting issues, risk assessment and data gaps and research needs,

c) to make recommendations on how to further integrate the work above to provide risk managers with comprehensive advice on which to base their decisions, for example through a working group, a grant, a procurement, recommendations for DG-Research (through the EFSA internal mandate on "research priorities and horizon 2020") and/or through the continuation of an internal TF to keep monitoring this area and ensure coordination of EFSA's activities across Directorates and with engaged stakeholders.

The outcome of this work will be the publication of a report describing the above items.

Conclusions and recommendations:

Not yet available.

In-house collaborations:

For these outputs, the EMRISK Unit received (and will receive for the second output to be finalised in May 2013) support from AHAW, GMO, PRAS, PLH and SAS Units.

3.7. EFSA communication on bee issues with stakeholders

To this point EFSA's communications activities have been largely sporadic and ad hoc, i.e. we have provided communications support to individual outputs. Since the formation of the bees TF, in line with both the communications strategy and the science strategy, the approach has been to treat EFSA's work on bees as a mini-theme, providing consistent, regular communication that gives the project a clear and logical narrative. Importantly, all communication support will emphasise that the TF is a cross-unit initiative that draws on expertise from all corners of EFSA.

3.7.1. EFSA and Anses

1) WG on bees "GECU Abeille: Groupe d'Expertise Collective d'Urgence"

The objective of this WG was to make a review of the article Vidau et al. (2011) untitled "exposure to sublethal doses of fipronil and thiacloprid highly increases mortality of honeybees previously infected by *Nosema ceranae*" (Saisine n° "2011-SA-0233"). The WG had to determine whether the results presented in this paper bring new evidence on the causal factors of honeybee mortalities, in particular on the implication of the interactions of several factors such as pesticides (e.g. thiacloprid) and bee infection (e.g. *Nosema*) in a view to make recommendations on beekeeping and farming practices. Finally, Anses was requested to formulate conclusions made on the risk assessment and marketing of the product SONIDO (DESIMO) containing thiacloprid.

The recommendations made by this WG were as follows:

i. Beekeeping practices: in order to reduce *Nosema* infection in hives, frames need to be changed regularly, frames need to be changed before wintering, beekeeping equipment need to be cleaned and disinfected, hives need to be placed in a dry place, with a strong light and low wind exposure and close to food resources of good quality.

ii. Pesticides risk assessment protocols: several new amendments were proposed to the current legislation - Directive 91/414 (EC, 1991) replaced by Regulation 1107/2009 (EC, 2009a). The WG reminded that the toxicokinetics of the tested substances

needs to be determined in order to refine the risk assessment procedure, that longer exposure periods are included (e.g. effects of long-term and low dose exposures on several bee generations) on endpoints such as population dynamics and foragers orientation, that co-exposures are routinely tested (e.g. bees are pre-exposed to various pathogens before they are treated with the tested substances), and finally the development of standardised methods for the assessment of bees exposure in field conditions.

iii. Further research on the effects of variability in bees at the individual and colony levels: age/group and genetic origin on bee tolerance to pesticides, the development of detailed and more standardised tests. In addition, more research is required in the area of *Nosema* (prevalence type, genetic diversity, virulence and pathogenicity, threshold level for infection (spores), parameters to determine the severity of the infection), on the host (sensitivity, compensation phenomenon), and on the host-parasite interactions. Finally, more research is needed in the area of pesticides bee toxicology (toxicological and toxicokinetic profiles; enzymes involved in metabolisation).

EFSA staff from the EMRISK Unit was involved in this WG.

3.7.2. EFSA and OECD

In November 2008, the Organization for Economic Cooperation and Development (OECD) WG on Pesticides (WGP) endorsed development of a survey to address issues related to pollinator declines. The WGP carried out the Survey of Pollinator Testing, Research, Mitigation and Information Management related to pollinator declines in 2009. Countries were surveyed on the following: how incident information on bees is handled, testing requirements for pollinators, active areas of research into pollinator issues, and approaches employed to mitigate potential risks to pollinators from pesticides. In 2010, the WGP published the results of the survey[16]. In response to the survey results, the OECD Registration Steering Group/Risk Reduction Steering Group (RSG/RRSG) joint session recommended the formation of a pollinator expert group and identified four main themes requiring potential work from the WGP. These four themes consisted of the following:

1. Timely and accurate communication of pollinator-related incidents between OECD member states;

2. Identification and improvement of pesticide exposure and toxicity study methods toward enhancing insect pollinator risk assessment methodologies;

3. Identification and enhancement of current risk mitigation measures based on sound science; and,

4. Identification of global research efforts on examining and potentially mitigating the effects of pesticides on insect pollinators.

In response to these recommendations, the WGP formed an expert group, *i.e.*, the Pesticide Effects on Insect Pollinators (PEIP) group, and adopted a work plan to address the four themes.

[16] OECD Survey of Pollinator Testing, Research, Mitigation and Information Management: Survey Results http://www.oecd.org/dataoecd/19/27/45275778.pdf

The WGP invited delegations to volunteer for the expert group, and volunteers were identified to serve on subgroups for each theme; members of the PEIP nominated co-chairs for each subgroup. Separate subgroups worked on each theme simultaneously; the work was further divided into distinct phases: Phase 1 consists of collecting and sharing of information and Phase 2 consists of implementation of information sharing mechanisms and test guidelines.

EFSA staff from the PRAS Unit is involved in the themes 2 and 3.

