

VAN DEN BIESEN KLOOSTRA ADVOCATEN

European Commission
Health and Consumers Directorate-General
Att. M. Tonio Borg
Request for internal review under Title IV
of the Aarhus Regulation
B-1049 Brussels

DE GROENE BOCHT
Keizersgracht 253
1016 EB AMSTERDAM
www.vdbkadvocaten.eu
tel +31.20.7371869
fax +31.20.5248246

Fax: +32 229-91856

E-mail: ENV-INTERNAL-REVIEW@ec.europa.eu

**Request for internal review of Commission Implementing Regulation (EU)
No 485/2013;**

**Request for internal review of the failure of the Commission to act as regards crops and
uses which do not fall within the scope of Commission Implementing Regulation (EU)
No 485/2013**

Amsterdam, 4 July 2013

Dear Sir,

It is in my capacity of attorney at law, based in Amsterdam, the Netherlands, I have on behalf of my clients, Pesticide Action Network Europe (PAN Europe), based in Brussels, Belgium (rue de la pépinière 1, 1000 Brussels), and the *syndicat agricole* Confédération Paysanne, based in Bagnolet, France 104, rue Robespierre, 93170, Bagnolet), which have instructed and duly authorised me to act on their behalf in this matter, that I have the honour to draw your attention to the following. PAN Europe is an international environmental organisation and has, for many years, campaigned for the reduction and, as far as possible, elimination of the use of chemicals, pesticides and biocides toxic for human health and the environment as follows from the bylaws of PAN Europe (**annex**). Confédération Paysanne acts in defence of its members beekeepers who are directly concerned by the before mentioned Commission decision and/or the failure to act of the Commission.

With this letter, PAN Europe and Confédération Paysanne ask for the internal review of the Commission Implementing Regulation (EU) No 485/2013 of 24 May 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid (hereafter: the Commission ban) and/or for the internal review of the omission to act of the Commission as regards crops and

uses of these three neonicotinoids which fall not within the scope of the before mentioned Commission Implementing Regulation 485/2013.

These requests for internal review are based on Regulation 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (hereafter: the Aarhus Regulation).

Introduction

1. PAN Europe and Confédération Paysanne are of the opinion that the Commission ban on neonicotinoids is a step in the good direction towards the protection of the environment and non-target organisms against harmful chemicals. But the requesting organisations are convinced, on the basis of the facts that will be set out hereafter, that this ban is not advanced enough to efficiently protect bees and the environment against adverse effects of the three highly toxic neonicotinoids concerned. They are of the opinion that the Commission ban wrongly does not forbid all uses and sales of the three neonicotinoids concerned and wrongly does not order the withdrawal by Member States of all the authorisations of plant protection products containing these active substances. In the following, PAN Europe and Confédération Paysanne will substantiate why a broader prohibition is necessary given the risks and dangers of neonicotinoids for honey bees, other non-target organisms and the environment. Furthermore they will set out on which basis the promise of the Commission to initiate the review of the contested Commission ban within two years from its entry into force is not justified in the light of the law.
2. Although the Commission ban has the form of a Regulation and constitutes an act of general and not of individual scope, PAN Europe and Confédération paysanne are entitled to request for the internal review thereof as for the review of the omission to act as regards other uses and crops that were not covered by the Commission ban and these requests are admissible. Given the recent case law of the General Court of 14 June 2012 (Case T-338/08), Article 10(1) of the Aarhus Regulation limits the concept of acts, as used in Article 9(3) of the Aarhus Convention, to administrative acts defined in Article 2(1)(g) of the Aarhus Regulation as measures of individual scope and the General Court ruled that in so far Article 10(1) of the Aarhus Regulation is not compatible with Article 9(3) of the Aarhus Convention.

3. The conclusion is that these requests are admissible and should lead to the reconsideration by the Commission of the contested Commission ban and to a prohibition covering all crops and uses of the three neonicotinoids and as a result should lead to new Commission decisions responding to the arguments put forward by PAN Europe and Confédération Paysanne in these requests.

