

To the President and Members of the General Court  
of the European Union  
Application for Annulment  
under Article 263 of the Treaty on the Functioning of the European Union

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**ClientEarth**  
**Pesticides Action Network Europe**

**Applicants**

**v.**

**European Food Safety Authority**

**Defendant**

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**Date of Lodgement:**

10 April 2011

**Addressee:**

Registrar of the Registry  
Rue du Fort Niedergrünwald  
L-2925 Luxembourg  
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## **Preliminary Information**

### **Representation by Lawyers**

Applicant: ClientEarth and Pesticides Action Network Europe

Names of Participating Lawyers/Agents: Pierre Kirch, Avocat, Partner at Paul, Hastings, Janofsky & Walker (Europe) LLP.

Vito A. Buonsante, Lawyer

In accordance with Article 44(3) of the Rules of Procedure of the European Communities of 2 May 1991, as amended, the lawyer representing ClientEarth and PAN Europe is Pierre Kirch, member of the Paris and Brussels Bar, having his offices at Avenue Louise 480, 1050 Brussels, Belgium and whose certificate of authorisation to practise before the Court is included with this application (Certificate of good standing, Paris Bar).

For purposes of these proceedings, in accordance with Article 44(2) of the Rules of Procedure of the European Communities of 2 May 1991, as amended, the Applicant agree to accept service through its designated agent Pierre Kirch for service of process via electronic mail at the following address: pierrekirch@paulhastings.com.

For purposes of these proceedings, in accordance with Article 44(2) of the Rules of Procedure of the European Communities of 2 May 1991, as amended, the Applicant agree to accept service through its designated agent for service of process via electronic mail at the following.

### **Information on Applicants**

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In accordance with Article 44(5) of the Rules of Procedure of the European Communities of 2 May 1991, as amended, the required proof of existence in law for ClientEarth and PAN Europe, as legal persons, and proof of the authority granted to the applicant's lawyers are included with this application.

## I. FACTUAL BACKGROUND

1. Article 8 of 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<sup>1</sup> (hereinafter “**Regulation 1107/2009**”), provides for what should be included in the summary dossier and in the complete dossier to the *rapporteur* Member States to request the authorisation for the placing on the market of a plant protection product.
2. In particular, Article 8(5) provides for “*Scientific peer-reviewed open literature, as determined by the Authority, on the active substance and its relevant metabolites dealing with side-effects on health, the environment and non-target species and published within the last 10 years before the date of submission of the dossier*” to be added by the applicant to the dossier”. On the basis of the mandate set by this provision, the European Food Safety Authority (hereinafter “**EFSA**”) requested the Assessment Methodology Unit (hereinafter “**AMU**”) to develop guidance for the applicants on how to implement Article 8(5).
3. The procedure for the drafting process of the Guidance, as described therein,<sup>2</sup> included close coordination and cooperation between AMU and another EFSA body: the Pesticide Risk Assessment Peer Review Unit (hereinafter “**PRAPeR**”). AMU established a working group that comprised EFSA external members and scientific officers who developed the Guidance. Moreover an advance draft of the Guidance document was submitted to the EFSA Panel on Plant Protection Products and their Residues (hereinafter “**PPR**”) and the Pesticide Steering Committee (hereinafter “**PSC**”). The feedback from both groups of experts was considered by the working group during a final meeting and was used to finalise the Guidance. The Guidance was then put under consultation between 23 July and 15 October 2010. Following the consultation the working group met another time. The Guidance was finally published on 28 February 2011 in EFSA’s Journal.

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<sup>1</sup> L 309/01 of 24.11.2009.

<sup>2</sup> European Food Safety Authority; Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (OJ L 309, 24.11.2009, p. 1-50). EFSA Journal 2011; 9(2):2092. [49 pp.], pages 4 and 5.

4. On 10 November 2010, the Pesticides Action Network EU (hereinafter “**PAN Europe**”) and ClientEarth (hereinafter “**the Applicants**”) submitted an application to EFSA requesting access to documents under Regulation (EC) No 1049/2001 regarding the public access to European Parliament, Council and Commission documents (hereinafter “**Regulation 1049/2001**”)<sup>3</sup> and Regulation (EC) No 1367/2006 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 (hereinafter “**Regulation 1367/2006**”). The application detailed several documents for disclosure that were generated in the process of drafting a guidance document. The following documents were requested:

- The original document (EFSA-Q-2009-00827) leading to the development of the draft Guidance including any annexes to it;
- On the request of EFSA (page 4 of the draft guidance) to the Assessment Methodology Unit (AMU), through a self-tasking mandate, to develop a guideline
- EFSA’s decision on the self-tasking mandate to develop the Guidance;
- The full project description of AMU’s task (EFSA output type, timelines);
- The internal mandate and the written decision, memos or other documents including the full list of tasks and people of AMU or invited external experts who were involved in the drafting of the Guidance;
- All documents showing how the close cooperation between AMU and PRAPeR was performed. In particular:
  - EFSA’s mandate to PRAPeR including tasks and people involved in the process;
  - All invitations sent from EFSA/AMU to PRAPeR on cooperation and coordination on the drafting of the Guidance;
  - Meeting documents from EFSA/AMU to PRAPeR, (all invitations, all minutes, all presence/absence lists);
  - All written feedback from PRAPeR to EFSA/AMU (documents, memos, e-mails).

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<sup>3</sup> Regulation (EC) No 1049/2001 of the European parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, L.145/43.

- All invitations send to participants of the working group sent from EFSA/AMU including the agendas;
- The detailed minutes of every meeting of the working group (in addition to the summary minutes posted on the website);
- The presence/absence lists of every working group meeting;
- The documents put forward by EFSA/AMU or other participants in the meetings of the working group. Particularly:
  - The document detailing the structure of the guidance (meeting 1);
  - The draft Guidance (meeting 2) as well as the documents outlining tasks and deadlines;
  - The draft Guidance sent to PPR and PSC (meeting 3) as well as the documents outlining tasks and deadlines agreed in this meeting;
  - The full invitation documents send from EFSA/AMU to the members of PPR and PSC (meeting 3);
  - The documents containing the feedback from PPR and PSC members to EFSA/AMU (E-mails, memos, letters, or other document including names of those sending feedback) (meeting 4);
  - The documents containing feedback received from working group members (meeting 4) in the ‘written procedure’;
  - The draft Guidance agreed at the 5th meeting.
- A detailed list of all the documents in its possession in relation to the working group and its establishment.

This application is hereinafter referred to as the “**initial application**” and is attached hereto as **Annex A.1**.

5. On **16 November 2010**, EFSA acknowledged by e-mail the receipt of the initial application. The letter is attached hereto as **Annex A.2**.

