## Complaint 1089/2012/BEH to the Ombudsman about the European Commission

### **Summary**

Since December 2010, we have had prolonged correspondence with the European Commissioners (and the Chemical Regulation Directorate, the US EPA and, more recently, the Australian APVMA) about the neonicotinoid insecticides. We pointed out their persistence in the environment. We asked them why the chemicals were not monitored in surface and ground-water and gave them examples of increasing levels (in the Netherlands, and New York State). Subsequently we found that all the registration documents stated they were highly toxic to bees and to aquatic invertebrates. Despite this, the agencies have been remarkably uniform in their replies: "no link between neonicotinoids, if correctly used, and the problem of bee mortality could be identified...on the basis of current knowledge, a ban would not be justified." No-one mentioned monitoring of these chemicals in water or in the environment. Subsequently we provided references to independent research from France and Italy to show that administration of tiny amounts of a systemic neonicotinoid or fipronil to Colony Collapse Disorder (CCD) bees was associated with a weakening of bee immunity, such that they became more susceptible to bee diseases such as Nosema. We observed that these chemicals could account for epidemics causing massive global declines in a wide variety of species (honey bees, amphibians, bats, bumblebees and birds) due to infections (in the US to start with, later in Europe, now in Australia). Neonicotinoid insecticides act on mammalian nicotinic acetylcholine receptors as well, but scientists considered that the selective nature of its binding (i.e. less affinity than in insects) made it safe for human exposure. But no-one anticipated the extent of their global use, or the fact that our protection agencies wouldn't be taking precautions by monitoring levels in water or soil. Or that the shift in pest management would move away from reactive to prophylactic (like humans receiving permanent antibiotic treatment).

## Chronology of Correspondence

On 7<sup>th</sup> December 2010 we wrote to John Dalli and Dacian Ciolos about Dr Henk Tennekes' new book: 'The systemic insecticides: a disaster in the making" and enclosed photocopies of the contents and conclusions. As an independent toxicologist, he had shown that the neonicotinoid insecticide imidacloprid had become a major contaminant of Dutch surface water, particularly in the western part of the Netherlands. The chemicals are continuing to build up in the environment. He had published a paper in Toxicology in 2010 to show that the toxicity of neonicotinoid insecticides to arthropods is reinforced by exposure time. The chemicals can produce effects at any concentration level provided the exposure time is sufficiently long. (1) They are "systemic". The chemicals coating the seeds are water-soluble so they permeate the whole plant and therefore contaminate the nectar and pollen, so that any insect that feeds on the plants or forages the nectar or pollen will take in some chemical. (2) The chemicals are neurotoxins and exert their effects by blocking certain mechanisms of neurotransmission in the adult insect or in the larvae and are non-selective. They bind irreversibly to receptors in the insect's central nervous system and repeated small doses are cumulative. The company's own information on one of their imidacloprid products acting as a termite control says: "they stop feeding and are unable to maintain their colonies". (3) They persist in the environment are easily washed into the groundwater. Not only have there been rapid declines in invertebrates on intensively-used farmland in the Netherlands, but Dr Tennekes had correlated these declines with similar crashes in populations of insectdependent bird species in the Netherlands, France, Germany and the UK. On marshes there were similar declines in invertebrate-dependent marsh birds, in contrast to fish-eating birds, which were unaffected.

We reminded the Commissioners that on 16<sup>th</sup> November 2006, seventeen different European Beekeeping Associations and Environmental Organisations had written to Mr Markos Kyprianou, the then Commissioner of Health and the Environment, about the effects of these pesticides on bees and the environment, and asked to meet him. We do not know what the reply was, but it was clear that the EU continued to approve them.

On 13<sup>th</sup> December 2010 we sent a similar letter to Janez Potocnik, but specifically mentioned the European Water Frame Directive and the Habitat Directive. Dr Tennekes sent him a copy of his book, *Systemic insecticides: a disaster in the making*.

On 25<sup>th</sup> January 2011, we received a reply from Michael Flüh, Head of Unit, Ref Ares (2011) 79418 - 25/01/2011) which only mentioned bees and quoted the EFSA 2009 Report Bee Mortality and Bee Surveillance in Europe, which concluded that there is: "insufficient knowledge of causative and risk factors for colony losses." He said: "In addition, I would like to reassure you that, in the framework of Regulation (EC) No 1107/2009, the Commission is currently revising the data requirements for the submission of pesticide dossiers and that the provisions as regards the assessment of effects on bees will be strengthened."