Background

4. Since years non-governmental organisations point at the risks and dangers for the environment and organisms as the honey bee of neonicotinoids, especially clothianidin, thiamethoxam and imidacloprid. More and more studies show the highly toxic effects of these substances at field-relevant doses on honey bees and bumblebees and the impact of neonicotinoids on the environment.
5. In 2010 the Commission, by adopting Commission Directive 2010/21/EU amended Annex I of Directive 91/414 concerning the inclusion of the three neonicotinoids, only authorising the use of these active substances in insecticides, including the use as seed treatment. These restrictions followed accidental releases of these active substances in several Member States that had resulted in substantial losses of honeybee colonies. The Commission writes in recital 4 of the contested decision that the publishing of new scientific information in spring 2012 led the Commission to asking the European Food and Safety Authority (hereafter: EFSA) for scientific and technical assistance to assess the new information and to review the risk assessment of neonicotinoids as regards their impact on bees.
6. The Commission ban is mostly based on the findings of EFSA following this request of the Commission resulting in the EFSA Conclusions on the peer review of the pesticide risk assessment for bees for clothianidin, thiamethoxam and imidacloprid of 16 January 2013. The EFSA identified, as follows from recital 6 of the Commission ban, high acute risks for bees from exposure via dust as regards several crops, from consumption of residues in contaminated pollen and nectar as regards some crops and from exposure via guttation fluid as regards maize. Furthermore EFSA identified a number of data gaps in particular concerning the long term risks to honeybees from dust exposure, from residues in pollen and nectar and from exposure via guttation fluid.
7. It is important to note that the Commission recognized the acute and high risks of neonicotinoids for bees. At the same time, notwithstanding the great number of scientific studies pointing out the risks of neonicotinoids and the still existing important data gaps as regards the exact effects of neonicotinoids, the Commission has not drawn the

conclusion that only a total ban of the three neonicotinoids concerned on all crops and crop seeds could lead to the necessary protection of bees and the Commission also seems to overlook the fact that these substances not only present great risks to bees, but also to other organisms and to the environment. It therefore is important that the Commission takes into account all the conclusions in the EFSA peer reviews and all the other relevant scientific information available and not only the publications that were assessed by EFSA.

8. The Commission ban seems to be based not only on the risks of neonicotinoids for honey bees, but for all bees, including bumblebees, solitary bees etc. Leastwise, this is the impression created by recital 14 of the Commission ban, where the Commission states that 'risks for bees from treated seeds have been identified in particular from exposure via dust as regards several crops, from consumption of residues in contaminated pollen and nectar as regards some crops and from exposure via guttation fluid as regards maize'. Close reading of the Commission ban though leads to the conclusion, as will be set out hereunder, that the Commission has not regarded all the conclusions of EFSA in the peer reviews concerned, especially the conclusions on other pollinators than honey bees as bumblebees and solitary bees and does not have considered the relevant recent studies about other sorts of bees than honeybees.

9. The Commission ban regards three possible ways of use of neonicotinoids: seed coating, granules and spraying. Plant seeds are coated by applying a coating composition, made of plant protection products, over the entire seed surface during a certain time span that is long enough for the seeds to absorb and integrate the plant protection product. The coated seeds are sown by farmers in the fields. The sowing process produces quantities of dust that have been proven to induce the death of bees and form a high risk to bees, as the Commission seems to admit in the Commission ban. When the seeds are planted, they will grow into plants which are, dependent on the specific part of the plant, more or less saturated with the plant protection product that was used for the coating. In this way, the plant itself will be lethal for target organisms. Coated seeds mostly are planted by seed-drilling machines. Normally, seed-drilling machines do not leave coated seeds uncovered but in practical, many observers could see uncovered seeds, especially in places machines turn around as mentioned in Lopez-Antia *et al.* (2013)¹. But also covered coated seeds lead to spreading of neonicotinoids in the

¹ Experimental exposure of red-legged partridges (*Alectoris rufa*) to seeds coated with imidacloprid, thiram and difenoconazole. Lopez-Antia A, Ortiz-Santaliestra ME, Mougeot F, Mateo R. *Ecotoxicology*. 2013 Jan;22(1):125-38. doi: 10.1007/s10646-012-1009-x. Epub 2012 Oct 31.

environment. After the sowing of coated seeds only a small proportion of the coating material will be absorbed by the plant that grows out of these seeds. The rest of the coating will spread in the soil and/or leaks to surface and ground water.