6. On **1 December 2010**, EFSA granted partial access to the requested documents. These documents were later sent by mail in a CD-rom. The following documents were provided:
- The internal mandate proposed by EFSA to AMU for a Working Group on the preparation of the Guidance;
  - The note from the Executive Director changing the deadline for the publication of the Guidance from May 2010 to 28 February 2011;
  - The emails sent by AMU administrative and scientific staff regarding the meetings (without attachments);
  - Action notes for the first 3 meetings;
  - Agenda of the meetings;
  - Minutes of PPR 44<sup>th</sup> plenary meeting, when the project was presented by AMU and PRAPeR and the presentation by AMU and PRAPeR to the PPR;
  - E-mail from AMU to PPR and PRAPeR units and e-mail from PPR and PRAPeR units respectively to PPR Panel and PSC (without attachments);
  - Emails related to the written procedure (without attachments);
  - A summary table of the 20 items listed in the access request of 10 November 2010.
7. EFSA explained the partial refusal with reference to the exception provided in Article 4(3) par. 2 of Regulation 1049/2001. EFSA stated that the reason for refusing disclosure of the documents concerned was to protect EFSA's ability to seek and obtain full and objective scientific and legal advice.
8. PAN Europe physically received the original letter with the CD Rom on **6 December 2010**. These documents are hereinafter referred to as "**EFSA's reply**" and are attached hereto as **Annex A.3**.
9. The following documents were not disclosed to the Applicants:

- The document containing the structure of the Guidance from the first meeting of the working group;
- The intermediate draft of the Guidance from meeting two;
- The intermediate draft of the Guidance submitted to PPR and PSC from meeting three;
- The feedback from PPR and PSC on the draft Guidance;
- All exchanges between AMU and PRAPeR.

10. On **23 December 2010**, the Applicants made a confirmatory application in accordance with Article 7(2) of Regulation 1049/2001 referred to “**the Applicants’ confirmatory application**” and attached hereto as **Annex A.4**.

11. On **20 January 2011**, EFSA responded to the Applicants’ Confirmatory Application, granting itself an additional 15 working days to reply under Article 8(2) of Regulation 1049/2001. It stated as follows: “*to substantiate the extension we would like to refer to the following points:*

- *The large number of documents requested in your application;*
- *The extra time EFSA would need to follow-up on your application in compliance with the legal framework and i.e. relevant case law, referred to in your application”.*

12. This document is hereinafter referred to as “**the 20 January 2011 Extension Letter**” and is attached hereto as **Annex A.5**. The new deadline was **11 February 2011**.

13. On **10 February 2011**, EFSA replied to the Applicants’ confirmatory application and confirmed the refusal to disclose the requested documents with the following reasons:

- Art. 4(3) second subparagraph of Regulation 1049/2001 applies to the requested documents because their disclosure would be “*detrimental to the whole drafting process of the final guidance and misleading for the final reader because reporting intermediate and provisional assessments addressed in the context of an ongoing dialogue*”.



- The full respect of the principles of transparency and openness is complied with by EFSA through the requirements of Regulation (EC) 178/2002 and the sectoral legislation on plant protection products which provide for the publication of scientific outputs without delay, the publication of minority opinions and the possibility to launch public consultations.
- Disclosure of the requested documents would *“undermine the decision making process of EFSA, and would affect the business needs and process by providing disclosure to intermediate versions of scientific outputs and to comments made on the drafts of the scientific experts involved”* that do not represent the views of EFSA.
- The requested documents are not environmental information because the draft versions of the guidance, as internal and intermediate documents, do not have any external effect or impact, a fortiori not on the environment and on the health as defined in the Regulation (EC) No 1367/2006.
- Information about internal meetings does not exist therefore no access can be granted: EFSA confirms that the documents on the exchanges between AMU and PRAPeR are not materialized in identifiable documents as the meetings held had purely informative and preparatory nature in view of working group meetings.

The document is hereinafter referred to as **“EFSA’s confirmatory application reply”** and is attached hereto as **Annex A.6**.

**14.** The Applicants hereby contest the refusal of EFSA to grant full access to the requested documents.

## **II. VIOLATIONS OF REGULATION 1049/2001, REGULATION 1367/2006 AND THE AARHUS CONVENTION**

**15.** The Applicants consider the contested decision to be incompatible with Article 8(1) and (2) of Regulation 1049/2001, Article 4 (1) (2) and (4) of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to

Justice in Environmental Matters<sup>4</sup>, Article 6(1), 4(2) (b) and 7 of Regulation 1367/2006, Article 4(2) third indent and last indent, Article 4(3) first subparagraph and Article 4(6) of Regulation 1049/2001.

16. Regulation 1049/2001 grants access to documents which are held by the European Parliament, Council or Commission. Other bodies, offices or agencies are not explicitly covered by that Regulation. However, Article 15(3) TFEU now gives a right of access to documents “*of the Union institutions, bodies, offices and agencies.*” As the provisions of the EU Treaties prevail over secondary EU law, the right of access is therefore now available to information which is held by EU bodies, offices or agencies, such as the European Food Safety Authority. An EU body, office or agency is not allowed to refuse access to information on the ground that Regulation 1049/2001 is limited to the institutions of the European Parliament, the Council and the Commission.
17. In environmental matters, Regulation 1367/2006, Article 1(1), gives access to documents which are held by EU “*institutions and bodies*”. The term “bodies” refers to all administrations set up by the EU institutions and includes in particular agencies and offices. Therefore EFSA has to comply both with Regulation 1049/2001 and Regulation 1367/2006.
18. We will demonstrate in a first section that the contested decision violates Article 8(2) of Regulation 1049/2001.
19. We will demonstrate in a second section that the contested decision violates Article 4(1) (2) (3) and (4) of the Aarhus Convention and Article 6(1) of Regulation 1367/2006.
20. We will demonstrate in a third section that the contested decision violates Article 4(3) first subparagraph of Regulation 1049/2001.
21. We will demonstrate in a fourth section that EFSA failed to assess whether there was any overriding public interest in disclosure and thus violated Article 4(3) second subparagraph.

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<sup>4</sup> Convention on Access to Information, Public participation in Decision-Making and Access to Justice in Environmental Matters adopted on 25 June 1998.

## 2.1. First plea in law – Ground for Annulment

### Section one - Violation of Article 8(2) of Regulation No 1049/2001

#### *Failure to provide sufficient reasons for requesting an extension*

22. The Applicants contest the use of Article 8(2) of Regulation 1049/2001 by EFSA. The requirements provided under Article 8(2) were not fulfilled by the request of the Applicant and EFSA failed to provide detailed reasons for extending the statutory time limit to respond.

23. Article 8(2) of Regulation 1049/2001 provides that:

*“In exceptional cases, for example in the event of an application relating to a very long document or to a very large number of documents, the time limit provided for in paragraph 1 may be extended by 15 working days, provided that the applicant is notified in advance and that detailed reasons are given”.*

24. Time extensions are only for exceptional cases and, in recognition of the exceptional nature of a time extension and its implications on public participation in the EU decision-making process, the EU legislature requires the institutions to provide detailed reasons when extending the time limit to respond to a request. The Courts have interpreted the detailed reasons requirement as necessary to allow applicants to determine whether the decision is vitiated by error.<sup>5</sup> These findings are equally applicable here.

25. Nothing in the Applicants’ confirmatory application could justify the use of Article 8(2) by EFSA. In the reply to the initial application, EFSA provided a document (“Summary table of the 20 items listed in the access request of 10 November 2010”) identifying the documents requested and whether disclosure was granted or not. Thus, as the documents had already been identified, EFSA could not argue that the large number of documents which the Applicants had asked for constituted a justification for extending the deadline for the response of EFSA.