On 29th January 2011, following an EU agricultural meeting, we received a reply from John Dalli, European Commissioner for the Health and Consumers Directorate. In it he said: "based on a first assessment by one of the Member State's authorities and followed by an EFSA peer review including all Member States experts, no link between neonicotinoids, if correctly used, and the problem of bee mortality could be identified" and later on in the letter: "... on the basis of current knowledge, a ban would not be justified".

On 7<sup>th</sup> February 2011 we wrote to the Commission again with new information about the chemicals. Ref Ares (2010931443 - 10/12/2010 and (Ref. Ares (236361- 03/03/2011) to our email to Ms Byrne for Vice-President Ashton (Ares135208 - 08/02/2011).

**On 3<sup>rd</sup> March 2011**, Michael Flüh again replied. He reiterated the points he raised in his previous letter. "In this context (Reg (EC) No 1107/2009), the Commission also asked the European Food Safety Authority (EFSA) for a scientific opinion to develop a Guidance Document on Risk Assessment of Plant Protection Products to Bees."

It was only recently, when we studied (EC) 1107/2009 more closely, that we found that clothianidin should never have been registered in the first place because it failed to fulfil the EU criteria for half-life in soil; this should be no greater than 120 days. (The US EPA conditional registration document for clothianidin in 2003 stated that the aerobic soil metabolism half-life under a variety of soil conditions was 148-1,155 days and the terrestrial field dissipation was 277-1,386 days.) The US EPA had excluded a figure at the top end, the extrapolated half-life of which was 6,931 days (2005). However, other EPAs have recorded soils in which there was no dissipation of clothianidin. Persistence in the environment is a characteristic of all the chloronicotinyl family of pesticides, since chlorine does not occur in nature. In fact, imidacloprid should not have been registered either (New York State quoted the half-life of imidacloprid in soil as "ranging from 120-365 days"). Clothianidin is a metabolite of thiamethoxam ('in calculating Maximum Residue Limits (MRLs) the sum of thiamethoxam is expressed as thiomethoxam').

On 23<sup>rd</sup> February 2011 we had written to Tom Moriarty, US EPA Office of Pesticide Programs and Head of the Bee Unit, suggesting, in view of the papers which showed immune suppression in honey bees exposed to minute doses of imidacloprid, the neonicotinoid insecticides might be responsible for the epidemics due to infections causing massive declines in a wide variety of global wildlife. He referred us to Ms Claire Gesalman, Head of the US EPA Communications Branch, who avoided answering the question.

On 14<sup>th</sup> April 2011, we wrote to the Commissioners and Vice-President Ashton with our hypothesis of Widespread Immune Deficiency Disease in Wildlife. We pointed out the global use of these pesticides, and the absence of monitoring levels in the environment.

On 20<sup>th</sup> May 2011, we had a postal reply (Ares (2011)550077) from Eric Poudelet, Director of the Safety of the Food Chain Directorate. He said we had no scientific proof of the hypothesis. However, once again he avoided the question about the European Commission's failure to require monitoring of surface- and groundwater.

On 28th May 2011 we replied to Eric Poudelet (also by post). By this stage we had found the US EPA Conditional Registration Document for Clothianidin, which mentioned evidence of immune deficiency in rats and a particular susceptibility in juveniles. We enclosed a newer version: 'Proof of Immune Deficiency in Wildlife', to which we had appended the references. We pointed out page 13, the effects on human health and page 9, the extensive exposure of the public, of which they were unaware.

We had also received evidence of contamination of imidacloprid in private wells and golf courses which led New York State to limit its use in 2003/4. NYS Department of Health never registered clothianidin because they were so concerned about the health of its citizens. There would have been an additional source of contamination in food residues. The EFSA has been raising Maximum Residue Limits (MRLs) of many pesticides in food crops at the request of industry, simply to accommodate intended uses or to take international trade into account (see Complaints against the EFSA).

On 17<sup>th</sup> April 2012 the EU Ombudsman issued Press Release No. 6/2012. Following a complaint by the Austrian Ombudsman Board, alleging that the Commission has failed to take into account new scientific evidence arguing in favour of restricting use of these insecticides, he is investigating whether the Commission should do more to combat increased bee mortality. The Ombudsman has asked the Commission to submit an opinion by 30<sup>th</sup> June 2012.

On 18<sup>th</sup> April 2012 The European Food Safety Assessment (EFSA) Panel on Plant Protection Products and their Residues published a 275-page document: "Scientific Opinion on the science behind the development of a risk assessment of Plant Protection Products on Bees." This had been previously requested by the Commissioners.