For theme 2 (Testing Requirements for Pollinators), the WGP recognized that study designs for field pollinator tests could be enhanced and that new tests are needed to better assess sub-lethal effects on pollinators and potential effects of systemic pesticides. To that end, the WGP recommended establishing an inventory of research to facilitate communication and to determine if, how, and when to advance new OECD test guidelines.

With respect to theme 3 (Regulatory Response to Potential Pollinator Risks), the WGP recommended the development of a mechanism for sharing risk management tools, including precautionary labelling, use restrictions, technologies, training materials, best management practices and integrated pest management practices used by different countries to mitigate potential risks and to develop performance measures for assessing the effectiveness of such risk mitigation measures.

3.8. Number and type of outputs

This inventory shows that up to September 2012, a total of 355 scientific outputs were identified of which 344 were already published (Table 3). Among the published outputs (n=344), the PRAS Unit and PPR Panel, the GMO and PLH Units and Panels and the SAS Unit produced 311, 29, 2 and 2 reports, respectively. Among the non yet published outputs (n=11), the PRAS Unit and PPR Panel, the AHAW Unit and Panel, and the SAS and EMRISK Units are expected to produce 7, 1, 1 and 2 reports, respectively. However, EFSA may well receive or initiate further mandates in this area during this period.

The majority of these outputs were related to applications (306 conclusions on the peer review of pesticide active substances and 12 opinions on applications, and clarifications of these opinions, for authorisation of GMOs). As highlighted in the title and keywords of the scientific outputs, 14 projects (6 currently published by 20.09.2012) could be identified as focusing on bee issues. These outputs were predominantly in the area of pesticides risk assessment and monitoring.

In addition to the above scientific outputs, COMMS published four news/press stories to communicate on the recent work coordinated by EMRISK, PRAS and SAS Units.

3.9. Publication of outputs over time

When the scientific outputs were screened over time (Table 4), it showed that the first publications were conclusions of pesticides peer review issued in 2005.

Among the 6 published scientific outputs focusing on bee issues, all were issued in 2012 and the same trend was observed for media releases.

3.10. In-house collaborations and relations with stakeholders

For in-house collaborations on projects related to bee issues, the EMRISK and SAS Units were found to be highly involved in such horizontal activities.

For EFSA's activities with external stakeholders, only a few of them were identified with Anses and OECD. The EMRISK Unit collaborated with Anses in the first half of 2012 on the assessment of interactions between pesticides and bee diseases and the PRAS Unit is currently collaborating with OECD on various aspects of bee risk assessment and bee monitoring such as pollinator incidence, testing methods, risk mitigation and communication on bee research.

Table 3: Number of scientific outputs (total, published, unpublished and focused on bee issues) per Unit and/or Panel

Units and/or Panels	Total number of published outputs	Total number of unpublished outputs	Total number of outputs focused on bee issues*	**Total Number of outputs**
PRAS (Pesticides Unit) and PPR Panel	311	7	9 (4 published)	**318**
AHAW (Animal Health and Welfare Unit and Panel)	0	1	1 (0 published)	**1**
GMO (Genetically Modified organisms Unit and Panel)	29	0	0	**29**
PLH (Plant Health Unit and Panel)	2	0	0	**2**
SAS (Scientific Assessment Support Unit)	2	1	2 (2 published)	**3**
EMRISK (Emerging Risks Unit)	0	2	2 (0 published)	**2**
TOTAL	**344**	**11**	**14 (6 published)**	**355**

*The inventory for EFSA conclusions made by PRAS was updated up to 20.09.2012. Therefore, outputs published after 20.09.2012 were considered as unpublished.

Table 4: Number of scientific ouputs published per year of adoption/publication and per Unit and/or Panel

	Years of publication										
Units and/or Panels	2004	2005	2006	2007	2008	2009	2010	2011	2012*	After 2012	**TOTAL**
PRAS (Pesticides Unit) and PPR Panel	1	21	31	19	60	28	72	53	32 (6 unpublished)	1	**318**
AHAW (Animal Health and Welfare Unit and Panel)										1	**1**
GMO (Genetically Modified organisms Unit and Panel)		2	4		5	3	2	5	8		**29**
PLH (Plant Health Unit and Panel)								2			**2**
SAS (Scientific Assessment Support Unit)					1	1				1	**3**
EMRISK (Emerging Risks Unit)									1 (1 unpublished)	1	**2**
TOTAL	**1**	**23**	**35**	**19**	**66**	**32**	**74**	**60**	**41 (7 unpublished)**	**4**	**355**

*The inventory for EFSA conclusions made by PRAS was updated up to 20.09.2012. Therefore, outputs published after 20.09.2012 were considered as unpublished (the detailed number of conclusions produced per year by PRAS is described in the table footnote #17 of Appendix A).

CONCLUSIONS AND RECOMMENDATIONS

The inventory presented in this report describes the past and current activities of EFSA addressing directly or indirectly bee risk assessment, risk mitigation and monitoring.

The number of scientific areas covered and the number of EFSA Units/Panels involved in bee issues mirrors the multidisciplinary nature of this topic, and demonstrates the breadth of the internal expertise available in this area at EFSA. It also reflects the growing attention on this subject from the scientific community, risk managers and the public. However, to be effective and to make the best use of its limited resources, EFSA needs to integrate its work on bees and expand its activities with stakeholders and other EU bodies involved in bee risk assessment.

In line with the ToR of the present EFSA mandate, the TF recommends to conduct a scientific assessment of the information presented in this report, in particular to analyse the conclusions and recommendations made for each output to identify potential gaps of knowledge and, where appropriate, to make further recommendations. The TF will perform this analysis in the second term of its mandate interacting with the respective Panels.