10. The second way of application of neonicotinoids is by spraying plant protection products on the crops concerned. Plant protection products are widely used in this way before as well as after the flowering period of crops amongst other crops on fruit trees. Spraying also leads to the dissemination of neonicotinoids in soils and surface and groundwater.
11. A third application means is the use of granules that are buried in the soil. Neonicotinoids are taken up by the plants' roots in a comparable way to that of coated seeds.
12. Neonicotinoids present in soil can, as is foreseen for such substances used in plant protection products, be taken up by plants in and around fields or in succeeding crops. Since these substances are easily spread by their high solubility, they are widely present in water systems which can supply water for wild and cultivated plants. The absorbance of water contaminated with neonicotinoids can lead to the forming of pollen and nectar containing these substances. Via the pollution of the soil and the water neonicotinoids thus find again their way to bees and other pollinators.
13. Not only the spraying of plant protection products containing neonicotinoids, but also seeds which have been treated with neonicotinoids will lead to the direct exposure to and to the spreading into the environment of these substances and therefore to the continuing of exposing bees, including honey bees and other non-target organisms to the harmful effects of these substances. Bonmatin and colleagues² have demonstrated that growing a non-treated crop the year following a crop grown from imidacloprid-treated seeds on the same field induces honey bee-toxic concentrations of imidacloprid in sunflowers. In the before mentioned Conclusions of the peer review of the pesticide risk assessment of imidacloprid, clothianidin and thiamethoxam on bees³, EFSA stressed the presence of a data gap preventing EFSA of concluding on the absence of risks to bees of the coating of seeds with plant protection products containing neonicotinoids.
14. Over the last decade more and more scientific proof of the harmfulness of neonicotinoids and the spreading of neonicotinoids in the environment was published. On the basis of these studies it is well established that these substances contaminate not only

² Bonmatin, JM; Moineau, I; Charvet, R; Colin, ME; Fleche, C; Bengsch. Behaviour of imidacloprid in fields. Toxicity for honeybees, ER in Environmental chemistry: green chemistry and pollutants in ecosystems (Ed. Lichtfouse, E; Schwarzbauer, J; Robert, D; Lichtfouse, E; Schwarzbauer, J; Robert, D) (2005) 483-494

³ <http://www.efsa.europa.eu/en/press/news/130116.htm?wtr1=01>

soils, but also ground water and surface water as mentioned above. According to Sur and Stork⁴ the maximum uptake of imidacloprid by corn, cotton, eggplant, potato or rice which is treated with a plant protection product containing imidacloprid is 20%. The rest of the insecticide, up to 80%, is not taken up by the crops, but remains in the ground or leaks into the groundwater and surface water. Imidacloprid water solubility is comparable to the solubility of clothianidin and thiamethoxam. The above mentioned quantities of residues remaining in the environment after the use of imidacloprid are therefore also relevant for clothianidin and thiamethoxam, and the results obtained are likely to be comparable to clothianidin and thiamethoxam. It is also clear that the residues of the three neonicotinoids as a result of the use of plant protection products on crops will remain for a long time in the environment, as it has been established that the half-lives of these active substances are of several years, up to sixteen years for clothianidin⁵. This means that the use of these substances can and will lead to a prolonged ground contamination.

15. Furthermore, a recent publication revealed high correlation between the level of imidacloprid in surface water in the Netherlands and the decline of biodiversity. Surface water is important for a considerably high number of insects that rely on this biotope to reproduce. A recent study from Van Dijk *et al.* (2013)⁶ has made a link between the concentration of imidacloprid in surface waters and the decline of macro-invertebrates in the Netherlands. Another recent study of Nyman *et al.* (2013)⁷ has demonstrated the lethality of imidacloprid on freshwater shrimps at concentrations of 15 ppb (parts per billion), where this study also states that in some Dutch ditches, the measured concentrations of imidacloprid reached to 320 ppb. Sublethal effects to bees can be observed under concentrations of 1 ppb.
16. The recent findings of Van Dijk *et al.* (2013) have put to light the important surface water contaminations by imidacloprid in the Netherlands. When observing the Dutch atlas of surface water contamination⁸ for imidacloprid, the region where the highest contamination of surface water is observed is precisely the Westland region where the

⁴ Sur R, Stork A. Uptake, translocation and metabolism of imidacloprid in plant. Bulletin of insectology: 56, 35-40, 2003.

⁵ Goulson D. An overview of the environmental risks posed by neonicotinoid insecticides. Journal of applied ecology.

⁶ Van Dijk, T.C., Van Staalduinen M.A, Van der Sluijs, J.P. Macro-invertebrate decline in surface water polluted with imidacloprid, PLoS One, 1 May 2013, <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0062374>

⁷ Nyman AM, Hintermeister A, Schirmer K, Ashauer R. The Insecticide Imidacloprid Causes Mortality of the Freshwater Amphipod *Gammarus pulex* by Interfering with Feeding Behavior. PLoS One. 2013 May 15;8(5):e62472.

⁸ http://81.93.58.66/bma_nieuw/begin.html

highest concentration of greenhouses is observed. Furthermore, a study by Dutch CLM research and advisory centre⁹ concluded that the European ban would induce only a 14% decrease in the use of imidacloprid in the Netherlands. These observations confirm the fact that pesticides use in greenhouses has a very high impact on the environment.