On 16<sup>th</sup> May 2012, we sent a 3-page email, and attached two supporting documents: one page summarising the US EPA 2003 conditional registration for clothianidin and a 10-page document of independent scientific papers showing the effects on human health, to the European Commissioners. We asked for acknowledgement that they had been received and that the documents had been read by the Commissioners themselves, rather than just by Senior Civil Servants in the EU. As of the 6<sup>th</sup> June, we have not even had an acknowledgement.

May 23<sup>rd</sup> 2012. The Swiss Federal Office for Agriculture reported that approximately 100,000 bee colonies in Switzerland (it approximates to half of all the colonies in the country) did not survive the winter. Dr Jochem Pflugfelder, who had been an invited delegate at the SETAC Pollinator Risk Assessment Workshop (see EFSA doc), was from the Swiss Bee Research Center. In a 5-minute radio interview, he placed the blame entirely on the parasitic *Varroa* mite. He never once mentioned pesticides.

May 29<sup>th</sup> 2012. The Ontario Ministry of Agriculture and Food investigated the occurrence of hundreds of thousands of dead bees in piles outside hives right across the province. Bee samples were taken and residues of clothianidin were found in 28 out of 37 samples.

On June 1<sup>st</sup> 2012 the EFSA issued a Press Release. "EFSA reviews studies on some pesticides and bee health."

The two documents published by the EFSA (18<sup>th</sup> April and 1<sup>st</sup> June) on Plant Protection Products and Bees cannot be called 'Scientific Opinion'. They are a cynical parody of science. As an organisation that is supposed to be protecting people and the environment in Europe, the EFSA cannot be taken seriously when it has no knowledge of the baseline levels of neonicotinoids in soil, surface and ground-water. They are using delaying tactics to protect the industry and keep the neonicotinoids on the market, just as the SETAC Workshop was in January 2011. In fact, the recommendations for further research are very similar to those identified in the SETAC Summary Report.

#### Persistence in the environment

Imidacloprid has been on the market in Europe since 1994 (US since 1991) and clothianidin since 2004 (US since 2003). Both are extremely persistent in the environment, toxic to bees and aquatic invertebrates. They should never have been registered in the EU.

## Evidence of water contamination and environmental residues

Evidence from competent authorities of increases in levels in water, and residues in soil, were first reported in 1996 by New York State for imidacloprid, the Dutch Water Boards from 2003 onwards, the California Department of Pesticide Regulation from 2008. In the study of multiple routes of exposure of bees in maize fields in Indiana, (Krupke *et al.* 2012), clothianidin/thiamethoxam residues were found in soil, in dead bees, in bee pollen fed to new queens, in wild flowers, as well as residues in fields that hadn't been planted for 2 years.

## Toxicity to aquatic invertebrates.

There are warnings on instructions for use on the products and on protection agency websites. "This product is highly toxic to aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high-water mark." These instructions are often ignored by farmers and risk managers. Flooding events, of which there have been many in the last few years, spread the chemicals into the surrounding areas where they are taken up by wild plants, whose pollen and nectar are foraged by bees.

# **Environmental proof**

The EFSA dismissed the new Whitehorn et al. study on bumblebees. They said the study was unrepresentative of "foraging under realistic field conditions." In the Press Release Notes to Editors: they compared the "actual exposure with the doses used in the published research" with previous EFSA data and that of the Member states that had authorised imidacloprid (data unspecified and unpublished). The Pesticides Industry has two standards; one for industry research and one for independent research. Ms Gesalman US EPA wrote to us on April 15<sup>th</sup> 2011: "With regard to potential effects on non-target invertebrates and surface water contamination, EPA is not aware at this time of any data demonstrating an imminent hazard from clothianidin..... If you are aware of reliable data that demonstrate an imminent hazard as defined by federal pesticide law, please forward to me the author's name, publication name (peer-reviewed publications are preferred). We replied on 24<sup>th</sup> April: "Dear Ms Gesalman, You do not need science to see what is happening to the environment." Just stand in the middle of a field of oil-seed rape. Where are all the insects? The peer-reviewed study on bumblebees by Whitehorn et al. reported: Treated colonies had a significantly reduced growth rate and suffered an 85% reduction in production of new queens compared to control colonies. Given the scale of use of neonicotinoids, we suggest that they may be having a considerable negative impact on wild bumble bee populations across the developed world. This was precisely what had been happening (and continues to happen). Massive declines in wild bumble bees in the US and Canada were reported in the late 1990s. In 2011 in the US, Cameron et al. said that: "relative abundances of four species had

