Request for internal review under Title IV of Aarhus Regulation
Environment Directorate-General
European Commission
B-1049 Brussels
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Brussels, 13 August 2012.

To: European Commission.

Request by Pesticide Action Network Europe, ClientEarth and Générations Futures for an internal review of Commission Implementing Regulation (EU) No 582/2012 of 2 July 2012.

1. Introduction and outline

Pursuant to Article 10 of Regulation (EC) No 1367/2006 of 6 September 2006[1] (the "Aarhus Regulation"), Pesticide Action Network Europe, ClientEarth and Générations Futures (together "the Applicants") hereby make a request of the Commission for the internal review of Commission Implementing Regulation (EU) No 582/2012 of 2 July 2012[2] (the "Bifenthrin Approval Regulation").

The contact details of the person empowered by **Pesticide Action Network Europe** for the purpose of the request for internal review are:

[1] Regulation (EC) 1367/2006 of the European Parliament and 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; OJ L264, 25.9.2006, p.13.
[2] Commission Implementing Regulation (EU) No 582/2012 of 2 July 2012 approving the active substance bifenthrin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and the Council concerning the placing of plant protection products on the market and amending the Annex to Commission Implementing Regulation (EU) No 540/2011; OJ L173, 3.7.2012, p.3.

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As a result of the Bifenthrin Approval Regulation, bifenthrin is now included in the list of active substances deemed to have been approved under Regulation 1107/2009[3] (the "PPP Regulation") from 1 August 2012 to 31 July 2019, subject to conditions set out in the Annexes to the Bifenthrin Approval Regulation.
The Applicants request the internal review on the grounds outlined in section 3 below and further discussed in section 5. The Applicants further propose that, following such review, the approval of bifenthrin as an active substance is withdrawn and any further application for approval proceeds as a new application under the provisions of the PPP Regulation.

2. Admissibility

2.1 Applicants satisfy Article 11 criteria[4]

Each of the Applicants meets the criteria set out in Article 11 of the Aarhus Regulation for eligibility of a non-governmental organisation to make a request for review.
In particular, each:

(i) is an independent non-profit making legal person in accordance with the law and practice of their respective Member States;

[3] Regulation (EC) No 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; OJ L309, 24.11.2009, p.1.
[4] Further details are provided in Annex 1 to this letter and supporting documentation is enclosed.

(ii) has the primary stated objective of promoting environmental protection in the context of environmental law; and

(iii) has existed for more than two years and is actively pursuing the objective referred to in (ii) above.

In addition, as further set out in Annex 1, the subject matter, in respect of which the request for internal review is made, is covered by the objectives and activities of each Applicant.

2.2 Act of Community institution under environmental law

The Aarhus Regulation is intended to implement the EU's obligations under the Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters[5] ("the Aarhus Convention"). Article 9(3) of the Aarhus Convention provides that access to administrative or judicial procedures is to be available ".....to challenge acts or omissions by....public authorities...." and further provides in Article 2(2) that the definition of "public authority" does "not include bodies or institutions acting in a judicial or legislative capacity."

The Applicants maintain that, for the purposes of Article 10 of the Aarhus Regulation, the Bifenthrin Approval Regulation is an administrative act under environmental law adopted by a Community institution. This argument is set out in more detail in section 2.2.1 below.

In the alternative, the Applicants maintain that, in accordance with the decisions of the Court in Case T-338/08[6] and Case T-396/09[7], the definition in the Aarhus Regulation of an act which may be the subject of an internal review request is too narrow and that an administrative act should not be limited to a measure of "individual scope". This argument is set out in more detail in section 2.2.2 below.

2.2.1 Administrative act under the Aarhus Regulation

The Aarhus Regulation[8] defines an "administrative act" as "any measure of individual scope, under environmental law, taken by a Community institution or body, and having binding and external effect".

In its Practical Guide[9], the Commission repeats that definition and further comments that "this excludes measures without external legally binding effects, such as internal instructions and guidelines and normative acts of general scope, such as regulations and directives. It covers decisions having legally binding and external effects, irrespective of their form, including those in the form of a letter".

The Applicants maintain that the Bifenthrin Approval Regulation is not a measure of general application. The Applicants argue that the acceptance by the Commission of the admissibility of two requests for review by Justice and Environment[10] of decisions

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[5] Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters, signed at Aarhus on 25 June 1998.

[6] Case T-338/08, Stichting Natuur en Milieu and Pesticide Action Network Europe v European Commission, Judgment of the General Court (Seventh Chamber) of 14 June 2012.

