16 Seed-dressing systemic insecticides and honeybees

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In 1994 French beekeepers began to report alarming signs. During summer, many honeybees did not return to the hives. Honeybees gathered close together in small groups on the ground or hovered, disoriented, in front of the hive and displayed abnormal foraging behaviour. These signs were accompanied by winter losses.

Evidence pointed to Bayer's seed-dressing systemic insecticide Gaucho®, which contains the active substance imidacloprid. This chapter presents the historical evolution of evidence on the risks of Gaucho® to honeybees in sunflower and maize seed-dressing in France, and analyses the actions in response to the accumulating evidence regarding these risks.

The social processes that ultimately lead to application of the precautionary principle for the ban of Gaucho® in sunflower and maize seed-dressing are described, with a focus on the ways in which scientific findings were used by stakeholders and decision-makers to influence policy during the controversy.

Public scientists were in a difficult position in this case. The results of their work were central to a social debate with high economic and political stakes. In certain cases their work was not judged according to its scientific merit but based on whether or not it supported the positions of some stakeholders. This situation tested the ability and courage of researchers to withstand pressure and continue working on imidacloprid.

Other European countries also suspended neonicotinoid seed-dressing insecticides. Evidence of the toxicity of neonicotinoids present in the dust emitted during sowing of coated seeds supported such decisions. Most important, the French case highlighted the major weaknesses of regulatory risk assessment and marketing authorisation of pesticides, and particularly neonicotinoids. These insights were recently confirmed by work by the European Food Safety Authority.

From this case study eight lessons are drawn about governance of controversies related to chemical risks. The study is followed by two additional texts. A first panel presents Bayer Crop Science's comments on the analysis in this chapter. A second contains the authors' response to the Bayer comments.

16.1 Introduction

Insecticides come in various forms. Many coat the surface of plants but systemic insecticides work differently, entering a treated plant's sap via the leaves or roots and coming into contact with insects when they feed on the plant. Seed-dressings and soil treatments operate in precisely this way. The active ingredient enters the roots and disperses to the aerial parts of the plant during growth, offering long-lasting protection from aerial and soil pests.

Some systemic insecticides are neonicotinoids, which have been widely used in seed-dressing and soil treatment since the early 1990s but can also be applied by spraying crops. Over the past decade they have become the most widely used class of insecticides worldwide, with total sales of EUR 1.5 billion in 2008 (24 % of the global insecticide market). By 2010, the first neonicotinoid, imidacloprid, was registered in more than 120 countries for foliar and seed treatment (Jeschke and Nauen, 2008; Jeschke et al., 2010).

In some situations, authorised doses of systemic insecticides can affect beneficial insects like honeybees, bumblebees, biological control agents (Smith and Krischik, 1999; Kunkel et al., 2001; Desneux et al., 2007; Rogers et al., 2007; Katsarou et al., 2009; Mommaerts et al., 2009), birds (Berny et al., 1999) and earthworms (Luo et al., 1999; Kreutzweiser et al., 2008; Capowiez et al., 2009). More than 25 000 species of bees exist and are crucial for the survival and evolution of about 80 % of the flowering plant species that depend on animal pollination (FAO, 2011).

The widespread use of systemic insecticides raises serious concerns about their threat to wild pollinators (EPA, 2003; Greatti et al., 2006; Bortolotti et al., 2002; Desneux et al., 2007). Declines in wild pollinators are reported worldwide (Allen-Wardell et al., 1998; Steffan-Dewenter et al., 2005; Biesmeijer et al., 2006), which is particularly worrying since they are essential for 35 % of global crop output (by weight) (Klein et al., 2006). This has lead to growing concern about agriculture's dependence on pollinators and fears of a global pollination crisis (Ghazoul, 2005a and 2005b; Klein, 2008; Aizen and Harder, 2009).

Many factors influence the state of honeybees and pollinators more generally. Land use practices and agrochemicals are regarded as particularly important (Kuldna et al., 2009). This chapter focuses on the risk to honeybees resulting from the seed-dressing systemic insecticide Gaucho®, whose active substance is imidacloprid. Specifically, it examines the vehement controversy in France over the use of Gaucho® and the justifications that ultimately lead to banning its use on sunflower and maize seed-dressing in that country. Another

Box 16.1 Honeybees, wild bees and other pollinators

In Europe, pollination (i.e. the transport of pollen from producing anthers to receiving stigma) is mainly achieved by three means:

- *passive self-pollination* (direct contact between anthers and stigma or transfer through gravity), which is rarely the dominant pollination route;
- *transport by the wind*, which is the dominant pollination route for about 10 % of flowering plants;
- *pollination by animals, particularly insects*, which is the dominant pollination route for the other flowering plant species — 87 of the leading global food crops depend on animal pollination, compared to 28 crops that do not (Klein, 2007).

Worldwide, honeybees have a major role in pollinating:

- *vegetable crops*, such as watermelon, cantaloupe, melon, cucumber, gherkin, pumpkin, squash, gourd, marrow and zucchini;
- *fruit crops,* such as apple, peach, nectarine, kiwi fruit, mango, avocado, plum, pear, sweet cherry, sour cherry, apricot, mirabelle, raspberry, blackberry, cloudberry, dewberry, rowanberry, cranberry, greengage, sloe, carambola, starfruit, durian, loquat, Japanese plum, Japanese medlar, rose hips and dogroses;
- *nut crops*, such as almond, cashew nut, cashew apple and macadamia;
- *edible oil and proteinaceous crops*, such as canola and turnip rape;
- *spices and condiments*, such as coriander, cardamom and fennel (Klein et al., 2007).

Box 16.2 The life of a honeybee

An adult summer worker honeybee lives about four or five weeks. Three days after being laid, the egg becomes a **larva**, which in turn becomes a **nymph** after about six more days. During the following 12 days, the nymph transforms into an adult honeybee.

During its **adult life**, the honeybee fulfils several roles. At first it stays in the hive as a **nurse**, cleaning the hive and nourishing the larvae. After 10–14 days it stores the collected nectar and pollen, ventilates the hive, covers the cells, secretes beeswax and builds new cells. At the end of the period spent inside the hive, it can be a **guard**. After about three weeks inside the hive and until death, the honeybee is a **forager**, and works outside the hive, collecting pollen, nectar, water and propolis. The division of tasks and the age for going from one task to another can vary, depending on the needs of the colony.

Honeybees feed exclusively on pollen, nectar and honey. It is estimated that most of the foraging activity is undertaken within 6 km of the hive, although honeybees can forage up to 12 km from the hive (von Frisch, 1967; Seeley, 1985; Winston, 1987).

Pollen foragers collect pollen on flowers and carry it to the hive on their posterior legs. Nectar foragers transport nectar in their crop and bring it to the colony. It can be consumed immediately or transformed into honey by water evaporation and changes in sugar composition. Pollen and honey are stored in the hive and can be consumed later.

Nectar and pollen are consumed differently by honeybees of different ages:

- Larvae essentially consume jelly, which is secreted from the glands in nurses' heads and also some pollen, depending on their age.
- Nurses consume pollen, essentially to develop their hypopharyngeal and mandibular glands and to produce jelly.
- Adult honeybees consume different quantities of nectar/honey, depending on the tasks they perform. Large amounts of nectar/honey are consumed for wax production, heat production in the hive (brood-attending bees and winter bees) and for foraging (Rortais et al., 2005; Benjamin and McCallum, 2008).

seed-dressing insecticide, Régent TS® (which contains the active substance fipronil) is also addressed, although not extensively as telling its story would require a chapter of its own.

In this chapter we describe and analyse the social processes that lead to the application of the precautionary principle in France. Scientific data played an important role in these processes. We describe the ways in which stakeholders have used scientific findings to influence policy during the controversy. The scientific data considered in this chapter are thus not exhaustive but selected to reflect the French debate.

The French ban on Gaucho® is significant because insecticides containing imidacloprid are among the most used globally (Jeschke et al., 2010) and have a wide range of uses. At its launch, Gaucho® was marketed as a means of reducing aerial pollution because it was supposedly confined to the soil and very small amounts are applied to seeds. For sunflower the application was 0.7 mg/seed, which amounts to 56–70 g of imidacloprid per hectare (Belzunces and Tasei, 1997). For maize the application was 0.98 mg/seed.

Despite these claimed advantages, France banned the insecticide's use in sunflower and maize seed-dressing due to concerns about its risks to honeybees. In this chapter, we present the historical evolution of the evidence regarding the risks of Gaucho® to honeybees in sunflower and maize seed-dressing and analyse the actions taken in response to the accumulating evidence regarding these risks.

Knowledge can vary in its relevance for supporting an action such as banning imidacloprid. Different stakeholders may perceive the relevance differently, with three factors playing a key role:

1. The scientific quality of the knowledge (**substantive quality**), which includes technical aspects (is the measurement accurate?), methodological aspects (is a particular method appropriate for the intended use?) and epistemological aspects (is enough knowledge available?).

Box 16.3 Uses of imidacloprid in France

In July 2010, imidacloprid was authorised in France to treat fruit trees such as apricot, peach, pear, quince, apple and plum trees. It is also present in products for disinfecting storage facilities, shelters for domestic animals, storage and transport material, treatment facilities for waste and transport material. Other uses include insecticidal treatment of rose bushes.

In France, imidacloprid is currently banned for seed-dressing of sunflower and maize but it is still used in seed-dressing for sugar beet, wheat and barley (Ministère de l'Agriculture, 2011). Residues subsisting in the soil might potentially be taken up by the crops cultivated after the seed-treated crop, or by wild plants (Bonmatin et al., 2005).

2. The quality of the research processes that have generated the knowledge and the expert processes that are used to assess its relevance to support an action (**procedural quality**) ([1]). This relates to researchers' and experts' competence, field experience, institutional affiliation, well-being at work, financial dependencies and other kinds of relationships among themselves and with other stakeholders (for instance, whether or not local knowledge is incorporated in the research).

3. The **social quality**, associated to the value judgments influencing the communication and use of scientific information by experts themselves and by stakeholders, in political debates.

In Sections 16.2, 16.3 and 16.4, we present the development of knowledge in these three areas. The first part of this chapter (Section 16.4.3 included) describes in detail the French controversy until the ban of Gaucho® on maize in 2004. Sections 16.4.4 and 16.4.5 are less exhaustive and result essentially from reactions to the different comments made during the reviewing process.

Many scientific and grey references have been produced in the world since 2004 and we could not include them all, in order not to loose focus but also for reasons of space limits. We have included post-2004 references if: 1) they were produced in France and 2) they were produced in European countries where regulatory decisions have been taken to ban imidacloprid.

The analysis yields lessons about the quality and use of knowledge in risk assessment and management ([2]), which are presented in Section 16.5. Conclusions and prospects are presented in Section 16.6.

16.2 Development of scientific understanding of the issue

16.2.1 Technical and epistemological quality of the evidence

1994: early warnings

In France, dressing seeds with Gaucho® was authorised in 1991 for sugar beet, in 1992 for maize and in 1993 for sunflower. Gaucho® was first used in sunflower farming in 1994. After that year, beekeepers started to report alarming clinical signs. After several days of foraging during the sunflower flowering, many honeybees did not return to their hives. Bee behaviour also caused concern: honeybees gathered close together in small groups on the ground or hovered disoriented in front of the hive; foraging behaviour was abnormal; and queens produced increased amounts of brood to compensate for the loss of foragers. In certain cases, dead honeybees were also reported in front of the hives.

In affected apiaries, most hives were impacted. Those apiaries suffered a 40–70 % loss in sunflower honey yield in the years after 1994, relative to the average yield obtained in previous years. Before 1994, the annual yield variation had been ± 10 %. At the end of winter, losses were up to 30–50 % of the hives, compared with the usual 5–10 % (personal communications from 20 beekeepers; Coordination des Apiculteurs, 2001; Alétru, 2003).

([1]) For example, the expert process by which the 'acceptability' of a calculated risk is assessed in official commissions or working groups. Such an assessment determines an action, that is, the use or not of a substance in crop protection.

([2]) For more details on the case, see Maxim and Van der Sluijs, 2007.

In the following years the beekeepers reported the same clinical signs and their specific impacts on honeybees foraging in sunflowers and maize areas (e.g. Belzunces and Tasei, 1997; CNEVA Sophia-Antipolis, 1997; Pham-Delègue et Cluzeau, 1998; Coordination des Apiculteurs, 2001; Alétru, 2003). The intensity of the clinical signs in France fluctuated, both temporally (from year to year) and spatially. They seemed to depend on factors such as the proportion of the different food resources present in the honeybees' environment (CST, 2003).

Appreciable declines in sunflower honey harvest were reported, implying major economic losses. Searching for possible causes, the beekeepers found that Gaucho® had been first used as a seed-dressing in sunflower farming in 1994. They reported honeybee problems increasing concomitantly with the area of Gaucho®-dressed sunflower (Chauvency, 1997; Belzunces and Tasei, 1997; CNEVA Sophia-Antipolis, 1997; Pham-Delègue and Cluzeau, 1998). Consequently, beekeepers asked Bayer (which manufactures Gaucho®) for information about the potential toxicity of the active substance imidacloprid for honeybees (Coordination des Apiculteurs, 2000).

This request was the start of a long series of scientific studies ([3]) involving Bayer-funded scientists, the Ministry of Agriculture, the French Food Safety Agency (AFSSA), beekeepers, and researchers working in public institutes ([4]) (henceforth 'public scientists').

Evolution of knowledge over time

When Gaucho® was launched commercially, the manufacturer considered that it posed no risk to honeybees, provided it was applied as seed-dressing (Bayer, 1992).

Bayer's reaction to the beekeepers demand was to conduct field and semi-field (under-tunnel ([5])) research. According to Bayer these studies showed that Gaucho® posed no risk to honeybees (Belzunces and Tasei, 1997).

However, the clinical signs continued. Bayer's experiments were presented at the Fourth International Conference on Pests in Agriculture, held in Montpellier on 6–8 January 1997, and also during a meeting organised by the Association de Coordination Technique Agricole (ACTA) in October 1997. They were criticised (ACTA, 1997; Belzunces and Tasei, 1997), so public scientists were also asked to research the issue.

