

# European Food Safety Authority (EFSA)

## Bee health

Beekeeping is an ancient tradition, and honey bees have been kept in Europe for several millennia. Bees are critically important in the environment, sustaining biodiversity by providing essential pollination for a wide range of crops and wild plants. They contribute to human wealth and wellbeing directly through the production of honey and other food and feed supplies such as: pollen, wax for food processing, propolis in food technology, and royal jelly as a dietary supplement and ingredient in food.

The Food and Agriculture Organization of the United Nations (FAO) estimates that of the 100 crop species that provide 90% of food worldwide, 71 are pollinated by bees[1]. The majority of crops grown in the European Union depend on insect pollination. Beyond the essential value of pollination to maintaining biodiversity, the global annual monetary value of pollination has been estimated at hundreds of billions of euros.

In view of the important ecological and economic value of bees, there is a need to monitor and maintain healthy bee stocks, not just locally or nationally, but globally.

### Bees in decline

Over the past 10 to 15 years, beekeepers have been reporting unusual weakening of bee numbers and colony losses, particularly in Western European countries including France, Belgium, Switzerland, Germany, the UK, the Netherlands, Italy and Spain. In North America, colony losses observed since 2005 have left the region with fewer kept bees than at any time in the past 50 years. American scientists have coined the term Colony Collapse Disorder (CCD) to describe this phenomenon. CCD is often characterised by the rapid loss from a colony of its adult worker bee population.

No single cause of declining bee numbers has been identified. However, several contributing factors have been suggested, acting in combination or separately. These include the effects of intensive agriculture and pesticide use, starvation and poor bee nutrition, viruses, attacks by pathogens and invasive species – such as the Varroa mite (*Varroa destructor*), the Asian hornet (*Vespa velutina*), the small hive beetle *Aethina tumida* and the bee mite *Tropilaelaps* – genetically modified plants, and environmental changes (e.g. habitat fragmentation and loss).

In May 2012, as part of its strategy for tackling declining bee numbers, the European Commission allocated €3.3 million to support 17 Member States carrying out surveillance studies aimed at gathering further information on losses of honey bee colonies. The commitment follows a report, *Bee Surveillance and Bee Mortality in Europe*, commissioned by EFSA which concluded that surveillance systems in the EU are weak and that there is a shortage of data at Member State level and a lack of comparable data at EU level (see EFSA's activities).

## EFSA's role

EFSA has an important role to play in ensuring that healthy bee stocks are maintained in Europe, given its mandate to improve EU food safety and animal health and to ensure a high level of consumer protection. A number of the Authority's Scientific Panels and Units contribute to this work, principally in the areas of **pesticides**, **animal health and welfare** and **plant health**, **genetically modified organisms (GMOs)**, **data collection** and **scientific assessment**.

Central to this work are the assessments EFSA carries out of the environmental safety of pesticides and GMOs that manufacturers would like to place on the EU market. EFSA's **Pesticides Unit** is responsible for the peer review of risk assessments of active substances used in plant protection products. The dossiers submitted by applicants must contain comprehensive information on the potential risk to the environment posed by their products.

The Unit also carries out risk assessments of Maximum Residue Levels (MRLs) of active substances in pesticides. These assessments take account of the potential effects of the substances on the environment in general and on non-target organisms such as bees in particular. The Unit compiles the annual European Union Report on Pesticide Residues in Food, which gives an overview of the control activities performed in the 27 EU Member States and two EFTA countries (Iceland and Norway) in order to ensure compliance of food with the standards defined in European legislation on pesticide residues. The most recent report, for 2009, shows that only 0.1% of honey samples contained pesticides which exceeded MRLs.

EFSA's **Panel on Plant Protection Products and their Residues** (PPR Panel) provides independent scientific advice on the risk assessment of plant protection products and their residues. This includes in particular looking at risks to operators, workers, residents and consumers as well as the environment, including wildlife. One of the main activities of the PPR Panel is to develop new or review existing guidance documents on the risk assessment of pesticides, including the development of risk

assessment approaches, methodologies and models. The Panel may provide opinions on the effects of specific active substances used in plant protection products or on any generic issue related to the safe use of pesticides.

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 the **GMO Panel** is to independently evaluate the risk assessments provided by companies and manufacturers and to give scientific advice to risk managers on any risks that GMOs may pose to human and animal health and the environment. The assessment covers several specific aspects of risk, one of which is the possible risk to "non-target organisms" such as bees. The Panel has developed guidelines for the safety assessment of GM plants and derived food and feed that assist companies and manufacturers to prepare applications for the authorisation of GM plants. In 2010, the GMO Panel updated its guidance with respect to environmental risk assessment of GM plants, and specific guidance has been developed on the evaluation of possible effects of GM plants on non-target organisms.