[7] Case T-396/09, Vereniging Milieudefensie and Stichting Stop Luchtverontreiniging Utrecht v European Commission, Judgment of the General Court (Seventh Chamber) of 14 June 2012.

[8] Article 2(1)(g).

[9] *Access to information, public participation and access to justice in environmental matters at Community level – a Practical Guide.*
http://ec.europa.eu/environment/aarhus/pdf/guide/AR%20Practical%20Guide%20EN.pdf

[10] Request by Justice and Environment of 3 December 2007 for an internal review of: Commission Decision 2007/701/EC of 24 October 2007 authorizing the placing on the market of products containing,

relating to genetically modified products is directly analogous to the position the Commission should take in relation to the request by the Applicants in this case. The effect of the Bifenthrin Approval Regulation is to apply individualised regulatory treatment to a particular substance and to regulate its specific use in identifiable plant protection products. Therefore, it only has meaning and effect in relation to an identifiable situation and when it is applied to an individual application for approval of the placing on the market and use of a specific plant protection product.

The Bifenthrin Approval Regulation resulted from an application by an individual identified applicant[11]. The measure contains specific obligations on the applicant set out in Part B of each of Annex I and Annex II. Part A of each of Annex I and II is specifically addressed to Member States. Furthermore, when applications are made to Member States for approval of individual plant protection products which contain bifenthrin, then the effect of the measure will be specifically applicable to an identifiable applicant and product.

It should also be noted that (as discussed in section 4.2 below), the measure previously taken by the Commission in relation to bifenthrin was adopted in the form of a "non-inclusion" decision. The Applicants maintain that it would be inconsistent for the Commission to seek to afford different treatment to a measure which results from the same process simply because under one regulatory regime that measure is called a decision; whilst under another it is called an implementing regulation.

This position can be distinguished from the finding of the Court in Case T-338/08 in relation to the admissibility of a review request of Commission Regulation (EC) No 149/2008[12] that such a measure was of general application to all products of plant and animal origin. As discussed below, this did not preclude the Court taking a different view from the Commission as to whether a request could be made for review of such acts.

On this basis, and in recognition of the spirit and purpose of the Aarhus Regulation and the desirability of consistency with the Commission's prior practice, the Applicants submit that this request for review must be treated as admissible.

2.2.2 Act of public authority under the Aarhus Convention

Article 9(3) of the Aarhus Convention provides that access to administrative or judicial procedures is to be available ".....to challenge acts or omissions by....public authorities...."

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consisting of, or produced from genetically modified maize NK603xMON810 (MON-OO6O3-6xMON-OO81O-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document number C(2007) 5140); Commission Decision 2007/702/EC of 24 October 2007 authorizing the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122 (DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document number C(2007) 5141); Commission Decision 2007/703/EC of 24 October 2007 authorizing the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507xNK603 (DAS-O15O7-1xMON-OO6O3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document number C(2007) 5142); Request by Justice and Environment of 14 April 2010 for an internal review of Commission Decision 2010/135/EU of 2 March 2010 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a potato product (Solanum tuberosum L. line EH92-527-1) genetically modified for enhanced content of the amylopectin component of starch and Commission Decision 2010/136/EU of 2 March 2010 authorising the placing on the market of feed produced from the genetically modified potato EH92- 527-1 (BPS-25271-9) and the adventitious or technically unavoidable presence of the potato in food and other feed products under Regulation (EC) No 1829/2003 of the European Parliament and of the Council (GMO authorization).

[11] FMC Chemical sprl.

[12] Commission Regulation (EC) No 149/2008 of 29 January 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council by establishing Annexes II, III and IV setting maximum residue levels for products covered by Annex I thereto; OJ 2008 L 58, p.1.

and further provides in Article 2(2) that the definition of "public authority" does "not include bodies or institutions acting in a judicial or legislative capacity**".**
In Case T-338/08 and Case T-396/09, the Court found that the Aarhus Regulation definition of an act in respect of which a request for review could be made (ie an administrative act of individual scope) was too narrow for the purposes of the implementation of the Aarhus Convention. As the Court commented: *"Measures of general application are not necessarily measures taken by public authorities acting in a legislative or judicial capacity".*
The Bifenthrin Approval Regulation is expressly stated to be an implementing measure and, therefore, should not be treated as a legislative measure.
On this basis, and in recognition of the position that the Court's decisions are binding and not of suspensory effect[13], the Applicants submit that this request for review must be treated as admissible.

