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Androulla Vassiliou
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DG Health and Consumer protection
B-1049 Brussels
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Utrecht, 21 Januari 2009
our reference: HM/jc/090120.01-4.1.0.40.N08
contact: Mr. H. Mullerman
subject: Re: Request for an internal review of Commission Regulation 116/2008

Dear Commissioner,

I am writing on behalf of undersigned organisations to submit a formal request for an internal review (based on Regulation 1367/2006, article 10) of Commission Directive 116/2008 of 15/12/2008 which was published in the Official Journal of 16/12/2008. It is the opinion of our organisations that Commission Directive 116/2008, including the active substance Imidacloprid in Annex I of Directive 91/414, is not justified on several grounds and should be reviewed as a matter of urgency. Please find below the basis of our request.

Procedural criteria:

Our organisations are entitled to make this request because we fulfil the criteria laid down in article 11 of Regulation 1367/2006. Stichting Natuur en Milieu, PAN-Europe, Inter Environnement Wallonie, Nature et Progres and MDRGF France are all independent non-profit-making legal persons in accordance with the national law. Promoting environmental protection is one of our central objectives which we are actively pursuing.

Grounds for internal review:

Article 5 of Directive 91/414 on the inclusion of active substances in Annex I requires that active substances are expected to fulfil the condition of having no unacceptable influence on the environment as provided for in Article 4.1.b. IV and V (the article which is the basis for member states authorising the use of formulations based on the active substance). In our opinion however, the evidence presented by the Commission does not support the conclusion that the effects of the use of Imidacloprid on bees are acceptable.

EFSA concludes in its peer review of 29/5/2008 that spraying of imidacloprid (and its two main metabolites) poses a high risk to bees. The report recommends risk mitigation measures (no application during flowering, flowering weeds are removed) but concludes that bees will still be not protected by the suggested risk mitigation measures. For tomato production, for example, the situation is even more acute, as the EFSA peer review states, because tomatoes are flowering all the time. In relation to all spraying applications it is clear that the Commission has not demonstrated that acceptable use is possible.

Regarding the use of imidacloprid as a seed coating we think the tests performed by the notifier are inadequate in relation to bees and more generally to other pollinators. Below we present further arguments and comment relating to the DAR by the Rapporteur Germany.

Annex VI of Directive 91/414 (Uniform principles) on testing determines in 2.5.2.3.: Where there is a possibility of honeybees being exposed, no authorization shall be granted if the hazard quotients for oral or contact exposure of honeybees are greater than 50, unless it is

clearly established through an appropriate risk assessment that under field conditions there are no unacceptable effects on honeybee larvae, honeybee behaviour, or colony survival and development after use of the plant protection product according to the proposed conditions of use.

Imidacloprid is simultaneously persistent, systemic, and highly toxic for bees (LD50 at 48 hours is 4.8 ppb (part per billion). Used in seed coatings, Imidacloprid is absorbed by the root system and transported by sap to all parts of the plant, including nectar and pollen. As the active substance is present in soil, even succeeding crops absorb residues and become toxic (cf. Annex B.9. p. 919 and following, and several scientific papers¹).

- 1) Because contaminated nectar and pollen may be brought to the hive by the foragers, all the bees classes (drones, queens, nurses, larvae etc.) are potentially exposed to the active substance. The sensitivity of bees is now well understood and differs according to their class². The necessary tests specific to each bee class have not been carried out. The closest estimates available document chronic toxicity (P. 965) in 'young bees' and 'old bees'. They show a difference of sensitivity between these two categories of bee.
- 2) Another important point is that no bee brood feeding test has been carried out (point B.9.4.2., p. 926). Following the report: 'it has to be expected that the active substance and the formulated compounds are as toxic to larvae as to adult bees'. There is absolutely no scientific argument to support this assertion. The toxicity of a pesticide to one category of bees cannot be deduced from its toxicity to another; some substances are more toxic to larvae than to adult bees and vice versa³. Moreover, we recall the statement of the French State Council suspending the Maize authorization of Gaucho, based on the absence of this test despite the very high HQ (Hazard Quotient) value of Imidacloprid (40 540; cf. Reasoned statement of the overall conclusion, p. 57). Authorizing Imidacloprid without carrying out the larvae test is a clear violation of Directive 91/414 and unacceptable from a scientific viewpoint, as the innocuousness for larvae is not proved. If the European Authority estimates that the HQ is not a valid concept for seed coatings, a new assessment scheme has to be described before to assess the concerned substance, and included in annex VI of the 91/414/EEC Directive. Until then, the clauses in Annex VI, point B and C 2.5.2.3 must fully be enforced. The HQ (or TER: Toxicity Exposure Ratio) concepts have been designed to avoid making higher tier tests with low risk substances. In no case the arbitrary choice of discarding the HQ (this HQ validity not being investigated so far) for seed coating substances can be used to lower the risk. Consequently all the prescribed tests should be realized. Moreover, Imidacloprid is also formulated for spraying (e.g. Confidor). From a legal point of view, the lack of bee brood feeding test is thus sufficient to definitely invalidate the assessment that the HQ is not relevant in this case.
- 3) The report does not include any test about the effects of contaminated pollen consumption during wintering. The amount of pollen consumed by winter bees is unknown at this time. Every beekeeper knows that wintering may succeed only if the bee colony has collected important quantities of pollen during summer. Most of this pollen will disappear during winter and early spring: it has been consumed by the bees, and particularly by the nurses

