



Reports of Cases

JUDGMENT OF THE GENERAL COURT (Fifth Chamber)

8 May 2018*

(REACH — Dossier evaluation — Compliance check of registrations — Check of information submitted and follow-up to dossier evaluation — Statement of non-compliance — Jurisdiction of the General Court — Actions for annulment — Challengeable act — Direct and individual concern — Admissibility — Legal basis — Articles 41, 42 and 126 of Regulation (EC) No 1907/2006)

In Case T-283/15,

Esso Raffinage, established in Courbevoie (France), represented by M. Navin-Jones, solicitor,

applicant,

v

European Chemicals Agency (ECHA), represented by C. Jacquet, C. Schultheiss, W. Broere and M. Heikkilä, acting as Agents,

defendant,

supported by

Federal Republic of Germany, represented by T. Henze, acting as Agent,

brought by

French Republic, represented by D. Colas and J. Traband, acting as Agents,

and by

Kingdom of the Netherlands, represented by M. de Ree, M. Bulterman and M. Noort, acting as Agents,

interveners,

APPLICATION pursuant to Article 263 TFEU seeking the annulment of the letter from ECHA of 1 April 2015 addressed to the French Ministère de l'écologie du développement durable, des transports et du logement (Ministry of Ecology, Sustainable Development, Transport and Housing) and entitled 'Statement of Non-Compliance following a Dossier Evaluation Decision under Regulation (EC) No 1907/2006'.

* Language of the case: English.

THE GENERAL COURT (Fifth Chamber),

composed of D. Gratsias, President, A. Dittrich (Rapporteur) and P.G. Xuereb, Judges,

Registrar: C. Heeren, Administrator,

having regard to the written part of the procedure and further to the hearing on 19 September 2017,

gives the following

Judgment

Background to the dispute

- 1 The applicant, Esso Raffinage, a company established in France, produces and markets a certain substance for which it submitted a registration dossier to the European Chemicals Agency (ECHA) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ 2006 L 396, p. 1; and corrigendum OJ 2007 L 136, p. 3).
- 2 On 17 November 2010, the applicant submitted an update to its registration dossier for the registered substance for the greater than 1 000 tonnes per annum tonnage band.
- 3 On 9 July 2010, ECHA initiated a compliance check on the registration dossier for the registered substance pursuant to Article 41(1) of Regulation No 1907/2006.
- 4 On 28 June 2011, in accordance with Article 50(1) of Regulation No 1907/2006, ECHA notified the applicant of a draft decision prepared according to Article 41(3) of that regulation. The draft decision required the applicant to provide a prenatal developmental toxicity study on one species.
- 5 After submitting its observations on the draft decision on 28 July 2011, the applicant updated its registration dossier for the substance on 6 September 2011 in order to address the issues of non-compliance found by ECHA.
- 6 On 14 June 2012, in accordance with Article 51(1) of Regulation No 1907/2006, ECHA notified the draft decision to the Member States' REACH competent authorities and invited those authorities to submit proposals for amendment under Article 51(2) of that regulation.
- 7 On 18 July 2012, ECHA notified the applicant of an amended draft decision pursuant to Article 51(5) of Regulation No 1907/2006. Attached to the amended draft decision were proposals for amendment from various Member States. In its proposal, the Kingdom of Denmark recommended that the applicant be required to perform a further study, namely a prenatal developmental toxicity study on a second species. According to that Member State, that second study constituted 'standard information', as laid down in section 8.7.2 of Annex X to Regulation No 1907/2006.
- 8 The applicant did not submit observations regarding that proposal for amendment.
- 9 On 30 July 2012, the amended draft decision was referred to the Member State Committee pursuant to Article 51(4) of Regulation No 1907/2006.