Honeybee exposure to imidacloprid: 1993–1999

One of the main issues in assessing exposure to Gaucho® was the precision of measuring very low concentrations of imidacloprid in pollen and nectar. In 1993, the detection limit established by Bayer-funded scientists for measuring the presence of imidacloprid in plants was 10 ppb ([6]) (Placke and Weber, 1993). However, it was later found that much lower detection limits (DL) were needed to identify imidacloprid's presence in pollen and nectar.

The studies undertaken by Bayer during this period either could not detect imidacloprid in pollen and nectar, or detected it but could not quantify it (CST, 2003). In 1999, a study quantified the substance in sunflowers treated with Gaucho® to be 3.3 ppb in pollen and 1.9 ppb in nectar (Stork, 1999).

When public research started (1997–1998), the General Directorate for Food of the Ministry of Agriculture (DGAL) demanded analyses using 'the lowest detection limit possible', but 'without going below 0.01 mg/kg' (10 ppb) ([7]). For the 1998 programme DGAL noted that 'it is not useful to try to work with the lowest detection limits' ([8]). This DL corresponded to the characteristics of the Bayer method (Pflanzenschutz Nachrichten Bayer, 46.1993.2 inverse chromatography in liquid phase and UV detection). Bayer representatives also participated in the committee charged with developing the research protocol.

At the time that the DGAL demanded the analysis, CETIOM (the Technical Center for Oilseed Crops ([9])) had already estimated that detection limits much

([3]) In the following, we have selected the data that played an important role in the debate, rather than uselessly trying to inventory all the data available. The complete list of the results available before 2003 is available in CST (2003).

([4]) In France, scientists working in national research institutes (e.g. INRA, CNRS) and universities are public servants. Their entire salaries and a part of their functioning (sometimes equipment) expenses are funded by the public institution.

([5]) A tunnel is a tent of several meters, which allows air to pass through and isolates the honeybee colony being used for testing from the exterior. The purpose of a tunnel is to ensure that honeybees only feed on the source chosen for the experiment (e.g. plants contaminated with imidacloprid), while simulating field conditions.

([6]) The unit 'ppb' (parts per billion) is used for very low mass concentrations, more precisely 10^{-9} (e.g. 1 ppb = 1 µg/kg).

([7]) In the original French: 'sans toutefois descendre à une valeur inférieure à 0.01 mg/kg'.

([8]) In the original French: 'il n'est pas utile de chercher à travailler avec la limite de détermination la plus basse possible'.

([9]) Centre Technique Interprofessionnel des Oléagineux Métropolitains.

lower than 10 ppb — about 1.4 ppb — were necessary to find imidacloprid in nectar.

Print media learned of the DGAL's recommendation and of Bayers implications in drafting the protocol, raising doubts about the DGAL's impartiality with respect to Bayer and about its willingness to find relevant results (Libération, 1999a).

These first studies of public researchers reported the presence (< 10 ppb) of imidacloprid in sunflower leafs and pollen but did not quantify it (Pham-Delègue and Cluzeau, 1998).

The findings from research 'raised suspicions about the effects of the product, without formally proving its responsibility' ([10]) (Ministère de l'Agriculture, 2001b). Doubts about the harmlessness of Gaucho® led to the application of the precautionary principle. In January 1999 the Minister of Agriculture, Jean Glavany, decided to ban the use of Gaucho® in sunflower seed-dressing (Libération, 1999b).

This ban was renewed in 2001 for two years, again in 2004 for three years and at present, February 2012, it is still in force.

Honeybee exposure to imidacloprid: 2000–2002
Beekeepers continued to report clinical signs of intoxication after Gaucho® use in sunflowers was suspended in 1999. Three explanatory hypotheses were proposed:

- honeybees were still being exposed to the pollen of maize treated with Gaucho® (sunflower and maize are in flower in the same time);
- imidacloprid persists in soil after treatments of other crops (such as sugar beet, wheat and barley) and was taken up by untreated sunflowers grown one or more years after a seed-dressed crop;
- honeybees were affected by the dressing of sunflower seeds with RégentTS®, which had been provisionally authorised in December 1995.

Following the extension of the ban on using Gaucho® on sunflower and the refusal to ban it on maize, in 2001 (Ministère de l'Agriculture, 2001a; Conseil d'Etat, 2002), the Ministry of Agriculture established a Scientific and Technical Committee for the Multifactor Study of the Honeybee Colonies Decline (henceforth the 'CST' ([11])).

Between 2000 and 2002, using different methods and lower detection limits, public scientists identified 2–4 ppb of imidacloprid in seed-dressed sunflower and maize pollen (Bonmatin et al., 2001 and 2002; Bonmatin and Charvet, 2002), 13.3 ppb of imidacloprid in seed-dressed sunflower pollen (Laurent and Scalla, 2001) and 1.6 ppb in seed-dressed sunflower nectar (Lagarde, 2000).

During these years, it was understood that honeybees could collect imidacloprid-contaminated nectar and pollen for up to a month of sunflower and maize flowering. Bees could show the effects of repeated consumption of contaminated pollen and nectar almost immediately or some days or weeks later because pollen and nectar are stored in the hive. Furthermore, different categories of bees could be exposed in different ways and to varying extents. For example, pollen foragers (which differ from nectar foragers) do not consume pollen, merely bringing it to the hive. The pollen is consumed by nurse bees and to a lesser extent by larvae (Rortais et al., 2005).

The exposure of nectar foragers to imidacloprid contained in the nectar they gather can vary depending on the resources available in the hive environment. In addition, foragers take some nectar or honey already stocked in the hive before they leave for foraging. Depending on the distance from the hive where they forage, the honeybees are obliged to consume more or less of the nectar/honey taken from the hive and/or of the nectar collected, for energy for flying and foraging. They can therefore ingest more or less imidacloprid.

In 2002, Bayer publicly declared that the levels of exposure of honeybees to imidacloprid present in pollen and nectar ranged between 0 and 5 ppb (AFSSA, 2002).

Honeybee exposure to imidacloprid: 2003–2006
Based on exposure assessments and using scientific quality criteria to select among the available measurements, CST validated the findings of 3.3 ppb of imidacloprid in the pollen of Gaucho®-treated sunflowers, 3.5 ppb in pollen of Gaucho®-treated maize, and 1.9 ppb in the nectar of Gaucho®-treated sunflowers (CST, 2003).

([10]) In the original French: 'Les résultats ont généré des suspicions sur l'effet du produit, sans pour autant prouver formellement sa responsabilité.'
([11]) Comité Scientifique et Technique de l'Etude Multifactorielle des Troubles des Abeilles.

After seed treatment, imidacloprid transforms in the plant (metabolised) into many derivatives (metabolites), more or less completely. The main metabolites are 5-hydroxy-imidacloprid, 4-hydroxy-imidacloprid, 4-5 hydroxy-imidacloprid, olefin, imidacloprid-guanidine, imidacloprid-urea and 6-chloronicotinic acid.

Although two ([12]) of these metabolites show acute toxicity for honeybees (olefin and 5-hydroxy-imidacloprid), no study measuring metabolites in sunflower nectar or in sunflower and maize pollen, could be validated by the CST. For this reason, this committee recommended the development of detection and quantification limits low enough for their identification and quantification in pollen and nectar.

Lethal and sublethal effects

Pesticides can produce four types of effects on honeybees: acute or chronic lethal effects and acute or chronic sublethal effects.

- **Acute lethal effects** are expressed as the lethal dose (LD) at which 50 % of the exposed honeybees die within 48 hours: abbreviated to 'LD_{50} (48 hours)'.

- **Chronic lethal effects** refer to honeybee mortality that occurs after prolonged exposure (e.g. about 10 days).

In contrast to acute lethal effects, there were no standardised protocols for chronic lethal effects. Therefore, for imidacloprid, they were expressed in three ways:

- LD_{50}: the dose at which 50 % of the exposed honeybees die within 10 days;

- NOEC (No Observed Effect Concentration): the highest concentration of imidacloprid producing no observed effect;

- LOEC (Lowest Observed Effect Concentration): the lowest concentration of imidacloprid producing an observed effect.

Sublethal effects are modifications of factors such as honeybee behaviour, physiology and immune system. They do not directly cause the death of the individual or the collapse of the colony but may become lethal in time and/or may make the colony more sensitive (for example, more prone to diseases), which may lead to its collapse. For instance, an individual with memory, orientation or physiological impairments might fail to return to its hive, dying from hunger or cold. This would not be detected in standard pesticide tests, which focus on acute mortality. In addition, a key aspect in honeybee biology is that the colony behaves as a 'superorganism' ([13]). Hence, sublethal effects affecting individuals performing specific functions can influence the functioning of the whole colony. As was the case for chronic lethal effects, standardised protocols for sublethal effects were lacking.

- **Acute sublethal effects** of imidacloprid and its metabolites were assessed by exposing honeybees only once to the substance (by ingestion or by contact), and observing them for some time (variable from one laboratory to another, from several minutes to four days).

- **Chronic sublethal effects** were assessed by exposing honeybees more than once to the substance during a certain period of time (for example, each 24 hours, for 10 days).

Both acute and chronic sublethal effects are expressed as NOEC and/or LOEC.

Studies of lethal and sublethal effects: 1997–2000

Whereas intoxication by sprayed pesticides is usually confirmed by the numerous dead and moribund honeybees in front of the hives, beekeepers reported disappearance of most foragers in many hives. This lead them to hypothesise that imidacloprid was affecting the general mobility and/or orientation of the honeybees.

From 1999 onwards, **Bayer-funded scientists** also conducted studies on chronic lethal and sublethal effects. They found much lower values of LOEC for imidacloprid than previously reported. Whereas three Bayer scientists (Ambolet, Crevat and Schmidt)

([12]) The other four metabolites do not show any particular toxicity for honeybees.

([13]) Moritz and Southwick (1992) define superorganisms as 'superorganismic units with organisms arranged in at least two non-uniform types and differentiated into sterile and reproductive organisms with different functions' (p. 4). They highlight that superorganisms should not be confounded with social groups because, among other things, 'superorganisms need a sufficient membership so that the number of organisms involved in a task rather than the individual quality of how a task is performed becomes important' (p. 5). These numerous colony members function as a cooperative unit. Superorganisms maintain intraorganismic homeostasis (food storage, nest hygienic) and they are either well armed or highly cryptic. Superorganisms only originate from other superorganisms. For example in the case of bees a large part of a colony with a fertile queen undergoes 'fission' from the initial population and forms a swarm. 'In the end, however, only one feature really counts. It makes absolutely no sense invoking such a definition if natural selection does not act upon the superorganism itself. As long as natural selection is only working on individuals we have no need for such an additional perspective' (p. 6).

had reported a LOEC value of 5 000 ppb at the Fourth International Conference on Pests in Agriculture (6–8 January 1997), the new estimates were just 20 ppb, equivalent to 0.5–1.4 ng per honeybee (Kirchner, 1998, 1999 and 2000).

Other values found in 1999 and 2000 by **Bayer-funded scientists**, for the **highest concentrations which do not produce** sublethal effects (**NOEC**) ranged from 0.25–0.7 ng/honeybee (10 ppb) (Kirchner, 1999, 2000) to 0.94 ng/honeybee, 1.25–3.5 ng/honeybee, 1.5 ng/honeybee, 8.2 ng/honeybee, and 9 ng/honeybee (Schmitzer, 1999; Schmuck and Schöning, 1999; Thomson, 2000; Wilhelmy, 2000; Barth, 2000).

Among the **lowest concentrations at which imidacloprid produces** sublethal effects (**LOEC**), **public researchers** reported: 0.075–0.21 ng/honeybee (3 ppb); 0.15–0.42 ng/honeybee (6 ppb); 0.25–0.7 ng/honeybee (10 ppb), and 0.31–0.87 ng/honeybee (12.5 ppb) (ACTA, 1998; Pham-Delègue, 1998; Pham-Delègue and Cluzeau, 1998; Colin, 2000; Colin and Bonmatin, 2000; Colin et al., 2002).

To enable comparison between the data obtained by Bayer and those obtained by public scientists, we note that, by definition, NOEC is the test concentration **immediately below** the LOEC. The NOEC values corresponding to data produced by public scientists were, by definition, below the LOEC values that they generated and which are presented here.

Having said this, one might find strange that among the values above, the **NOECs** from Bayer are **larger** than most of the **LOEC** obtained by public scientists. However, this strange result can be partially explained by the fact that the values of NOEC of Bayer come from sublethal **acute** intoxication, whereas the two values cited from public scientists are sublethal **chronic** values.

Indeed, the differences between the values above might arise from different sources. For example, as no standard tests existed, the laboratories used differing testing protocols. In addition, various sublethal effects were studied (knockdown effect, locomotion coordination, quantity of syrup ingested, pollen consumption, wax production, parent recognition, memory, visits to the food source, odour recognition, etc.). Of course, the results depend on what, and how, one measures.

Studies of lethal and sublethal effects: 2001–2004
In 2001, **public scientists** identified chronic lethal effects at LD_{50} = 12 pg/honeybee after 10 days of feeding with imidacloprid-containing syrup (0.1 ppb) (Suchail, 2001).

In 2002, **Bayer** declared that 'Bayer's studies established that below 20 ppb, no negative effect can be observed on honeybee colonies' ([14]) (AFSSA, 2002).

Properties of imidacloprid: persistence in soils and presence in untreated crops
In its dossier submitted to the Ministry of Agriculture (Bayer, 1999), **Bayer** quoted half-lives for Gaucho® (DT50) ([15]) of 188 ± 25 days and 249 ± 40 days for two soil types. It should be noted that this exceeds the threshold of three months established in EU Directive 91/414/EEC (Annex VI, Part C, point 2.5.1.1) for conducting detailed ecotoxicological studies:

> 'No authorization shall be granted if the active substance and, where they are of significance from the toxicological, ecotoxicological or environmental point of view, metabolites and breakdown or reaction products, after use of the plant protection product under the proposed conditions of use during tests in the field, persist in soil for more than one year (i.e. DT90 > 1 year and DT50 > 3 months) […] unless it is scientifically demonstrated that under field conditions there is no accumulation in soil at such levels that unacceptable residues in succeeding crops occur and/or that unacceptable phytotoxic effects on succeeding crops occur and/or that there is an unacceptable impact on the environment...'

Gaucho® was authorised in France on the basis of this EU Directive and a French regulation ([16]).

The average levels of imidacloprid found in the soil by **public scientists** were 10.25 ppb during the year that the crop was treated with Gaucho® and 4.4 ppb the following year (Bonmatin et al., 2000).