¹ E.g. Bonmatin J-M, Marchand P., Charvet R, Moineau I., Bengsch E.R., Colin M-E. Quantification of imidacloprid uptake in maize crops.

² Alix, A., and Vergnet, Chr., 2007: *Risk assessment to honey bees: a scheme developed in France for non-sprayed systemic compounds*, Pest Manag Sci. **63**: 1069 – 1080

³ For instance, refer to : Alix, A., and Vergnet, Chr., 2007: *Risk assessment to honey bees: a scheme developed in France for non-sprayed systemic compounds*, Pest Manag Sci. **63**: 1069-1080, point 4.2.

for feeding the early brood. The winter bees are not numerous (5,000-10,000) and, as they live much longer than summer bees, they will feed brood for a long period. This means that pollen consumption per winter bee may be very important compared to summer bees. Thus the pollen toxicity for winter bees has to be tested specifically. Before carrying out this test, it is necessary to quantify the pollen amounts consumed by winter bees with great care in order to define their exposure.

- 4) The dossier includes a point about chronic mortality, examining the LD_{50c} of Imidacloprid and several metabolites. This point doesn't allow to conclude to Imidacloprid innocuousness for reasons as follows:
 - a) Data are provided for two metabolites only (urea and 6-chloronicotinic acid). No values are provided for olefin and 5-hydroxy-imidacloprid when these metabolites are hazardous for bees (they have a low acute LD₅₀) and are detected in pollen and nectar. The explanation of this choice (point B.9.4.7.4.1 p. 962) is not credible: it is based on a scientific article (Suchail et al. 2001) that in contrary shows the significant lethal toxicity of olefin and 5-hydroxy-imidacloprid.
 - b) The study (Suchail et al. 2001) shows firstly that the chronic toxicity is significantly higher than the acute toxicity, and secondly that for most of the metabolites, the mortality is the same for all the tested concentrations including very low concentrations (0.1ppb, more or less 0.1 ng/bee). This study is invalidated in the DAR (p. 961 sq), based on its discrepancy with other studies of the scientific literature. We cannot agree with this argument because:
 - i) the study (Suchail et al. 2001) tests substances amounts and concentrations that are significantly lower than the other studies and concludes to an equal substance toxicity for all the low concentration for most of the metabolites; if these other studies didn't test such low concentration, it is logical that they only detect higher LD_{50c}.
 - ii) the study (Suchail et al. 2001) is published and peer-reviewed; moreover, it was validated by the French Comité scientifique et technique, based on the validity criteria elaborated by this Comité for analysing the existing literature⁴. The DAR considers it non-valid by comparison with LD_{50c} measured in other studies, without verifying these other studies validity, what is not admissible from a scientific point of view.
 - iii) An Imidacloprid characteristic is the great variance shown by the mortality measurements, acute as well as chronic. For instance (Suchail et al. 2001) itself concludes to a acute toxicity of 57 ± 28 ng/bee, that to say to an acute LD₅₀ significantly higher than the figure finally considered by the DAR (4,8 ng/bee). As a consequence a study cannot be invalidated on the single reason that the measured lethal toxicity figure departs from those found in other studies, without further verification.
- 5) The substance is neurotoxic and can have sub-lethal effects, making the bee unable to perform all its behavioural schemes, which are necessary for the colony survival. The report estimates that the NOEL (No Observed Effect Level) is 1.2 ng per bee, leading to a non-effect concentration of 46 ppb (point B.9.4.7.3.1, p. 959). This figure is incorrect because it is based on a consumption of 20 µl per bee, corresponding to the syrup amount given to each bee following the DL50 test design. In reality a bee consumes much more