2.2.3 Environmental law

The control of the use of plant protection products and the active chemical substances used in them is a quintessentially environmental law measure. In both Council Directive 91/414[14] ("the PPP Directive") and the PPP Regulation, substances are subject to pre-market authorisation in order to ascertain that plant protection products do not cause unacceptable harm to human health and the environment.

3. Grounds for review

The Applicants maintain that the adoption of the Bifenthrin Approval Regulation by the Commission:

(a) does not satisfy the requirements of the PPP Directive (as applied pursuant to the transitional provisions of the PPP Regulation[15]); and

(b) violates the precautionary principle; one of the fundamental principles of environmental law of the European Union.

4. Regulatory context for the request for review

4.1 Background

The PPP Directive[16] established a regulatory framework for the assessment and approval of plant protection products, including the active substances used in those products. That framework was stated to take account of the fact that their use "may involve risks and hazards for humans, animals and the environment, especially if placed on the market without having been officially tested and authorised and if incorrectly used".
Under the PPP Directive, a procedure was established whereby active substances which satisfied the requirements of the Directive would be listed in Annex 1 to the PPP

[13] Article 278 TFEU: "Actions brought before the Court of Justice of the European Union shall not have suspensory effect; and Article 60 of Statute of the Court: "Without prejudice to Articles 278 and 279 of the Treaty of the Functioning of the European Union or Article 157 of the EAEC Treaty, an appeal shall not have suspensory effect".
[14] Council Directive of 15 July 1991 concerning the placing of plant protection products on the market (91/414/EEC); OJ L230, 19.8.1991, p1.
[15] Article 80(1)(c).
[16] PPP Directive, Recitals 4, 9, 10, 11.

Directive. The PPP Directive has been repealed and replaced by the PPP Regulation. However, the procedures and approval conditions of the PPP Directive still apply in certain cases; in particular, to active substances, including bifenthrin, which had not been included in Annex 1[17] but for which a detailed programme of work was established by the Commission.[18] Detailed substantive and procedural rules are set out in Commission Regulation (EC) No 33/2008[19].

An applicant wishing to secure inclusion of an active substance in Annex 1 of the PPP Directive has to demonstrate that the active substance fulfils the requirements provided for in Article 5 of the PPP Directive.[20]

4.2 Initial non-inclusion decision

The provisions of the PPP Directive have been applied to bifenthrin on two separate occasions. In the first case, the Commission Decision (2009/87/EC) of 30 November 2009[21] (the "Bifenthrin Non-inclusion Decision") determined that: (a) bifenthrin could not be included in the list of authorised active substances; and (b) Member States should ensure that: (i) authorisations for plant protection products containing bifenthrin were withdrawn by 30 May 2010; and (ii) no authorisations for plant protection products containing bifenthrin be granted or renewed from the date of publication of the decision. The Bifenthrin Non-Inclusion Decision, Recital 5, lists a number of issues of concern[22] which led the Commission to conclude that, on the basis of the information made available within the required legal deadlines, it was not possible to find that bifenthrin met the criteria laid down in Article 5 (1) (a) and (b) of the PPP Directive for inclusion in Annex 1. These concerns reflected those expressed in the Commission's Review Report (SANCO/125/08)[23] supporting the Bifenthrin Non-Inclusion Decision and the EFSA 2008 'Conclusion on the peer review of bifenthrin' [24](the "EFSA 2008 Report").

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[17] *Ibid.,* Article 8(2).

[18] Commission Regulation (EC) No 1490/2002 of 14 August 2002 laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000; OJ L224, 21.8.2002, p.23 as amended by Commission Regulation (EC) No 1095/2007 of 20 September 2007; OJ L246, 21.9.2007, p.19.

[19] Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I, OJ L15, 18.1.2008, p.5.

[20] PPP Directive, Article 3.

[21] Commission Decision of 30 November 2009 concerning the non-inclusion of bifenthrin in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products concerning that substance, OJ L318, 4.12.2008, p. 41.

[22] The concerns identified by the Commission were: (a) it was not possible to assess the possible contamination of groundwater by a major soil degradation product (TFP Acid); (b) a possible underestimation of risk to consumers, due to: the limited number of residue data made available; and the lack of investigation on the metabolism pattern of the two isomers constituting bifenthrin and (c) in relation to ecotoxicology: the risk to aquatic vertebrates has not shown to generate acceptable uses; there is remaining uncertainty as regards the effects of the experienced bio-accumulation in fish of the active substance; high risks have been identified for: mammals (long-term risk and secondary poisoning); earthworms (long-term risk); and non-target arthropods (in-field); and the risk to non-target plants and non-target soil macro-organisms has not been sufficiently addressed.