([14]) In the original French: 'Les études Bayer ont établi que jusqu'à 20 ppb, aucun effet négatif ne pouvait être observé sur des colonies d'abeilles'.

([15]) DT50 is the degradation half-life, or period required for 50 % dissipation/degradation of the initial concentration of substance. DT90 is the time needed for the dissipation/degradation of 90 % of the initial concentration of substance.

([16]) Arrêté du Ministre de l'Agriculture de 6 septembre 1994 portant application du décret no 94-359 du 5 mai 1994 relatif au contrôle des produits phytopharmaceutiques, modifié par l'arrêté du 27 mai 1998.

16.2.2 *Methodological quality of the evidence*

Method of risk assessment
The risk of sprayed ('classic') pesticides to honeybees were assessed using mortality studies in laboratory conditions, followed by semi-field studies and finally field studies (Halm et al., 2006). The first step in such studies is to calculate a hazard quotient (HQ = the field application rate/oral or contact LD_{50}) (OEPP/EPPO, 2003). Further studies are demanded if the HQ exceeds a certain threshold (Halm et al., 2006).

Bayer used the LD_{50} methodology in its dossier applying for marketing authorisation for Gaucho® (Bayer, 1999). However, the methodology based on LD_{50} is designed to assess the risk of sprayed pesticides and has been shown to be inappropriate for seed-dressing systemic insecticides for several reasons:

- Seed-dressing systemic insecticides are applied on seeds and disperse in the plant during growth. The field application rate of active substance as an exposure parameter is therefore a highly inadequate measure for the true exposure of honeybees (Halm et al., 2006). What is important for the effects of seed-dressing insecticides on honeybees is not the amount applied per hectare, but the amount of imidacloprid (and metabolites) in the pollen and nectar.

- Both acute and chronic effects are important for the colony (given the clinical signs observed), whereas LD_{50} only considers the acute effects on adult honeybees.

- Seed-dressing systemic insecticides can have sublethal effects affecting the performance of the whole colony, not just individuals, because foragers can bring the pesticide inside the hive via pollen and nectar.

- The risks of seed-dressing systemic insecticides vary, depending on the age and role of the honeybees in the colony (Rortais et al., 2005).

Consequently, the risk assessment procedure that the **CST** chose for imidacloprid was based on evaluating the ratio PEC:PNEC. This approach, which is used to assess the environmental risk of industrial chemicals, allows comparisons between the levels of exposure (Predicted Exposure Concentration — PEC) and toxicity (Predicted No Effect Concentration — PNEC), and considers both lethal and various sublethal effects in the short and longer term, for different age groups and casts of honeybees and for different matrices (e.g. honey and pollen) (Halm et al., 2006). Thus, the PEC:PNEC approach results in a probability (risk) that effects found in controlled studies of specific items of toxicity are found in real conditions.

Field and laboratory studies
The **Bayer-funded scientists** and **public scientists** disagreed about the relative relevance of laboratory and field studies ([17]). Bayer held that the results of field experiments would either prove or disprove the risk of the active substance, regardless of whether they conformed to the results of laboratory studies. The public scientists argued that field studies cannot be decisive for deciding on the risk of a pesticide to honeybees.

The principle of an experiment is to vary one factor, keeping all the others constant. This cannot be done in current field experiments with bees, because the combination of abiotic and — especially — biotic factors is never identical in control fields (where the insecticide has not been used) and test fields. Bee

Photo: © istockphoto/Youra Pechkin

([17]) A distinction is made between 'field experiments' and 'monitoring', which measures clinical signs in real conditions.

colonies themselves are not identical, and the food sources available in the environment for honeybees are always diverse.

Furthermore, in field tests, it is impossible to prevent honeybees visiting fields not in the experiment. For example, the distance separating control and test areas is often too small to prevent bees foraging in other fields ([18]). Many differences have been reported in honeybees' mortality, both by beekeepers and during open field experiments (CST, 2003). Therefore, it is probable that observations made in a particular field experiment are not representative of the range of effects that could occur in real conditions. Due to the large variability of factors that cannot be controlled (e.g. soil structure, climate, combination of plants attractive for bees etc.), current field experiments only give information about the particular situation in which they were done.

In the end, it was not a scientific institution but the highest judicial administrative institution in France, the **State Council**, that decided (29 December 1999) that the results of both field experiments and laboratory studies may be legitimately used in risk assessment (Fau, 2000). This is common practice in risk assessment of chemicals, which is based on the PEC:PNEC ratio.

16.3 Processes of generating knowledge and assessing risk

16.3.1 Knowledge producers: public scientists

Public scientists were in a very difficult position in this case. The results of their work were central to a social debate with high economic and political stakes. In certain cases their work was not judged based on scientific merits but whether or not it supported the positions of certain stakeholders. This situation challenged the ability and courage of researchers to continue their work on imidacloprid.

One stated: 'From the beginning of the programme, in January 1998, I personally received a letter from Bayer threatening me with a lawsuit for defamation' ([19]) (AFP, 2003). The letter written by Bayer's lawyers warned of both judicial action and financial reparations (personal letter).

Bayer also wrote a letter to the researcher's hierarchical superior, asking him to use his position to influence the researcher's interventions in the press (personal letter). The superior refused the demand of Bayer but advised his researcher to take extreme care with the press.

Another researcher said: 'I worked for three years on the topic and the management… my managers […], asked me to change topic' ([20]) (Elie and Garaud, 2003).

In 2000, one public scientist acquired European funds to analyse the risk of imidacloprid to honeybees. However, the researcher's hierarchical superior suddenly stopped the programme, even though the researcher had already produced some first results in previous studies on imidacloprid, the funding was confirmed and the work had both social and scientific relevance (personal communication).

We lack information about the experiences of Bayer-funded scientists. During the process of reviewing this chapter a Bayer researcher was directly asked for such information but none was provided.

16.3.2 Official evaluators of evidence of the risk of Gaucho® to honeybees

Commission for Toxic Products (CTP)
In 1993, in the light of Bayer's claims that honeybees were not exposed to imidacloprid applied in seed-dressing, the Commission for Toxic Products (CTP) ([21]) issued an assessment in favour of

([18]) Semi-field (tunnel) studies are also unable to provide a decisive indication of a pesticide's risk to honeybees for several reasons. First, the quantity of food and the time of exposure to the contaminated source are much less important in semi-field experiments than in real conditions. Second, one cannot know if the honeybees really consume the collected pollen and nectar (contaminated for the purpose of the test) or if they continue to consume the reserves already present in the hive at the beginning of the experiment. Third, the foraging distance is very small, and therefore some distance-dependent behavioural effects (for instance, orientation troubles) may not be seen under semi-field experiments but could appear in real conditions, when honeybees have to forage far from the hive.

([19]) In the original French: 'Dès le début du programme, en janvier 1998 j'ai reçu personnellement une lettre de Bayer me menaçant d'un procès en diffamation.'

([20]) In the original French: 'J'ai travaillé trois ans sur le sujet et la direction… ma direction […], m'a demandé de changer de sujet.'

([21]) La Commission d'étude de la toxicité des produits anti-parasitaires à usage agricole et des produits assimilés, des matières fertilisantes et des supports de culture, known as Commission for Toxic Products, was under the aegis of the Ministry of Agriculture. It was composed of experts in toxicology and eco-toxicology. Its remit was to analyse authorisation dossiers from toxicological and eco-toxicological points of view. In 2006, the Commission was replaced by expert groups headed by the French Food Safety Agency AFSSA (called DIVE).

authorising Gaucho®, without consulting its specialist Honeybee Working Group ([22]).

After the emergence of clinical signs in the field and the first evaluation report (Belzunces and Tasei, 1997), the assessment of the CTP (11 December 1997) was ambiguous. It found that in the light of the information available, it was impossible to confirm or deny a causal link between the use of Gaucho® and honey yield losses. The CTP continued to issue ambivalent assessments until December 2002.

From 1997 to 2001, the CTP considered that there was not enough knowledge to pronounce clear conclusions and repeatedly recommended further studies. For example, in 1997: 'The demonstration, made by Bayer that Gaucho® is not involved, is not made in a rigorous and complete manner. On the other hand, the declarations coming from beekeepers are not rigorous and stable enough for saying that Gaucho® is the **only** ([23]) cause of honeybee colonies problems' ([24]) (CTP, 1997).

In 1998 the CTP stated that, 'the data examined do not allow us to conclude to an **unquestionable effect** of imidacloprid and/or of its metabolites on honeybees and honey production. Conversely, it is also not possible **to completely exclude** the effect of imidacloprid and/or its metabolites, given the toxic effect at low doses, which have to do with the concentrations potentially present in the plants at the foraging time' ([25]) (CTP, 1998).

In 2002, the conclusion of the CTP was expressed in unclear language and referred vaguely to all honeybee losses in France instead of focusing on the clinical signs observed in areas of intensive agriculture: 'The risk assessment does not allow us to demonstrate that maize seed-dressing with Gaucho® can be **solely** responsible, at national level, for **all** colony losses, behavioural troubles, honeybee mortalities or general decline in the honey production' ([26]) (CTP, 2002, p. 22).

In all these cases, the CTP conclusions were answering a question that had never been asked, that is, is Gaucho® responsible for all honeybee losses, **everywhere in France**? They thus avoided a clear answer to the question really asked: is Gaucho® responsible for honeybee losses **in intensive sunflower and maize seed-dressed cultures**?

The CPT lacked clear operating procedures and the assessment of the dossiers submitted by companies during the authorisation processes was based on unstructured expert judgement. It did not involve a systematic reflection on the quality of the results presented in these dossiers, based on clear assessment criteria. During their meetings, the workload was such that members of the CTP were often dealing with several dossiers simultaneously and therefore could not have in depth discussions on each of them.

While the CTP issued advice to the Ministry several times during 1997–2002, only one member of the CTP was a bee specialist. The CTP had a Honeybee Working Group but this was not consulted until late in the debate (in 2000). A former member of the CTP argued that they were not consulted earlier because two members were beekeepers and were considered to have an interest in banning Gaucho® (personal communication). Even in the Honeybee Working Group, honeybee scientists were under-represented. Overall, the divergent data coming from different sources, the lack of sufficient expertise on honeybee biology and the absence of enough time and rigorous criteria for evaluating the dossiers, all contributed to producing ambiguous advice.

State Council

In the case of Gaucho®, different stakeholders, persons, and evaluation and decision bodies used varying criteria to judge the quality of the scientific evidence available. Thus, in contrast to the CTP, which was formally charged with assessing the

([22]) The Honeybee Group was a CTP working group set up to report the risks to honeybees of plant protection products (PPP) submitted for authorisation for marketing. It advised on awarding a product the 'honeybee label' indicating that it poses no risk to honeybees when used on flowering plants.

([23]) The underlining in this quote and all subsequent quotes has been added by the authors of the present paper.

([24]) In the original French: 'La démonstration par Bayer que le Gaucho est hors de cause n'est pas établie de façon suffisamment rigoureuse et complète. D'autre part, il n'y a pas assez de rigueur et de stabilité dans les rapports de terrain provenant des apiculteurs pour affirmer que le Gaucho est la seule cause de troubles dont les colonies d'abeilles sont victimes.'

([25]) In the original French: 'Les données examinées ne permettent pas de conclure à un effet indiscutable de l'imidaclopride ou de ses métabolites sur les abeilles et la production de miel. Inversement, il n'est pas possible d'exclure totalement l'effet de l'imidaclopride et de ses métabolites, compte tenu de l'effet toxique à faible doses, doses en rapport avec des concentrations potentiellement présentes dans les plantes à l'époque du butinage.'

([26]) In the original French: 'L'évaluation du risqué réalisée ne permet donc pas de démontrer que le traitement de semences de maïs par la préparation Gaucho puisse être le seul responsable au niveau national de l'ensemble des dépopulations de ruches, des troubles comportementaux, des mortalités d'abeilles et plus globalement de la baisse de production apicole.'

conformity of the existing evidence with the regulatory demands for pesticides risk assessment, the State Council employed legal criteria, assessing conformity with the law.

The first intervention of the State Council was in 1999, immediately after the ban on using Gaucho® on sunflower seeds, when Bayer mounted a legal challenge to the ministerial decision. About that time, several international consortia of seed producers (Monsanto, Novartis, Rhône-Poulenc, Pionneer, Maisadour and Limagrain) rallied behind Bayer and formulated a similar case against the Minister's decision. The beekeepers syndicate UNAF ([27]) co-defended the Minister's decision in court. The State Council decided in favour of the beekeepers and the Minister, judging that the Minister's precautionary decision was based on an appropriate evaluation of the results from the 1998 scientific programme and the conclusions of the CTP, which expressed doubts about the harmlessness of Gaucho® for honeybees.

The State Council was involved again in 2002 and 2004, calling on the Minister to reconsider his decisions refusing to ban Gaucho® in maize seed-dressing (see Section 16.4.2), on the grounds that the Ministry had not rightly evaluated its harmlessness in the way demanded by French legislation ([28]). In its conclusion in 2002, the State Council pointed out that, given the reasons for concern about Gaucho®, the Ministry should have examined all the necessary data to evaluate its effects on honeybees in maize seed-dressing. That is, the Ministry should have asked for quantification of the use of maize pollen by honeybees, as well as of the nature and intensity of the effects on honeybees of maize pollen containing imidacloprid. In 2004, the State Council again stated that the CTP's risk assessment of Gaucho®-treated maize for the Ministry failed to comply with the law as the effects on larvae had not been assessed.

Other cases in court

In 2001, Bayer took three representatives of beekeepers' syndicates to court in their home towns (Châteauroux, Mende and Troyes), accusing them of discrediting Gaucho® (GVA, 2001). In all cases, the courts decided in favour of beekeepers, based on the freedom of the syndicates to play their role in society and to express their opinions publicly. One of the courts explicitly criticised the attempt of Bayer CropScience to intimidate a syndicate leader who was defending the interests of his profession (UNAF, 2004).

An investigation into Gaucho® was launched in a court in Paris, following a charge brought by UNAF in 2001. The investigation continues to stagnate. Since its beginning, two judges have been replaced for different reasons. The judge currently dealing with the case has proceeded with new interrogation of experts and parties involved. In March 2011, the judge was still investigating the available evidence, in order to decide if there will be a trial or not.