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APPENDICES

A. INVENTORY OF SCIENTIFIC OUTPUTS FROM THE PRAS UNIT AND PPR PANEL

Subject	Keywords	Mandate	Question Number and/or Project Number	Question type	Starting date [(a)]	Publication date[(b)]	URLs to EFSA website	Legislation related to the subject	Reference
Scientific Opinion on the development of specific protection goal options for environmental risk assessment of pesticides, in particular in relation to the revision of the Guidance Documents on Aquatic and Terrestrial Ecotoxicology (SANCO/3268/2001 and SANCO/10329/2002)	protection goals, ecosystem services, environmental risk assessment, pesticides, plant protection products,	M-2009-0271	EFSA-Q-2009-00861	Art 29 – Scientific opinion	22/10/209	11/10/2010	http://www.efsa.europa.eu/en/efsajournal/pub/1821.htm	EC, 2009a	#1 EFSA, 2010a
Scientific Opinion on the science behind the development of a risk assessment of Plant Protection Products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)	guidance documents, ecotoxicology	M-2011-0185	EFSA-Q-2011-00417	Art. 29 - Scientific Opinion	11/05/2011	23/05/2012	http://www.efsa.europa.eu/en/efsajournal/pub/2668.htm	EC, 2009a	#2 EFSA, 2012d
Statement on the findings in recent studies investigating sub-lethal effects in bees of some neonicotinoids in consideration of the uses currently authorised in Europe	Neonicotinoids, sub-lethal effects, honeybees, bumblebees, exposure, nectar	M-2012-0121	EFSA-Q-2012-00556	Art 31 – Scientific and technical assistance - Pesticides	11/04/2012	01/06/2012	http://www.efsa.europa.eu/en/efsajournal/pub/2752.htm	EC, 2009a	#3 EFSA, 2012e
Statement on the assessment of the scientific elements supporting the Italian precautionary suspension of the placing on the market of treated maize seeds	honeybees, neonicotinoids, fipronil, maize coated seeds, dust exposure, lethal and sub-lethal effects	M-2012-0124	EFSA-Q-2012-00554	Article 31 - Scientific and Technical Assistance	26/04/2012	27/06/2012	http://www.efsa.europa.eu/en/efsajournal/pub/2792.htm	EC, 2009a	#4 EFSA, 2012f

Completion of a data entry of pesticides ecotoxicology Tier 1 study endpoints in XLM schema - database CFT/EFSA/PPR/2010/03	Ecotoxicological endpoints; IUCLID 5.2; ecotoxicologcal properties data base; Plant Protection Products	M-2010-0565	EFSA-Q-2010-01013	Procurement	27/05/2010	23/07/2012 (date of the finalisation of the mandate)	Not yet published (see #12)	EC, 2009a	#5 Not yet published
Procurement on the interaction between pesticides and other factors in effects on bees	Honeybees, bumble bees, pesticides, disease, mixtures, synergism	M-2011-0218	EFSA-Q-2011-00789	Procurement	06/08/2011	06/09/2012	http://www.efsa.europa.eu/en/supporting/pub/340e.htm	EC, 2009a	#6 EFSA, 2012g
Conclusion[17] on the peer review of the pesticide risk assessment of the active substances	Pesticide active substances, peer review, risk assessment	n.a.[17]	n.a.[17]	Application	From March 2005	Up to 20/09/2012 (on-going process)	n.a.[17]	EC, 2009a	#7 n.a.[17]
Public consultation on the draft Guidance Document on the Risk Assessment of Plant Protection Products on bees (including Apis mellifera, Bombus spp. and solitary bees)	Honey bees, risk assessment, Guidance document, pesticides, *Apis mellifera*, solitary bees	M-2011-0185	EFSA-Q-2011-00794	Public consultation	11/05/2011	31/12/2012	EFSA (in preparation), URL not yet available	EC, 2009a	#8 EFSA, in preparation
EFSA Conclusions in accordance with Article 21 of Regulation (EC) No 1107/2009 to perform an evaluation of thiamethoxam as regards the risk to bees	not yet available	M-2012-0160	EFSA-Q-2012-00553	Application	30/04/2012	31/12/2012	EFSA (in preparation), URL not yet available	EC, 2009a	#9 EFSA, in preparation

[17] The output #7 includes 306 conclusions for 280 active substances published by EFSA-PRAS from October 2004 to 20.09.2012 (number of conclusions per year of adoption or publication: 1 in 2004, 21 in 2005, 31 in 2006, 19 in 2007, 60 in 2008, 28 in 2009, 71 in 2010, 53 in 2011 and 22 in 2012).

EFSA Conclusions in accordance with Article 21 of Regulation (EC) No 1107/2009 to perform an evaluation of imidacloprid as regards the risk to bees	not yet available	M-2012-0160	EFSA-Q-2012-00792	Application	30/04/2012	31/12/2012	EFSA (in preparation), URL not yet available	EC, 2009a	#10 EFSA, in preparation
EFSA Conclusions in accordance with Article 21 of Regulation (EC) No 1107/2009 to perform an evaluation of clothianidin as regards the risk to bees	not yet available	M-2012-0160	EFSA-Q-2012-00793	Application	30/04/2012	31/12/2012	EFSA (in preparation), URL not yet available	EC, 2009a	#11 EFSA, in preparation
Compilation of a DB on ecotoxicological properties of active substances and plant protection products/Technical support to the Commission	not yet available	M-2010-0277	EFSA-Q-2010-00865	Art 31 – Scientific and technical assistance	28/06/2010	31/12/2012	EFSA (in preparation)	EC, 2009a	#12 EFSA, in preparation
EFSA Conclusions in accordance with Article 21 of Regulation (EC) No 1107/2009 to perform an evaluation of fipronil as regards the risk to bees	not yet available	M-2012-0268	EFSA-Q-2012-00788	Application	08/08/2012	31/03/2013	EFSA (in preparation), URL not yet available	EC, 2009a	#13 EFSA, in preparation