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<sup>5</sup> Case C-64/05 P, *Kingdom of Sweden v. Commission of the European Communities and Others* (2007); Case C-64/05 P, *Kingdom of Sweden v. Commission of the European Communities and Others* (2007), paragraph 69; Case T-264/04, *WWF European Policy Programme v. Council of the European Union* (2007), paragraph 36, citing Case T-187/03, *Scippacercola v Commission* (2005), paragraph 66.

26. EFSA also mentioned, as a supporting reason for the time extension:

*“The extra time EFSA would need to follow up on your application in compliance with the legal framework and i.e. relevant case law referred in your application”*

27. However, the existence of a legal framework on access to documents is not foreseen as a reason to allow a time extension under Article 8(2). EFSA should be aware of its obligations under Regulations 1049/2001, 1367/2006 and the Aarhus Convention and comply with them within the prescribed time limits provided for under them.

28. Therefore EFSA had all the relevant tools to assess the confirmatory application without a time extension since the documents had already been identified within the 15 working days after the initial application from the Applicants.

## **2.2 Second plea in law – Ground for Annulment**

### **Section two - Violation of Article 4(1)(2)(3) and (4) of the Aarhus Convention and Article 6(1) of Regulation 1367/2006**

*Failure to demonstrate that the requested documents fall under the scope of an exception under the Aarhus Convention and Regulation 1367/2006*

29. The requested draft Guidance and scientific advice constitute environmental information. The exceptions available to environmental information are governed by the Aarhus Convention and Regulation 1367/2006.

30. The Aarhus Convention does not provide any exceptions to the right of access to environmental information relating to the internal decision-making of public authorities as provided under article 4(3) of the same regulation. These exceptions should therefore not be applied by EU institutions to withhold documents containing environmental information. Any decisions refusing to disclose environmental information on the basis of these provisions are in breach of the Aarhus Convention.

31. In withholding the requested documents on the basis of Article 4(3) of Regulation 1049/2001 EFSA therefore violated Article 4(1)(2)(4) of the Aarhus Convention and Article 6(1) of Regulation 1367/2006.<sup>6</sup>

### ***2.2.1 The requested documents constituted environmental information***

32. The preparatory documents for the Guidance on peer reviewed scientific literature constituted “*environmental information*” within the meaning of the Convention.

33. Indeed, Article 2(3) of the Convention provides that:

*“Environmental information” means any information in written, visual, aural, electronic or any other material form on:*

*(a) The state of elements of the environment, such as air and atmosphere, water, soil, land, landscape and natural sites, biological diversity and its components, including genetically modified organisms, and the interaction among these elements;*

*(b) Factors, such as substances, energy, noise and radiation, and activities or measures, including administrative measures, environmental agreements, policies, legislation, plans and programmes, affecting or likely to affect the elements of the environment within the scope of subparagraph (a) above, and cost-benefit and other economic analyses and assumptions used in environmental decision-making;*

*(c) The state of human health and safety, conditions of human life, cultural sites and built structures, inasmuch as they are or may be affected by the state of the elements of the environment or, through these elements, by the factors, activities or measures referred to in subparagraph (b) above”*

34. Article 2(1)(d) points (i) and (ii) of Regulation 1367/2006 provides for almost an identical definition of environmental information:

*“environmental information” means any information in written, visual, aural, electronic or any other material form on: ...*

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<sup>6</sup> Regulation (EC) No 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, OJ L264/13.

*(i) The state of the elements of the environment, such as air and atmosphere, water, soil, land, landscape and natural sites including wetlands, waste and marine areas, biological diversity and its components, including genetically modified organisms, and the interaction among these elements;*

*(ii) Factors, such as substances, energy, noise, radiation or waste, including radioactive waste, emissions, discharges and other releases into the environment, affecting or likely to affect the elements of the environment referred to in point (i);*

*(iii) measures (including administrative measures), such as policies, legislation, plans, programmes, environmental agreements, and activities affecting or likely to affect the elements and factors referred to in points (i) and (ii) as well as measures or activities designed to protect those elements;*

*(iv) the state of human health and safety including the contamination of the food chain, where relevant, conditions of human life, cultural sites and built structures in as much as they are or may be affected by the state of the elements of the environment referred to in point (i) or, through those elements, by any of the matters referred to in points (ii) and (iii)”*

**35.** It derives from the above that measures, including administrative measures, affecting or likely to effect the environment, are environmental information. The EFSA Guidance aims at providing support to applicants submitting dossiers for the approval of active substances of plant protection products under Regulation 1107/2009. This EFSA Guidance will also provide support to competent authorities of EU Member States in charge of evaluating the submitted dossiers and preparing the draft assessment reports, and EFSA, as the authority responsible for peer-reviewing and drawing conclusions on the dossiers. The correlation between the role of the Guidance and the placing on the market of plant protection products is evident.

**36.** As plant protection products are factors that that can affect the environment and EFSA’s Guidance is a measure that can affect the placing on the market of such substances, it follows that the Guidance is environmental information.

**37.** The documents that EFSA refused to disclose to the Applicants are intermediate drafts and scientific advice from two scientific bodies (PPR and PSC) of EFSA on the same

draft Guidance. The Guidance will have the direct impact on the procedure for the authorisation of plant protection products because independent studies may highlight environmental and health effects that other studies may not include. It follows that the screening criteria set by the Guidance will have an influence on the placing on the market of hazardous substances for human health and the environment.

38. EFSA's confirmatory application reply states that the requested documents do not fall in the scope of the definition of environmental information because "*the draft versions of the Guidance, as internal intermediate documents, do not have any external effect or impact, a fortiori not on the environment and on the health as defined in the Regulation (EC) No 1367/2006*".

39. EFSA's opinion is clearly erroneous. The definition of environmental information, given in Article 2(3)(b) Aarhus Convention and Article 2(1)(d) of Regulation 1367/2006 shows that this interpretation is too narrow. These provisions state that environmental information means any information "on" the state of the elements of the environment and "on" factors such as substances or on measures affecting or likely to affect the environment, the state of human health. Nowhere do the Aarhus Convention or Regulation 1367/2006 provide that to constitute environmental information, the requested information itself shall have external effect or impact on the environment or on the health as such. Indeed, cost-benefit studies and economic analyses, or reports on the environment which are explicitly mentioned in these definitions, do not directly affect the environment. The notion of "environmental information" which shall, according to the introductory words of Article 2 (1)(d) of Regulation 1367/2006, include "any information" has to be interpreted in a broad sense. Therefore whether the requested document is the final or the intermediate guidance is not relevant to determine whether it is environmental information. What matters is the subject matter of the guidance and whether it contains information on the environment or information on factors or measures that affect or are likely to affect the elements of the environment or health.

40. This is clearly the case as the requested draft Guidance sets out criteria under which scientific studies on the impacts, dangers and sometimes lack of impacts, of pesticides on the environment and health will be taken into account to authorise pesticides. The "*scientific peer-reviewed open literature*" constitutes information on the state of the

elements of the environment and of health and safety. Guidance, therefore, must contain information on how environmental information, the “*scientific peer-reviewed open literature*”, will be used or -- on the contrary -- ignored by authorities authorizing the use of pesticides. Guidance must also contain information on measures that are described, recommended or criticised in the said literature that affect or are likely to affect the elements of the environment for the purpose of Article 2(3)(b) of the Aarhus Convention and Article 2(d)(iii) of Regulation 1367/2006 .