16.3.3 Scientific and Technical Committee

Based on the analysis of 338 bibliographical references, the CST concluded that seed-dressing sunflower and maize posed serious risks to honeybee colonies via larvae feeding, pollen consumption by nurses, nectar ingestion by foragers, and honey consumption by honeybees living inside the hive:

> 'Based on our current state of knowledge and on the scenarios we developed to evaluate exposure, and based on the uncertainty factors chosen to evaluate the dangers, the PEC:PNEC ratios determined are of concern. They are in agreement with the field observations reported by numerous beekeepers' areas of intensive corn and sunflower growing, relating to the mortality of foragers (scenario 4), their disappearance, behavioural disturbances and certain winter mortalities (scenario 5). Consequently, the dressing of sunflower seeds with Gaucho® poses significant risks for bees of different ages, with the exception of the pollen ingestion by foragers during the making of pollen balls (scenario 3).
>
> 'Regarding corn seed dressed with Gaucho®, the PEC:PNEC ratio turns out to be, as for the sunflower, of concern in the case of pollen consumption by nurse bees, which would lead to an accrued mortality of these and be one of the explanatory elements for the weakening of bee populations observed

([27]) UNAF (Union Nationale de l'Apiculture Française) is one of the three French beekeeping syndicates, representing about 22 000 beekeepers.
([28]) Arrêté du 6 septembre 1994.

despite the ban on Gaucho® on sunflowers. Finally, given that other factors can contribute to the weakening of bee colonies, research should be continued on the frequency, mechanism and causes of these clinical signs' ([29]) (CST, 2003, p. 11).

Although the interim CST report on the risks of Gaucho® to honeybees was completed in 2002, DGAL (the General Directorate for Food, within the Ministry of Agriculture) did not submit it then to the Management Committee ([30]) of the CST. Just before publication in 2003, the Ministry of Agriculture withdrew its logo. One interpretation of this was that it emphasised the independence of the CST, alternatively it could be seen as demonstrating that the Ministry of Agriculture did not want to show any support for the results. This last interpretation is reinforced by a post-publication letter from the DGAL, in which the Directorate considered that the findings of CST were too precise and asked for more studies.

16.4 Societal debate and the policy responses

16.4.1 Stakeholder strategies

Beekeepers systematically presented and compared the results of studies conducted by Bayer, the Ministry of Agriculture, public research and their own field observations. Their objective was to make the results public in order to show the congruity of their own observations with the scientific results and to mobilise civil society for support. The beekeeping sector was supported by civil society, as the issues were of major concern to the French public. The sector's arguments received good coverage in the national press.

DGAL's public statements were ambiguous. Its lack of transparency undermined trust: for example, when beekeepers' requested the authorisation dossier for Gaucho®, DGAL only released limited information (Clément, 2000). DGAL communicated all the documents requested by beekeepers only after intervention from both the Minister of Agriculture himself and the Commission for Access to Administrative Documents.

There was variance in the public positions of different ministries of the French government and different services within the Ministry of Agriculture. The decisions of the Ministers of Agriculture to suspend the use of Gaucho® in seed-dressings for sunflower (1999, 2001, 2003) and maize (2004) contrasted with DGAL's procrastination.

Bayer had an inappropriate communication strategy on scientific figures, which contributed to increasing mistrust from the other stakeholders. For example, in 2002, Bayer publicly acknowledged exposure 'between 0 and 5 ppb, which is the quantification limit' ([31]) (AFSSA, 2002, p. 32). This statement represented a major step forward in Bayer's communication of scientific figures but was still vague about the information available on imidacloprid. However, Bayer-funded scientists had already obtained precise figures for sunflower, i.e. 3.3 ppb in pollen and 1.9 ppb in nectar (Stork, 1999) ([32]). In addition, between 2000 and 2001 public scientists had also reported quantification limits well below 5 ppb, i.e. 1 ppb for quantifying imidacloprid in pollen and nectar (Lagarde, 2000, Bonmatin et al., 2001) and detection limits of 0.3 ppb for pollen (Bonmatin et al., 2001) and 0.8 for nectar (Lagarde, 2000). These quantification and identification limits, as well as the precise measures of imidacloprid in pollen and nectar, available from public scientists, were ignored by Bayer in its statements on Gaucho® despite being publicly available ([33]).

([29]) In the original French: 'Dans l'état actuel de nos connaissances, selon les scénarios développés pour évaluer l'exposition et selon les facteurs d'incertitude choisis pour évaluer les dangers, les rapports PEC/PNEC obtenus sont préoccupants. Ils sont en accord avec les observations de terrain rapportées par de nombreux apiculteurs en zones de grande culture (maïs, tournesol), concernant la mortalité des butineuses (scénario 4), leur disparition, leurs troubles comportementaux et certaines mortalités d'hiver (scénario 5). En conséquence, l'enrobage de semences de tournesol Gaucho® conduit à un risque significatif pour les abeilles de différents âges, à l'exception de l'ingestion de pollen par les butineuses lors de la confection de pelotes (scénario 3).
'En ce qui concerne l'enrobage Gaucho® de semences de maïs, le rapport PEC/PNEC s'avère, comme pour le tournesol, préoccupant dans le cadre de la consommation de pollen par les nourrices, ce qui pourrait entraîner une mortalité accrue de celles–ci et être un des éléments de l'explication de l'affaiblissement des populations d'abeilles encore observé malgré l'interdiction du Gaucho® sur tournesol. Enfin, étant donné que d'autres facteurs peuvent contribuer à l'affaiblissement des colonies d'abeilles, il convient que les recherches soient poursuivies sur la fréquence, les mécanismes et les causes de ces symptômes.'

([30]) The Management Committee's remit was to supervise the scientific, economic and regulatory aspects of the CST's work and to ensure communication with the Minister of Agriculture, stakeholders and the public.

([31]) In the original French: 'comprise entre 0 et 5 ppb, qui est la limite de quantification'.

([32]) The data obtained by Bayer using radiolabelled imidacloprid have been published in 2001 (Schmuck et al., 2001).

([33]) For instance, Apiservices (2001) presents a synthesis of the available data and was published online on 16 February 2001.

Bayer steadfastly maintained that using Gaucho® in sunflower seed-dressing had no effect on honeybees (Bayer CropScience, 2006). In 2006, the case dossier on the company's website did not mention the CST's conclusion that 'in the actual state of our knowledge […] the PEC:PNEC ratios obtained are worrisome' ([34]), or the findings from French public scientists regarding the risks of Gaucho® for honeybees ([35]).

16.4.2 Policy response to scientific evidence on risk

A dossier prepared by the Ministry of Agriculture (2001c) frames the 1999 decision of the Minister to ban Gaucho® on sunflower in the following terms:

> 'The Ministry of Agriculture has conducted a first series of laboratory studies, as well as field studies in three test departments: Vendée, Indre and Deux-Sèvres. The results yielded suspicions about the effects of the product, without, however, formally proving its responsibility. **Applying the precautionary principle**, the Minister of Agriculture has decided, in January 1999, to temporarily ban the product in sunflower seed-dressing' ([36]).

The Minister of Agriculture's ban on Gaucho® as maize seed-dressing was introduced later. The stakes were higher for Bayer (only 10 % of Gaucho® revenue came from use on sunflower, the area under maize in France being 2.5 times that under sunflower ([37])), for farmers, for beekeepers, for the general public (as articulated by the media) and probably for the Minister himself as a politician. In addition to the economic importance of maize, it is frequently cultivated without rotation. Therefore the pressure from pests (and maize growers) can be higher than for sunflower. Justifying his decision not to ban Gaucho® in maize seed-dressing, the Minister of Agriculture stated to the State Council that maize does not produce nectar and therefore honeybees do not visit this plant for producing honey, apparently unaware that honeybees do, however, visit maize to collect its pollen, which they consume (Conseil d'Etat, 2002).

Although a procedure for the reversal of this authorisation was under way at the State Council, on 21 January 2002 the Ministry of Agriculture renewed the authorisation of Gaucho® on maize for ten more years. Subsequently, the judicial inquiry on Gaucho® was extended to challenge this renewed authorisation (Saunier, 2005). In October 2002 the State Council concluded its re-examination of the scientific evidence and advised the Minister to reconsider his decision. In 2003, the Minister of Agriculture refused again to ban the use of Gaucho® in maize seed-dressing. In September 2003 the CST concluded that imidacloprid in maize seed-dressing posed a serious risk to honeybees (specifically the nurses consuming pollen). Again, in March 2004, the State Council advised the Minister to reconsider their decision but it was not until July 2004 that this use of Gaucho® on maize was banned. The press release communicating the Ministry's decision refers to the CST report, and states that 'the risk for honeybees seems less important than in case of sunflower seed-dressing because exposure occurs only via pollen but is, however, of concern' ([38]) (Ministère de l'Agriculture, 2004).

Prior to this, in a letter published on 21 November 2003, the head of the Bureau for the Regulation of Pesticide Products of the DGAL had revealed various shortcomings of the official risk assessment and management procedure: there were only three public servants to deal with 20 000 applications for authorisation per year; risk assessments were performed jointly with the industry; there was lack of transparency in the procedures; and insufficient attention was paid to the issue of pesticide residues in food during the risk assessment. In consequence,

([34]) In the original French: 'Dans l'état actuel de nos connaissances [...] les rapports PEC/PNEC obtenus sont préoccupants.'

([35]) On the Bayer CropScience France website (www.bayercropscience.fr) in 2006, there was a file entitled 'Honeybees'. In November 2009, on this website, if one searches for 'honeybee' ('abeille'), no document can be found. On the website of Bayer Cropscience World, searching 'honeybees' gives no specific reference to Gaucho®, but searching 'Gaucho' results in some documents on the French case. Among them, the document referring to the ban of Gaucho® on maize still does not mention the conclusions of the CST or of French scientists. In January 2011, seaching for honey + bee + gaucho gives 1 result, referring to the judgement of the court of Chateauroux, whereas searching bee + gaucho gives 14 results, among which 4 refer to honeybees.

([36]) In the original French: 'Le ministère de l'Agriculture et de la Pêche a conduit une première série d'études en laboratoire, comme sur le terrain dans trois départements tests: la Vendée, l'Indre et les Deux-Sèvres. Les résultats ont généré des suspicions sur l'effet du produit, sans pour autant prouver formellement sa responsabilité. En application du principe de précaution, le ministre de l'Agriculture et de la Pêche a décidé en janvier 1999 le retrait provisoire de l'autorisation de mise sur le marché du produit sur traitement de semences de tournesol.'

([37]) Official figures from the website of the Ministry of Agriculture (Agreste, 2011) for the year 2000 put the area used for maize at 1 764 767 ha and for sunflower 728 555 ha.

([38]) In the original French: 'le risque pour les abeilles, s'il apparaît moins important que dans le cas de l'usage pour l'enrobage des graines de tournesol du fait de la seule exposition au pollen, reste préoccupant.'

the Bureau chief concluded, 'it is impossible for the Bureau to accomplish its mission' ([39]).

16.4.3 Costs and benefits of the policy responses

In the last 20 years, the **chemical industry** has been increasingly regulated. Directive 91/414/EEC required the reassessment of active substances contained in plant-protection products already on the EU market. Many active substances have since been withdrawn. Furthermore, some pests have developed resistance to formerly used pesticides.

European manufacturers of agricultural chemicals face higher research and development costs. On average, it costs some USD 50 million to develop a new product. Nevertheless, systemic insecticides represent a highly profitable investment. For example, imidacloprid-based insecticides ([40]) brought Bayer DM 800 million of global sales in 1998 (approximately EUR 409 million) (Bayer, 1998) and EUR 556 million in 2007 (Bayer CropScience, 2008). Furthermore, focusing on these products also represents a networking investment for the industry because partnerships are made with seed producers and distribution chains. We do not have information about the economic consequences for the chemical industry of banning Gaucho® or RégentTS® in France.

The economic situation of the **French beekeeping sector** worsened significantly between 1994 and 2004. In 1994, there were 1 370 220 beehives and 84 800 beekeepers. By 2004, there were 1 360 973 beehives and 68 800 beekeepers (GEM-ONIFLHOR, 2005). Many small producers abandoned beekeeping in the interim. The apparent stability of the number of hives between 1994 and 2004 belies the higher turn-over of colonies to replace those lost. The decrease in the sunflower average honey yield (Belzunces and Tasei, 1997; CNEVA Sophia-Antipolis, 1997; Pham-Delègue et Cluzeau, 1998; Coordination des Apiculteurs, 2001; Alétru, 2003), and the increase in colony mortality forced professional beekeepers to increase the number of hives to compensate for their losses.

The relative contribution of insecticides and other factors (e.g. the international market for honey and honeybee diseases) to the decline of French beekeeping is unclear. France's honey imports per annum rose from 6 000 tonnes in 1993 to 17 000 tonnes in 2004, whereas domestic honey consumption stayed constant at about 40 000 tonnes per annum (GEM-ONIFLHOR, 2005). A study of the cooperative France Miel ([41]) for western France showed that severe losses in the sunflower honey yield started in 1995 and continued over the following years (Figure 16.1).

Data similar to those obtained for western France exist for the cooperative Poitou-Charentes (Figure 16.2) and for the department of Deux-Sèvres, produced by the Agricultural Chamber (Chambre d'Agriculture). In 2005, the important decrease in the production of sunflower honey is also referred to in a national audit report of the beekeeping branch (GEM-ONIFLHOR, 2005).

These data are not exhaustive but they show that the losses of sunflower honey yield were significant, started around 1994 and continued in the following years.

Among the beekeeping sector's expenses, there was also additional outlay on research (funding research to assess the risk of Gaucho® and RégentTS® through European funds for beekeeping) and legal fees (for the different judicial interventions). The financial burden was double because the funds had been intended to support the development of beekeeping. Having been spent on defending beekeepers' stakes in the debate, some could not be used to achieve the development goals.

The beekeepers have not been compensated for their economic losses but after 2003, France was granted financial support from the European Commission to restore honeybee colonies, as general support for beekeeping in a time of economic hardship.

