

**To the President and Members of the  
GENERAL COURT OF THE EUROPEAN UNION**

**APPLICATION  
FOR ANNULMENT**

pursuant to Article 263 of the  
Treaty on the Functioning of the European Union

On behalf of:

1. **PESTICIDE ACTION NETWORK EUROPE,**

An association (ASBL, association without lucrative aim) possessing a legal personality under Belgian law,  
domiciled in Brussels, Belgium,

Applicant,

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who is represented in this case by Joost Rutteman, Advocate, member of the Amsterdam Bar (**Annex 1**), having his office at Habitat Advocatenkantoor, at Panamalaan 6-H, Amsterdam, The Netherlands (postal address: Postbus 1685 1000 BR Amsterdam, The Netherlands); the Applicant has expressly agreed that documents may be served on him at the aforementioned address of Mr Rutteman's office and by telefax (+31 20 2400 701) or electronic mail ([rutteman@omgeving.nl](mailto:rutteman@omgeving.nl)),

v.

**COMMISSION OF THE EUROPEAN UNION,**

Rue de la loi 200, B-1049 Brussels, Belgium,

Defendant,

in the matter of:

Decision of the Commission of the European Union (Commission) of 9 March 2012 (SANCO/E3/LC/sf Ares(2012)284818). By this Decision (the contested measure) a request for internal review made by the Applicant has been declared inadmissible. A copy of the contested measure is hereby submitted (**Annex 2**).

The required proof of existence in law of PAN Europe as a legal person is included in this application (**Annex 3**), as well as the proof of the authority granted to the Applicants lawyer (**Annex 7**).

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## LIST OF ANNEXES

1. Certificate of registration as attorney at law at the Amsterdam Bar Association of Mr Rutteman;
2. The Commission's Decision of 9 March 2012 (SANCO/E3/LC/sf Ares(2012)284818) whereby the applicants' request for internal review was found inadmissible (the contested measure);
3. The statutes of ASBL PAN Europe;
4. Memorandum and Articles of Association of PAN Europe;
5. Yearly report of PAN Europe 2009
6. Yearly report of PAN Europe 2010
7. Authorisation on behalf of PAN Europe;
8. Commission Implementing Regulation (EU) No 1143/2011
9. Request for internal review, addressed to the Commission by letter of 21 December 2011 (with Appendix);
10. Conclusion on the peer review of the pesticide risk assessment of the active substance prochloraz, EFSA 13 July 2012, EFSA Journal 2011; 9(7):2323

## SUMMARY

1. By decision of 9 March 2012 the Commission has declared unacceptable a request for internal review made by PAN Europe of Commission Implementing Regulation (EU) No 1143/2011 approving the active substance prochloraz under Regulation (EC) No 1107/2009. This request for internal review was based on Regulation (EC) No 1367/2006. PAN Europe is an environmental non governmental organisation deploying activities to limit the use of harmful pesticides in the European Union. Prochloraz is an active chemical agent used in plant protection products and approval under Regulation (EC) No 1107/2009 is a precondition to this substance being used as a component in plant protection products in the European Union. Approval of this substance is therefore instrumental in determining size and conditions of its emission into the environment.
2. The reasons the Commission gave for dismissing the request were that PAN Europe does not meet the criterion that it should have existed as a legal person for a period of more than two years before being able to make a request and furthermore that the request was aimed at the review of an act of general scope, while article 10 of Regulation (EC) No 1367 only allows requests for review of an act of individual scope.
3. The reasons for PAN Europe to seek annulment of the Commission's decision of 9 March 2012 are that it can prove that it already existed for more than two years when it made its request for internal review and that furthermore the decision to approve prochloraz is sufficiently individual in its effects and content to make it an administrative act as is meant in Article 10(1) of Regulation (EC) No 1367/2006. The criteria for making a request for internal review are therefore met.
4. PAN Europe as a consequence asks for annulment of the Commissions' decision of 9 March 2012 and an instruction to the Commission to assess the substance of its request for internal review and decide upon this within a period of time determined by the Court.