41. Similarly, the feedback from the PPR and the PSC must directly relate to “*scientific peer-reviewed open literature*”. The PPR Panel provides independent scientific advice on the risk assessment of plant protection products and their residues, looking at risks for the user, worker, the consumer and the environment. The PSC is responsible for planning and monitoring the safety review process from the initial application for an active substance to be authorised through to the publication of an opinion by EFSA on the safety of that substance. Both bodies provide scientific advice and received an advance draft of the EFSA Guidance to comment and provide their input upon. It follows that their comments and feedback on the Guidance may have had a direct impact on forming the decision of the working group on the making of the final draft put under consultation.

42. EFSA’s confirmatory application reply states that:

*“the broad definition of environmental information provided in Regulation 1367/2006, article 2 paragraph 1) d) does not apply to the specific documents requested and the reference made by case law C-266/09 does not find application to the specific case. [...] Secondly, as regards your reference made in your letter to Court case C-266/09, I would like to draw your attention to the fact that the ruling applies to a national procedure on the authorisation of pesticides, and it focuses on the information submitted by the applicant which may directly affect human health and the environment and therefore falls under the broad definition of the environmental information provided in the Regulation 1367/2006. This is clearly not the case for the draft version of a Guidance that does not include any kind of scientific data and does not have any external effect until its publication. It is evident from the above that both conditions put forward by in the C-266/09 do not apply.”*



43. EFSA is of the opinion that documents, in order to constitute environmental information, must have an external effect. However the list of environmental information provided by the Aarhus Convention and by Regulation 1367/2006, refers to documents that do not have any external effect (e.g. reports on the implementation of environmental legislation). Moreover EFSA's argument is flawed as it suggests that the Guidance will have external effects only after its publication. As mentioned above, what matters is the subject matter of the Guidance and whether it contains information on the environment or information on factors or measures that affect or are likely to affect the elements of the environment or health.
44. Regarding the applicability of the findings of the Court in Case C-266/09, although the Guidance does not contain information on specific substances, it has a direct impact on the national procedure on the authorisation of pesticides and will influence how the information on the substances will be evaluated in the course of those procedures in all 27 EU Member States.
45. As provided by Article 22 of Regulation 178/2002, EFSA's role is to provide scientific advice and the advice it has to provide is clearly environmental.: *“all fields which have a direct or indirect impact on food and feed safety”* and *“contribute to a high level of protection of human life and health, and in this respect take account of animal health and welfare, plant health and the environment”*.
46. Moreover, Regulation 1107/2009 which requires EFSA to adopt the relevant guidance on how to identify and select “scientific peer-reviewed open literature” says:
- “3. [...] to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market of plant protection products, while improving agricultural production.*
- 4. The provisions of this Regulation are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment. In particular, Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the*

*environment posed by the plant protection products to be authorised in their territory.”*

47. In the instant case, EFSA’s Guidance refers to the environment, as it explains how information (scientific literature) on the safety of plant protection products shall be treated. Administrations and economic operators are expected to align their activities to the orientations given in the Guidance, and EFSA itself implicitly declared, by making the Guidance public, that it would orient its assessment activities to the indications contained in the Guidance. The Guidance thus constitutes “*environmental information*”.
48. It derives from the foregoing that the requested documents constitute environmental information for the purpose of Article 2(3)(a)(b) of the Aarhus Convention which provide a right of access to these documents. The requested documents also constitute environmental information for the purpose of Article 2(1)(d)(iii) of Regulation 1367/2006.
49. EFSA should therefore have interpreted the grounds for refusal, as regards the exceptions set out in Article 4 of Regulation 1049/2001, “*in a restrictive way, taking into account the public interest served by disclosure and taking into account whether the information requested relates to emissions into the environment*” for the purpose of Article 4(4) last indent of the Convention and Article 6(1) of Regulation 1367/2006.

### ***2.2.2 Article 4(3) of Regulation 1049/2001 does not apply to environmental information***

50. The Aarhus Convention does not provide for any exception on public authorities’ internal decision-making such as the one provided under Article 4(3) of Regulation 1049/2001. EFSA cannot therefore argue that disclosure of the drafts of the Guidance and of the feedbacks from its internal bodies would seriously undermine EFSA’s decision-making process. The Aarhus Convention allows, under Article 4(3)(c), a refusal of access to environmental information when “*the request concerns material in the course of completion or concerns internal communications*”. However the different versions of the draft Guidance were drafted after each meeting of the drafting working group as well as the contribution of the PPR, of the PSC and of the

PRAPeR. Thus, each draft Guidance is a final document and none are in the course of completion. The same applies to the requested comments, opinions and positions of the relevant bodies.

- 51.** Nor do the documents, to which access is requested, constitute “*internal communications*”. The applicants requested access to comments, opinions and positions which persons outside of EFSA have made on different drafts of the Guidance. It is clear that such communications are not “internal”, but come from persons who are outside the administrative hierarchy of EFSA. For the Applicants, it is important to know who influenced the drafting of the Guidance, and with which kind of arguments, in order to be able to potentially raise objections to one or several conclusions of the Guidance. As the Guidance has already been published, disclosure may not either be refused with the argument that the request concerns material in the course of completion. Rather, with the adoption of the Guidance by EFSA and its publication, the material is already completed.
- 52.** Article 4(4) of the Aarhus Convention also allows the Contracting Parties to refuse disclosure to environmental information where the disclosure would adversely affect the proceedings of public authorities.
- 53.** However, this provision is not applicable to the present case. Indeed, EFSA has published the Guidance which it had developed under Article 8(5) of Regulation 1107/2009. Thus, the proceedings regarding the production of this Guidance are finished. Under these circumstances, there is no reason for which the different documents which served EFSA to prepare the Guidance should not be made publicly accessible. The Applicants have a legitimate interest in knowing how EFSA came to the different conclusions which were inserted into the Guidance, which scientific opinions were accepted by EFSA and which were not accepted, and which vested interest groups influenced the final content of the Guidance.
- 54.** Furthermore, even if the exception set out under Article 4(3) of Regulation 1049/2001 were in compliance with the Aarhus Convention and could thus apply to environmental information held by EU institutions, bodies and agencies, they would still not apply to the requested documents.

**2.2.3 Article 4 of the Aarhus Convention is directly applicable and prevails over Regulation 1049/2001**

55. The Aarhus Convention was approved by the Council's Decision 2005/370/EC.<sup>7</sup>
56. Pursuant to Article 216(2) TFEU, "*Agreements concluded by the Union are binding on the institutions of the Union and on its Member States*". The Convention is thus an integral part of the EU legal order which makes it binding on EU institutions. Because EFSA is, in accordance with Article 13 TEU, one of the EU institutions, it is subject to the provisions of the Convention.
57. The Court of Justice, in Case C-240/09<sup>8</sup> ruled that "*a provision in an agreement concluded by the European Union with a non-member country must be regarded as being directly applicable when, regard being had to its wording and to the purpose and nature of the agreement, the provision contains a clear and precise obligation which is not subject, in its implementation or effects, to the adoption of any subsequent measure (see, in particular, Case C-265/03 Simutenkov [2005] ECR I-2579, paragraph 21, and Case C-372/06 Asda Stores [2007] ECR I-11223, paragraph 82).*"
58. The Convention is an agreement concluded by the European Union with non-member countries.
59. Article 4(1) of the Convention provides that:

*"1. Each Party shall ensure that, subject to the following paragraphs of this article, public authorities, in response to a request for environmental information, make such information available to the public, within the framework of national legislation, including, where requested and subject to subparagraph (b) below, copies of the actual documentation containing or comprising such information:*

*(a) Without an interest having to be stated;*

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<sup>7</sup> Council Decision 2005/370/EC of 17 February 2005 on the conclusion, on behalf of the European Community, of the Convention on access to information, public participation in decision-making and access to justice in environmental matters, OJ L 124/1.