(a) Date of acceptance of the mandate by EFSA
(b) Date of publication on the EFSA website (or anticipated date of publication corresponding to the deadline for publication if the project has not yet been published)
n.a.: not applicable

B. INVENTORY OF SCIENTIFIC OUTPUTS FROM THE AHAW UNIT AND PANEL

Subject	Keywords	Mandate	Question Number and/or Project Number	Question type	Starting date [(a)]	Publication date[(b)]	URLs to EFSA website	Legislation related to the subject	Reference
Scientific opinion concerning the risk of entry of the small hive beetle (*Aethina tumida*) and *Tropilaelaps* in the EU.	not yet available	M-2012-0158	EFSA-Q-2012-00550	Art. 29 - Scientific Opinion	03/05/2012	28/02/2013	URL not yet available	EC, 1992a EC, 2003a, b EC, 2010	EFSA, in preparation

(a) Date of acceptance of the mandate by EFSA
(b) Date of publication on the EFSA website (or anticipated date of publication corresponding to the deadline for publication if the project has not yet been published)

C. INVENTORY OF SCIENTIFIC OUTPUTS FROM THE GMO UNIT AND PANEL

Subject	Keywords	Mandate	Question Number and/or Project Number	Question type	Starting date [(a)]	Publication date[(b)]	URLs to EFSA website	Legislation related to the subject	Reference
Opinion of the Scientific Panel on genetically modified organisms [GMO] related to the notification (Reference C/ES/01/01) for the placing on the market of insect-tolerant genetically modified maize 1507 for import, feed and industrial processing and cultivation, under Part C of Directive 2001/18/EC from Pioneer Hi-Bred International/Mycogen Seeds	GMO, maize, health, cultivation, environment, import, Regulation (EC) 258/97, Regulation (EC) 1829/2003, Directive 90/220/EEC, Directive 2001/18/EC. Zea mays, 1507, insect protection, Cry1F, PAT, feed safety, human	M-2004-072	EFSA-Q-2004-072	Application	28/05/2004	03/03/2005	http://www.efsa.europa.eu/en/efsajournal/pub/181.htm	EC, 1990 EC, 1997 EC, 2001 EC, 2003c	#1 EFSA, 2005a
Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the notification (Reference C/F/96/05.10) for the placing on the market of insect resistant genetically modified maize Bt11, for cultivation, feed and industrial processing, under Part C of Directive 2001/18/EC	GMO, maize, health, cultivation, environment, import, Directive 90/220/EEC, Directive 2001/18/EC. Zea mays, Bt11, insect protection, Cry1Ab	Not available	EFSA-Q-2004-012	Application	Not available	19/05/2005	http://www.efsa.europa.eu/en/efsajournal/pub/213.htm	EC, 1990 EC, 2001	#2 EFSA, 2005b
Opinion of the Scientific Panel on genetically	GMO, potato,Solanum	M-2005-022	EFSA-Q-2005-023	Application	07/04/2005	24/02/2006	http://www.efsa.europa.e	EC, 1990 EC, 2001	#3 EFSA, 2006b

modified organisms [GMO] related to the notification (Reference C/SE/96/3501) for the placing on the market of genetically modified potato EH92-527-1 with altered starch composition, for cultivation and production of starch, under Part C of Directive 2001/18/EC from BASF Plant Science	tuberosum, EH92-527-1, starch, amylopectin, amylose, kanamycin, feed safety, human health, cultivation, environment, Regulation (EC) 1829/2003, Directive 90/220/EEC, Directive 2001/18/EC.						u/en/efsajournal/pub/323.htm	EC, 2003c	
Opinion of the GMO Panel related to GM crops (Bt176 maize, MON810 maize, T25 maize, Topas 19/2 oilseed rape and Ms1xRf1 oilseed rape) subject to Safeguard clauses invoked according to Article 16 of Directive 90/220/EEC	GMO, Bt176, T25, MON810, Ms1xRf1, Topas 19/2, oilseed rape, maize, safeguard clause, human/animal health, environment, Directive 90/220/EEC	M-2005-0220	EFSA-Q-2005-294	Art 29 – Scientific opinion	17/11/2005	27/07/2006	http://www.efsa.europa.eu/en/efsajournal/pub/338.htm	EC, 1990	#4 EFSA, 2006c
Opinion of the Scientific Panel on genetically modified organisms related to the safeguard clause on MON810 maize invoked by Greece according to Article 23 of Directive 2001/18/EC and to Article 18 of Directive 2002/53/EC	Not available	M-2006-0045	EFSA-Q-2006-048	Art 29 – Scientific opinion	05/07/2006	17/11/2006	http://www.efsa.europa.eu/en/efsajournal/pub/411.htm	EC, 2001 EC, 2002c	#5 EFSA, 2006d
Clarifications of the Scientific Panel on Genetically Modified	Not available	M-2006-0241	EFSA-Q-2006-00330	Art 29 – Scientific opinion	16/08/2006	19/11/2006	http://www.efsa.europa.eu/en/efsajour	EC, 2001	#6 EFSA, 2006a