17. In the before mentioned Conclusions of the peer review of the pesticide risk assessment of imidacloprid, clothianidin and thiamethoxam on bees¹⁰, EFSA stressed the presence of a data gap preventing EFSA of concluding on the absence of risks of the coating of seeds to bees. In its 2008 conclusions of the peer-review (CPR) of imidacloprid, EFSA noticed a data gap on earthworms' toxicity. Information on seed treatment and spraying risk to birds was considered not to be completed and also for effects on birds a data gap remains. Furthermore, Lopez-Antia *et al.* (2013)¹¹ have demonstrated that the oral intake by red-legged partridges of seeds coated with imidacloprid at a field-realistic dose for ten days induced major physiological, immunological and reproductive effects and death in case of exposure of these birds to this substance.
18. In the Conclusions of the peer review on neonicotinoids as mentioned before EFSA identified the risk posed by honeydew on bee health. Honeydew can be produced by many plants, among which by fruit trees. Authorising the spraying of neonicotinoids on fruit trees after flowering of the plants thus poses a risk to bees that is ignored by the Commission ban.
19. In the Draft guidance document published by EFSA in 2012¹², EFSA created a table (p.104) representing the frequency of occurrence of guttation droplets on several crops. Among these, oat and barley (winter cereals) for which guttation droplets production happens "very often", as mentioned following EFSA in this document. In its Conclusions of the peer-review of the pesticide risk assessment of imidacloprid, clo-

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http://www.google.be/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CCwQFjAA&url=http%3A%2F%2Fwww.clm.nl%2Fuploads%2Fpdf%2F825-Ge-bruik_toepassing_verbod_neonicotinoiden.pdf&ei=nNHSUcZkgsu1BprQgKgG&usg=AFQjCNHGUS4u8K5cInq3IxmQ6TGblxooNQ&bvm=bv.48705608,d.Yms

¹⁰ <http://www.efsa.europa.eu/en/press/news/130116.htm?wtrl=01>

¹¹ See footnote 1

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<http://www.google.be/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CCwQFjAA&url=http%3A%2F%2Fwww.efsa.europa.eu%2Fen%2Fconsultationsclosed%2Fcall%2F120920.pdf&ei=WF-4UY2BH4SZ0QXJw4CACw&usg=AFQjCNFHZKpEjQG3CeA2dksRc1jttFMVbw&bvm=bv.47810305,d.d2k>

thianidin and thiamethoxam on bees, EFSA stated that guttation droplets could pose high risk to bees.

20. Winter cereals are sown in the period of blooming of green cover crops (mustard, phacelia). These crops are very attractive to bees. Dust production during sowing of winter cereals could, as expressed by EFSA in its Conclusions of the peer review on the risk to imidacloprid, clothianidin and fipronil, contaminate nectar produced by these flowers or intoxicate bees flying through the dust cloud. Exposing honey bee colonies to neonicotinoids in autumn and winter in the field or directly in the hive has more severe negative effects than in other periods of the year, because it endangers their survival during overwintering, period of major susceptibility to toxics. Indeed, sowing of coated seeds of cereals in autumn takes place in a period of the year that is crucial to honeybee colonies, when honey bees are finalizing the constitution of their stocks of pollen and honey to overwinter and in which period honeybees raise the workers which will ensure the renewal of the colony at the end of the winter.
21. For these reasons, maintaining the approval for seed coating of winter cereals prolongs the risk of intoxication of honey bees and other pollinators through dust emission, succeeding crops and through the spreading in soil and water systems and the absorbance by plants and continues the exposing of other organisms as birds and organisms living in the soil, while data gaps continue to exist and even clear adverse effects of neonicotinoids on birds have been demonstrated, as was set out above.
22. In its Conclusions of the peer-review, EFSA also stressed that soil-nesting insects and insects using treated cultures plant material for nesting can be negatively impacted by the use of seed coating. This could be the case for bumblebees, solitary bees, etc. A similar observation could be drawn from the use of neonicotinoids spraying, which has not been forbidden in the Commission ban, while the spraying of plant protection products containing neonicotinoids can also contaminate the ground and plant material which is used by pollinators for nesting.

Legal framework

23. The neonicotinoids concerned were included in Annex I of Directive 91/414 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market and therefore could be used as an active substance in plant protection products on the basis of Article 5 of Directive 91/414. Clothianidin was included through Commission Directive 2006/41, thiamethoxam through Commission

Directive 2007/6 and imidacloprid through Commission Directive 2008/116. In 2010, the Commission amended Annex I of Directive 91/414 concerning the inclusion of the three neonicotinoids as a reaction on Member State reporting serious adverse effects of neonicotinoids on honeybees.