<sup>8</sup> Case C-240/09 Lesoochránárske zoskupenie VLK v Ministerstvo životného prostredia Slovenskej republiky O.J. 2009/C 233/05, paragraph 44.

*(b) In the form requested unless:*

*(i) It is reasonable for the public authority to make it available in another form, in which case reasons shall be given for making it available in that form; or*

*(ii) The information is already publicly available in another form”.*

60. This provision establishes a general rule of freedom of access to information. The provision is unconditional, as it grants the right of access to environmental information without requiring further measures to be adopted by the Parties to the Convention. If a Contracting Party does not take the measures which are necessary to render enforceable a right provided by a convention that has been ratified by it, then it may not invoke its own omission in order to contest the direct applicability of the provisions of the said convention. Article 4 of the Convention is also precise enough as it specifies to what information the right of access applies to.

61. Additionally, according to the Convention’s implementation guide, the provision “*within the framework of national legislation*” means “*both that (i) national legislation should set out a framework for the process of answering information requests in accordance with the Convention and that (ii) national legislation may limit access to information in accordance with the optional exceptions outlined in article 4, paragraphs 3 and 4<sup>9</sup>.*” The said provision is therefore not subject to the adoption of any subsequent measure at national level by the Parties to the Convention since the national framework established at national level may only reproduce the one provided for by the Convention. Indeed, Parties do not have any discretion as to the information that should be disclosed or not. The Convention’s implementation guide confirms that in stating that “*paragraphs 3 and 4 outline the only circumstances under which exceptions to the general rule apply*”.<sup>10</sup>

62. The Court of Justice of the EU has confirmed this point in Case C-344/04, holding that “*Article 300(7) EC [now Article 216(2) TFEU] provides that ‘agreements concluded under the conditions set out in this Article shall be binding on the*

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<sup>9</sup> United Nations Economic Commission for Europe, *The Aarhus Convention, an implementation guide*, prepared by S. Stec and S. Casey-Lefkowitz in collaboration with J. Jendroska, p.54.

<sup>10</sup> *The Aarhus Convention, an implementation guide*, *ibid*, p.53.

*institutions of the Community and on Member States'. In accordance with the Court's case law, those agreements prevail over provisions of secondary Community law"*<sup>11</sup>.

63. The exceptions to the right of access to environmental information laid down in the Aarhus Convention may thus not be enlarged or completed by any exception which is mentioned in Regulations 1049/2001 or 1367/2006, given that the Aarhus Convention prevails over secondary EU legislation. The fundamental right of access to information, granted by the Aarhus Convention and its ratification by the EU cannot, therefore, be restricted by secondary EU legislation. This is confirmed by Article 2(6) of Regulation 1049/2001 which provides that *"this shall be without prejudice to rights of public access to documents held by the institutions which might follow from instruments of international law or acts of the institutions implementing them."*
64. It follows that the Aarhus Convention prevails over Regulation 1049/2001 and that Article 4 of the Convention is unconditional and sufficiently clear and precise to be directly applicable. EFSA in withholding the requested documents on the basis of Article 4(3) of Regulation 1049/2001 therefore violated Article 4(1)(2)(3)(4) of the Aarhus Convention.

#### ***2.2.4 Violation of Article 6(1) of Regulation 1367/2006***

65. Any exception to the right of access to environmental information must be interpreted in a restrictive way. Article 4(4) last indent of the Convention provides that the *"aforementioned grounds for refusal shall be interpreted in a restrictive way, taking into account the public interest served by disclosure ..."*.
66. This provision is applied by Article 6(1) of Regulation 1367/2006 at EU level which also requires a restrictive interpretation of the exceptions to the right of access to environmental information:

*"As regards Article 4(2), first and third indents, of Regulation (EC) No 1049/2001, with the exception of investigations, in particular those concerning possible infringements of Community law, an overriding public interest in disclosure shall be deemed to exist where the information requested relates to emissions into the environment. As regards the other exceptions set out in Article 4 of Regulation (EC)*

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<sup>11</sup> See Case C-344/04, paragraph 35.  
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*No 1049/2001, the grounds for refusal shall be interpreted in a restrictive way, taking into account the public interest served by disclosure and whether the information requested relates to emissions into the environment.”*

67. Therefore, even if the exceptions relied upon by EFSA were applicable in this case, EFSA should have interpreted the grounds for refusal, as regards the exceptions set out in Article 4 of Regulation 1049/2001, “*in a restrictive way, taking into account the public interest served by disclosure and taking into account whether the information requested relates to emissions into the environment*” for the purpose of Article 4(4) last indent of the Convention and Article 6(1) of Regulation 1367/2006. Yet, it is clear that EFSA has not fulfilled this obligation. EFSA's replies as set out in its 1 December 2010 letter and in its 10 February 2011 letter to the initial application of the Applicants did not comply with the requirements of Article 4(1)(2)(4) of the Convention or Article 6(1) of Regulation 1367/2006.

#### ***2.2.5. EFSA's decision is based on an erroneous analysis of the law and the relevant case-law***

68. EFSA's confirmatory application reply states that:

*“The full respect of the principles of transparency and openness in the decision making process governing the issuing of the Guidance has been already granted and embedded by the legislator in the horizontal and sectoral legislation. In fact the legislator has translated the need to be fully transparent in the delivering of the scientific outputs by imposing on EFSA an exhaustive set of rules governing the prompt publication of final scientific outputs. This strict obligation to publish without delay the scientific outputs is complemented by several tools foreseeing the interaction with the interested parties during the drafting process, fully in compliance with the provisions foreseen by the Treaty on the Functioning of the European Union governing the regular dialogue and contacts with the interested parties. It results that in doing so the legislator opted for the full transparency in the publication of EFSA's final scientific outputs and the regular dialogue with the interested parties offsetting*

*the risk related to the misunderstandings possibly connected to the disclosure of provisional drafts”.*

69. According to EFSA, the access and transparency provisions foreseen by the Treaty on the Functioning of the European Union (TFEU) are complied with merely by publishing the final version of the Guidance while keeping confidential all the intermediate drafts and all the scientific and other type of opinions, comments and recommendations made by official bodies such as the PPR, PSC and PRAPeR. The whole decision-making process leading to the adoption of the Guidance which will have an impact on the use of pesticides throughout the whole EU and thus on all the EU citizens’ health as well as on the environment must, according to EFSA, be kept confidential. Not only is this concept of the decision making process not transparent, it does not allow the citizens to have access to any document produced during this process. It also prevents any public participation from taking place outside submitting comments on the draft. Even such comments will be made without knowing the basis on which one set of advice is preferred by EFSA to another. This is clearly in breach of the relevant provisions of TFEU.