- 10 During its 25th meeting, which was held from 19 to 21 September 2012, the Member State Committee reached a unanimous agreement as regards the amended draft decision, including the proposal from the Kingdom of Denmark on the second species prenatal developmental toxicity study. The applicant was present at that meeting. In the course of the open session, the members of the committee and the applicant discussed the requirement for a second species prenatal developmental toxicity study.
- 11 As is clear from the minutes of the 25th meeting of the Member State Committee, at the open session, the applicant submitted that, because of the limited use of the substance concerned, further testing of that substance was not justified. In particular, a second species prenatal developmental toxicity study was, according to it, not necessary. The members of the Member State Committee told the applicant that its interpretation of Regulation No 1907/2006 was incorrect as regards the need to submit information gained from a second species prenatal developmental toxicity study.
- 12 On 6 November 2012, ECHA issued and notified the applicant of a decision based on Article 41(3) of Regulation No 1907/2006 ('the decision of 6 November 2012'). In the decision of 6 November 2012, ECHA found that the registration dossier did not comply with Regulation No 1907/2006 and gave the applicant until 6 November 2013 to submit information concerning ten separate matters, which included a 'prenatal developmental toxicity study in rabbits, oral route' and a 'Long-term toxicity testing to sediment organisms'.
- 13 The decision of 6 November 2012 states that ECHA considered that that information was required in order to satisfy the standard information requirements, such as were set out, first, as regards the first study, in point 8.7.2 of Annex X to Regulation No 1907/2006 and, second, as regards the testing on sediment organisms, in point 9.5.1 of Annex X of the same regulation.
- 14 The applicant did not lodge an action for annulment of the decision of 6 November 2012.
- 15 By letter of 12 December 2012, the French Ministry of Ecology, Sustainable Development, Transport and Housing ('the French Ministry of Ecology'), which is the competent authority in France for the registration, evaluation, authorisation and restriction of chemicals, also notified the applicant of the decision of 6 November 2012. In that letter, that ministry pointed out to the applicant that 'the absence of a response from [the applicant] would constitute a failure to fulfil the obligations under [Regulation No 1907/2006], for which the Environmental Code provides for administrative and criminal penalties'.
- 16 On 6 November 2013, in response to the decision of 6 November 2012, the applicant chose not to provide all the information requested by ECHA in the decision of 6 November 2012. Instead, as regards the two studies referred to in paragraph 12 above, it added to the registration dossier a 103-page document which, according to it, constituted a 'weight of evidence' within the meaning of point 1.2 of Annex XI of Regulation No 1907/2006. According to the applicant, the information provided in that document had not involved any animal testing and had not been brought to ECHA's attention before the adoption of the decision of 6 November 2012. In particular, the aim of that document was to show that carrying out a second species prenatal developmental toxicity study was unnecessary.
- 17 On 1 April 2015, ECHA sent a letter to the French Ministry of Ecology, copying the applicant, which was written in English and entitled 'Statement of non-compliance following a dossier evaluation decision under Regulation (EC) No 1907/2006' ('the letter of 1 April 2015').
- 18 Attached to that letter was a document, also dated 1 April 2015, entitled 'Attachment to the statement of non-compliance following a dossier evaluation decision under Regulation (EC) No 1907/2006'. That document set out ECHA's conclusions and the reasons for considering that the most recent update by the applicant to the registration dossier was not acceptable (the letter of 1 April 2015 and the document attached thereto are hereinafter together referred to as 'the contested act').

19 The letter of 1 April 2015 reads as follows:

‘Helsinki, 1 April 2015

[To the] French REACH Competent Authority ...

Communication number ...

Submission number subject to follow up evaluation. ...

Date of submission subject to follow up evaluation: 6 November 2013

Statement of Non-Compliance following a Dossier Evaluation Decision under Regulation (EC) No 1907/2006

Pursuant to Article 41(3) of Regulation No 1907/2006 (REACH Regulation), the European Chemicals Agency (ECHA) has performed a compliance check on the dossier [on the registered substance]. ECHA has taken the decision [of 6 November 2012] attached to this letter in accordance with the procedure laid down in Articles 50 and 51 of the REACH Regulation.

The decision set a deadline for the Registrant to submit the information requested by that decision to ECHA in the form of an updated dossier by 6 November 2013. An update of the dossier was submitted on 6 November 2013, submission number: ...

ECHA has examined the information submitted in the updated dossier. In conclusion, the updated registration dossier does not contain all of the information requested by the ECHA decision. A respective analysis of the reasons for this conclusion is enclosed. Other information in addition to the updated dossier has been submitted in consequence of the decision by the Registrant and is attached.

On this basis ECHA states that:

- The Registrant has not met the obligations following from [the decision of 6 November 2012];
- The registration dossier is not in compliance with Article 5 of the REACH Regulation; and
- The Registrant is in breach of Article 41(4) of the REACH Regulation.

The non-compliance with ECHA’s decision and the REACH Regulation may be subject to enforcement actions by the national authorities of the Member States as established in Article 126 of the REACH Regulation.

On this matter, you are therefore asked to address the non-compliance in your own competence by means of enforcement to execute ECHA’s decision.

ECHA expects that the further communication on the non-compliance with ECHA’s decision is taking place between the registrant and the FR Authorities until the case is resolved. When the Registrant submits an update of his registration in response to the decision, he is expected to inform the FR Authorities on this fact.

ECHA is looking forward to receiving your feedback concerning national actions taken on this case of non-compliance.

Authorised by ... Director of Evaluation

Attachments: ...

CC: Registrant (via REACH IT)'.