Organisms following a request from the Commission related to the opinions on insect resistant genetically modified Bt11 (Reference C/F/96/05.10) and 15072 (Reference C/ES/01/01) maize							nal/pub/1561.htm		
Request from the European Commission related to the safeguard clause invoked by Greece on maize MON810 according to Article 23 of Directive 2001/18/EC - Scientific opinion of the Panel on Genetically Modified Organisms	GMOs, maize (Zea mays), MON810, Greece, safeguard clause, human health, animal health, environment, Directive 2001/18/EC, Directive 2002/53/EC	M-2008-0130	EFSA-Q-2008-313	Art 29 – Scientific opinion	15/05/2008	11/07/2008	http://www.efsa.europa.eu/en/efsajournal/pub/757.htm	EC, 2001 EC, 2002c	#7 EFSA, 2008b
Request from the European Commission related to the safeguard clause invoked by Hungary on maize MON810 according to Article 23 of Directive 2001/18/EC - Scientific opinion of the Panel on Genetically Modified Organisms	GMOs, maize (Zea mays), MON810, Hungary, safeguard clause, human health, animal health, environment, Directive 2001/18/EC	M-2008-0133	EFSA-Q-2008-316	Art 29 – Scientific opinion	15/05/2008	11/07/2008	http://www.efsa.europa.eu/en/efsajournal/pub/756.htm	EC, 2001	#8 EFSA, 2008c
Request to review recent scientific studies relating to the impact on the environment of the cultivation of two genetically modified maize plants: 1507 and	GMOs, maize (Zea mays), Bt11, 1507, insect resistance, Cry1Ab, Cry1F, human health, animal health, environment,	M-2008-0708	EFSA-Q-2008-679	Art 29 – Scientific opinion	08/08/2008	31/10/2008	http://www.efsa.europa.eu/en/efsajournal/pub/851.htm	EC, 2001	#9 EFSA, 2008a

Bt11	Directive 2001/18/EC								
Safeguard clause invoked by France under Article 23 of Directive 2001/18/EC on MON810 maize.	GMOs, maize (Zea mays), MON810, France, safeguard clause, emergency measure, human health, animal health, environment, Directive 2001/18/EC, Regulation (EC) No 1829/2003	M-2008-0077	EFSA-Q-2008-077	Art 29 – Scientific opinion	09/04/2008	31/10/2008	http://www.efsa.europa.eu/en/efsajournal/pub/850.htm	EC, 2001 EC, 2003c	#10 EFSA, 2008d
Safeguard clause invoked by Austria under Article 23 of Directive 2001/18/EC on MON810 and T25 maize.	GMOs, maize (Zea mays), MON810, T25, Austria, safeguard clause, human health, animal health, environment, Directive 90/220/EEC, Directive 2001/18/EC	M-2008-0131	EFSA-Q-2008-314	Art 29 – Scientific opinion	15/05/2008	10/12/2008	http://www.efsa.europa.eu/en/efsajournal/pub/891.htm	EC, 1990 EC, 2001	#11 EFSA, 2008e
Application for authorisation of genetically modified Maize NK603 and derived food and feed including Cultivation submitted under Regulation (EC) No 1829/2003 by Monsanto (EFSA-GMO-NL-2005-22)	GMO, maize (Zea mays), NK603, herbicide tolerant, glyphosate, cultivation, food and feed uses, food safety, feed safety, human and animal health, environment, Regulation (EC) No 1829/2003, Directive	M-2005-0300	EFSA-Q-2005-249	Application	12/05/2006	11/06/2009	http://www.efsa.europa.eu/en/efsajournal/pub/1137.htm	EC, 2001 EC, 2003c	#12 EFSA, 2009b

	2001/18/EC, renewal, existing products								
Application for renewal of authorisation for continued marketing of feed consisting and/or containing maize MON 810 and maize MON 810 for feed uses (including CULTIVATION) submitted under Regulation (EC) No 1829/2003 by Monsanto (EFSA-GMO-RX-MON810_20-1a)	GMO, maize (Zea mays), MON810, insect resistant, Cry1Ab, food safety, feed safety, human and animal health, environment, Regulation (EC) No 1829/2003, Directive 2001/18/EC, Directive 90/220/EEC, renewal, existing products	M-2007-0129	EFSA-Q-2007-153	Application	29/01/2008	30/06/2009	http://www.efsa.europa.eu/en/efsajournal/pub/1149.htm	EC, 1990 EC, 2001 EC, 2003c	#13 EFSA, 2009c
Development of guidance for the assessment of genetically modified plants used for non-food or non-feed purposes (Self-task WG)	Molecular farming, plant production platforms, GMO, GM plants, risk assessment, non-food, non-feed, phytoremediation, ornamental use, plant-made industrial compound (PMI), plant-made medicinal product (PMP), Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 726/2004, Regulation (EEC)	M-2007-0951	EFSA-Q-2007-176	Art 29 – Scientific opinion	26/09/2005	07/07/2009	http://www.efsa.europa.eu/en/efsajournal/pub/1164.htm	EC, 1993 EC, 2001 EC, 2003c EC, 2004b	#14 EFSA, 2009d