## I. BACKGROUND

### I.1 Relevant facts

5. Following Article 29 of Regulation (EC) No 1107/2009<sup>1</sup>, substances that have a general or specific action against harmful organisms or on plants, parts of plants or plant products, in the Regulation referred to as ‘active substances’, may only be used in or as plant protection products if these ‘active substances’ have been approved according to the Regulation.
6. In accordance with article 80 (1)(c) of Regulation (EC) No 1107/2009, Council Directive 91/414/EEC<sup>2</sup> applies to active substances for which completeness has been established in accordance with Article 16 of Commission Regulation 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 an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, but have not been included into its Annex I<sup>3</sup>.
7. Prochloraz is an active substance that was originally included in the list that was established by Commission Regulations (EC) No 451/2000 and (EC) No 1490/2002, that also laid down the rules for the implementation of the second and third stages of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC. The notifier of the active substance prochloraz however withdrew its support of including prochloraz in Annex I to Directive 91/414/EEC after adoption of Commission Regulation (EC) No 1095/2007 of 20 September 2007<sup>4</sup>. Consequently Commission Decision

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<sup>1</sup> OJ L 309, 24.11.2009, p.1

<sup>2</sup> OJ L230, 19.08.91, p. 1

<sup>3</sup> OJ L 15, 18.1.2008

<sup>4</sup> OJ L 246, 21.9.2007

2008/934/EC concerning the non-inclusion of certain active substances in Annex I was adopted on the non-inclusion of prochloraz.

8. The original notifier then submitted a new application requesting the accelerated procedure to be applied, that is provided for in Articles 14 to 19 of Regulation (EC) No 33/2008. This application was submitted to Ireland, the originally designated rapporteur Member State for prochloraz following Regulation (EC) No 1490/2002. According to Article 15 of Regulation (EC) No 33/2008 the applicant has to demonstrate that the requirements in Article 5 of Directive 91/414/EEC are met. The applicant has to supply additional data that address the specific issues that led to the adoption of the non-inclusion Decision.
9. After Ireland evaluated the additional data provided by the applicant it prepared an additional report that was evaluated according to the procedure laid down in article 20 of Regulation (EC) No 33/2008, after which the Commission decided that prochloraz in general may be expected to meet the requirements in article 5 of Directive 91/414/EEC and that it was therefore appropriate to approve prochloraz in accordance with Regulation (EC) No 1107/2009, though including some conditions and restrictions in the light of current scientific and technical knowledge. The Commission then issued Commission Implementing Regulation (EU) No 1143/2011, approving the active substance prochloraz and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 as regards the list of approved active substances.
10. PAN-Europe does not agree with the Commission that the information contained in the new application made for prochloraz allows approval of prochloraz as an active substance and inclusion in the Annex of Commission Implementing Regulation (EU) No 540/2011. The Conclusion of the Peer review of the pesticide risk assessment of prochloraz of 13 July 2011 (**Annex 10**) shows that the new application for prochloraz still contained several important data gaps (summarized on pages 19 and 20 of this Peer Review). That important data were missing is reflected in Commission Implementation Regulation (EU) No 1143/2011, Annex I part B and Annex II part B, that oblige the applicant to submit confirmatory information. Furthermore the evaluation disregarded information from open literature sources about

endocrine disruptive effects. The request for internal review made by PAN Europe (**Annex 9**) lists the information from open scientific literature that was not taken into account when the decision was taken. According to PAN-Europe this amounts to a decision that is not in accordance with the requirements of articles 5 and 4 of Directive 91/414/EEC where an important condition is that evaluations of active substances comply with the current state of science and technology.

## I.2 Proceedings

11. By letter of 21 December 2011 PAN Europe (**Annex 9**) requested from the Commission the internal review of Commission Implementing Regulation (EU) No 1143/2011, approving the active substance prochloraz, under Article 10 of Regulation (EC) No 1367/2006<sup>5</sup> 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. A copy of the Commission Implementing Regulation 1143/2011 and of the request for internal review of 21 December 2011, including the Annex thereto, are attached to this application (**Annex 8** and **Annex 9**). PAN Europe respectfully requests that the information and arguments put forward in this request for internal review be considered as being part of this application for annulment.
12. In short, in its request for internal review, PAN Europe has argued that the Commission has wrongfully decided to approve the active substance prochloraz for inclusion in the Annex to Regulation (EU) 540/2011. It has not taken into account the fact that important gaps existed in the information submitted in the application for inclusion in Annex I and disregarded publicly available information and findings about endocrine disruptive effects of prochloraz.
13. By Decision of 9 March 2011 (**Annex 2**) the Commission replied to the request for internal review of PAN Europe. The Commission stated that the