In the **agricultural sector**, the economic repercussions are unclear. A large proportion of French crops (such as sunflower, maize and cereals) were rapidly given seed-dressing protection, even when pest control was rarely needed (for example for sunflowers). The Technical Center for Oilseed Crops (CETIOM) website specifies ([42]) that 'sunflower has a low attractiveness for [click beetle]

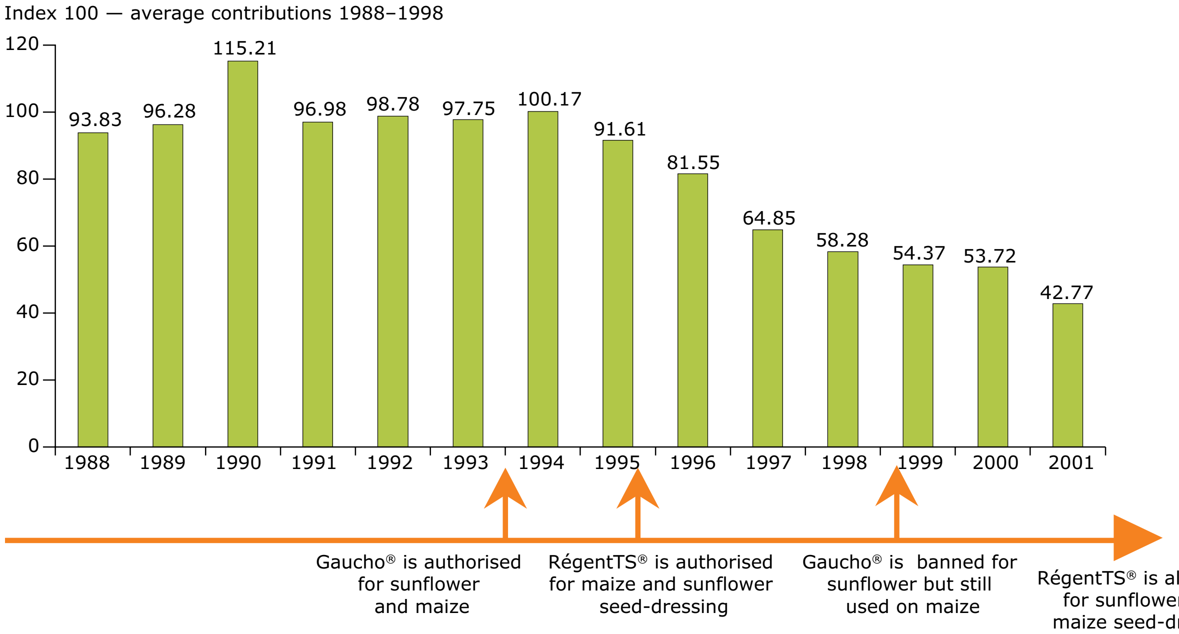
([39]) 'Trois fonctionnaires pour traiter 20 000 demandes d'autorisation par an, 'une cogestion de l'évaluation des risques avec les industriels', 'une absence de transparence dans les procédures'. 'En matière d'évaluation des risques, le domaine des résidus de pesticides dans les aliments est insuffisamment couvert.' Enfin, 'Le bureau est dans l'impossibilité de remplir ses missions.' (Le Point, 21 November 2003).

([40]) Gaucho®, Confidor®, Admire® and Provado® in 1998 and Confidor®, Admire®, Gaucho® and Merit® in 2007.

([41]) Additional figures for the evolution of sunflower honey are available in France Miel (2000).

([42]) This information has been already present on this website in 2003.

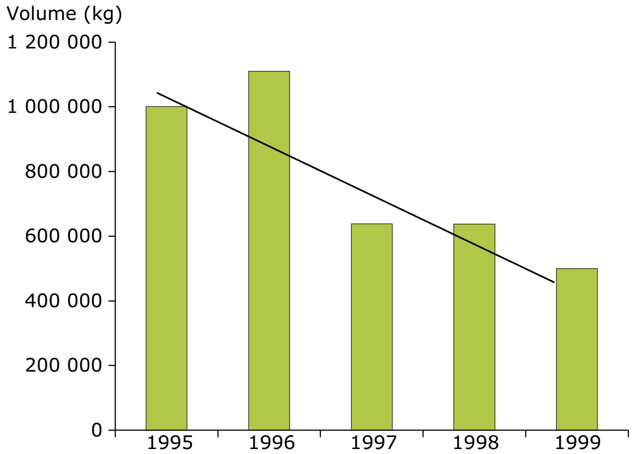
Figure 16.1 Sunflower honey harvest in western France (*)



Note: * The method for obtaining these data was communicated to Laura Maxim by France Miel. The quantities of sunflower honey comprise all the quantities brought to France Miel between 1988 and 1998 by a representative sample of professional beekeepers providing honey to France Miel, from the departments 72 (Sarthe), 49 (Maine-et-Loire), 85 (Vendée), 17 (Charente-Maritime), 33 (Gironde) and 32 (Gers). The vertical axis represents an index 100 — which is the average of the quantities of sunflower honey provided to France Miel between 1988 and 1994. Beekeepers are committed to supply all of their annual harvests to the cooperative. A laboratory further checks the floral origin of the supplied honey. It was not possible to calculate the evolution of the quantity of sunflower honey beyond 2001 because some beekeepers from the sample abandoned beekeeping, left the cooperative, developed other activities in addition to beekeeping or retired. Note that sunflower seeds were also dressed with another insecticide after 1995, RégentTS®.

Source: Laura Maxim.

Figure 16.2 Sunflower honey yearly harvest totals since 1995, for the Cooperative Poitou-Charentes



Source: Coordination des Apiculteurs, 2000.

larvae and the time lag during which the plant is sensitive to these larvae is relatively short' ([43]). Furthermore, for 'most of the areas where sunflower is cultivated in France', the risk is 'low or zero' ([44]) (CETIOM, 2011).

Contrary to the use of curative treatments usually recommended to farmers when pest density was above an economic threshold, the new control method was preventive regardless of the presence and abundance of pests.

Seed-dressing reduces the work needed for crop protection, so it could be economically attractive to farmers. But some farmers said that their productivity was unchanged or diminished, and reported more empty seeds in the flowerheads, suggesting a possible link with the poor pollination associated with Gaucho® (Elie and Garaud, 2003).

([43]) In the original French: 'le tournesol est faiblement attractif pour les larves et la période de sensibilité aux attaques est relativement brève.'

([44]) In the original French: 'Population de taupins nulle à faible, dégâts très peu probables sur tournesol: Majorité des situations où le tournesol est cultivé aujourd'hui en France.'

Mainstream (intensive) farmers' organisations such as the General Association of Maize Producers (AGPM) ([45]) argued that banning seed-dressing insecticides increased pressure from pests, particularly on maize (Beulin et al., 2005; AGPM, 2008).

In 2002 the rapporteur on 'insecticides' in the Committee for Pesticides Authorisation ([46]) stated that, at that time, the two 'really effective' plant protection products that served as alternatives to Gaucho® and were available for certain maize pests were terbufos (which was due to be withdrawn from the EU market in 2003) and RégentTS® (Comité d'homologation, 2002).

In 2005, farmers reported losses of 500 000 tonnes of maize-grain in France (worth EUR 50 million) and some of them linked this figure to the ban on seed-dressing insecticides (Dossier de la protection des sémences, 2005). However, others blamed the productivity drop on the exceptionally hot and dry summer that year. AGPM itself has pointed towards the decrease in maize yield from 2003 due to increasingly drier summers.

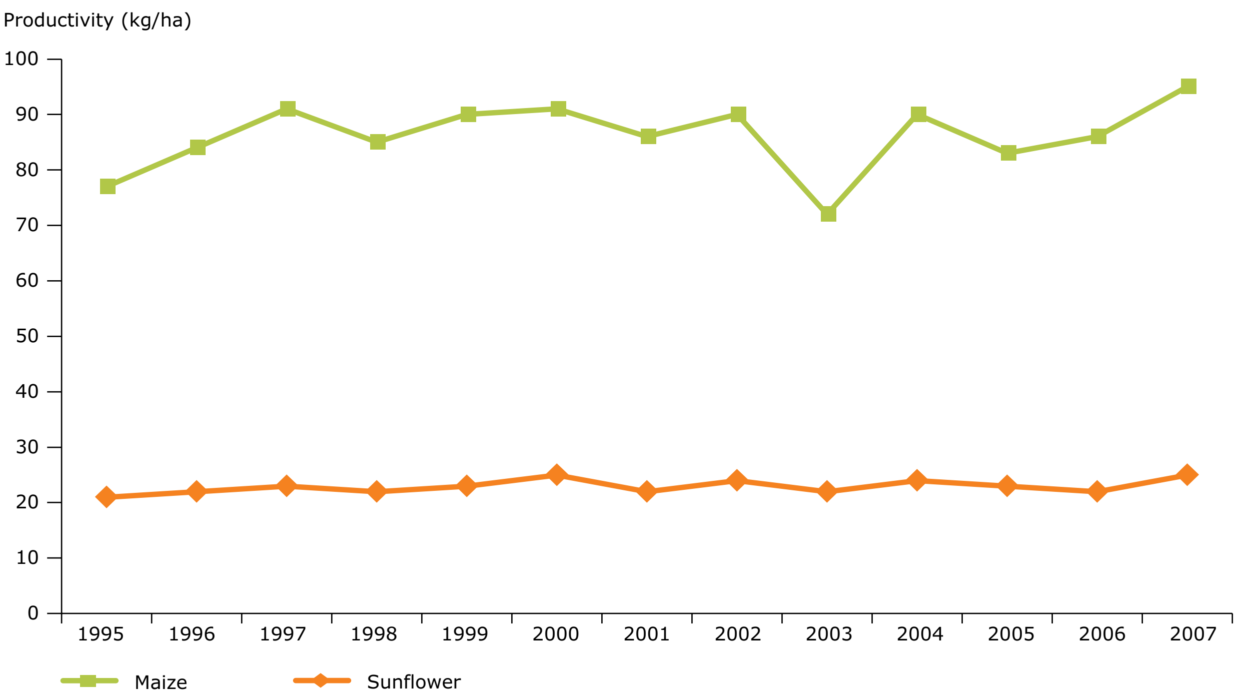
Figure 16.3 shows that the seed-dressing ban is not directly correlated with productivity: 2007 was the best year in over a decade. For maize, production was worst not after 2004, when Gaucho® was banned on this crop and RégentTS® on all uses, but in 2003, when a major heatwave hit Europe.

Beekeepers contended that, because not all maize crops in France were seed dressed, maize could be cultivated without seed-dressing insecticides. Contrastingly, the website of the General Association of Maize Producers (Dossier de la protection des secmences, 2005) reports that there is no authorised alternative treatment to control wireworms.

The losses for agriculture associated to the potential decline in pollination during this period (1994–2004) have not been assessed.

Finally, resistance to insecticides is more likely with the long persistent molecules of seed-dressings (such as imidacloprid, fipronil and thiametoxam) which exert a constant pressure on natural selection, compared to sprays.

Figure 16.3 Trends in maize and sunflower yields in France from 1995 to 2007



Source: Data from AGRESTE, Statistiques agricoles annuelles.

([45]) L'Association Générale des Producteurs de Maïs — also a defender of industrial agriculture, for example through cultivating GMOs and intensive biofuel crops.
([46]) Comité d'homologation — one of the two authorities previously involved in evaluating applications for authorisation of pesticides in France. The other instance was the CTP.

16.4.4 Debate in France: 2004–2011

The figures for bee mortality in France are very diverse and heterogeneous among sources. According to UNAF, since 2003 honeybee colonies have partially recovered in France. UNAF reported that high **summer** mortality has stopped in intensive agriculture areas and the general state of the French hives improved (Clément, 2005; UNAF, 2007 and 2008).

An AFSSA study between 2002 and 2005 on 120 hives reported normal activity of honeybees, and usual winter mortalities (5–10 %) (Aubert et al., 2008).

AFSSA (Faucon and Chauzat, 2008) and some beekeepers (Schiro, 2007) reported high mortality for the **winter** 2005–2006. However, according to EFSA (2008), only 1.2 % of French beekeepers made declarations regarding mortality in 2006 and 0.6 % did so in 2007.

Following the 2006–2007 **winter**, apiaries were reported to be in good condition in early spring 2007 (Clément, 2007).

For the 2007–2008 winter, an inquiry by the National Center for Apicultural Development (CNDA), based on 168 professional beekeepers' answers (representing about 5 % of French hives and 10 % of French professional beekeepers), found an average **winter** loss of colonies for France of around 30 %. That was some 12 % higher than CNDA figures for the two previous winters (De Boyer des Roches et al., 2009).

The reality is that no system exists in France for the accurate and extensive monitoring of honeybees. The national statistics of the French Ministry of Agriculture are recognised to support neither accurate quantification of bee mortality, nor identification of causes. Furthermore, official statistics focus on the survey of bee contagious diseases. The Ministry of Agriculture's data on the influence of diseases on French hives differ markedly from those collected by the AFSSA (2009).

AFSSA has produced several reports after 2004, presenting results from its eco-epidemiological studies, suggesting that honeybee problems had multiple causes, with diseases being important in winter mortalities. They showed that varroa is currently a pressure in French hives, as few drugs against this mite are available (AFSSA, 2009).

The reports AFSSA (2009) and CST (2003) differ in terms of their objectives and, therefore, in their methods. These differences are apparent in their respective bibliographies. Of the 338 bibliographic references considered in the CST report, only five were included in AFSSA (2009). Similarly, 173 of the references available before 2003 and included in AFSSA (2009) report were not included in the CST report.

The majority of the references considered by the CST concern imidacloprid. Contrastingly, 43 % of the documents considered in the AFSSA report concern diseases and viruses and only about 15 % concern ecotoxicological issues, with only 3 % focusing on imidacloprid.

Nevertheless, the AFSSA report describes its analysis as '**An almost exhaustive study** of French and European investigations carried out on the issue of bee morbidity and mortality' (p. 12). It also asserts that 'This information has allowed an almost exhaustive inventory of the causes of bee diseases and particularly bee colony mortality to be drawn up' (p. 101). However, the statistics regarding references demonstrate that almost none of the documents reviewed during the CST were considered by AFSSA. The AFSSA analysis only refers to some of the references available on honeybee losses in France — mainly those referring to diseases. Therefore the AFSSA inventory of sources cannot be considered as being 'almost exhaustive'.

AFSSA (2009) does not assess the influence of Gaucho® and Régent® on honeybees in sunflower and maize areas (e.g. the word Gaucho® is present four times in the main text of the document, twice in naming the precautionary decision of the Ministry and twice in naming the corresponding CST report).