24. Active substances which have been included in Annex I of Directive 91/414 now fall within the scope of Regulation 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC and are deemed to be authorised under that Regulation through the Commission Implementing Regulation 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.
25. The purpose of Regulation 1107/2009 is, as has been set out in recital 8 of Regulation 1107/2009, to ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the competitiveness of Community agriculture. Recital 10 of Regulation 1107/2009 states that substances should only be included in plant protection products where it has been demonstrated that they present a clear benefit for plant production and they are not expected to have any harmful effects on the environment. Following recital 24 of Regulation 1107/2009 the provisions governing authorisation must ensure a high standard of protection. In particular, when granting authorisations of plant protection products, the objective of protecting human health and the environment should take priority over the objective of improving plant production. Therefore, it should be demonstrated, before plant protection products are placed on the market, that they present a clear benefit for plant protection and do not have any harmful effect on human or animal health, including that of vulnerable groups or any unacceptable effects on the environment.
26. Plant protection products only may contain active substances that have been approved. Following Article 4(1) of Regulation 1107/2009, an active substance shall be approved in accordance with Annex II of Regulation 1107/2009 in the light of current scientific and technical knowledge, and taking into account the approval criteria set out in points 2 and 3 of that Annex.
27. Furthermore, Article 4(1), second paragraph, of Regulation 1107/2009 states that the assessment of the active substance shall first establish whether the approval criteria set out in – amongst other points – 3.7 of Annex II about ‘Fate and behaviour in the environment’ are satisfied. If these criteria are satisfied the assessment shall continue to es-

establish whether the other approval criteria set out in points 2 and 3 of Annex II are satisfied.

28. Following Article 4(2), the residues of the plant protection products, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements:

“(a) they shall not have any harmful effects on (...) animal health, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available, or on groundwater;

(b) they shall not have any unacceptable effect on the environment.”

Article 4(3) states that a plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements:

“(a) it shall be sufficiently effective;

(b) it shall have no immediate or delayed harmful effect on (...) animal health, directly or through drinking water (taking into account substances resulting from water treatment), food, feed or air, or consequences in the workplace or through other indirect effects, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available; or on groundwater;”

29. Point 2 of Annex II describes ‘General decision-making criteria’. Point 2.2. contains the following general criteria:

“In principle an active substance (...) shall only be approved where a complete dossier is submitted”

Point 3 of Annex II contains the ‘Criteria for the approval of an active substance’. It contains amongst other criteria under point 3.7 ‘Fate and behaviour in the environment’ a criterion on the ‘Potential for long-range environmental transport’ under point 3.7.1.3. Following this criteria an active substance fulfils the potential for long-range environmental transport where measured levels of the active substance in locations distant from the sources of its release are of potential concern and/or monitoring data show long-range environmental transport with a potential transfer to a receiving environment via air, water or species.

30. In point 3.8 of Annex II of Regulation 1107/2009 criteria on ‘Ecotoxicology’ are set out. Following criteria 3.8.1 the assessment of an active substance must take into account the severity of effects, the uncertainty of data and the number of organism groups which the active substance is expected to affect adversely by the intended use. On the basis of criteria 3.8.3 an active substance shall be approved only if it is established that the use of this substance:

“- will result in a negligible exposure of honeybees, or

- has no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour”.

Criterion 3.10 ‘Fate on behaviour concerning groundwater’ states that an active substance shall only be approved where it has been established that the predicted concentration of the active substance in groundwater complies with the criteria of the uniform principles for evaluation and authorisation for plant protection products referred to in Article 29(6) of Regulation 1107/2009.

31. Following Article 29(6) of Regulation 1107/2009 uniform principles for evaluation and authorisation of plant protection products shall be adopted and shall contain the requirements set out in Annex VI of the retired Directive 91/414. These uniform principles seem to not have been formulated yet.
32. Furthermore it is for the matter of these requests for internal review relevant that EFSA published on 18 March 2013 for public consultation a draft ‘Guidance on the Risk Assessment of Plant Protection Products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)’ containing draft texts on risk assessment for exposure of bees to water, including guttation, surface water and water in puddles. In the draft Guidance EFSA recognises the importance for bees of guttation water, especially when other sources of water are absent, of surface water present in the agricultural environment as bees drink of it, and of water in puddles also present in agricultural environments (EFSA draft ‘Guidance on the Risk Assessment of Plant Protection Products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) 18 March 2013, p. 12 – 13).