[23] European Commission, 2009, Review Report for the active substance bifenthrin finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 12 March 2009 in support of a decision concerning the non-inclusion of bifenthrin in Annex I of Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance. SANCO/125/08-final, 6 March 2009. These were summarised as being: insufficient information available to satisfy the requirements set out in Annex II and Annex III of the PPP Directive in particular with regard to: the fate

4.3 Subsequent approval as active substance

Following the Bifenthrin Non-Inclusion Decision, a further application for authorisation was undertaken pursuant to the accelerated procedure set out in Commission Regulation (EC) No 33/200825.

On this occasion, the Commission decided that bifenthrin would be approved for inclusion in Annex 126. The approval was set out in the Bifenthrin Approval Regulation. The Commission noted, in Recital 4, that the substantive and procedural requirements of Article 15 of Commission Regulation (EC) 33/2008 were satisfied. The Commission further stated, in Recitals 7 and 8, that, as regards the three areas of concern identified in the Bifenthrin Non-Inclusion Decision, the additional information provided by the applicant led to the conclusion that the specific concerns which gave rise to the original non-inclusion decision had been removed.

The Applicants submit that the key aspects of the Bifenthrin Approval Regulation which underlie the request for review of the decision to grant approval are the duration of the approval and the conditions set out in the Annexes to the Regulation which are justified by the reasoning of the Commission set out in Recitals 10-12.

In particular, in Recital 10, the Commission acknowledges that bifenthrin has a potential to show bioaccumulation effects which leads to a decision of an approval period to run for seven years (from 1 August 2012 to 31 July 2019) rather than ten.

In Recital 11, the Commission references Article 13(2)27 and Article 6 of the PPP Regulation, as well as current scientific and technical knowledge, as the basis for setting conditions in the Annexes. However, a number of those conditions do not prescribe action, but rather require certain matters to be taken into account.

Member States are required to pay particular attention to:
persistency in the environment;
the risk for bioaccumulation and biomagnifications;
the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate;
the risk to aquatic organisms, in particular fish and invertebrates, non-target arthropods and bees, ensuring that conditions of authorisation include risk mitigation measures where appropriate.

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and behaviour of soil and water; the risk to aquatic organisms; the risk to several species of mammals, non-target arthropods, non-target plants and non-target soil macro-organisms; and concerns regarding: the risk to consumers; the potential for contamination of groundwater by the major soil metabolite – TFP acid; the unacceptable high risk to mammals; the risk from secondary poisoning of earthworm-eating mammals; the bioaccumulation assessment and the risk to non-target arthropods (in field), non-target plants and non-target soil macro-organisms.

[24] Conclusion on the peer review of bifenthrin; issued on 30 September 2008. EFSA Scientific Report (2008) 186, 1-109.

[25] Articles 13-22.

[26] Substances approved in accordance with the Directive 91/414 regime are now deemed to have been approved under the PPP Regulation (Art 78(3)).

[27] Article 13(2) specifically references the "review report, other factors legitimate to the matter.. and the precautionary principle.

Specific reference is also made to the need to take into account conclusions of the review report (the EFSA 2011 Report) finalised in the Standing Committee on the Food Chain and Animal Health.28

The Annexes impose obligations on the applicant who is required, by 31 July 2014, to submit confirmatory information as regards:
the residual toxicity for non-target arthropods and the potential for recolonisation;
the fate and behaviour of soil metabolite 4'-OH bifenthrin;
the degradation in soil of the isomers which constitute bifenthrin, 4'-OH bifenthrin and TFP acid.

Finally, the applicant is required to present to the Commission, by 31 July 2013, a monitoring programme to assess the potential for bioaccumulation and biomagnification in the aquatic and terrestrial environment. By 31 July 2015, the results of that programme are to be submitted as a monitoring report to the rapporteur Member State (France), the Commission and EFSA.

These information requirements are justified in Recital 12 as being "appropriate". No further explanation is given; but, in any event, the requirements are stated to be without prejudice to the conclusion that bifenthrin should be approved.

5. **Grounds for review**

The Applicants maintain that the Bifenthrin Approval Regulation is unlawful because:

(a) it does not comply with the requirements of the PPP Directive;

(b) the Commission has not provided a fully detailed reasoned analysis and explanation as to how and why the problems which gave rise to the original Bifenthrin Non-Inclusion Decision no longer pertain; and

(c) it violates the precautionary principle, one of the fundamental principles of environmental law of the European Union.