	No 2309/93								
General mandate - aspects of the environmental risk assessment (ERA) and the ERA guidance	GM plant, GMO, guidance document, environmental risk assessment, environmental safety, import, processing, cultivation, Regulation (EC) No. 1829/2003, Directive 2001/18/EC.	M-2008-0100	EFSA-Q-2008-262	Art 29 – Scientific opinion	19/03/2008	12/11/2010	http://www.efsa.europa.eu/en/efsajournal/pub/1879.htm	EC, 2001 EC, 2003c	#15 EFSA, 2010b
Self-tasking Working Group on the assessment of potential impacts of genetically modified plants on non-target organisms	Ecosystems services, environmental risk assessment (ERA), focal species, genetically modified (GM) plants, non-target organisms (NTOs), protection goals, species selection, unintended effects, tiered approach.	M-2008-0089	EFSA-Q-2008-089	Art 29 – Scientific opinion	18/03/2008	12/11/2010	http://www.efsa.europa.eu/en/efsajournal/pub/1877.htm	EC, 2001	#16 EFSA, 2010c
Update of the Guidance document for the risk assessment of food and feed from genetically modified plants	GMOs, GM plants, GM food, GM feed, guidance, applications, Regulation (EC) No 1829/2003, food safety, feed safety, risk assessment, comparative approach, stacked events, comparator, conventional	M-2003-0025	EFSA-Q-2008-05020	Art 29 – Scientific opinion	29/02/2008	24/05/2011	http://www.efsa.europa.eu/en/efsajournal/pub/2150.htm	EC, 2003c	#17 EFSA, 2011d

	counterpart								
Mandate to update the 2006 Opinion of the GMO Panel on the Post-Market Environmental Monitoring (PMEM) of GM plants.	Genetically Modified Plant (GMP), Environmental Risk Assessment (ERA), Post-Market Environmental Monitoring (PMEM), risk management strategies, Case-Specific Monitoring (CSM), General Surveillance (GS), protection goals, Directive 2001/18/EC.	M-2010-0444	EFSA-Q-2010-01253	Art 29 – Scientific opinion	10/01/2011	02/08/2011	http://www.efsa.europa.eu/en/efsajournal/pub/2316.htm	EC, 2001	#18 EFSA, 2011e
Application for authorisation of genetically modified Maize MON 88017 for cultivation submitted under Regulation (EC) No 1829/2003 by Monsanto (EFSA-GMO-CZ-2008-54)	GMO, maize (Zea mays), MON 88017, insect resistance, herbicide tolerance, cry3Bb1, CP4 epsps, risk assessment, food and feed safety, environment, environmental safety, food and feed uses, import and processing, cultivation, Regulation (EC) No 1829/2003	M-2008-0129	EFSA-Q-2008-312	Application	12/09/2008	10/11/2011	http://www.efsa.europa.eu/en/efsajournal/pub/2428.htm	EC, 2003c	#19 EFSA, 2011a
Updating the evaluation of the environmental risk assessment and risk	GMO, maize (Zea mays), 1507, insect resistance, non-	M-2010-0520	EFSA-Q-2010-01470	Art 29 – Scientific opinion	16/12/2010	18/11/2011	http://www.efsa.europa.eu/en/efsajour	EC, 2001	#20 EFSA, 2011b

management recommendations on insect-resistant genetically modified maize 1507 for cultivation	target organisms, Lepidoptera, environmental safety, post-market environmental monitoring, mathematical modelling						nal/pub/2429.htm		
Application for authorisation of genetically modified maize event GA21 and derived food and feed for import use including cultivation (EFSA-GMO-UK-2008-60)	GMO, maize (Zea mays), GA21, herbicide tolerance, mepsps, risk assessment, food and feed safety, environment, environmental safety, food and feed uses, import and processing, cultivation, Regulation (EC) No 1829/2003	M-2008-0464	EFSA-Q-2008-481	Application	21/10/2008	16/12/2011	http://www.efsa.europa.eu/en/efsajournal/pub/2480.htm	EC, 2003c	#21 EFSA, 2011c
Request to assess maize MON 810 PMEM report for the 2009 cultivation season	GMO, PMEM, annual report, cultivation, case-specific monitoring, general surveillance, insect-resistance management	M-2010-0445	EFSA-Q-2010-01254	Art 29 – Scientific opinion	21/01/2011	23/02/2012	http://www.efsa.europa.eu/en/efsajournal/pub/2376.htm	EC, 2001	#22 EFSA, 2012j
Request to assess the PMEM report of BASF for the cultivation of amylopectin potato EH92-527-1 (Amflora) in 2010	GMO, potato, PMEM, annual report, cultivation, case-specific monitoring, general surveillance	M-2011-0182	EFSA-Q-2011-00761	Art 29 – Scientific opinion	01/07/2011	23/02/2012	http://www.efsa.europa.eu/en/efsajournal/pub/2558.htm	EC, 2001	#23 EFSA, 2012k
EC request on complementary	GMO, maize (Zea mays), Bt11,	M-2011-0001	EFSA-Q-2011-00005	Art 29 – Scientific	06/01/2011	24/02/2012	http://www.efsa.europa.e	EC, 2001	#24 EFSA, 2012h