⁴ CST (non daté): Imidaclopride utilisé en enrobage de semences (Gaucho®) et troubles des abeilles – pp. 50 and 61.

nectar than that. Rortais et al (2005)⁵ estimate the forager consumption to be between 224 and 898.8 mg in seven days. We can make a quick estimation: a colony harvests 60 kg of honey, that is to say 150 kg nectar during one month (an average during the sunflower blossom). Two foragers generation must be considered, or about 20,000 foragers (it is commonly considered that a hive has about 10,000 foragers simultaneously). In his life, each bee will harvest 7.5 g of nectar from which about 10 % is used for the forager itself. So each bee will ingest about 750 mg in 2 weeks, or 107 mg in 48 hours. The other part of nectar is brought to the hive, but is in contact with the oesophagus and the stomach of the bee and so can have a contact toxicity. So the calculated NOEC in real conditions should be at least 10 times lower than the value estimated in the report. The real calculated NOEC should be below 5 ppb.

- 6) The DAR quotes the study (Guez et al. 2001) that shows significant sub-lethal effects on bees for concentrations between 0.1 and 10ppb. This study is also peer-reviewed. However, the DAR (p. 960) turns down this study conclusion on the grounds that the bees were reared in an incubator and subjected to an ice narcosis, and that these practices are suspected to modify bees learning abilities. This argument ignores the fact that the authors have observed the sub-lethal effects by comparison between a treated sample and a control sample that was subjected to the same rearing and narcosis; thus the argument is inadmissible and the study may not be dismissed.
- 7) None of the field and tunnel tests submitted in the report proves that the treated pollen has really been consumed during the test. Pollen consumption is always postponed by the bees as pollen needs a lactic fermentation during at least 10 days to be digested, and may remain several months in the combs cells. During all tests, the hives are put in the tunnel or fields contain feed combs. The submitted tests don't take this fact into account; they don't prove that the bees consume the contaminated food rather than the comb food; since it is more likely they use first the comb feed. Thus the tests conclude on the absence of effects while the real exposition is not proved. This is scientifically unacceptable.
- 8) Several tests leave us in doubt. For example, it is impossible to assess the queen eggs-laying in a small colony of 500 bees, as described in several tests, particularly in cage tests (point B.9.4.4). The queen eggs-laying depends on the number of nurses able to take care of the larvae. A normal queen lays 1000 to 1500 eggs per day, assuming a colony of more than 50 000 bees, that's to say 100 times more than the small colonies used in the tests. So the really eggs-laying cannot be fully assessed in so small colonies. Moreover the small colonies are unable to develop all the behaviours needed by the survival of a normal colony (e.g. developing a drone population, vitality, sufficient cells production...).
- 9) All these concerns are closely linked to the irrelevance of the current assessment scheme for systemic insecticides since they are susceptible to remain in contact with bees during long period of time because they potentially contaminate the foraged matrices: pollen and honey stocks. The scheme irrelevance has been emphasized by scientific papers⁶ and is currently widely accepted. This definitely invalidates the global assessment process. Scientists admit today a PEC/PNEC (Predicted Environmental Concentration / Predicted No

⁵ Rortais A, Arnold G, Halm MP, Touffet-Briens F, 2005 : *Modes of honeybees exposure to systemic insecticides : estimated amounts of contaminated pollen and nectar consumed by different categories of bees*, *Apidologie* 36 (2205), 71 – 83

⁶ Alix, A., and Vergnet, Chr., 2007, op. cit.