Regarding, generally, the influence of pesticides on honeybees, AFSSA (2009) states that 'The group's deliberations do not confirm the hypothesis of a predominant role attributed to pesticides by beekeeping professionals in French bee colony mortality'. This statement takes an important place, because it is found in the conclusions section. However, this general conclusion lacks precision in several respects that are relevant to the present chapter:

- It is not clear to which 'pesticides' the text refers. Do the authors refer to all pesticides?
- It is not clear to which 'beekeeping professionals' the text refers. Is it beekeepers in maize and sunflower areas or beekeepers in other areas (for example mountain regions)?

- It is not clear which 'French bee mortality' this statement refers to because the time period is not specified. Is it before 2004 (before the ban on imidacloprid in maize seed-dressing and on fipronil in all agricultural uses?) or is it after 2004?
- The method used to draw this conclusion is not clear either. How were the 'group deliberations' organised in order to produce this conclusion? On which bibliographic basis were these conclusions drawn, given that less than 15 % of the documents considered refer directly to pesticides? How were these documents chosen, among all the references available on the effects of pesticides on honeybees, and used to reach this conclusion?

Suchail et al. (2001) investigated the oral acute and chronic toxicity of imidacloprid and its main metabolites (5-hydroxyimidacloprid, 4,5-dihydroxyimidacloprid, desnitroimidacloprid, 6-chloronicotinic acid, olefin, and urea derivative) in *Apis mellifera*. Regarding two metabolites (urea and 6-chloronicotinic acid), their results were contested in a study published by a Bayer-funded scientist (Schmuck, 2004). This study could not find any increased treatment-related mortality or behavioural abnormalities following chronic exposure of honeybees to these two metabolites, at 0.0001, 0.001, and 0.010 mg/L 50 % sucrose solution.

Schmuck (2004) did not address the parent molecule, imidacloprid, in an experimental way but through a literature analysis. The author argued that comparison with other studies should be considered sufficient to reject the results found by Suchail (2001), based on the argument that Suchail's results are lower than others. This comparative literature survey neither analysed the sources of the differences between the results, nor examined comparatively the protocols used by the various researchers to understand the sources of these differences.

Post-2003 studies also found that exposure to imidacloprid is also possible through aerial pollution, through foraging on wild flowers coated with imidacloprid-containing dust as a result of sowing-related activities (Greatti et al., 2006) and through consumption by honeybees of leaf guttation drops of corn plants germinated from imidacloprid-coated seeds (Girolami et al., 2009).

Public scientists in France found that the persistence of imidacloprid resulted in its presence in untreated crops cultivated after seed-treated crops. Bonmatin et al. (2005) found 1–2 ppb imidacloprid in flowerheads of untreated sunflowers grown a year after seed-dressed sunflowers. Imidacloprid was still detectable two years after treatment (detection limit = 0.1 ppb). In pollen, imidacloprid was detected one year after treatment (detection limit = 0.3 ppb).

Immunodepression caused by sublethal exposure to insecticides may favour lethal diseases (Glinski and Kauko, 2000; ISIS, 2011). Indeed, beekeepers formulated this hypothesis and launched a call for research (Alétru, 2003). Results of a survey initiated in France showed that the most frequently found pesticide residue in pollen samples was imidacloprid (in 49.4 % of the samples), followed by one of its metabolites, 6-chloronicotinic acid (in 44.4 % of the samples). At least one of these two molecules was present in 69 % of the samples (Chauzat et al., 2006).

Alaux et al. (2009) found that honeybees that were both infected with the pathogen Nosema and exposed to imidacloprid at concentrations encountered in the environment showed the highest mortality rate comparing to honeybees infected with Nosema alone or treated with imidacloprid alone. Although imidacloprid contamination in the hive is usually found at sublethal doses, infection with Nosema increases the energy demands of bees and therefore their food intake. By this means bees could be exposed to lethal doses. Alaux et al. (2009) found that in the long term the synergy between Nosema and imidacloprid induced the immunosupression of an enzyme essential in sterilising larval food, leading to higher susceptibility of the colony to pathogens.

Authorisation has been requested since 2004 for two other seed-dressing insecticides in France. Poncho® (with the active substance clothianidin), produced by Bayer, has not been authorised for maize. Cruiser® (with the active substance thiametoxam), produced by Syngenta, has been authorised and honeybees were monitored in three regions in 2008 and six in 2009. In June 2009, the Minister of Agriculture decided not to renew the marketing authorisation of Cruiser® until autumn 2009. In December 2009, Cruiser® was reauthorised for use on maize for 2010.

Relationships between beekeepers and the Ministry of Agriculture seem to have improved. The decisions of the Ministers of Agriculture to ban Gaucho® on sunflower and maize significantly calmed the controversy and a Technical Beekeeping Institute has been created.

16.4.5 Assessment of Gaucho® at the European level

In the framework of Directive 91/414/EEC, imidacloprid has been assessed at European level for inclusion on the list of active substances allowed for marketing in the European Union. The rapporteur Member State for imidacloprid was Germany, which submitted a Draft Assessment Report (DAR) to the EFSA in 2005 (Rapporteur Member State, Germany, 2006). In 2008, imidacloprid was included on the list of active substances allowed for marketing in the EU ([47]).

Several studies produced in France, relating to the risk of Gaucho® to honeybees were not considered in the DAR. Notably missing were relevant studies on the exposure of honeybees to contaminated pollen and nectar (e.g. none of Jean-Marc Bonmatin's studies was included). In addition, the DAR report accorded only limited importance to sublethal effects, although there were at the core of the investigations in France because of their potential to create lethal effects in field conditions. Finally, the risk assessment methodology was not adapted to seed-dressing formulations.

Several NGOs (Stichting Natuur en Milieu, PAN-Europe, Inter Environment Wallonie, Nature et Progres and Mouvement pour le Droit et le Respect des Générations Futures (MDRGF)), analysed the DAR in a letter sent to the European Commissioner for Health. They articulated several criticisms of the DAR: the absence of necessary tests for each bee category (e.g. larval tests); underestimation of the nectar consumption per bee, meaning that the non-effect concentration was set too high; validation of studies without any validation criteria; discrediting of reports non-favourable to imidacloprid but thorough validation of reports favourable to the thesis that there were no risks to honeybees; flawed consumption tests and colony sizes too small to test egg-laying; insufficient measurement of sowing dust effects; and no consideration of synergic effects between the active substance and bee pathogens (Kindemba, 2009).

16.5 Lessons on the governance of controversies

The lessons developed in the present chapter are based on the case study of Gaucho® but may be relevant for governance of the controversy about systemic insecticide risks in general, in France and in Europe.

The most important factor fuelling the debate in France was increasing mutual mistrust between the parties involved, arising, in part, from a failure to generate and ensure access to information. This reinforces one of the lessons from the first volume of *Late lessons from early warnings* (EEA, 2001), namely the need to 'Provide adequate long-term environmental and health monitoring and research into early warnings'.

Initially, various local/regional government services confirmed the clinical signs described by beekeepers (CNEVA, 1997; AFSSA, 2001; Chambre d'Agriculture de la Vendée, FDSEA de la Vendée and FDSEA des Deux-Sèvres in Alétru, 2003). However, beekeepers have stated that on several occasions they could not access raw field data held centrally by the Ministry of Agriculture. Thereafter, beekeepers viewed further initiatives of the DGAL with suspicion, criticised the 'paralysis by analysis', the diversion of the 'official' research towards too 'complex' subjects and their exclusion from creating the research protocols. The Ministry of Agriculture did, however, finance two post-doctoral projects for two years, which made an important contribution to the work of the CST.

Another important lesson from the first volume of *Late lessons from early warnings* is the need to 'Ensure the use of "lay" and local knowledge, as well as relevant specialist expertise in the appraisal' (EEA, 2001) to ensure a correct understanding of the problem and to deal with conflicting social processes.

The first volume highlighted the importance of rigorous monitoring to identify early warnings and the need to provide sufficient funding to achieve that goal. We could add that the experience of honeybee colony decline in France shows that **bodies performing monitoring studies should have the trust and acceptance of the field actors directly concerned** (in our case, beekeepers and farmers). From the first alert, particular attention should have been given to the professional beekeepers, who have daily experience and good knowledge of the land and of the insects they breed. Where key actors are not properly engaged, the monitoring process becomes discredited and ineffective. For example, the actors directly concerned may cease to participate or the monitoring protocols may be poorly designed, leading to a focus on non-essential features of the

([47]) France maintains its ban on sunflower and maize seed-dressing.

problem. Furthermore, extensive local observations from such actors can help understand variability in clinical signs and the reasons that different circumstances produce varying exposures and effects.

Ensuring that relevant specialist expertise is involved is also of key importance to increase trust and the quality of information. As the current case exemplifies (see Section 16.3.2 above), there is a need to ensure that specialists involved in risk assessments are selected based on competence and transparent procedures. Furthermore, the risk assessment process should involve the relevant disciplines and the experts should have the relevant research experience (i.e. articles on the topic, published in peer-reviewed journals). For example, members of the official commissions assessing the evidence in risk assessment of honeybees must include more honeybee specialists than, for example, plant specialists. Where a causal pattern is being researched, balance should be ensured among the different fields of specialisation (such as honeybee diseases, toxicology and climate) because specialists in, for example, diseases are more prone to produce conclusions on diseases than on ecotoxicological aspects.

Governance of controversies about chemical risks must therefore be guided by a continuous focus on promoting mutual trust between the stakeholders, including scientists and policymakers.

With that goal in mind, **eight new lessons can be drawn from the present case study**.

First, governance must focus on identifying potential properties of new chemicals and anticipating surprises that may arise from them. It is unwise to assume that methods used to assess the risks of existing technologies are also appropriate for assessing risks from new technologies ([48]). In the present case, even though the nature of the risk posed by systemic pesticides was different from the one associated with sprayed insecticides, the same assessment tools (LD_{50} and HQ) were used for authorisation, without any assessment of their adequacy for new patterns of exposure and effects. The lesson learned is: **when dealing with new technologies, verify whether the methods already in use for risk assessment are relevant, given the specific new properties and characteristics of new risks**.

A second lesson deals with the adequacy of the present standardised tests regarding the assessment of pesticide risks to honeybees. The lesson is: **develop new tests to assess sublethal effects of pesticides, their chronic effects and their effects on the colony**.

The laboratory studies measuring imidacloprid's sublethal effects or chronic lethal effects showed a range of different results. One important reason for this diversity is the lack of standardised protocols for such studies, resulting in each laboratory using different approaches. From one study to another, several factors can be a source of variability (the subspecies of honeybees used, their age, the temperature, the fasting time, etc.). Each of these parameters can induce differences in the results. For example, it has been shown that there is considerable genetic variation between colonies regarding the immune responsiveness of colony members (Evans and Pettis, 2005). Alaux et al. (2009) also found differences between the responses of colonies to their experiment, despite the fact that these colonies came from the same location and were exposed to the same environment. They suggested that genetic background and colony history (pathogens, food sources) can produce these differences.

The differences between existing protocols are producing results that are difficult to compare. To address sublethal and chronic lethal effects of pesticides on honeybees, new official directives using standardised protocols are therefore needed.

Today, field experiments play a decisive role in determining the risks of a substance. However, the complexity of environmental factors and of bee colonies themselves means that the same conditions can never be reproduced. A particular combination of such factors arising in a field experiment cannot be considered representative of some kind of 'average' environmental conditions to which honeybees or other organisms could be exposed.

After 2004 a group of honeybee experts appointed (but not funded) by the French Ministry of Agriculture was tasked to develop new tests for honeybees for inclusion in risk assessment practice. This group had proposed several draft tests to the Commission for Biological Essays, charged with validating methods for risk assessment in France.

In Europe, until 2010, honeybee tests followed the European and Mediterranean Plant Protection Organisation (EPPO) 2001 norms (OEPP/EPPO, 2001). The International Commission on Plant-Bee

([48]) This is a very old lesson, developed in detail in the analysis of DDT by Dunlap (1978).

Relations (ICPBR) proposed a modified honeybee risk assessment scheme for systemic pesticides and changed the test guidelines for semi-field and field studies. Both have been submitted to EPPO for consideration (Thompson, 2010). The modified risk assessment scheme has been adopted as EPPO norm in 2010 (OEPP/EPPO, 2010a, b).

However, the process of revising this norm failed to significantly change the risk assessment pattern. The 2010 norm still does not consider sublethal and chronic effects properly. Furthermore, standardised laboratory tests are still missing for chronic and sublethal effects. Therefore, the European Commission has mandated the European Food Safety Authority (EFSA) to create a working group to assess the current risk assessment scheme.

The third lesson is not to underestimate the resources needed to implement policies. The case of Gaucho® revealed the French administration's difficulties managing the authorisation of new pesticides. Policymakers need to **ensure adequate personnel (in number and competence) and financial resources to design efficient regulatory procedures for risk governance and thus reinforce their ability to manage risks effectively**.

The fourth lesson is that **the independence and competence of the experts on the issue at hand must be assured, as well as complete transparency of the research process**. This lesson refers to researchers working both in private and in publicly funded structures.

Publically funded researchers can be also at risk of conflicts of interest. First, the low funding of public research can mean that some laboratories are obliged to find external sources of funding (including pesticide-producing companies). Second, some public researchers may also be consultants for the chemicals industry (e.g. addressing the effects of certain substances on honeybees or other subjects such as the development of anti-mite products against *Varroa jacobsoni* for companies which are also producing insecticides used in crops visited by honeybees).

Conflicts of interest can be financial, with the funding potentially influencing a researcher's work in favour of the funder. They can also be intellectual, where the prior commitment of a scientist to a particular world view prevents him or her seeing other perspectives. However, even if no scientist is 'completely free' of subjectivity, some strive to be as impartial as possible. All the conditions for them to be able to do so must be institutionally insured.

Furthermore, building a clear framework for their expertise, which reduces the possibility of selective use of information, of avoiding responsibility or of ambiguous statements, could reinforce the legitimacy of expertise and diminish its potential for generating controversies.

Research policies and funding should be balanced between two core goals: science explicitly targeting the development of knowledge with commercial purposes (resources for the 'knowledge economy'); and science targeting the development of socially valuable knowledge (resources for the 'knowledge society'), such as knowledge on health and environmental risks. The first kind of science can draw largely on private funding. The second type of knowledge requires publicly managed funding and a particular status for the researchers involved, ensuring the 'highest possible level' of independence from vested interests and institutional pressure. Research developed in public structures can complement the evidence on chemical risks produced by the industry pursuant to existing regulatory frameworks.