Legal grounds

Regulation 1107/2009 and the EFSA conclusions

33. As set out before, PAN Europe and Confédération Paysanne welcome the Commission ban, but are in the same time of the opinion that this ban does not protect bees sufficiently from the harmful effects of plant protection products containing neonicotinoids. As the Commission considered in recital 7 of the Commission ban, there are indications that the approved uses of these neonicotinoids no longer satisfy the approval criteria provided for in Article 4 of Regulation 1107/2009. As the Commission recognises, merely on the basis of the EFSA conclusions on each of the three neonicotinoids concerned the existence of indications that the criteria of the before mentioned Article are no longer met, it is important to analyse the Commissions’ position in relation to the underlying EFSA peer reviews. It is notable that the Commission did take over from these EFSA reports some conclusions, but did not so concerning other EFSA conclusions in the same reports. To give more insight in which conclusions regard-

ing which subject were taken over and which were not, PAN Europe and Confédération Paysanne refer to the following table:

EFSA risks or data gaps identifications	Compliance of the Commission's ban with EFSA's risk assessment
Dust exposure during sowing	Partial: ban does not concern winter cereals seed coating despite the fact these crops can be sown during fall, when bees are still harvesting (ivy, mustard, phacelia...). EFSA nevertheless identified high risks posed by dust emission during sowing of cereals.
Honeydew	Partial: ban does not concern winter cereals seed coating despite the fact these crops produce honeydew. Spraying is approved after flowering of crops, even though these can produce honeydew
Non-honeybee pollinators	Partial: ban does not concern winter cereals seed coating despite the fact that most of the coating will contaminate soil where soil-nesting insects can be exposed and that contaminated plant material can be used for nesting by insects. Spraying is authorised after flowering and will thus contaminate soil, water and plants as well.
Succeeding crops	Partial: ban does not concern winter cereals seed coating despite EFSA's concerns on succeeding bee-attractive crops' contamination due to neonicotinoids residues in soils.

34. The Commission did not rely on any objective criteria distinguishing between the different conclusions in the EFSA peer review and did not justify why some conclusions led to a ban on the use of plant protection products containing neonicotinoids in and on certain crops (so called summer crops), while other uses will continue to be allowed (in and on so called winter crops), even under the contested Commission ban, while the conclusions in the EFSA peer review equally justify a ban on these other uses. This distinguishing between uses and thus between crops is not justified by the scientific information available or by the European legislation. Regarding seed coating the Commission seems to have taken the position that the use of the neonicotinoids concerned would be less harmful to bees in certain periods of the year while EFSA identified high risks of dust emissions during the sowing of cereals as well in spring and summer as in other periods of the year. In the same way EFSA concluded that the spraying of plant protection products may lead to contamination with neonicotinoids of honeydew, as well before as after the flowering of crops. EFSA thus found also indications about the spreading and thus about the harmfulness of neonicotinoids when

applied to winter crops. But the Commission disregarded these conclusions and did not prohibit the spraying of neonicotinoids after the flowering of crops.

35. Now that the ban does not concern seed coating of winter crops it does not, next to the direct exposure to neonicotinoids as mentioned before, prevent honeybees and other pollinators from exposure to neonicotinoids via the contamination of soils, water and other plants. As has been set out by EFSA, the use of neonicotinoids leads to the disseminations of these substances in the environment, regardless of in which period of the year these are applied and to which crops and thus cause exposure of bees to neonicotinoids. This could be particularly the case for soil-nesting pollinators as solitary bee and bumblebee, when soils are contaminated with neonicotinoids. As has been set out before, it is also clear on the basis of recent studies that neonicotinoids are disseminated in ground and surface water by their high solubility and EFSA recognises the risk of exposure via water. EFSA has also found that bees drink the surface water and water in puddles available in agricultural environments and thus are being exposed to neonicotinoids through contaminated waters. The Commission disregarded also these conclusions in the EFSA peer reviews.
36. The Commission ban was based on Article 4 of Regulation 1107/2009, which Article does not contain criteria justifying any distinction between uses or crops which do not rely on objective indications of risks. On the basis of Article 296(2) of the Treaty on the Functioning of the European Union legal acts, as the Commission ban, shall state the reasons on which they are based. According to settled case-law, the statement of reasons required by Article 296(2) TFEU must be appropriate to the act at issue and must disclose in a clear and unequivocal fashion the reasoning followed by the institution which adopted the measure in question in such a way as to enable the persons concerned to ascertain the reasons for the measure and to enable the competent Court to exercise its power of review as was set out by the Court in its ruling following preliminary questions of the Maltese Civil Court in the case *AJD Tuna Ltd versus Direttur tal-Agricoltura u s-Sajd, Avukat Generali* (ECJ 17 March 2011, Case C-221/09, paragraphs 58-60).
37. From the settled case-law also follows as has been ruled by the Court in the before mentioned case that the scope of the obligation to state reasons depends on the nature of the measure. The Court has also held that the obligation to state reasons laid down in Article 296(2) TFEU is an essential procedural requirement, as distinct from the question whether the reasons given are correct, which goes to the substantive legality of the contested measure.