These grounds are explained in more detail below and, on the basis thereof, the Applicants request an internal review by the Commission of the Bifenthrin Approval Regulation.

5.1 Failure to meet the requirements of the PPP Directive

The Applicants maintain that the Bifenthrin Approval Regulation does not comply with the PPP Directive because, in particular, it fails to meet the substantive requirements of Article 15 of Regulation (EC) No 33/2008 which requires that the applicant must demonstrate that the requirements of Article 5 of the PPP Directive are fulfilled, including dossier completeness.

Article 5 of the PPP Directive contains a number of detailed provisions against which to determine whether an active substance may be included in Annex 1. The effect of these

[28] The details of which were not available for consideration at the date of submission of this request.

provisions is that a substance may only be included if it may be expected that the plant protection product containing the active substance will have no harmful effects on human or animal health or on ground water or any unacceptable influence on the environment. Article 5 also provides that the approval process operates "in the light of current scientific knowledge".
The Bifenthrin Approval Regulation fails to do this because it does not:

(a) properly address:
    (1) identified data gaps and inconsistent data; or
    (2) identified risks of harmful effects on human or animal health; or
(b) take due account of current scientific knowledge.

The deficiencies in the Bifenthrin Approval Regulation fall within three main groups:

(a) inadequacy of the dossier – addressed in section 5.1.1 below;
(b) failure to ensure compliance with approval criteria – addressed in section 5.1.2 below;
(c) arbitrary selection of data – addressed in section 5.1.3 below.

5.1.1 Inadequacy of the dossier

EFSA's Report of 2011[29] (the "EFSA 2011 Report") is a scientific peer review of the Draft Assessment Report given by DG SANCO and the Additional Report[30] made by France, as Rapporteur Member State, taking into consideration the additional information given in the second application dossier.
In the EFSA 2011 Report, data gaps (some of which had already been noted in the EFSA 2008 Report) were identified regarding:

- the scope of the consumer risk assessment;[31]
- several uncertainties in the model assumptions and parameterization leading to the conclusion that a high risk from biomagnification in the terrestrial food chain could not be excluded on the basis of the available data[32];
- degradation on the two enantiomers[33];
- mobility of a metabolite in soil[34];
- exposure of bifenthrin to surface water[35];

[29] European Food Safety Authority (EFSA), 2011. Conclusion on the peer review of the pesticide risk assessment of the active substance bifenthrin. EFSA Journal 2011;9(5):2159. [101 pp.]. doi:10.2903/j.efsa.2011.2159
[30] France, 2010. Additional Report to the Draft Assessment Report (DAR) on the active substance bifenthrin prepared by the rapporteur Member State France in the framework of Commission Regulation (EC) No 33/2008, August 2010.
[31] EFSA 2011 report p.20 "It should be noted that the consumer risk assessment has to be regarded as provisional pending the outcome of the required additional residue trials on head cabbage".
[32] EFSA 2011 Report p.25 "The experts agreed to identify a data gap".
[33] EFSA 2011 Report p.20, "Therefore a data gap regarding this issue remains".
[34] EFSA 2011 Report p.22, "Consequently, these experimental data did not fulfil the data gap agreed by the Member State experts".
[35] EFSA 2011 Report p.23, "Consequently, a data gap was identified for PECSW/SED calculations for outdoor use in ornamentals".

- biomagnification of bifenthrin in terrestrial food chain[36] ;

- biomagnification in the aquatic food chain[37] ;

- chronic risks of the metabolite for bifenthrin for earthworms[38];

- risks for non-target plants[39].

As indicated above, the Commission appears to have sought to address these data gaps by including provisions in Annexes to the Bifenthrin Approval Regulation.
The Applicants maintain that it is contrary to the underlying objectives of the PPP Directive (and certainly the PPP Regulation and the precautionary principle) that data gaps can be considered to be filled by the request for confirmatory data which will be provided *ex post facto*.
The Applicants further maintain that, if the data gaps and risks which were sufficient to cause a decision of non-inclusion in 2009 remain (ie the gaps have not been filled and the risks have not been removed or addressed), there is no basis on which a different conclusion could be reached in 2012.
If there remains uncertainty which requires clarification by further data, then it cannot be argued, as the Commission does, in Recital 9, that bifenthrin "may be expected to satisfy, in general, the requirements laid down in Articles 5(1) (a) and (b) of the PPP Directive". The requirements of Article 5 must be demonstrated by the applicant. Because the Bifenthrin Approval Regulation anticipates that information will be produced in future, then it cannot be said that compliance with Article 5 had been demonstrated at the time the Regulation was adopted.