In addition, the contractual relationship between industry sponsors and public or private researchers of risk could provide for a legal guarantee that, for example, findings will be published regardless of their content.

Industry dossiers that support the authorisation of chemicals must be transparent. External parties should be allowed to scrutinise the dossiers and the original studies, contributing to content and to the overall quality of the dossier. The capacity of different stakeholders to provide comments should be balanced, thereby preventing the most powerful stakeholder from capturing the process with repeated comments. Complete information on the assessment of health and environmental risks should be easily available to both scientists and NGOs, and opportunities to comment should be created and stimulated. One option could be Substance Information Review Forums, similar to the Substance Information Exchange Forums organised in the framework of the REACH Regulation. To create real opportunities for review, the original studies on which risk assessments are based should be available through a cost-free database. Such a library could be also useful for cases where doubts arise about the risks of a substance after is has been authorised.

All researchers, private or public, publishing or involved in regulatory risk assessments should communicate their conflicts of interest. This is already the case in many situations but these declarations should also be readily available to the public (e.g. on the internet). Researchers should not be involved in evaluating the risk of pesticides produced by the company financing them or their laboratories.

The fifth lesson is: **be aware that the social quality of the scientific information you communicate in the debate determines your public trustworthiness**. The present case study showed major deficiencies in the communication of scientific information by Bayer and by certain administrative services of the French State, contributing to the distrust of other stakeholders and intensification of the debate. We have six recommendations for the social quality of information communicated in a contested policy process:

- be reliable — base your arguments on all available scientific knowledge;
- be robust — answer criticism instead of ignoring it;
- be complete — do not ignore the information produced by other stakeholders, especially those contradicting your own views;
- have a discourse relevant for the issue under debate (e.g. regarding the particular clinical signs or the geographical area evoked), instead of referring to general issues only distantly related to the problem addressed;
- be logical, do not contradict yourself except if you change your views and you explicitly recognise this;
- ensure the legitimacy of your sources (make appeal to competent researchers, who do not have conflicts of interests) (for further details, see Maxim and van der Sluijs, 2007).

The sixth lesson is that **structures responsible for assessing the scientific adequacy of applications for marketing authorisation should develop clear and standardised scientific quality criteria to enable existing studies to be evaluated and compared**.

All the existing literature, including scientific papers, should be taken into account in risk assessments and the scientific quality of the data submitted by the industry should somehow be assessed. An important issue is the balance between the burden of proof (i.e. who has the responsibility to produce evidence for decision-making on risks) and its credibility. The selection of valid studies (e.g. for obtaining marketing authorisation) should be based on uniform and clear criteria of scientific quality, not on some unjustified 'expert appreciation' of their relevance. Lack of precise criteria for evaluating the quality of a study can lead to arbitrary or subjectively justified exclusion of certain studies from the risk assessment process. This exclusion can potentially have a decisive influence on the final result.

In addition to existing practices for the quality of the laboratory work, criteria for evaluating the scientific quality of studies should be established. Good Laboratory Practice (GLP) standards ensure a framework in which laboratory studies are controllably planned, performed, monitored, recorded, reported and archived. However, the GLP certification only provides guarantees about the transparency and the traceability of the laboratory work. It does not guarantee the scientific quality of the study. For non-standardised tests, GLP does not warrant, for example, that the protocol chosen for a study adequately takes into account the biology and the behaviour of the studied organism or that the results are correctly interpreted. However, whereas new patterns of risk need to be assessed, novel tests that are not yet standardised are increasingly needed.

The seventh lesson deals with multicausality: **prioritise the potential causal factors and address them separately before assessing potential correlation or synergies among them**. Honeybee losses can be influenced by many factors but this should not become an excuse for not dealing with particular clinical signs and particular causes. Action should not be hampered because several potential causes are involved. On the contrary, potential causes have to be prioritised before being addressed. The different causes could play different roles, e.g. some might be 'primary' (i.e. influencing the expression of other causes), whereas others may be 'secondary' (e.g. immunodepression due to pesticides could favour diseases, as was shown for imidacloprid and Nosema) (see also Maxim and Van der Sluijs, 2010).

The discourse on multicausality is only apparently contradictory with the discourse on the risk of Gaucho® to honeybees. Thus, the fact that many factors influence honeybees **all over the country** does not contradict the fact that Gaucho® posed a risk to honeybees **in Gaucho®-treated extensive sunflower and maize areas**. It is obvious that some causes can mainly act in some geographical areas and other factors can be present everywhere in a country. Certain factors could act at particular moments of the year (e.g. during the summer), whereas others could act throughout the year.

In choosing which factor to focus research on first, considerations such as feasibility, potential to reduce the final effects, and co-benefits (e.g. reduction of social conflict) need to be taken into account. Investment in research, to improve understanding of synergistic effects between low doses of systemic insecticides and other factors like diseases, seems important for addressing losses of bee colonies.

The eight lesson is: **build the regulatory background needed to protect early-warning scientists**. The case of Gaucho® raises questions about science's role in democracy and about the resources scientists receive from society. There are many critics of science but how many also address society's obligations towards scientists? How much freedom of thought and responsible action are science professionals institutionally given in such conflicting cases? How does society recognise and provide legal protection to early warning scientists?

Although the impacts of pesticides are important and have high social relevance, generalised social conflict associated with this issue is likely to discourage scientists from working on the subject.

In the European 'knowledge society', democratic production of knowledge should benefit from institutional structures favouring scientific accountability (based on sound peer review and validation) and the freedom of scientists to pursue their work independently on socially sensitive issues. If science is to continue to inform decision-making, open discussion and criticism, respectfully expressed, is to be encouraged. Misuse of scientific results to support predetermined conclusions, and actions that provoke anxiety and psychological pressure are unacceptable (see also Gleick, 2007).

16.6 Conclusions and prospects

Imidacloprid seems to be a substance particularly 'fit for the precautionary principle'. The effects on living beings are highly variable, both for honeybees (the lowest oral LD_{50} is 21 times lower than the largest LD_{50}, a factor of 40 separates the lowest and largest contact LD_{50}s and a factor of 1 000 separates the LOECs for chronic toxicity) and for other organisms, for example wild bees (Tasei et al., 2000; Morandin and Winston, 2003; Desneux et al., 2007; Colla and Packer, 2008; Mommaerts et al., 2009). Calculated half-lives of imidacloprid range from 83 days to 1–2 years.

Imidacloprid's persistence in soil is affected by various factors, including temperature, soil composition and whether the field is cropped or not (Canadian Council of Ministers of the Environment, 2007). It is thus plausible to say that the risks of imidacloprid are dependent on a specific assembly of environmental factors, such as temperature, humidity and soil composition. Furthermore, more than one study failed to find a dose-effect relationship between imidacloprid and chronic effects (Suchail, 2001; Schmuck, 2004). Given this variability, it seems likely that some of the effects of Gaucho® are **uncontrollable**.

The present chapter focused on the **social** consequences of this diversity of ecotoxicological effects. It is interesting to find that a diverse ecotoxicological portfolio allows each stakeholder to identify their own 'scientific arguments' and use them for defending opposite positions in the debate.

Declining honeybee colonies have been reported in several European countries (e.g. Belgium, Italy, Portugal, Germany, the Netherlands and the United Kingdom) and have sometimes been related to seed-dressing insecticides (CARI, 2003; Panella, 2001; Ministério da Agricultura, do Desenvolvimento Rural e das Pescas, 2000; COLOSS, 2009). The European Parliament has officially acknowledged the issue since December 2001, when a resolution dealing with the production and marketing of honey was adopted (European Parliament, 2001). It states that: 'extremely serious damage has been caused to bee populations in several Member States by systemic insecticides with extremely long residual activity periods used in arable seed coatings, which have led to the mass poisoning of colonies.'

The precautionary principle has been applied in other European countries for seed-dressing insecticides. Imidacloprid, clothianidin, thiametoxam and fipronil have been temporarily banned in Italy, on oilseed rape, sunflower and maize seed-dressing. A research programme (APENET) has been started to improve understanding of relationships between these active substances and the honeybee losses found in this country. APENET found that after the ban, the number of reports of high mortality during spring decreased from 185 cases in 2008 to two cases in 2009 (Il punto coldiretti, 2009). The ministry decided on 14 September 2009 to extend the ban until 20 September 2010 (Ministero della Salute, 2009) and then until the 30 June 2011 (Ministero della Salute, 2010). Italian researchers found a clear indication that honeybees were killed by the dust emitted during sowing neonicotinoid-coated maize in conditions of high humidity (Marzaro et al., 2011).

In Slovenia, clothianidin, thiametoxam and imidacloprid in oilseed rape and corn seed treatment have been successively banned, reapproved and then banned again between 2008 and 2011.

In Germany, eight insecticidal seed treatment products with the active substances clotianidin, thiametoxam and imidacloprid were temporarily banned on maize in May 2008 and the bans were renewed for February 2009 (BVL, 2009). In January 2011, certain formulations of the three active substances were suspended, whereas others were authorised in agricultural uses (BVL, 2011). Germany lifted the suspensions except for the use of the neonicotinoid clothianidin in corn seed-treatment (EPA, 2011).

Since 2006, American apiaries have reported 'Colony Collapse Disorder', where colonies are suddenly lost (MAAREC, 2011). Because the clinical signs of disappearing adult honeybees recalled the clinical signs found by French beekeepers, the popular and scientific media — rightly or wrongly — drew parallels with honeybee colony decline in France. Clearly, before any conclusions are drawn, the specific characteristics ('fingerprints') of the clinical signs and their spatial and temporal patterns must be properly compared.

There is growing evidence in some European countries of parallel declines in pollinators and pollinated plants (Biesmeijer et al., 2006; Vaissière, 2005). In some cases, such as China's Sichuan province (Newsweek, 2008), honeybee declines have forced farmers to pollinate fruit trees by hand. Can Europe afford this?

Domestic honeybees are managed by humans and represent a source of revenues. Much less is known about other species. The role of the honeybee as a bioindicator for the state of the environment was highlighted during the debate in France. A study published in the journal *Nature* (The Honeybee Genome Sequencing Consortium, 2006) found that honeybees tend to respond faster than other insects to environmental pollution. It seems that the size of the major detoxifying gene families is smaller in the honeybee, which makes it unusually sensitive to certain pesticides; honeybee losses can be interpreted as an 'alarm bell' of harm to other entomofauna and indirectly to plants, birds and other species.

Our case study highlights the importance of ensuring scientists' independence (which is never absolute but varies significantly). Knowledge of risks can be limited by a number of factors: funding constraints, which necessitate the need for private sector resources; a dearth of research positions in toxicology and eco-toxicology; or assessing the quality of the research by institutional rather than scientific criteria.

Social concerns are essential to establishing a relevant research agenda. As pollinators, honeybees have an ecologic impact on the survival of plants in the wild. But they have important impacts on people, most notably the economic value of free pollination of many fruits and vegetables.

Table 16.1 Early warnings and actions

1991	First authorisation of Gaucho® in France, for sugar beet seed-dressing. Adoption of Council Directive 91/414/EEC
1993	Authorisation of Gaucho® for sunflower seed-dressing
1994	First use of Gaucho® in sunflower seed-dressing First clinical signs observed by beekeepers, during sunflower nectar flow. Analysing all the potential factors involved, beekeepers suspect Gaucho® of harm to their apiaries
1995–1997	Bayer conducts several studies on the risk of Gaucho® for honeybees. All report absence of harm. Greater declines in honeybee colonies are reported. At the same time, the areas growing Gaucho® seed-dressed sunflower are also rapidly increasing
1997	During an important meeting with representatives of Bayer and the Ministry of Agriculture, beekeepers publicly point to Gaucho® as cause for observed massive honeybees' losses. The first report of the Commission for Toxic Products is published. It recommends further research
1998	The first research programme involving publicly funded researchers detects imidacloprid in sunflower nectar and pollen. RégentTS® is suspected of contributing to the clinical signs in honeybees. On 17 December, more than 1 000 beekeepers demonstrate in Paris, in front of the Eiffel Tower, demanding a ban on Gaucho®. In the apiaries affected, sunflower honey yields 30–70 % below normal potential are reported
1999	In January, the Ministry of Agriculture decides to ban Gaucho® in sunflower seed-dressing for two years, applying the precautionary principle. The conflict shifts to court, as Bayer challenged the ministerial decision in the administrative court of Paris (March 1999). The UNAF defends the Minister's decision in court
2000	In response to new scientific findings detecting imidacloprid in maize pollen and confirming high persistency in soils, beekeepers demand to ban imidacloprid for all uses
2002–2003	Intoxication episodes severely affect several thousand hives; residues of fipronil are found in dead honeybees
2004	The Minister of Agriculture temporarily bans Gaucho® in maize seed-dressing and RégentTS® for all agricultural uses
2005–2007	French beekeepers report cessation of high summer mortality. Colony recovery is gradual but winter losses vary annually
2009	Scientific publication proving synergic effects between imidacloprid and Nosema
2010	UNEP publishes report on global honeybee colony disorders and other threats to insect pollinators (UNEP, 2010)
2011	French/German beekeepers ask EEA to consider bees as sentinel species for their ecosystems (EEA, 2011)

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Panel 16.1 The Bayer CropScience view on Maxim and van der Sluijs 'Seed-dressing systemic insecticides and honeybees

Dr Richard Schmuck, Head of the Department of Environmental Safety of Bayer CropScience

The authors' efforts to analyse the challenge for democratic governance of controversies on chemical risks are commendable in their aims. There are, however, shortcomings in the focus they chose. Democratic governance is a complex matter. It requires looking at the root causes of societal and political reactions and to separate them from emotional and intellectual forces involved. Moreover, policymakers are often under pressure to take rapid decisions: thus as long as causal patterns are far from clear, all potential ones should at least be addressed.

The publication focuses on chemical governance in response to bee colony losses in France. The insecticidal seed treatment Gaucho® is taken *a priori* by the authors as THE key cause of these losses. This approach can not arrive at a balanced conclusion since it fades out numerous scientific papers that cover the multiple factors contributing to bee losses (such as bee diseases, habitat loss and with that loss of bee feeding-grounds, changing agro–ecosystems, including due to economic and trade reasons, or unfavourable climatic conditions that add stress on honey bee health). The authors also omit to consider literature (Rivière-Wekstein, 2006) that covers the sum of the socio-political, economic and other drivers that led to the suspension of Gaucho® in France. This would, however, have been an essential source when undertaking this research, especially in the context of governance.