environmental risk assessment of GM maize Bt11	Cry1Ab, insect resistance, non-target organisms, Lepidoptera, environmental safety, post-market environmental monitoring, mathematical modelling			opinion			u/en/efsajournal/pub/2478.htm		
Request to assess maize MON 810 PMEM report for the 2010 cultivation season	GMO, PMEM, annual report, cultivation, case-specific monitoring, general surveillance, insect-resistance management, maize, MON 810	M-2011-0348	EFSA-Q-2011-01161	Art 29 – Scientific opinion	16/12/2011	11/04/2012	http://www.efsa.europa.eu/en/efsajournal/pub/2610.htm	EC, 2001	#25 EFSA, 2012l
Mandate for the assessment of the scientific elements supporting the prohibition of the placing on the market of GM maize MON 810 for cultivation purposes in France	GMO, maize (Zea mays), MON 810, France, emergency measure, environment, Regulation (EC) No 1829/2003	M-2012-0086	EFSA-Q-2012-00345	Art 29 – Scientific opinion	13/03/2012	21/05/2012	http://www.efsa.europa.eu/en/efsajournal/pub/2705.htm	EC, 2003c	#26 EFSA, 2012m
Establishing a database of bio-ecological information of non-target arthropod species to support the environmental risk assessment of genetically modified crops in the EU.	Biological control, non-target risk assessment, species selection, transgenic crops, genetically engineered crops	M-2010-0143	EFSA-Q-2010-00222	Procurement	25/03/2010	13/09/2012	http://www.efsa.europa.eu/en/supporting/pub/334e.htm	EC, 2001	#27 EFSA, 2012n
Application for authorisation of genetically modified soybean 40-3-2 for	GMO, soybean (Glycine max), 40-3-2, herbicide tolerance, CP4	M-2005-0302	EFSA-Q-2005-251	Application	29/09/2006	21/06/2012	http://www.efsa.europa.eu/en/efsajournal/pub/2753	EC, 2003c	#28 EFSA, 2012i

Cultivation submitted under Regulation (EC) No 1829/2003 by Monsanto (EFSA-GMO-NL-2005-24)	epsps, risk assessment, food and feed safety, environment, environmental safety, cultivation, Regulation (EC) No 1829/2003						.htm		
Request from the European Commission related to the safeguard clause invoked by Greece on maize MON810 according to Article 23 of Directive 2001/18/EC - Scientific opinion of the Panel on Genetically Modified Organisms	GMOs, maize (Zea mays), MON810, Greece, safeguard clause, human health, animal health, environment, Directive 2001/18/EC	M-2012-190	EFSA-Q-2012-00612	Art 29 – Scientific opinion	23/05/2012	11/09/2012	http://www.efsa.europa.eu/en/efsajournal/pub/2877.htm	EC, 2001	#29 EFSA, 2012o

(a) Date of acceptance of the mandate by EFSA
(b) Date of publication on the EFSA website (or anticipated date of publication corresponding to the deadline for publication if the project has not yet been published)

D. INVENTORY OF SCIENTIFIC OUTPUTS FROM THE PLH UNIT AND PANEL

Subject	Keywords	Mandate	Question Number and/or Project Number	Question type	Starting date [(a)]	Publication date[(b)]	URLs to EFSA website	Legislation related to the subject	Reference
Scientific opinion on the assessment of the risk of solanaceous pospiviroids for the EU territory and the identification and evaluation of risk management options	emergency measures, pepper, pospiviroids, potato, PSTVd, solanaceous ornamentals, tomato.	M-2010-0248	EFSA-Q-2010-00911	Art 29 – Scientific opinion	16/07/2010	3/11/2011	http://www.efsa.europa.eu/en/efsajournal/pub/2330.htm	EC, 2000a	#1 EFSA, 2011f
Guidance on the environmental risk assessment of plant pests	Biodiversity, ecosystem functioning, ecosystem services, environmental impact, environmental risk assessment, global change.	M-2010-0182	EFSA-Q-2010-00794	Art 29 – Scientific opinion	29/04/2010	09/12/2011	http://www.efsa.europa.eu/en/efsajournal/pub/2460.htm	EC, 2000a	#2 EFSA, 2011g

(a) Date of acceptance of the mandate by EFSA
(b) Date of publication on the EFSA website (or anticipated date of publication corresponding to the deadline for publication if the project has not yet been published)

E. INVENTORY OF SCIENTIFIC OUTPUTS FROM THE SAS UNIT

Subject	Keywords	Mandate	Question Number and/or Project Number	Question type	Starting date [a]	Publication date[b]	URLs to EFSA website	Legislation related to the subject	Reference
Bee Mortality and Bee Surveillance in Europe - A Report from the Assessment Methodology Unit in Response to Agence Francaise	not available	M-2008-0428	EFSA-Q-2008-428	Art 31 – Scientific and technical assistance	17/03/2008	11/08/2008	http://www.efsa.europa.eu/en/efsajournal/pub/154r.htm	EC, 1986 EC, 1996 EC, 2005	#1 EFSA, 2008f
Bee mortality and bee surveillance in Europe	Honey bee mortality, colony losses, colony collapse disorder, CCD, overwintering mortality, surveillance system, passive surveillance, active surveillance, risk factors, causative factors, Europe, assessment, SNAT, bee diseases, Varroa, Nosema, Acarapis, viral diseases, fungal diseases, beekeeping practice, pesticides, neonicotinoids, environmental factors, climatic factor, pollen quality, multifactorial, literature search method, epidemiological indicator, nutrition, weakening, migration, immunosuppression	M-2008-0428	EFSA-Q-2008-428 or CFP/EFSA/AMU/2008/02	Art. 36 - Grant	14/03/2008	03/12/2009	http://www.efsa.europa.eu/en/supporting/doc/27e.pdf	EC, 2011a	#2 EFSA, 2009a

Review of statistical methods and data requirements to support post market environmental monitoring of agroecosystems	not yet available	M-2012-0196	EFSA-Q-2012-00721	Art 31 – Scientific and technical assistance	09/07/2012	01/10/2014	EFSA (in preparation), URL not yet available	EC, 1992b EC, 2000a, b EC, 2009b, c EC, 2011a	#3 EFSA, in preparation