70. Article 15(1) TFEU states that: *“In order to promote good governance and ensure the participation of civil society, the Union institutions, bodies, offices and agencies shall conduct their work as openly as possible.”*

71. Article 15(3) TFEU further adds that *“each institution, body, office or agency shall ensure that its proceedings are transparent”*. The basic principles which govern the functioning of the EU institutions and agencies are openness and transparency, and the objective is to grant access to information as widely as possible. This is also formulated in the recitals of Regulation 1049/2001:

*“(1) The second subparagraph of Article 1 of the Treaty on European Union enshrines the concept of openness, stating that the Treaty marks a new stage in the process of creating an ever closer union among the peoples of Europe, in which decisions are taken as openly as possible and as closely as possible to the citizen.*



*(2) Openness enables citizens to participate more closely in the decision-making process and guarantees that the administration enjoys greater legitimacy and is more effective and more accountable to the citizen in a democratic system. Openness contributes to strengthening the principles of democracy and respect for fundamental rights as laid down in Article 6 of the EU Treaty and in the Charter of Fundamental Rights of the European Union."*

72. In addition to committing a breach of the Treaty's provisions, EFSA has breached Regulation 178/2002.

73. EFSA considers that compliance with the transparency procedures of Article 178/2002 is sufficient to guarantee transparency. However, Article 38 of Regulation 178/2002 requires EFSA to carry out its activities with a high level of transparency, in particular it requires EFSA to make public without delay:

*"(a) agendas and minutes of the Scientific Committee and the Scientific Panels;  
(b) the opinions of the Scientific Committee and the Scientific Panels immediately after adoption, minority opinions always being included;  
(c) without prejudice to Articles 39 and 41, the information on which its opinions are based;"*

74. Among the documents requested by the Applicants are the opinions from three internal bodies and panels of EFSA (PPR, PRAPeR and PSC). Although EFSA claims to be complying with the founding regulation of the agency, in fact it is not complying with the obligation deriving from Article 38(1)(a) which provides for the advice of the Scientific Panels to be disclosed.

75. EFSA has also the obligation to make public the information on which its opinions are based with the exception of information that is deemed to be confidential. Article 39 of Regulation 178/2002 provides: *"By way of derogation from Article 38, the Authority shall not divulge to third parties confidential information that it receives for which confidential treatment has been requested and justified, except for information which must be made public if circumstances so require, in order to protect public health."*

76. Furthermore, Article 41 of Regulation 178/2002 provides for the obligation of EFSA to "*ensure wide access to the documents which it possesses*".

77. EFSA's obligation to provide access to the documents that it holds applies without prejudice to the general principles governing the access to documents of EU institutions as set out by Regulations 1049/2001 and 1367/2006 and by the Aarhus Convention.

78. The decision concerning access to documents was adopted by the Management Board on 16 September 2003 (MB 16.09.2003) pursuant to Article 41(2) of Regulation 178/2002 (as amended) and classifies documents in two categories: (1) public documents and (2) protected documents which are further divided into confidential documents and restricted documents.

79. It is worth listing the documents EFSA deems to be confidential:

#### ***"2.1 Confidential documents***

*This classification shall be applied to information and material the unauthorized disclosure of which could harm the essential interests of the European Union Institutions, the Member States, the Authority and its constitutive bodies, their members and experts and, in particular, would be likely to:*

- *Cause financial loss or facilitate improper gain or advantage for individuals or companies;*
- *Breach undertakings to maintain the confidence of information provided by third parties;*
- *Breach statutory restrictions on disclosure of information;*
- *Impede or undermine the effective management or operations of EFSA.*

*Documents classified as confidential include:*

*All Scientific Committee, Panel and Working Group meeting documents contributing to the formation of scientific opinion (correspondence, presentations, draft contributions from members, informal notes, working papers).*

- *Except for minority opinions published with the final opinion, all documents stating personal opinions of the members of the Committee, a Panel, a Working Group or an expert, and relating to a question which has not yet been subject to a scientific opinion*
- *Correspondence and minutes of meetings between and with members of Committee or Panels, experts, stakeholder representatives, petitioners and undertakings*
- *Documents given by third parties concerning sensitive industrial and commercial matters, and/or for which confidentiality has been requested and agreed. This includes petitions and evaluation tables for a given substance*
- *Background scientific references not yet published*
- *All documents drawn up by EFSA for internal use or received by it, relating to matters on which it has not yet taken a decision”*

80. This last paragraph is clearly in breach of Article 4(3) of Regulation 1049/2001 which provides that disclosure of such documents may be refused unless there is an overriding public interest in disclosure and does not provide the institutions and bodies with an unconditional veto to the right of access.

81. The Decision further lists the documents considered as “restricted”:

### ***“2.2 Restricted***

*Restricted documents are typically characterized by the fact that their disclosure might be prejudicial to the interests of EFSA, including relations with EU Institutions, the Member States, third countries, petitioners and undertakings. These include:*

- *Agendas and minutes of the meetings of Working Groups created by the Advisory Forum, the Scientific Committee or a Scientific Panel Draft opinions from the Scientific Committee or a Scientific Panel. These may however be released totally or partially for public consultation where EU legislation so requires and/or where a technical hearing has been expressly authorized by the Scientific Committee or a Panel*
- *Draft scientific reports from EFSA*
- *Any press release or public announcement prior to the lifting of any embargo”*

82. Such classification is clearly in breach of the principles provided by the TFEU on openness and transparency and as already mentioned also of Regulation 1049/2001, Regulation 1367/2006 and the Aarhus Convention for keeping whole categories of documents confidential without having to weigh the different interests at stake or assessing whether there is an overriding public interest in disclosure. It is also important to note that EFSA refuses to disclose certain documents that other institutions and agencies already make publicly accessible such as minutes of meetings of working groups and opinions. Other types of documents mentioned in the Decision have also already been deemed by the Court to be documents that should be publicly accessible such as scientific opinions.

83. However, EFSA's confirmatory application reply states: *"It stems from the above arguments related to the need to protect the decision making process in drafting its scientific outputs, the disclosure of the scientific outputs foreseen by the legislator in several provisions of the horizontal and vertical legal framework and the principles put forward by the Court case C-121/05 are all consistent and properly applied in the reasoning rejecting access to the draft versions of the Guidance"*.