declined historically by up to 96%. Geographical ranges had contracted by 23-87%, some within the past two decades. Those species that had declined had significantly higher infection levels of the pathogen Nosema bombi and had low genetic diversity compared with those that had not." In 2008 Goulson et al. had reported bumblebee declines in the UK, but at that stage, they were not as drastic as in the US. In fact it was Prof Dave Goulson of Stirling University who led the Whitehorn study (unfunded). In bumblebee communities, unlike honey bees, the queen is the only one to survive the winter and start a new colony the spring. With a survival rate of only 15% it is understandable why US bumblebees have been wiped out.

The other new study was from France by Henry et al.: 'Non-lethal exposure of honey bees to thiamethoxam (neonicotinoid systemic pesticide) causes high mortality due to homing failure at levels that could put a colony at risk of collapse. Simulated exposure events on free-ranging foragers labeled with an RFID tag suggest that homing is impaired by thiamethoxam intoxication. These experiments offer new insights into the consequences of common neonicotinoid pesticides used.'

## The European Commission, the EFSA and the Pesticides Industry

The European Commission asked the EFSA to give a scientific opinion in relation to an emergency ban by France in March 2012 on Monsanto's MON810 GMO, herbicide-resistant maize. On 21 May 2012, the EFSA GMO panel reported that there was no specific scientific evidence "in terms of risk to human health, animal health or the environment" to support France's emergency measure. However, in the application by the UK competent authority on behalf of Syngenta, (EFSA-GMO-UK-2008-481) for the approval of GMO glyphosate-tolerant maize GA21 (adopted 30 November 2011) it is apparent that all three (the UK agency (presumably Defra), the EFSA GMO panel and Syngenta) were aware of the environmental effects quoted below, but the EFSA GMO panel has nevertheless "adopted" the application. (see EFSA doc)

#### Reduction in farmland biodiversity

- 1) "Changes in botanical diversity with the selection due to weed shifts, with the selection of weed communities mostly composed of tolerant species"
- 2) "The selection of glyphosate resistant weeds."
- 3) The EFSA admits to "potentially harmful effects at the level of arable weeds, farmland biodiversity, food webs and the ecological functions they provide".

The French have already had experiences of MON810 maize, but Monsanto is still trying to force it through, using the Courts. Monsanto persuaded the European Court of Justice on September 8<sup>th</sup> 2011, to rule that France's farm ministry "could not justify its authority" in banning the planting of a Monsanto genetically modified corn variety, MON810. On November 28<sup>th</sup> 2011, France's Conseil d'Etat backed that decision. Nevertheless, the French Agriculture Minister still banned it; planting statistics for Roundup® Ready GM Maize MON810 suggest that by 2008, France it had had enough of glyphosate- resistant 'super weeds' and Monsanto's seed patenting policy.

2003: 17 hectares 2004: 17 hectares 2005: 500 hectares 2006: 5,200 hectares 2007: 22,135 hectares

2008-2012: 0 hectares

In the US (Page 9, Evidence to the EU Commission) the farmers are trapped into a herbicide treadmill.

"The dramatic increase in the volume of herbicides applied swamps the decrease in insecticide use attributable to GE corn and cotton, making the overall chemical footprint of today's GE crops decidedly negative. The primary cause of the increase is the emergence of herbicide-resistant weeds. Weed control is now widely acknowledged as a serious management problem within GE cropping systems. Farmers and weed scientists across the heartland and cotton belt are now struggling to devise affordable and effective strategies to deal with the resistant weeds emerging in the wake of herbicide-tolerant crops. Herbicides and insecticides are potent environmental toxins. The USDA has been essentially silent on the impacts of GE crops on pesticide use for almost a decade. The vast majority of Glyphosate Resistant weed populations have emerged in Roundup Ready cropping systems. However, after in March the European Commission asked the EFSA for their opinion related to France's emergency measure.

# The European Commission seems to have pre-empted the Ombudsman's Investigation into Bee Mortality

According to the EFSA's Press Release of June 1<sup>st</sup> 2012, the European Commission has recently given them a mandate to provide an in-depth review of the effects of the neonicotinoid active substances thiamethoxam, clothianidin, imidacloprid, acetamiprid and thiacloprid. The review will be published in December 2012. The European Commission must have tacitly assumed that the EFSA would reject the new papers and suggest more studies; which it has.

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