5.1.2 Failure to ensure compliance with approval criteria

The Bifenthrin Approval Regulation fails to include any requirements or measures which would ensure that no harmful effects on human or animal health or on ground water or unacceptable influence on the environment will occur. A significant number of concerns were expressed in the EFSA 2011 Report, but they are not reflected or addressed in the substantive provisions of the Bifenthrin Approval Regulation. In particular, note should be made of the following:

- Regarding tumours seen in mice in liver, lung and bladder, EFSA concluded [40] that the relevance for humans cannot be excluded. EFSA determined category 3 carcinogenicity but neither EFSA nor the Commission proposed any prevention measure for exposure of people and the environment.

- Biomagnification in the aquatic food chain is not properly managed. EFSA stressed that: "In conclusion, the experts agreed that a high risk from bioaccumulation through the food chain for aquatic organisms could not be

[36] EFSA 2011 Report p.25, "Therefore the experts agreed to identify a data gap to further address this risk for the outdoor representative uses".
[37] EFSA 2011 Report p.27, "a data gap was identified to further address the risk from biomagnification in the aquatic food chain".
[38] EFSA 2011 Report p.29, "a data gap for the applicant to address the chronic risk to earthworms for this metabolite was identified".
[39] EFSA 2011 Report p.30, "a data gap was identified for the submission of a risk assessment to non-target plants".
[40] EFSA 2011 Report p.13.

excluded on the basis of the available data"[41]. EFSA identified this as a "critical area of concern"[42]. But risk mitigation measures, as proposed by EFSA[43], namely, "No-spray buffer zones of 20-25 m and run-off reduction are required to protect aquatic organisms for the uses in cereals and cabbage" are not part of the Bifenthrin Approval Regulation.

- Risks for bees are not properly managed. EFSA noted[44] that: "The experts at the PRAPeR 53 meeting concluded that a high risk to bees could not be excluded for bifenthrin and appropriate mitigation measures should be applied (SPe safety phrase)". The mitigation measure proposed (not spraying during flowering) is of questionable efficacy since there will always be flowering weeds around and no system is to be put in place to guarantee enforcement. Additionally, the requirement for this strict mitigation measure is not included in Bifenthrin Approval Regulation. It appears as a matter to which Member States are to "pay particular attention" and so could easily be disregarded by them.

- Risks for non-target arthropods are not properly managed. EFSA noted[45] that: "It was concluded, from the available information, that there was a high risk to non-target arthropods within the treated area from the use in cereals. Risk mitigation measures are required to protect non-target arthropods in the off-field areas. An in-field no-spray buffer zone of 5 m is required for cereals"[46]. The requirement for an in-field no-spray buffer zone was not, however, included in the Bifenthrin Approval Regulation and the issue could, again, be disregarded by Member States.

5.1.3 Arbitrary selection of data

The EFSA 2011 Report[47] shows what data are available for deriving the bioaccumulation value for bifenthrin. A 357-day study in fish (P.promelas) showed a bioconcentration factor (BCF) of 21000 – 30000 in parents and 7900 – 10000 in live embryos. Another 42-day study in fish (L.macrochirus) showed a BCF of 6090 (whole body). A further 60-day fish study (L.macrochirus) concluded a finding of a BCF of 1709. In the Bifenthrin Non-inclusion Decision, these very high BCF values were at the heart of the reasons for the non-inclusion of bifenthrin. However in the resubmission procedure, France proposed in the Additional Report to disregard the two studies with the highest value. In the EFSA 2008 Report, EFSA accepted the two studies, but the EFSA 2011 Report reached a contrary conclusion and supports France as Rapporteur with the justification "On the basis of the re-evaluation provided in the additional report, the studies on *Pimephales promelas* and *Lepomi Macrochirus* were considered not reliable because weak and flawed". It is difficult to understand how such an important decision could be changed that easily and a conclusion completely reversed. If the two studies had such

[41] EFSA 2011 Report p.27.
[42] EFSA 2011 Report p.39.
[43] EFSA 2011 Report p.38.
[44] EFSA 2011 Report, p.28.
[45] EFSA 2011 Report, p.29.
[46] EFSA 2011 Report, p.29.
[47] P. 91.

weaknesses and flaws, it would be expected that this would have been noted in the first peer-review. And if the flaws are established, the only rational conclusion should be to request new studies and not to base the conclusion on the only available study with such a deviating low BCF value. The low BCF-value of 1709 is, subsequently, used by EFSA to calculate risks and lead to several risks being removed.
The Applicants maintain that this way of concluding a BCF-value is not a proper scientific approach and does not provide a sound basis on which the Commission could reasonably rely.