Procedure and forms of order sought

- 20 By application lodged at the Court Registry on 29 May 2015, the applicant brought the present action.
- 21 By a separate document, lodged at the Court Registry as an annex to the application, the applicant made a request for confidential treatment of some of the information contained in the application and its annexes, in particular, the composition and registration number of the registered substance. As ECHA did not oppose the request for confidential treatment of that information within the prescribed time limit, that request was granted in accordance with the Rules of Procedure of the General Court.
- 22 By documents lodged at the Court Registry on 5 November 2015, the Federal Republic of Germany and the Kingdom of the Netherlands sought leave to intervene in support of the forms of order sought by ECHA. By two orders of the Court of 7 June 2016, the President of the Fifth Chamber of the General Court, after hearing the main parties, granted those applications to intervene.
- 23 By document lodged at the Registry of the General Court on 24 November 2015, the French Republic also sought leave to intervene in support of the form of order sought by ECHA. By order of 7 June 2016, the President of the Fifth Chamber of the General Court, after hearing the main parties, granted that application to intervene under Article 116(6) of the Rules of Procedure of the General Court of 2 May 1991.
- 24 The statement in defence was lodged at the Court Registry on 26 November 2015.
- 25 The reply was lodged at the Court Registry on 21 February 2016.
- 26 The rejoinder was lodged at the Court Registry on 15 June 2016.
- 27 The Federal Republic of Germany and the Kingdom of the Netherlands lodged their statements in intervention and the main parties lodged their observations on those statements within the prescribed time limit.
- 28 The applicant claims that the Court should:
- declare that the action is admissible and well founded;
 - annul the contested act;
 - order the case be referred back to the ECHA Executive Director with a direction that any new ECHA decision taken in the future regarding the REACH dossier evaluation of the applicant's registration dossier for [the registered substance] take into account the reasons for annulment stipulated in the General Court judgment and all relevant, up-to-date information;
 - order ECHA to pay the costs;
 - take such other or further measures as justice may require.
- 29 ECHA contends that the Court should:
- dismiss the application;

– order the applicant to bear the costs.

30 The Federal Republic of Germany submits that the Court should dismiss the action and order the applicant to pay the costs.

31 The Kingdom of the Netherlands submits that the Court should dismiss the action and order the applicant to pay the costs.

32 The French Republic submits that the Court should dismiss the action as inadmissible.

Law

The jurisdiction of the General Court

33 According to the applicant, there is no right of appeal to the ECHA Board of Appeal against the contested act, whether pursuant to Article 91 of Regulation No 1907/2006 or otherwise. Therefore, the General Court has jurisdiction to hear the action in accordance with Article 94 of Regulation No 1907/2006.

34 As a preliminary matter, it should be recalled that Article 94(1) of Regulation No 1907/2006 provides that ‘an action may be brought before [the General Court] or the Court of Justice, in accordance with Article [263 TFEU], contesting a decision taken by the Board of Appeal or, in cases where no right of appeal lies before the Board, by [ECHA]’.

35 In that regard, Article 91(1) of Regulation No 1907/2006 provides that ‘[a]n appeal may be brought [before the Board of Appeal] against decisions of the [ECHA] taken pursuant to Article 9, Article 20, Article 27(6), Article 30(2) and (3) and Article 51 [of Regulation No 1907/2006]’.

36 In the present case, the contested act was not adopted on the basis of Article 91(1) of Regulation No 1907/2006. In particular, it is clear from the information in the file that the contested act was not adopted following the procedure set out in Article 51 of Regulation No 1907/2006.

37 Having regard to the foregoing, it must be held that the General Court has jurisdiction to determine the present case, pursuant to Article 94(1) of Regulation No 1907/2006.

Admissibility of the third and fifth heads of claim

38 At the hearing, the General Court asked the applicant whether, having regard to Article 266 TFEU, it considered it necessary to maintain its third and fifth heads of claim. In essence, the applicant replied that, in the event that those heads of claim were ‘inadmissible’ it could withdraw them. If, however, they could be regarded as ‘admissible’ they would be maintained. Those replies are unclear and they do not enable it to be established whether the applicant has in fact withdrawn the third and fifth heads of claim. In those circumstances, it is necessary to examine those claims also.

39 In that regard, it must be recalled that, in accordance with Article 266(1) TFEU, the EU institution, body, office or agency whose act has been declared void is required to take the necessary measures to comply with the judgment of the Court of Justice of the European Union. In the event that the first and second heads of claim are upheld, it will be necessary for ECHA to determine the consequences of the operative part and grounds of the General Court’s judgment. Therefore, it is not for the General Court to issue directions to ECHA, such as those referred to in the applicant’s third and fifth heads of claims. Those heads of claim must therefore be rejected as inadmissible.