38. The conclusion is that the Commission did wrongly, in the light of the criteria set out in Article 4 of Regulation 1107/2009 not substantiate the distinction made in the Commission ban between summer and winter crops, prohibiting the use of neonicotinoids one part of the year and not during the whole year, while the EFSA peer reviews justify as much a prohibition of the use of neonicotinoids during all seasons and on all crops as of the uses that were prohibited in the Commission ban. This leads to the conclusion that the Commission ban itself is unlawful and/or that the Commission omitted to act where other uses of these neonicotinoids and uses on other crops still are allowed despite the great risks of these substances for bees and the environment. For this reason PAN Europe and Confédération Paysanne request the review of the Commission ban and a reviewed decision extending the prohibition to all uses on all crops to repair the omissions as described.

Regulation 1107/2009 and new scientific data

39. As has been set out before the Commission based the ban on neonicotinoids on the observation that there are indications that the approvals of the three neonicotinoids do no longer satisfy the criteria laid down in Article 4 of Regulation 1107/2009. As has been set out before, following Article 4 of Regulation 1107/2009 an active substance shall be approved in accordance with Annex II of the Regulation and only if it may be expected, in the light of *current scientific and technical knowledge*, that the requirements laid down in paragraphs 2 and 3 of that Article are met. In the case of the neonicotinoids concerned this means that it is not only on the basis of EFSA findings that the Commission needs to act on the ground of Article 4 of Regulation 1107/2009, but that the Commission is also under the obligation to take measures in case of other scientific studies demonstrating new risks and dangers of the use of these substances.

40. Next to the fact that the Commission wrongly did not base its Commission ban on all the risks and data gaps that were noted by EFSA in the peer reviews concerned, PAN Europe and Confédération Paysanne also are of the opinion that the Commission wrongfully did not rely its partial ban on all the other current scientific data available, which demonstrate additional risks and data gaps on the spreading and effects of neonicotinoids. New studies show that the dissemination of neonicotinoids has been underestimated. It has been recently demonstrated that the use of neonicotinoids has led to high levels of residues in surface waters in the Netherlands, and to honeybee-toxic levels of imidacloprid in crops that were not treated with plant protection products containing this substance, but that were sown the year after crops that had been treated with imidacloprid containing plant protection products. Furthermore new studies indicate, as has been set out above, adverse effects of neonicotinoids on birds and fresh-

water shrimps, while a link was established between the use of these active substances and the decline of macro-invertebrates.

41. The current scientific data show risks and data gaps concerning the effects of neonicotinoids on animal health, as referred to in Article 4(2) and in Annex II, criterion 3.8 'Ecotoxicology'. And in particular requirement 3.8.3 that the use of these neonicotinoids has "no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour" is not fulfilled. Furthermore on the basis of recent studies it seems questionable that the neonicotinoids concerned continue to satisfy the criteria laid down in points 3.7.1.3 and 3.10 of Annex II of Regulation 1107/2009 on 'Potential for long-range environmental transport' and 'Fate on behaviour concerning groundwater'.
42. Next to that recent studies in the Netherlands lead to the conclusion that the use of the neonicotinoids concerned in greenhouses also can lead to the wide spreading of these substances in the environment and thus to the exposure of bees and non-target organisms to high levels of neonicotinoids.
43. The conclusion is that the Commission did wrongly, in the light of the criteria set out in Article 4 of Regulation 1107/2009 not substantiate the distinction made in the Commission ban between summer and winter crops, prohibiting the use of neonicotinoids one part of the year and not during the whole year, while the EFSA peer reviews justify as much a prohibition of the use of neonicotinoids during all seasons and on all crops as of the uses that were prohibited in the Commission ban. Next to that the Commission did wrongly, in the light of the criteria set out in Article 4 of Regulation 1107/2009 not substantiate the distinction made in the Commission ban between the use of neonicotinoids on fields in the open are and in greenhouses. For this reason PAN Europe and Confédération Paysanne request the review of the Commission ban and a reviewed decision extending the prohibition to all uses on all crops and/or a new additional Commission decision repairing the mentioned omissions.