5.1.4 Failure to take approval decision "in light of current scientific and technical knowledge"

In addition, several scientific studies were not taken into consideration with regard to the harmful effects on human and animal health:

- In reaching its conclusions, the Commission did not consider the cumulative effects of bifenthrin. Bifenthrin is part of a group of about 20 pyrethroids used in agriculture and biocides. People and wildlife are potentially exposed to more than one pyrethroid and this should be taken into account. Methods to assess such effects for motor activity[48] are available based on the relative potency factor, while for endocrine disrupting effects, a cumulative assessment is also necessary.

  Based on current scientific knowledge, the Commission should have assessed cumulative effects. Cumulative effects are not only a scientific reality but also a political one since the Commission already in 2005 included cumulative effects in the measures relating to pesticide residue levels[49].

- Developmental neurotoxicity. More attention needs to be given to the developmental neurotoxicity of bifenthrin. It is widely known that pyrethroides are linked to these effects[50] and bifenthrin needs to be assessed thoroughly for these effects on several endpoints according to the latest tests. As Shafer states, "many of the developmental neurotoxicity studies suffer from inadequate study design, problematic statistical analyses, use of formulated products, and/or inadequate controls" and it should be ensured the tests are performed properly. Therefore, the reliance of Commission on a single, likely outdated, test[51] is not sufficient. The Commission should have considered studies from independent scientists such as the ones referred to above, especially since this is a feature of the pyrethroid group. It is a signal that pups showed tremors[52] after drinking bifenthrin-contaminated milk. This is the more worrying since bifenthrin is also analysed in human milk. This certainly should have led to taking a closer look at

[48] M. J. Wolansky, C. Gennings, and K. M. Crofton, Relative Potencies for Acute Effects of Pyrethroids on Motor Function in Rats, TOXICOLOGICAL SCIENCES 89(1), 271–277 (2006).

[49] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (as amended) OJ L 70, 16.3.2005, p.1.

[50] Timothy J. Shafer, Douglas A. Meyer, and Kevin M. Crofton, Developmental Neurotoxicity of Pyrethroid Insecticides: Critical Review and Future Research Needs, Environmental Health Perspectives, Volume 113 No.2, February 2005.

[51] EFSA 2011 Report p.13.

[52] *Ibid.*

this evidence, especially also considering exposure of the unborn and effects in later life.

- Endocrine disrupting effects. Bifenthrin has been shown to be a clear endocrine disrupting chemical with estrogen properties. In an E-screen test[53], enantiomer 1S of bifenthrin showed estrogen properties at 10^{-9} Mol. In another study, Liu[54] showed disruption of ovulatory gene expression patterns as well as prostaglandin synthesis, and suggests that exposure to bifenthrin may increase the risk of ovulatory dysfunction in females. Additionally, bifenthrin was shown to have anti-androgen properties[55] *in vitro*. Any mention of endocrine disruption is lacking in the EFSA 2011 Report and did not, therefore, appear to have been taken into account by the Commission.

- Cytotoxicity and apoptosis. Bifenthrin has two enantiomers with different properties. 1R is more genotoxic than 1S[56] while 1S has far more estrogenic potency[57]. In a study on developmental effects on locomotion in Zebrafish, Jin[58] showed different effects and even opposite effects of the enantiomers. It is, therefore, of great importance that the adverse effects of the enantiomers are elucidated in order to evaluate consumer risks. In a recent study[59], it is shown that enantiomer 1S-cis-BF is responsible for these effects by changing gene expression. As noted above, in the EFSA 2011 Report, EFSA states this to be a data gap.

- Effects on bees. The EFSA 2011 Report concludes that there is a high risk of bifenthrin on bees and advises mitigation measures. EFSA does not indicate any basis on which it could be confident that these mitigation measures would be sufficient, even if they were imposed. This is the more relevant since EFSA did not consider sublethal effects of bifenthrin. Independent literature[60] provides evidence for sublethal effects of bifenthrin and this could mean that acceptable

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[53] Lumei Wan, Weiping Liu, Caixia Yang, Zhiyan Pan, Jianying Gan, Chao Xu, Meirong Zhao and Daniel Schlenk, Enantioselectivity in Estrogenic Potential and Uptake of Bifenthrin, Environ. Sci. Technol. 2007, 41, 6124-6128

[54] Jing Liu, Ye Yang, Yan Yang, Ying Zhang, Weiping Liu, Disrupting effects of bifenthrin on ovulatory gene expression and prostaglandin synthesis in rat ovarian granulosa cells, Toxicology 282 (2011) 47–55.