84. Yet, in case T-121/05 the Court stated:

*"that scientific opinions obtained by an institution for the purpose of the preparation of legislation must, as a rule, be disclosed, even if they might give rise to controversy or deter those who expressed them from making their contribution to the decision-making process of that institution. The risk, relied upon by the Commission, that public debate born of the disclosure of their opinions may deter experts from taking further part in its decision-making process is inherent in the rule which recognises the principle of access to documents containing opinions intended for internal use as part of consultations and preliminary deliberations, which obviously include consultations of experts. It cannot, however, be inferred from the existence of such a risk that any disclosure of a scientific opinion with significant consequences, particularly economic or financial, for the economic operator concerned, will have a deterrent effect as regards its author or, even if that were shown, that the risk is such as seriously to*

*undermine the institution's decision-making process, as where that institution would find it impossible to consult other experts.*"<sup>12</sup>

85. It derives from the foregoing that the scientific advice provided by the PSC, the PPR, and the external experts involved in the working group for the preparation of the Guidance must be disclosed.
86. In this regard, it is to be pointed out that the Guidance, as published, is intended to continuously serve as an authoritative interpretation of Article 8(5) of Regulation 1107/2009, at least as long as the EU Courts have not determined another interpretation. In the practice of management of authorisations for plant protection products, the Guidance will thus play a role which is largely similar to that of legislation: it will be of application in an indefinite number of future cases. EU administrations, the administrations of Member States, economic operators and civil society representatives will align their activities upon the content of said Guidance.
87. These principles also apply in the present case, all the more as EFSA's own considerations with regard to the Guidance have already led to various conclusions. Furthermore, it should be noted the General Court decided in Case T-166/05, that scientific opinion which was submitted to the Commission, in order to prepare a decision by the Commission, could not be the subject of a refusal to be disclose.<sup>13</sup>
88. Nevertheless, EFSA's confirmatory application reply argues that "*the interim drafts are the result of "a work of analysis, reflection and criticism exclusively for internal purposes and not intended to be brought to the attention of the public" of selected scientific experts that in their capacity do not represent the final expression of the authority*" thus referring to point 48 of Case T-403/05. However, EFSA's argument is based on a case that does not support the decision to refuse access to the requested scientific advice. Case T-403/05 refers to "*a document containing opinions for internal use as part of deliberations and preliminary consultations within the [Commission]*", for the purposes of the second subparagraph of Article 4(3) of

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<sup>12</sup> Case T-121/05, Borax Europe v Commission, paragraph 70

<sup>13</sup> T-166/05, Borax v. Commission

Regulation No 1049/2000.”<sup>14</sup> Moreover point 48 of the judgement refers to documents containing personal opinions where “*the authors were requested to put forward their views, even critical ones*” whereas the requested document refer to the results of meetings of the working group set up both with internal and external experts and to feedbacks from internal bodies in EFSA.

89. Moreover in Case T-121/05 the Court stated that “*The Commission’s argument that the recordings cannot be disclosed because they contain individual opinions expressed for internal purposes in a preliminary phase of the final decision conflicts with the very letter of the second subparagraph of Article 4(3) of Regulation No 1049/2001. That provision, in fact, expressly allows access to a document containing opinions for internal use as part of deliberations and preliminary consultations within the institution concerned.*”<sup>15</sup> Further, the Court stated: “*Indeed, while the Community legislature has provided for a specific exception to the right of public access to the documents of the Community institutions as regards legal advice, it has not done the same for other advice, in particular scientific advice, such as that expressed in the recordings at issue. The Court of Justice has ruled that it could not correctly be held that there is a general need for confidentiality in respect of advice from the Council’s legal service relating to legislative matters (Sweden and Turco v Council, paragraph 57). A fortiori, the same principle must be applied to the advice at issue, for which the Community legislature has not laid down a specific exception and which remains subject to the general rules applicable to the public right of access to documents.*”<sup>16</sup>

90. It derives therefrom that, even according to the case law referred to by EFSA, Article 4(3) of Regulation 1049/2001 cannot be used to refuse access to the requested documents that include scientific advice. EFSA thus violated Article 4(3) of Regulation 1049/2001 and Article 38 of Regulation 178/2002.

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<sup>14</sup> Paragraph 44

<sup>15</sup> Paragraph 66

<sup>16</sup> Paragraph 68

## 2.3 Third plea in law – Ground for annulment

### Section three - Violation of Article 4(3) second subparagraph of Regulation No 1049/2001

*Failure to demonstrate that the disclosure of the requested documents would seriously undermine EFSA internal decision-making, particularly after the decision has been taken*

91. As the Court explained in numerous cases, if an EU institution decides “to refuse access to a document which it has been asked to disclose, it must explain,(…), how access to that document could specifically and effectively undermine the interest protected by an exception laid down in Article 4 of Regulation No 1049/2001 relied on by that institution”.<sup>17</sup>
92. EFSA must also prove how the risk for the protected interest is real and reasonably foreseeable, and not only hypothetical.<sup>18</sup>
93. Yet, EFSA’s confirmatory application reply only stated that “*The disclosure of these documents would be detrimental to the whole drafting process of the final Guidance and misleading for the final reader because reporting intermediate and provisional assessment in the context of an ongoing dialogue. [...] In fact their disclosure would undermine the decision making process of EFSA, and would affect the business needs and process by providing disclosure to intermediate versions of scientific outputs and to comments made on the drafts of the scientific experts involved that do not represent the position of the Authority on a specific scientific issue for which the legislator foresaw specific and detailed means for disclosure in their final versions that EFSA is fully applying and implementing.*”
94. It is not clear how the decision-making process would be undermined by the disclosure of intermediate drafts which were prepared before each meeting of the working group and included as part of the documents to be discussed in the meetings. Further it is not explained how the disclosure of the opinions from EFSA’s panels and committees

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<sup>17</sup> Joined Cases C-39/05 P and C-52/05 P *Sweden and Turco v Council* [2008] ECR I-4723, paragraph 49; Case C-139/07 P, *Technische Glaswerke Ilmenau GmbH* [2010], paragraph 53.

would undermine EFSA's decision-making process even after the final Guidance has been published.

95. EFSA's confirmatory application reply states "*that the draft versions of the Guidance do fall within the exception foreseen by Article 4(3) second paragraph of Regulation 1049/2001. In fact their disclosure would undermine the decision making process of EFSA, and would affect the business needs and process by providing disclosure to intermediate versions of scientific outputs and to comments made on the drafts of the scientific experts involved*" that do not represent the views of EFSA.
96. EFSA thus argues that its "business needs and process" prevail not only over the right to access documents provided by Regulations 1049/2001 and 1367/2006 but also over the principle of Article 1 of the EC Treaty that provides decisions to be taken as openly as possible and as closely to the citizen. Indeed business needs are not a sufficient justification to refuse access to documents from public institutions.
97. EFSA should have provided evidence that disclosure of the documents in question would "seriously undermine" the decision making process. In view of the fact that the actual decision-making process is already finished, and the Guidance was published for consultation at the time of the initial request, the threat can only exist, if at all, for future decision making processes.
98. The only impact of disclosing these documents would be that the nature of the comments of the several bodies involved in the procedure would be clarified and that the role of each body would be understood by the public. EFSA involved five bodies in the decision making-process of the Guidance. Each body must have a separate role which justifies the need for the involvement in the process. Moreover, most of these bodies include experts that are not part of EFSA staff and can be either independent experts or experts seconded by Member States authorities.

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<sup>18</sup> Case T-237/05, *Editions Odile Jacob v Commission*, [2010] paragraph 41; Case T-437/05, *Brink's Security Luxembourg SA v Commission* [2009] paragraph 213; Joined Cases C-39/05 and 52/05, *Sweden and Turco v. Council*, [2008] ECR I-00001; paragraph 63; joined Cases T-391/03 and T-70/04, *Franchet and Byc*, [2006] ECR II-2023, paragraphs 115-118, Case T-2/03, *Verein für Konsumenteninformation v Commission* [2005], paragraph 69.