In addition, each application for authorisation of a GM plant has to be accompanied by a Post-Market Environmental Monitoring (PMEM) 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 PMEM is to identify possible unanticipated adverse effects on the environment which could arise directly or indirectly from cultivation of GM plants. In 2006, EFSA's GMO Panel provided applicants with guidance for developing PMEM plans, which was updated in 2011. Since 2010, the GMO Panel has been responsible for assessing the annual PMEM reports which are submitted to the European Commission for each GM crop authorised for cultivation in the EU (currently maize MON810 and the Amflora potato).

The **Panel on Plant Health** provides independent scientific advice on the risks posed by organisms which can cause harm to plants, plant products or plant biodiversity in the European Community. Every pest risk assessment includes the assessment of environmental risk, but to clarify and harmonise approaches in this area the Panel has published specific guidance on the environmental risk assessment of plant pests. EFSA's work in the area of plant health is specifically relevant to bee health as some pests that are a threat to bees can be transported by, and live on, plants. The small hive beetle, for example, can live without bees, surviving on fruit and vegetables. It could therefore be introduced into the EU in consignments of such products.

The **Panel on Animal Health and Welfare** provides independent scientific advice on all aspects of animal diseases and animal welfare. Its work chiefly concerns food-producing animals.

The **Dietary and Chemical Monitoring Unit** publishes an annual report summarising data on the presence of residues of veterinary medicinal products and other substances in live animals and animal products – such as honey – in the European Union. The latest report, for 2010, shows that only 0.33 % of the 418,081 targeted samples were non-compliant, a similar figure to that recorded in 2009 (0.32%).

## EU framework

In 2010 the European Commission issued a Communication on Honeybee Health, which clarified the key issues related to bee health and the key actions that the Commission is taking to address them.

- [Communication from the European Commission on honeybee health](#)

### Animal health and welfare

Bees are covered by the Animal Health Strategy for the European Union 2007-2013, and legislation on animal health certification and requirements for the movement of bees between Member States (Directive 92/65/EEC). These requirements are intended to prevent and control a number of bee diseases and pests such as the small hive beetle (*Aethina tumida*) and the *Tropilaelaps* mite, which can spread via the movement of bees and trade in hive products, plants and fruit. There are also animal health requirements for imports from third countries of live bees and bumble bees to avoid introduction into the EU of exotic bee diseases. These have been applied since 2000 (Regulation 206/2010).

The Animal Health Strategy is intended to provide a single and clear regulatory framework for animal health. The Commission is currently preparing a proposal for an **Animal Health Law** which will over time replace the current basic veterinary legislation of almost 60 Directives and Regulations on animal health conditions for trade and import of live animals and their products. The Commission is still assessing possible implications for the bee sector. However, a general Animal Health Law could provide the legal framework for essential elements such as general definitions, and principles for disease control measures and movements, while other elements could be established through delegated or implementing acts.

- [Animal Health Strategy](#)
- [Directive 92/65/EEC](#)
- [Regulation \(EU\) No 206/2010](#)

## Pesticides

Pesticide residues may be taken up by bees during the collection of nectar and/or pollen and water. A Regulation was adopted in 2009 concerning the placing of plant protection products on the market, replacing Council Directive 91/414/EEC. The new Regulation – 1107/2009 – maintains the provision that pesticides can be approved at EU level only if their use has no unacceptable effect on bee health or leads to negligible exposure of honey bees. This regime is underpinned by MRLs, which are set to protect consumers and to make trade possible in products containing residues. MRLs for pesticide residues are set in the framework of Regulation 396/2005.

- [Regulation 1107/2009](#)
- [Regulation 396/2005](#)

## Genetically modified organisms

Before a GMO can be used or cultivated, it must be authorised under Directive 2001/18/EC or Regulation 1829/2003 following a thorough scientific evaluation by EFSA that includes the potential adverse effects on bees.

- [Directive 2001/18/EC](#)
- [Regulation 1829/2003](#)

## Plant health

The aim of the EU plant health regime, established by [Council Directive 2000/29/EC](#), is to prevent the introduction of organisms harmful to plants or plant products or their spread within the EU. Every pest risk assessment includes the assessment of environmental risks.

- [Council Directive 2000/29/EC](#)

## Residues of veterinary medicinal products in foodstuffs of animal origin

Regulation 37/2010 establishes maximum limits for residues of veterinary medicinal products in animals and animal products, including honey. Council Directive 96/23/EC lays down measures to monitor certain substances and residues thereof, mainly veterinary medicinal products, in live animals and animal products. Additionally, Commission Decision 97/747/EC lays down levels and frequencies of sampling for certain animal products.