(a) Date of acceptance of the mandate by EFSA
(b) Date of publication on the EFSA website (or anticipated date of publication corresponding to the deadline for publication if the project has not yet been published)

F. INVENTORY OF SCIENTIFIC OUTPUTS FROM THE EMRISK UNIT

Subject	Keywords	Mandate	Question Number and/or Project Number	Question type	Starting date [a]	Publication date[b]	URLs to EFSA website	Legislation related to the topic of the scientific output	Reference
Inventory of studies conducted on bees, inside and outside EFSA, to identify cross-cutting issues and further research needs for a more integrated approach on the evaluation of risks to bees and their ecosystem services (inside EFSA inventory)	Inventory, bee, risk assessment, pesticides, genetically modified, animal and plant health, monitoring	M-2012-0151	EFSA-Q-2012-00530	Art 34 – Emerging risks	18/04/2012	31/10/2012	This report	EC, 2002a	#1 This report
Inventory of studies conducted on bees, inside and outside EFSA, to identify cross-cutting issues and further research needs for a more integrated approach on the evaluation of risks to bees and their ecosystem services (outside EFSA inventory and gap analysis)	not yet available	M-2012-0151	EFSA-Q-2012-00531	Art 34 – Emerging risks	18/04/2012	31/05/2013	URL not yet available	EC, 2002a	#2, EFSA, in preparation

(c) Date of acceptance of the mandate by EFSA
(d) Date of publication on the EFSA website (or anticipated date of publication corresponding to the deadline for publication if the project has not yet been published)

G. INVENTORY OF STORIES ON BEES FROM THE COMMS DIRECTORATE

Output/project	Type of communication	Date published and reference	URL	Reference
Scientific report: Bee Mortality and Bee Surveillance in Europe	**News story**: EFSA initiates pan-European research project on bee decline	15 December 2009	http://www.efsa.europa.eu/en/press/news/amu091215.htm	EFSA, 2009e
Bees Task Force set up	**News story**: Bee health - How EFSA is helping to protect our pollinators	30 March 2012	http://www.efsa.europa.eu/en/press/news/120330a.htm	EFSA, 2012p
Scientific Opinion on the science behind the development of a risk assessment of Plant Protection Products on bees	**News story**: Pesticides and bee health: EFSA reviews the science	23 May 2012	http://www.efsa.europa.eu/en/press/news/120523a.htm	EFSA, 2012q
Statement on the findings in recent studies investigating sub-lethal effects in bees of some neonicotinoids in consideration of the uses currently authorised in Europe	**Press release**: EFSA reviews studies on some pesticides and bee health	1 June 2012	http://www.efsa.europa.eu/en/press/news/120601.htm	EFSA, 2012r
Understanding Science. EFSA video clips	**Video**: Why bees are under threat?	17 July 2012	http://www.efsa.europa.eu/en/news/videos.htm	EFSA, 2012s

GLOSSARY

AF-SCO	Advisory Forum and Scientific Cooperation of EFSA
AHAW	Animal Health and Welfare Unit of EFSA
Anses	Agence Nationale de Sécurité Sanitaire de l'Alimentation, de l'Environnement et du Travail
APENET	National Italian Bee Monitoring Network
bt	*Bacillus thuringiensis*
CSM	Case-Specific Monitoring
CCD	Colony Collapse Disorder
COLOSS	Prevention of Honeybee Colony Losses
COMMS	Communications Directorate of EFSA
CSM	Case-Specific monitoring
DAR	Draft Assessment Report
DG	Direction-Générale
EC	European Commission
EEA	European Environment Agency
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EMRISK	Emerging Risks Unit of EFSA
EP	European Parliamant
ERA	Environmental Risk Assessment
EU	European Union
EURL	European Union Reference Laboratory
EUROSTAT	organization within the European Union that collects and collates statistical information relating to member states
FAOSTAT	FAO Statistical Databases (*United Nations*)
FP	Framework Programme
GECU	Groupe d'Expertise Collective d'Urgence
GM	Genetically Modified

GMO	Genetically Modified Organism
GMP	Genetically Modified Plant
GS	General Surveillance
IRM	Insect Resistance Management
IUCLID	International Uniform ChemicaL Information Database
LD50	Dose required killing half the members of a tested population after a specified test duration
MEA	Millenium Ecosystem Assessment
MRL	Maximum Residue Level
MS	Member States
NOAEL	No Observable Adverse Effect Level
NT	Non Target
NTO	Non Target Organism
OECD	Organization for Economic Co-operation and Development
PEIP	Pesticide Effects on Insect Pollinators
PLH	Plant Health Unit of EFSA
PMEM	Post Market Environmental Monitoring
PPP	Plant Protection Product
PPR	Plant Protection Residue
PRAS	Pesticide Risk Assessment Unit of EFSA
PSTVd	*Potato spindle tuber viroid*
QSAR	Quantitative Structure-Activity Relationships
RA	Risk Assessment
RoQ	Register of Questions
RRSG	Registration Steering Group
RSG	Risk Reduction Steering Group
RUD	Residue Unit Dose
SAS	Scientific Assessment Support Unit of EFSA

SCISTRAT	Science Strategy and Coordination Directorate of EFSA
SCoFCAH	Standing Committee on the Food Chain and Animal Health
SPG	Specific Protection Goal
STEP	Status and Trends of European Pollinators
TF	Task Force
ToR	Terms of Reference
UK	United Kingdom
UNEP	United Nations Environment Programme