Precautionary principle

44. In the foregoing, PAN Europe and Confédération Paysanne based their conclusions that the Commission did wrongfully not consequently apply to all uses and to all crops the new scientific information as provided in the EFSA peer reviews and in other recent scientific studies concerning the three neonicotinoids concerned in the first place on Article 4 of Regulation 1107/2009. Secondly, and not of less importance, is the fact that the Commission was under the obligation to apply the precautionary principle. PAN Europe and Confédération Paysanne are of the opinion that the good application

of the precautionary principle should have led to a total ban of the three neonicotinoids for all uses and all crops concerned. From the recitals of Regulation 1107/2009, especially from recital 24, already follows that within the framework of Regulation 1107/2009, the objective of protecting the environment should take priority over the objective of improving plant production. This also follows from the precautionary principle that can, dependent on the facts, lead to the obligation for the competent authorities to take measures restraining the use of certain substances to protect the environment against potential risks for the environment.

45. Following the General Court in its recent judgement of 12 April 2013, the precautionary principle requires the authorities in the particular context of the exercise of its powers on the basis of the relevant rules, to take appropriate measures to prevent specific potential risks to the environment, by giving precedence to the requirements related to the protection of those interests over economic interests (*Du Pont de Nemours e.a. versus the Commission*, Case T 31/07, paragraph 134). The General Court thus ruled that the precautionary principle does not only allow the Commission to take measures, but even can require the taking of appropriate measures.
46. The requesting organisations are of the opinion that the Commission was and is under the obligation to take further measures by extending the Commission ban concerning neonicotinoids to all uses and crops, given the facts that the Commission acknowledges the risks and dangers of these substances for bees and for the environment as follows from the partial Commission ban as has been decided in the contested decision. There are no objective reasons that justify the position of the Commission to not take further measures now that the need for additional measures follow from the EFSA peer reviews and other new scientific data.
47. Already from Commission ban itself, where the Commission recognises important risks and dangers for bees from the use of these three neonicotinoids it is clear that the criteria for the application of the precautionary principle as set out by the General Court are fulfilled. The precautionary principle therefore yet should have led the Commission to the conclusion that the potential risks identified for bees and for the environment, also of the use of the neonicotinoids concerned on and in winter crops, in greenhouses and by spraying are not more acceptable than the risks and dangers that led the Commission to act and to set the contested Commission ban. For that reason PAN Europe and Confédération Paysanne also request for the review of the Commission ban and for the extension of the ban as described on the basis of the precautionary principle and/or to an act by the Commission that repairs the failure to act of the Commission and the omissions described.

Review of the present regulation within two years

48. In recital 16 of the Commission ban the Commission states that a review of the contested Regulation will be initiated within two years from the date of the entry into force of the Regulation. Given the data gaps described by EFSA and the further research necessary to further evaluate the exact risks and dangers of neonicotinoids to honeybees, bumblebees, solitary bees and other non-target organisms, this term is not realistic and can only lead to research that cannot give the necessary degree of certitude required by Article 4 of Regulation 1107/2009. For this reason PAN Europe and Confédération paysanne are of the opinion that the Commission ban should also be reviewed concerning this aspect. In the light Article 4 of Regulation 1107/2009 and of the precautionary principle the announced evaluation in view of an eventual review of the Commission ban in the sense of abolishing the restrictive measures towards neonicotinoids should only take place when all the existing data gaps have been filled, especially by independent studies. For this reason recital 16 as it is formulated should not be maintained. The exact formulation could raise the expectation of the industry producing neonicotinoids that, regardless of the quantity and quality of the scientific data available, the Commission would be under the obligation to initiate a review of the Commission ban. PAN Europe and Confédération Paysanne are of the opinion that Regulation 1107/2009 only leads to the obligation for the Commission to initiate the review of the Commission ban if sufficient scientific data will be available to conclude that the criteria of Article 4 of Regulation 1107/2009 would be met.

Conclusions

PAN Europe and Confédération Paysanne respectfully request the Commission to review Commission Implementing Regulation 485/2013 as described above and to replace it by a total ban for the time necessary to exclude the recently identified potential high risks for bees and the environment and the existing important data gaps and/or request the Commission to recognise that the Commission failed to act in accordance with Regulation 1107/2009 and the precautionary principle concerning the uses of neonicotinoids which are still allowed, and to repair this omission by adopting an additional decision to prohibit the above described uses of the three neonicotinoids.



Bondine KLOOSTRA