Bee losses were first attributed to imidacloprid in France during the 1990s. They were not related to specific product incidents. Rather the product market introduction coincided with a time when bee health issues had increased. Later, an accident with another neonicotionoid insecticide occurred in Germany which was attributed to an inappropriate quality of the seed treatment process. This was very regrettable, although lessons were learned and resulted in enhanced mitigation measures to prevent reoccurrence. Due to both these situations much research — partly pioneering new testing designs was undertaken. As a consequence more is known today about bee safety of the neonicotinoids.

For some years now, the majority of researchers have highlighted the multi-factorial nature of bee colony losses. A series of long-term, large-scale monitoring programmes confirm these findings. They have been conducted in Belgium, France, Germany, the US and other countries. In these programmes, exposure to pesticides was measured as well as colony health and safety. None of them have found a correlation between colony losses and exposure to neonicotinoid seed-dressing products (Chauzat et al., 2009, 2010; Nguyen et al., 2009; Genersch et al., 2010).

Bayer CropScience is committed to finding solutions to enhance honeybee health, e.g. by providing Varroa mite management products including potential new treatments, and bee safety, e.g. by ensuring the sustainable use of its pesticides through research and promotion of 'bee-responsible' farming practices. When evaluating new pesticides (this costs about EUR 250 million per compound) prior to market release we follow legal requirements and the spirit of precaution in a way that is as practical and responsible as possible; we also acknowledge that perceptions will vary among stakeholders of what constitutes an acceptable level of precaution, depending on their knowledge, perspectives and interests. The positive tension between innovation and precaution we see, continues to drive both technological progress and the move towards enhanced pesticide regulation — to the benefit of agriculture, the consumer and the environment. This is what was generated through the Gaucho® case, especially in the context of bee safety. Suspending products may be helpful in some instances. It does however bear the risk of stopping innovation if it is not handled carefully, thus being made reversible — should new data confirm the lack of plausibility of earlier decisions.

From field observation of aphids, we were already able to deduce, before the first registration of Gaucho®, that bees would not be affected by systemic residues in treated sunflowers. Laboratory tests had shown that aphids are ten times more sensitive to Gaucho® than bees. Despite treatment of seeds with Gaucho®, aphids were observed in the field re-invading sunflower plants before blooming, so it was logical to conclude that there would no longer be effects on bees either at the time of blooming. Since its registration in the early 90s, Gaucho® has met all post-registration re-evaluation requirements and NO evidence of a causative link between Gaucho® use and bee colony losses could be found. (e.g. Faucon and Chauzat, 2008; Nguyen et al., 2009). In addition, large-scale monitoring programmes run under field conditions during the

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post-authorisation period confirmed the original findings of 1998 (no causative link to Gaucho®) of the ACTA monitoring programme (Association de Coordination Technique Agricole).

Gaucho® continues to be registered for use in sunflower crops in various countries, including Argentina, Australia, Bulgaria and Croatia. In none of these countries have bee colony losses been reported in connection with sunflower growing (Neumann and Carreck, 2010; Ivanova and Petrov, 2010; Tlak Gajger et al., 2010). During the years following the suspension of Gaucho® in France, bee colonies have continued to suffer losses (e.g. Faucon and Chauzat, 2008; AFSSA, 2009; Chauzat et al., 2010b). According to a statement made in November 2007 by the then French Minister of Agriculture, Michel Barnier to the National Assembly bee losses were also observed in regions where Gaucho® had not been applied.

We are thankful for the opportunity to share our view here with various stakeholders. Further information on the subject can be found in Bayer's 2011 publication on 'Honey bee care: Challenges and solutions' http://www.bayercropscience.com/bcsweb/cropprotection.nsf/id/EN_Bee_Health_Crop_Protection_2010/$file/Honey_bee_care.pdf.

See the full comprehensive review, including additional references:
http://www.eea.europa.eu/publications/late-lessons-2/bees-insecticides-debate.

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Laura Maxim, Jeroen van der Sluijs

Mr Schmuck insists on how complex and uncertain things are and on how policymakers are taking decisions under pressure. However, the decision to ban Gaucho® was taken in France about five years after the first clinical signs in bees and two years after the public boom of the controversy — for sunflower. The corresponding delay for maize was ten, respectively seven, years. The word 'rapid' does not seem adequate to us for these time frames.

Further in the text, these same policymakers (Mr Barnier) are subsequently quoted in Mr Schmuck's text as legitimate and reliable sources. Should one understand that policymakers 'act under pressure' when they apply the precautionary principle as they did in banning Gaucho®, and that they are 'good policymakers' when they see reality as being too complex to take a decision but actually decide to maintain the status quo?

The speech of Mr Barnier is, by the way, perfectly reasonable, stating that honeybees' losses are not all due to only one factor (indeed, nobody ever claimed that one factor causes all honeybee losses!). He also says that several factors influence honeybees, and that all these factors do not act at the same time and at the same place, which are truisms. The fact that honeybee losses can be due to Gaucho® is not at all contrary to the fact that honeybee losses can also be due to diseases or lack of food, just as human beings can die of many causes, such as car accidents, diseases or cancer. This is not an argument for not trying to limit car accidents or treat cancer, just as the fact that many factors can influence honeybees is not an argument for not dealing with Gaucho®.

Multicausality cannot become an argument for avoiding dealing with specific causes, or for avoiding establishing priorities among causes and addressing them. There is clear value in prioritising those causes that are easier to control. For example, it is much more difficult to address climate change than to limit the use of a specific pesticide.

The phrase 'The insecticidal seed treatment Gaucho® is taken *a priori* by the authors as THE key cause of these losses' is a blunt misrepresentation of our text, Mr Schmuck then arguing against this misrepresentation. If read carefully, our text is precise: 'In this chapter, we present the historical evolution of the evidence regarding the risks of Gaucho® for honeybees in sunflower and maize seed-dressing, and analyse the actions in response to the accumulating evidence regarding these risks.' Our subject is not all honeybee losses, in France or in the world, in all times. We address honeybee losses 'in sunflower and maize areas', from the start of the controversy in 1994, to the political decisions to ban Gaucho® in sunflower and maize seed-dressing, in 1999 and 2004, and analyse the developments in science and society that ultimately lead to these decisions. As we have also specified in our chapter, 'many factors can play a role in the state of honeybees and pollinators more generally'.

We disagree with Mr Schmuck that the book of Gil Rivière-Wekstein can be considered an 'essential source'. Its author is the director of a firm providing consultancy for companies, who has produced papers on diverse subjects not related to honeybees such as USA Elections 2004: eleven democrat candidates facing George W. Bush and Enron, the crush of an empire.

More generally and beyond this particular reference, the length of our paper did not allow us to include extensive reference to several insightful and relevant books written in France on the subject of Gaucho® by journalists, policymakers or NGOs, including:

- Cicolella, André and Benoît-Browaeys, Dorothée, 2005. Alerts on health: experts and citizens face to private interests [49].
- Nicolino, Fabrice and Veillerette, François, 2007. Pesticides: revelations about a French scandal [50].

[49] Alertes santé : experts et citoyens face aux intérêts privés.
[50] Pesticides : revelations sur un scandale français.

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Massive bee-poisoning events from dust emissions during sowing of maize coated with neonicotinoids such as the one in 2008 in Germany are not incidents or accidents but have continued to happen since in many countries. The Italian moratorium on seed dressing with neonicotinoids lead to a reduction of the number of such reported poisoning incidents from 185 beekeepers (6 328 hives) per year to 3 beekeepers per year, these 3 remaining cases could all be linked to illegal use of neonicotinoid seed dressing (APENET) ([51]).

The loss of 2 500 bee colonies during maize sowing in the Pomurje region in Slovenia in April 2011 demonstrates that the prescribed mitigation measures are still insufficient (Drofenik, 2011).

A series of recent field trials by Girolami's group (Marzaro et al., 2011; Girolami et al., 2012; in press) has demonstrated that even when all mitigation measures are implemented such as deflectors and improved coatings, the pneumatic maize sowing machines still produce a ellipsoidal toxic cloud of dust particles of 3 meter high and 20 meter wide that is acute lethal to honeybees that cross this cloud on their flight. A single flight though that dust cloud showed to provide an average dose of 300 ng imidacloprid per honeybee.

The use of 'Gaucho®' in sunflower crops in countries such as Argentina and Australia cannot be compared to its previous use in France. The concentration of imidacloprid presently used in the 'Gaucho®' product is much lower than it was in France in the 1990s. The two situations are therefore not comparable, since that lower doses of imidacloprid lead to lower exposure of bees, and might have more long-term than short-term effects. As well, it can be hypothesised that national characteristics such as soil, climate, relative attractiveness of the plants for honeybees etc. could significantly influence the imidacloprid uptake from soils and its availability to honeybees.

It seems that Mr Schmuck used extrapolation from aphids to honeybees for being 'able to deduce, before the first registration of Gaucho®, that bees would not be affected by systemic residues in treated sunflowers'. He does not specify if this extrapolation was based on scientific publications or on some sort of 'expert judgment'. So we have searched in the Web of Science — Current Contents database (including 8 500 major journals and 9 000 web sources) with the key words (in topic): aphid AND honeybee (variant: honey bee) (+ AND extrapolation). Only two relevant records were found (Matsuda, 2009 and Guez, 2003), which did not exist at the time when the extrapolation had apparently been done before the registration of Gaucho®. These publications rather support evidence against this extrapolation.

Moreover, several important differences between honeybees and aphids raise doubts about the relevancy of such an extrapolation:

- looking at aphids behaviour on sunflower plants only considers short-term effects but ignores the long-term effects. Indeed, honeybees store pollen and nectar in the colony and can consume them on the long run. The honeybees could repeatedly ingest the contaminant on the long term, leading to chronic effects.
- different ages of individuals in a honeybee colony vary in their sensitivity to insecticides. Even if foragers (collecting pollen and nectar in the fields) are not affected, other honeybees in the colony could be intoxicated (nurses, larvae)
- all the aspects related to the complex social organisation of honeybees are missing in aphids
- observing aphids cannot account for synergic effects of neonicotinoids on the honeybees colonies, as those highlighted by Cummins (2007), Alaux et al. (2009), Videau et al. (2011) and Pettis et al. (2012) for imidacloprid and the pathogen Nosema.

We are astonished that the effects in aphids were assumed to be similar to the effects in honeybees. Such extrapolative assumption would indicate lack of selectivity of imidacloprid on target and non-target species and should have, on the contrary, raised worries about the potential effects on honeybees.

([51]) http://www.bijensterfte.nl/sites/default/files/Piotr_Medrzycki_-_Apimondia_2009.pdf and http://pub.jki.bund.de/index.php/JKA/article/view/146/131.

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Several other sources cited by Mr Schmuck merit consideration. First, it is normal that different signs and potential causes will be identified depending on the protocol used and the specific situation studied. Ivanova and Petrov (2010) and Tlak Gajger et al. (2010) employed surveys that did not address summer mortalities but winter colony losses. In both papers, the causal investigation used only beekeepers' opinions but did not undertake chemical analysis. The Bulgarian survey looked at 1.3 % of beekeepers, the Croatian one at 3.6 %. One of the two papers, Ivanova and Petrov (2010), refers to sunflower, mentioning: 'untypical behaviour of honeybees in some regions of north Bulgaria manifested by avoiding flowering sunflower was also reported'. No indication is given about how this behaviour had been measured or observed, for example whether it was apparent in diminishing sunflower honey production or behavioural signs. The paper mentions that 'the problem appeared to be more serious for areas with cultivated fields and grasslands due to crop protection activities, such as the north-central and north-eastern parts of Bulgaria….'

Neumann and Carreck (2010) is another undue reference for addressing honeybees' intoxication on sunflower crops, as sunflower is not referred to at all. The paper notes, however, that 'These interactions are particularly worrying, as sub-lethal effects of one driver could make another one more lethal; for example a combination of pesticides and pathogens' (p. 3).

Another paper by Bacandritsos et al. (2010), which was not cited in Mr Schmuck's response, refers to summer losses in Greece. This paper reports results of chemical analysis of honeybee tissues showing that 60 % of the samples analysed contained imidacloprid, in an average concentration of 27 ng/g tissue. A high level of virus and N. ceranae infection accompanied this contamination. Also, the study by Krupke et al. (2012) shows a link between clothianidin coated maize and bee mortality in spring in the same area.

Some of the authors quoted by Mr Schmuck have recently published papers on pesticide loads in France (Chauzat et al., 2010). Imidacloprid was found to be widely available to honeybees. The average levels of imidacloprid found in pollen is 0.9 ppb (with a maximum of 5.7 ppb). These results are in line with results published four years earlier by Chauzat et al. (2006), who found that the most frequently found pesticide residue was imidacloprid (identified in 49.4 % of the samples), followed by one of its metabolites, 6-chloronicotinic acid (in 44.4 % of the samples). At least one of these two molecules was present in 69 % of the samples. Statistical tests also showed no variance in concentrations between sampling locations, meaning that imidacloprid is present *everywhere* in the 5 sites considered, and that it is present in pollen loads *throughout the year*, with a maximum presence during July–August but comparable concentrations during spring and autumn.

The presence of imidacloprid in pollens all through the year, even long after the treatment moment, shows that honeybees are exposed all through the year, and not only during the agricultural season. This could also be an indication that imidacloprid is so persistent that it might be uptaken in non-treated crops or wild plants. Indeed, imidacloprid is currently banned in France for seed-dressing of sunflower and maize but it is still used in seed-dressing for sugar beet, wheat and barley. It is also authorised to treat fruit trees such as apricot, peach, pear, quince, apple and plum trees, in products for disinfecting storage facilities, shelters for domestic animals etc.

In conclusion, our chapter responds to one of the main objectives of the present report, which is to describe and analyse cases of application of the precautionary principle and reflect on what can be learned from these cases. The partial French ban of Gaucho® in sunflower and maize seed-dressing is one such explicit application of the precautionary principle.

See the full answer at: http://www.eea.europa.eu/publications/late-lessons-2/bees-insecticides-debate.

Panel 16.2 Response to the Bayer Cropscience (Richard Schmuck) comments on the chapter (cont.)

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