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<sup>5</sup> JO L264, 25.09.06, p. 13

request for internal review cannot be accepted, because the applicant does not meet the criteria set out in Article 11 of Regulation (EC) 1367/2006. Furthermore the request for internal review according to the Commission concerns an act of a general scope and therefore does not comply with the definition of an administrative act in Article 2(2)(g) of Regulation (EC) 1367/2006.

## II. LEGAL GROUNDS

### II.1 Introduction

14. The Applicants consider the Commission Decision of 1 March 2011, the contested measure, to be incompatible with the Articles 2(1)(g), 10 and 11 of Regulation 1367/2006/EC (Aarhus Regulation) and with the Articles 2(5) and 9(3) of the Convention on access to information, public participation in decision-making and access to justice in environmental matters, of 25 June 1998 (Aarhus Convention). Therefore the Commission Decision constitutes a violation of the Aarhus Regulation and the Aarhus Convention.

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### III.1 First ground for annulment

#### **PAN Europe complies with the conditions of eligibility set in Article 11 of Regulation (EC) No 1367/2006**

15. The Commission states, as one of the reasons for not accepting the request for internal review made by PAN Europe, that the ASBL PAN Europe was founded only on 21 May 2010, and therefore does not comply with the conditions for eligibility set in article 11 of Regulation (EC) No 1367/2006. The Commission does not specify what conditions are not met, but it follows from the explicit mentioning of the date of the founding of the ASBL PAN Europe that the most important objection is that PAN Europe had not existed for more than two years at the time the request was made, as is a condition



under Article 11 of Regulation (EC) No 1367/2006.

16. Though it is true that ASBL PAN Europe was founded as a Belgian legal entity on 21 May 2010, PAN Europe has existed as an organisation much longer. Before 21 May 2010 PAN Europe was since 2003 a registered legal entity in the United Kingdom. Both with respect to activities as with respect to statutory goals ASBL PAN Europe is still the same organisation. The statutes of the organisation in the United Kingdom (**Annex 4**) and the annual reports of 2009 and 2010 (**Annexes 5 and 6**) show that PAN Europe in the United Kingdom and in Belgium is in fact one and the same organisation that has existed and deployed activities before it moved its statutory seat to Brussels in 2010. It thus existed as a legal entity prior to 2010, having the appropriate statutory goals and deploying the necessary activities to meet the requirements set in Article 11 of Regulation (EC) No 1367/2006. In addition to this PAN Europe proved its existence in law in 2008 and started proceedings before the Court of first instance (Case T-338/08).

17. The conclusion is that PAN Europe meets the criteria laid down in Article 11 of Regulation (EC) No 1367/2006.

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### **III.2 Second ground for annulment**

#### **Implementing Regulation (EU) No 1143/2011 is not an administrative act of general application and can be considered an administrative act within the meaning of Article 2(1)(g) of Regulation (EC) No 1367/2006**

18. The Commission states that Commission Implementing Regulation (EU) No 1143/2011 cannot be considered an administrative act within the meaning of Article 10 of Regulation 1367/2006, as it is defined in Article 2(1)(g) of that Regulation. This is the second reason for not accepting the request for internal review. The reason for considering Regulation (EU) 1143/2011 as an administrative act of general application is according to the Commission that Regulation 1143/2011 is valid for any operator intending to apply for authorisation for the placing on the market of plant protection products containing prochloraz.