- [Regulation 37/2010](#)
- [Directive 96/23/EC](#)
- [Decision 97/747/EC](#)

## EFSA's activities

In 2009 EFSA launched a project to assess bee surveillance systems in the EU, and to collate and analyse data and publications related to honey bee colony mortality across Europe. The Agence Française de Sécurité Sanitaire des Aliments (AFSSA, forerunner of Anses) set up a consortium of seven European bee disease research institutes to answer the call for data and a literature review. The subsequent report *Bee Mortality and Bee Surveillance in Europe* made a number of recommendations to improve surveillance as well as identifying consensus across the EU on the multifactorial origins of the decline in bee numbers. It also helped to shape the Commission's strategy for tackling the decline in bee numbers across Europe, which was clarified in a key communication on honey bee health published in 2010.

- [Communication from the European Commission on honeybee health](#)

In February 2012 the Pesticides Unit reviewed the risk of thiamethoxam to honeybees, as requested by the European Commission, on the basis of new information submitted. Thiamethoxam is a member of the neonicotinoid group of insecticides, which some studies suggest could be a contributing factor to bee colony losses. The use of neonicotinoids is restricted in Germany, Italy, France and Slovenia.

In April 2012, EFSA's **Emerging Risks Unit** participated in a working group set up by Anses to review a scientific paper on the combined impact of bee pathogens (*Nosema ceranae*) and low doses of pesticides on honey bee mortality and to ensure

closer scientific collaboration between EFSA and Anses on the risk assessment of bees. The working group concluded that more research is required on the toxicokinetic characteristics of the chemicals with which bees come into contact in the environment and that the new schemes for assessing the potential risk to bees from plant protection products (see Main work in progress) need to include bee exposure to low and repeated doses of pesticides. Anses is to set up a new working group to follow up on this issue.

## Main work in progress

In line with the strategy of EFSA to consider risk assessments in a wider, more integrated manner so as to provide risk managers with comprehensive advice on which to base their decisions, the Authority established in May 2012 an internal task force drawn from the relevant Units to compile a state-of-the-art review of the work carried out at EFSA, as well as the current activities conducted outside EFSA, in the area of bees.

The task force, coordinated by the Emerging Risks Unit, will identify gaps in knowledge and research needs and prepare a report giving an overview of EFSA's current activities and making recommendations on how this work should be continued.

- [Internal task force mandate](#)

The main focus of the Authority's work on bees is a major guidance document on the risk assessment of pesticides in relation to honey bees, bumble bees and solitary bees, which is being developed by the PPR Panel. As a precursor, in April 2012 the Panel adopted an opinion outlining the scientific basis for the development of the guidance document.

- [Opinion on science behind guidance on risk assessment of plant protection products and bees](#)

In addition to the above, the PPR Panel has commissioned literature reviews on topics of relevance to its revision of the guidance documents for assessing risks from pesticides related to aquatic and terrestrial ecotoxicology. One of these topics concerns the effects on bees of the interaction between pesticides and other factors.

- [Mandate to revise guidance on Aquatic Ecotoxicology](#)
- [Mandate to revise guidance on Terrestrial Ecotoxicology](#)

The Pesticides Unit has also delivered a statement on two articles published recently in the journal *Science* which suggested links between neonicotinoids and bee colony survival. The first article highlighted research showing that honey bees exposed to sub-lethal doses of thiamethoxam suffer from impaired orientation skills, and concluded that commonly encountered concentrations of thiamethoxam can contribute to the collapse of colonies. The second article concluded that imidacloprid, another neonicotinoid, can inhibit the reproductive health of bumble bees. The European Commission asked EFSA to examine whether the doses used in the studies are comparable to the actual doses to which bees are exposed.

- [Statement on the findings in recent studies investigating sub-lethal effects in bees of some neonicotinoids](#)

EFSA will continue its work in this area by carrying out an in-depth review of the effects of thiamethoxam, imidacloprid and three other neonicotinoids: clothianidin, acetamiprid and thiacloprid. The review, due to be published in December 2012, will pay particular attention to acute and chronic effects on bee colony survival and development, taking into account the effects on bee larvae as well as bee behaviour. In this context, an assessment of effects of sub-lethal doses on bee survival and behaviour will be further considered.

Experts from EFSA's Animal Health and Welfare and Plant Health Panels and Units, and the Emerging Risk Unit are currently drafting a scientific opinion on the risk of introduction and spread in the EU of the small hive beetle (*Aethina tumida*) and the *Tropilaelaps* bee mite through the importation from third countries of live bees and bee products, and of products such as fruit and vegetables.

In addition, EFSA is assessing the scientific basis for Italy's precautionary suspension of the placing on the market of treated maize seeds. The Authority has been requested to deliver a statement on the results of an Italian research project (APENET).