Halm, M.P., Rortais, A., Arnold, G., Taseř, J.N., Rault, S., 2006: *New Risk Assessment Approach for Systemic Insecticides: The Case of Honey Bees and Imidacloprid (Gaucho)*, *Environ. Sci. Technol.* **2006**, *40*, 2448-2454

Effect Concentration) approach to be more relevant to assess the risk for bees of systemic, neurotoxic and persistent active substances or plant protection products (PPP). Halm et al (2006) and the French Comité Scientifique et Technique (CST) have tried this approach⁷; both of these papers conclude on the fact that the Imidacloprid PEC/PNEC ratio is alarming. We quote here the CST conclusions:

(1) *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 des butineuses lorsqu'elles ingèrent du pollen 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.*

- 10) The sowing dust effects are not assessed in the report. It is however a very important way of contamination, already scientifically studied in Italy⁸. Recently high bees mortalities occurred in Italy (Padanian plain, during spring 2007 and 2008) and Germany (Land of Baden-Württemberg during spring 2008). The DAR's conclusions about the risk for bees (Reasoned statement of the overall conclusion, p. 58) are entirely based on the postulate that the bee exposure doesn't exceed a 5 ppb concentration. This postulate appears illusive. Investigating hives damages in the Lombardian plain (spring 2008), the Servizio Veterinario della Lombardia have found up to 144 ppb of Imidacloprid in bees. A single pollen sample was analyzed, giving the amazing Imidacloprid concentration of 311 ppb. During the Baden-Württemberg damages, the veterinarian services of the Land asked the beekeepers to destroy feed combs because hive pollen was contaminated. The study of Chauzat et al, 2006⁹, showed that Imidacloprid was detected in 40 pollen trap samples (81 samples were taken during this study, coming from 5 different regions). Imidacloprid persistence in the environment appears thus much more important than reported in the DAR (Draft Assessment Report).
- 11) The DAR does not include studies about the potential synergies between the active substance and bees pathogens. Imidacloprid shows such synergic properties with some pathogens agents¹⁰. In the case of bees this hypothesis has never been investigated in

⁷ CST, 2004? (non daté): Imidaclopride utilisé en enrobage de semences (Gaucho®) et troubles des abeilles - Rapport final

⁸ Greatti, M., Sabatini, A.G., Barbattini R., Rossi S., Stravisi A., 2003 : *Risk of environmental contamination by the active ingredient imidacloprid used for corn seed dressing. Preliminary results*, Bulletin of Insectology **56** (1): 69-72

Greatti M., Barbattini R., Stravisi A., Sabatini A.G., Rossi S., 2006 : *Presence of the a.i. imidacloprid on vegetation near corn fields sown with Gaucho® dressed seeds*, Bulletin of Insectology **59** (2): 99-103.

⁹ Chauzat, M.P., Faucon, J.P., Martel, A.C., Lachaize, J., Cougoule, N., Aubert, M., 2006: *A survey of pesticides residues in pollen loads collected by honey bees in France*, J. Econ. Entomol. **99** (2): 253 - 262

¹⁰ voir par exemple :

Cuthbertson AG, Walters KF and Deppe C., 2005: *Compatibility of the entomopathogenic fungus *Lecanicillium muscarium* and insecticides for eradication of sweet potato whitefly, Bemisia tabaci*. Mycopathologia. 2005 Aug;160(1):35-41

detail but is likely to occur with *Nosema* spp., and could explain the increase of bees pathologies noted by beekeepers and scientists during the last years. A PPP called Premise 200SC, whose active substance is Imidacloprid, is described as disorientating termites and making them ill by stopping the grooming behaviour. The PPP advertising paper explains that the grooming behaviour stopping allows soil fungi to attack termites. What about bees? Some hive micro-organisms are fungi, for instance the genus *Nosema* (usual pathogen of the bees) or *Beauveria* (in normal condition non-pathogen for bees). In the same paper we can read (last page) that "independent trials in Japan have Found Premise SC to be effective for at least five years". This fact is not in agreement the provided Imidacloprid DT₅₀.