99. The fact that each of these bodies has a specific webpage where their outputs are published reinforces the idea that each of their scientific output is relevant in a different way to the final outcome of the drafting process of the Guidance.
100. The risk of EFSA's decision-making process being seriously undermined in the future is thus purely hypothetical.

## 2.4 Fourth plea in law – Ground for annulment

### Section four - Violation of Article 4(3) second subparagraph

*The failure to weigh the interests in balance and to assess whether there was an overriding public interest in disclosure*

101. No reference is made in EFSA's confirmatory application reply to the assessment of the existence of an overriding public interest in disclosure.
102. Yet Article 4(3) last indent of Regulation 1049/2001 requires the institutions to balance the different interests at stake and to disclose the documents if there is an overriding public interest in disclosure.
103. Moreover, recital (1) of Regulation 1049/2001's preamble refers to the second subparagraph of Article 1 of the EC Treaty which enshrines the concept of openness, stating that the "*Treaty marks a new stage in the process of creating an ever closer union among the peoples of Europe, in which decisions are taken as openly as possible and as closely to the citizen*". Article 4(3) of Regulation 1049/2001 must thus be construed in accordance with the principles set out in Article 1 EC granting the public the widest possible access to EU institutions' documents.
104. The fact that the protected interest under Article 4 of Regulation 1049/2001 would be undermined by the disclosure of the requested documents is not a sufficient ground to refuse access to the said documents. It is incumbent upon the EU institution, in this case EFSA, to ascertain whether there is an overriding public interest justifying disclosure despite the fact that the decision making process in

drafting its scientific outputs would be undermined.<sup>19</sup> If the institution refuses, after having weighed the different interests, to disclose the documents it must then give a detailed statement of reasons for such a refusal<sup>20</sup>.

**105.** Similarly, in Case T-105/95,<sup>21</sup> the General Court decided to annul the Commission's decision refusing to grant access to the requested documents because the decision did not "*enable the applicant and, therefore, the Court to ascertain whether the Commission fulfilled its obligation to undertake a genuine balancing of interests involved as required by the Code of Conduct ..., given that [the decision] relies upon the confidentiality exception and make[s] no mention of any balancing of the interests involved.*" The Court thus considered that the contested decision failed to meet the requirements to state reasons in accordance with Article 190 of the Treaty establishing the EC and had therefore to be annulled.

**106.** In the instant case, EFSA did not weigh the interests at stake, it only asserted that there was no overriding public interest in disclosure. This reply certainly does not constitute a genuine examination of the different interests at stake or of the likely weighting of these various interests. It does not constitute a detailed statement of reasons for the refusal to disclose the requested documents. Nor does the fact that the transparency provisions foreseen by Regulation 178/2002 were applied count as a means of balancing the interests at stake.

**107.** In Regulation 1107/2009 (as well as its predecessor Directive 91/414/EEC) the approval of plant protection products is based on the fact that "*in the light of current scientific and technical knowledge*" a pesticide is expected to meet the requirements for authorisation. Scientific peer-reviewed open literature is an essential element in the evaluation of the adverse effects of a pesticide to be able to take a decision based on current knowledge.

**108.** Article 8(5) of Regulation 1107/2009 allows, for the first time, independent peer reviewed scientific literature to be included in the dossiers for the authorisation of plant protection products. This means that thousands of studies that were

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<sup>19</sup> joined Cases C-39/05 and C-52/05 P *Turco*, *ibid*, paragraph 44.

<sup>20</sup> joined Cases C-39/05 and C-52/05 P *Turco*, *ibid*, paragraph 69.

<sup>21</sup> see Case T-105/95, *WWF UK v Commission* [1997] ECR II-00313, paragraph 76.

traditionally excluded from risk assessments will become criteria for accepting or rejecting a plant protection product for the market.

- 109.** The Applicants believe that EFSA's Guidance on the use of scientific peer-reviewed open literature gives Good Laboratory Practice (GLP) studies a higher level of reliability particularly through reference to the "*Klimisch study*<sup>22</sup>" from 1997. According to this study, scientific peer-reviewed open literature is given a lower level of reliability. It will follow that, using EFSA's Guidance, many studies from open literature may be disregarded and classified as not reliable. Furthermore EFSA's Guidance allows studies to be disregarded based on relevance criteria which are largely drawn from the way standard studies are done, (e.g. specifying specific doses, animal strains). This means GLP compliant studies are put on a platform because they will generally comply with these standards while scientific peer-reviewed open literature may be disregarded because they seldom follow standard protocols because it would be pointless in science when the aim to find new evidence.
- 110.** The Guidance will be used in a very large number of cases by Member States public authorities in the authorisation procedure for plant protection products. Thus it will affect a large number of people and will trigger substances to be put in the environment and the public to be exposed to potentially toxic substances.
- 111.** The Applicants requested the preparatory documents for the Guidance in order to understand how the decisions on the criteria for the selection of scientific peer-reviewed open literature were taken and how they were justified in order to be included in the final Guidance.
- 112.** It follows that there is an overriding public interest in disclosing the intermediate drafts of EFSA's Guidance and the scientific advice from all bodies involved in the drafting process of the Guidance.
- 113.** It thus derives therefrom that the contested decision breached Article 4(3) second subparagraph last indents of Regulation 1049/2001.

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<sup>22</sup> Klimisch, H.-J., Andreae, M., Tillmann, U. 1997. A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data. *Regulatory Toxicology and Pharmacology*, 25, 1-5.

### III. FORM OF ORDER SOUGHT

114. For the reasons outlined above, the Applicants respectfully request the Court to:

*a. Declare EFSA in violation of the Aarhus Convention, namely*

- (i) Article 4(1) (2) and (4) of the Aarhus Convention for failure to provide the Applicants access to the requested preparatory documents and intermediate drafts of the Guidance on the Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009.

*b. Declare EFSA in violation of Regulation 1367/2006, namely:*

- (i) Article 6(1) of Regulation 1367/2006 for failure to interpret the exceptions provided under Article 4 of Regulation 1049/2001 in a restrictive way;

*c. Declare EFSA in violation of Regulation 1049/2001, namely:*

- (i) Articles 8(2) of Regulation 1049/2001 for not replying within the prescribed time limits to the Applicants' request and not providing detailed reasons for doing so;
- (ii) Article 4(3) second subparagraph of Regulation 1049/2001 for failure to provide the Applicants access to the requested preparatory documents and intermediate drafts of the Guidance on the Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009;
- (iii) Article 4(3) second subparagraph of Regulation 1049/2001 for failure to assess whether there was an overriding public interest in disclosure.

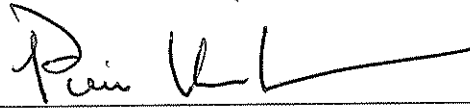
*d. Annul the negative reply by which EFSA withheld the requested documents;*

*e. Order EFSA to pay the Applicant's costs pursuant to Article 87 of the Rules of Procedure of the General Court, including the costs of any intervening parties.*

Dated: 10 April 2011

Respectfully submitted,

CLIENTEARTH

By:  \_\_\_\_\_

Pierre Kirch, Avocat

On behalf of ClientEarth