19. From definition in Article 2(1)(g) of Regulation (EU) No 1367/2006 of “administrative act” it is not apparent what is meant by “any measure of individual scope under environmental law taken by a Community institution or body, and having legally binding and external effect”.
20. There is no dispute with respect to the legally binding and external effect of the Regulation, nor of the fact that it was issued by a Community institution. The reason to dismiss the request of PAN Europe is only that the Regulation has not an individual scope.
21. The Commission in its decision however gives a very narrow interpretation of the definition ‘individual scope’ by using as an only criterion that the group of persons who may be affected by this decision is not a completely predicable group. The Commission in this way disregards the nature of decisions based on plant protection products legislation. The ‘object’ of this type of decision is by its very nature always a substance, whether it is the active substance when this is included in Annex I, or a plant protection product when an authorisation is granted by a Member State. In the case of an Authorisation it is also unpredictable who will actually use the plant protection product, and where it will be applied. The interpretation of ‘individual scope’ by the Commission therefore has as a consequence that it would be virtually impossible to challenge a decision about plant protection products. In particular the decision to approve an active substance under Regulation (EC) No 1107/2009 is crucial to the later use of this substance in plant protection products and thus its introduction into the environment. Due to the nature of this decision it is difficult to challenge its validity in a later stage like the national or regional authorisation of an individual plant protection product. In fact the most important part of the environmental assessment evaluation takes place during the approval procedure and sets the conditions for the actual use of the product.
22. In the light of the structure of the legislation concerning plant protection products the decision to approve an active substance has an individual scope, as it is the result of an individual evaluation of the properties of this substance if it is used under specific conditions. The decision is furthermore the result of an application that is introduced by one identifiable applicant or group of applicants. This applicant also has specific individual rights during

the procedure (e.g. data protection upon request). The decision to approve the active substance and include it in the Annex to Regulation (EU) 540/2011 concerns one identifiable chemical substance and is a constituent requirement for authorisations of plant protection products by Member States. It specifies specific conditions of use that apply to these plant protection products. It has also consequences for already existing authorisations and for actual use of plant protection products. As such it has foreseeable and individual consequences and direct consequences for the interests that PAN Europe represents, that should be seen as its direct personal interests according to Article 2(5) of the Convention on access to information, public participation in decision-making and access to justice in environmental matters, of 25 June 1998 (Aarhus Convention).

23. Therefore the decision contained in Regulation 1143/2011 has a sufficiently 'individual' component as to be considered as an administrative act as described in Article 2(g) of the Aarhus Regulation. Therefore the request for internal review of PAN Europe meets the criteria of Article 10(1) of the Aarhus Regulation.

24. A broad interpretation of the definition of "individual scope" would also be consistent with the purpose of the Aarhus Treaty to which the European Union is a party. In this regard, the Court of Justice has recently ruled that, whenever possible, the Court should interpret rules on access to justice to the fullest extent possible in accordance with the Aarhus Convention. The Court ruled as follows:

"It is, however, for the referring court to interpret, to the fullest extent possible, the procedural rules relating to the conditions to be met in order to bring administrative or judicial proceedings, in accordance with the objectives of Article 9(3) of that convention and the objective of effective judicial protection of the rights conferred by European Union law, in order to enable an environmental protection organisation, such as the Lesoochránárske zoskupenie, to challenge before a court a decision taken following administrative proceedings liable to be contrary to European Union environmental law." (Judgment of the Court of Justice of 8 March 2011, C-240/09, Lesoochránárske zoskupenie VLK v Slovakia, declaratory judgment).

25. Another example of case-law supporting a broad interpretation of the definition 'act of individual scope' where the definition of Article 2(1)g of Regulation (EC) No 1367/2006 is concerned, is the Judgment of the Court of Justice of 18 November 2011, Joined Cases C-128/09 to 131/09, C-134/09 and C-135/09, Antoine Boxus, Willy Roua and others v. Région wallonne, especially considerations 49 to 57.

### THE ORDER SOUGHT

For the reasons outlined above the Applicants respectfully request the General Court to:

- I. declare the Commission's Decision of 9 March 2012 contrary to Regulation 1367/2006 and the Aarhus Convention;
- II. annul the Commission's Decision of 9 March 2012;
- III. instruct the Commission to assess, nonetheless, the substance of the request for internal review, within a period of time determined by the Court;
- IV. order the Commission to pay the costs of the proceedings.

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Respectfully submitted for  
PAN Europe



Joost Rutteman, Advocate

Amsterdam, 2 May 2012