- 12) We have noticed amazing discrepancies between the results of the different tests: for example between the DL50 for honeybees and for wild bees (*Bombus terrestris*). Both studies (De Ruijter 1999, p. 913) conclude that Imidacloprid has effects for all tested doses, without correlation between the dose and the effect, including mortality. Similar discrepancies appear during cage, tunnel or field tests. Some tests highlight a lack of foraging activity (Bakker 2003, p. 943) where others find an increase of bee activity (Stadler 2000, p. 947). Such inconsistent results should be considered with caution: sufficient margins of security are necessary to consider the risk for bees. The conclusion on the acceptable risk for bees doesn't take such margins in account, since the figures accepted by the assessment report are a NOEC of 10 ppb, a nectar and pollen concentration of 5 ppb (the average of real concentration is 2 to 3.5 ppb, cfr. report of the French CST).
- 13) Importance of scientific studies validity criteria
 - a) The DAR considers the tests valid or not valid without having defined any validity criterion. The conclusions about the studies validity doesn't tally with those of the French Comité scientifique et technique, who has defined validity criteria. Invalidation of several studies as Guez et al. 2001, Suchail et al. 2001 or of results published by Pham-Delègue and Cluzeau 1999 is questionable when, for instance, the residues studies of Schmuck et al. (point B.9.4-5, p. 920) are considered valid, in spite of insufficient limits of detection (5 or 10 ppb). (Schmuck et al.) studies never detect any residue when other studies show a frequent presence of Imidacloprid in the foraged matrices (for instance, following a study about the pollen contaminations in France, Imidacloprid is detected in the half part of the trap pollen samples (40/81)¹¹). The methods used in this lab should be analysed in order to verify that they are able to detect actually the substances in the foraged matrices, particularly in the pollen since the potential contamination is inside the grains.
 - b) A statistic validation should be provided for the studies and their conclusions. Such validations are all the more necessary since the results variance is very great, for the acute and chronic LD₅₀ and for the sub-lethal effects as well (see e.g. Kirchner 1998 and 2000, pp. 950 – 951).
- 14) We observe that the DAR dismisses all the studies that seem to be unfavourable to the molecule authorization, when the favourable studies obviously are not so carefully analysed from their validity point of view. Once time more this fact raises the problem of the scientific assessment independence since the assessment is integrally submitted by

Ramakrishnan, R., Suiter, D.R., Nakatsu, C.H., Humber, R.A., and Bennett, G.W., 1999: *Imidacloprid-Enhanced Reticulitermes flavipes (Isoptera: Rhinotermitidae) Susceptibility to the Entomopathogen Metarhizium anisopliae*, J. Econ. Entomol. **92**(5): 1125-1132

¹¹ Chauzat, M.P., Faucon, J.P., 2007: Pesticide residues in beeswax samples collected from honey bee colonies (*Apis mellifera* L.) in France, Pest Management Sci, **63**: 1100–1106.

the applicant, without confirmation of any test by independent laboratories, even in case of doubt. In the current context, where seed coating insecticides remain the suspect number one in the worldwide bees mortalities, such a situation fosters suspicion, what is prejudicial to the beekeepers, to the concerned industry, and overall to the public authorities, which fail to ensure the general interest protection and the necessary arbitration between the interests of the concerned sectors.

The conclusion is very clear: the report evaluation doesn't respect Article 4 of Directive 91/414/CEE. It definitely fails to demonstrate that there is no unacceptable impact on bees or on other foraging species.

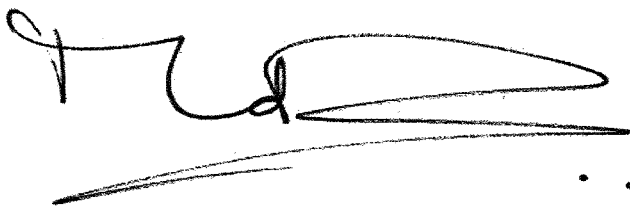
Moreover, the European Authorities have recently moved to offer greater support to the wider adoption of 'Integrated Pest Management' in the Framework Directive on the sustainable use of pesticides.

The major advantage of integrated pest management is to avoid permanent pesticide residues in soils and plants that may lead to the development of resistant pest populations, as well as unwanted effects on human health. Using pesticides only when needed, against a well-defined pathogen, with limited effect on non-target species and during a limited period of time is the basement of integrated management.

Seed coatings are just following the opposite approach: they are used in all case, even when there is no pathogen target to destroy. They use very persistent active substances in order to protect the plant from seeding to harvest. They remain in soil and plant for very long periods. They are not specific and destroy non-targets species.

Given the catalogue of serious flaws in the Commission's decision-making process PAN Europe wishes to request for a review of Regulation 149/208 and asks you to withdraw or suspend this Regulation in preventing harm to consumers.

Yours sincerely,
Stichting Natuur en Milieu,



Mirjam de Rijk
general director

also in naam of:

Ms. J. Kivits

Mr. E. Cannell

M. F. Veillerette

M. F. Giot

Inter Environment Wallonie, Belgium

PAN-Europe, Pesticide Action Network Europe, England

MDRGF, Mouvement pour le droit et le respect des générations futures, La France

Nature et Progres, Belgium