[55] Frances Orton, Erika Rosivatz, Martin Scholze, and Andreas Kortenkamp, Widely Used Pesticides with Previously Unknown Endocrine Activity Revealed as in Vitro Anti-Androgens, doi: 10.1289/ehp.1002895

[56] Huigang Liu, Meirong Zhao, Cong Zhang, Yun Ma, Weiping Liu, Enantioselective cytotoxicity of the insecticide bifenthrin on a human amnion epithelial (FL) cell line, Toxicology 253 (2008) 89–96.

[57] Jing Liu, Ye Yang, Yan Yang, Ying Zhang, Weiping Liu, Disrupting effects of bifenthrin on ovulatory gene expression and prostaglandin synthesis in rat ovarian granulosa cells, Toxicology 282 (2011) 47–55.

[58] Meiqing Jin, Ying Zhng, Jing Ye, Changjiang Huang, Meirong Zhao and Weiping Liu, Dual enantioselective effect of the insecticide bifenthrin on locomotor behaviour and development in embryonic-larval zebrafish, Environmental Toxicology and Chemistry, Vol. 29, No. 7, pp. 1561–1567, 2010.

[59] Xianting Lu, Enantioselective effect of bifenthrin on antioxidant enzyme gene expression and stress protein response in PC12 cells, J. Appl. Toxicol. 2011, DOI 10.1002/jat.1774.

[60] Dai PL, Wang Q, Sun JH, Liu F, Wang X, Wu YY,yz and Zhou T, 2010: Effects of sublethal concentrations of bifenthrin and deltamethrin on fecundity, growth, and development of the honeybee apis mellifera ligustica, Environmental Toxicology and Chemistry, Vol. 29, No. 3, pp. 644–649.

exposure levels are even lower. EFSA should have insisted on finding out more about the sublethal effects on bees, which can be as devastating for a colony as acute effects. In particular, it should have examined further research on acceptable levels and, on the basis of this, consider if mitigation measures would protect bees to a sufficient level. The present approach does not take into account current scientific knowledge.

5.2 Lack of reasoned analysis by the Commission

In light of the arguments and comments above, the Applicants submit that the conclusions reached by the Commission in the Bifenthrin Approval Regulation do not appear to necessarily follow from the assumptions and assertions made by the Commission, especially where they appear to be internally consistent.

The change in position between the first application and subsequent resubmission of the applicant's dossier is not clearly apparent on the face of the documents available to the Applicants.

5.3 Violation of the precautionary principle, one of the fundamental principles of the law of the European Union.

The precautionary principle is a critically important underpinning for the environmental policy of the EU and appears in Article 191 of the Treaty on the Functioning of the European Union. In addition, it is expressly applied in the PPP Regulation, Article 13(2). The paragraphs above highlight the significant degree of scientific uncertainty and data gaps which still remain following the conclusion of different reports and discussions. Risks to human health and the environment are also clearly recognised by all parties and even where not fully studied, cannot be ruled out because of the numerous data gaps. The precautionary principle requires that this situation cannot allow a substance to be put on the market for a specified period and treat humans (and the other species identified) as "guinea pigs". It is totally unacceptable for the Commission to provide an approval of bifenthrin in these circumstances.

6. Conclusion

The Applicants respectfully request that the Commission:

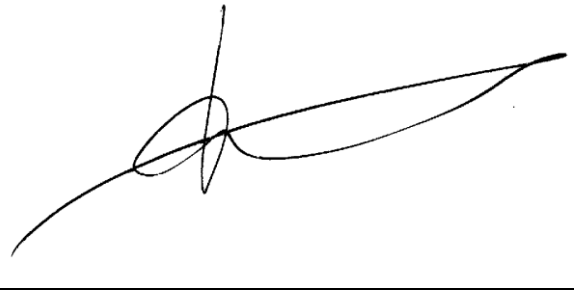
- reviews the Bifenthrin Approval Regulation, particularly In light of the above analysis and arguments; and

- remedies the defects in the Bifenthrin Approval Regulation by withdrawing the approval of the active substance, bifenthrin.

We hope you will soon review your Commission Implementing Regulation (EU) No 582/2012 of 2 July 2012.

Yours sincerely,

Hans Muilerman	Vito A. Buonsante

	
Pesticide Action Network Europe	ClientEarth, Brussels

Francois Veillerette

Generation Futures, Paris, France.