Admissibility of the first and second heads of claim

Whether the contested measure is open to challenge

- 40 ECHA, supported by the interveners, submits that the contested act is not a measure against which an action for annulment may be brought and therefore the present action is inadmissible.
- 41 In the first place, according to ECHA, in drawing up the ‘statements of non-compliance’, it was never its intention for those documents to be binding on the competent national authorities or the registrants concerned. Since November 2012, ECHA has prepared ‘statements of non-compliance’ which, according to it, allowed it to set out its point of view on the question of whether the decisions on the evaluation of the registration dossiers had been complied with by the registrants. The practice of sending ‘statements of non-conformity’ to Member States was intended to provide technical and scientific opinions without binding effects, so that the Member States could carry out their own checks. The fact that, at the time it drafted the contested act, ECHA merely wished to provide the French Ministry of Ecology with a non-binding technical and scientific opinion is confirmed by a fact sheet published by ECHA on its website in October 2013, entitled ‘Follow up to dossier evaluation decisions’. According to that document, in essence, a ‘statement of non-compliance following a dossier evaluation decision under Regulation (EC) No 1907/2006’ is only a document containing an evaluation by the ECHA Secretariat’s assessment which is sent to a Member State and states that a registrant did not respond to a request for information within the time limit prescribed.
- 42 In the second place, ECHA, supported expressly on this point by the Federal Republic of Germany and the French Republic, points out the fact, which is not contested by the applicant, that it has agreed a mechanism with the competent national authorities that enables the management of situations in which ECHA considers that the registrant has not provided, within the time limit referred to in Article 41(4) of Regulation No 1907/2006, the information requested in a decision on a compliance check. More specifically, the Forum for Exchange of Information on Enforcement, established under Article 76(1)(f) and Article 86 of Regulation No 1907/2006, asked ECHA to inform the Member States, informally, of updates to the registration dossiers received in response to a decision on a compliance check, and of ECHA’s scientific opinion regarding the situations in which the dossier still does not, according to it, comply with the provisions of Regulation No 1907/2006. That informal system of cooperation between ECHA and the Member States is relevant for the enforcement of decisions on a compliance check and leaves the Member States free to adopt a different position from that expressed by ECHA in a ‘statement of non-compliance’. In that regard, more specifically, both ECHA and the Federal Republic of Germany and the French Republic emphasise, in essence, the fact that the enforcement of a decision on a compliance check is within the competence of the Member State concerned, which means that Member States are free to adopt measures or not, if, after assessment, they consider that the dossier allows the missing elements to be established, contrary to what ECHA may have concluded in the ‘statement of non-conformity’. It follows that, Member States are free to take into account or not an act such as the contested act.
- 43 In the third place, in its reasons in the contested act, ECHA did not express a final position on the ‘alternative documentation’ provided by the applicant. According to ECHA, at the stage at which a decision such as that of 6 November 2012 is enforced, there is an interaction between the competent national authorities and the registrant in order to examine the questions and the shortcomings which are identified in a ‘statement of non-compliance’. It is possible, in ECHA’s opinion, that following such discussions, other information is provided by the registrant that is sufficient and complies with the requirements flowing from a decision such as that of 6 November 2012. Therefore, far from being ECHA’s definitive position as regards the ‘alternative documentation’ provided by the registrant on 6 November 2013, the contested act is merely an opinion that reminds the French competent authority that it must adopt a final decision regarding the enforcement of the decision of 6 November 2012.

- 44 In the fourth place, in ECHA's opinion, an examination of the contested act in the light of the criteria developed in the case-law regarding what may be called a 'confirmatory act' also does not lead to the conclusion in the present case that the contested act is an act against which an action may be brought. In that regard, ECHA recalls the position stated by one of its boards of appeal in a decision of 29 July 2015 (Case A-019-2013) concerning an appeal brought by Solutia Europe SPRL/BVBA against a 'statement of non-compliance' which had a similar content to that of the contested act ('the Solutia case'). Relying on the case-law of the European Union courts on the examination of confirmatory acts, the Board of Appeal held in that decision that, since the information provided by the registrant in question was substantial and new, ECHA should have made another decision on the basis of Article 42(1) of Regulation No 1907/2006, in accordance with the procedure set out in Articles 41, 50 and 51 of that regulation. Against that background, the Board of Appeal of ECHA considered that the evaluation contained in a 'statement of non-compliance' was equivalent in effect to a decision adopted on the basis of Article 42 of Regulation No 1907/2006.
- 45 If it was necessary, in the present case, to make the analogy made by the Board of Appeal of ECHA in the Solutia case, the contested act would be regarded as an act that was purely confirmatory of the decision of 6 November 2012. On 6 November 2013, the applicant submitted an adaptation on the basis of Annex XI of Regulation No 1907/2006 which rested on information that was neither new nor substantial.
- 46 As regards the Solutia case, both the Federal Republic of Germany and the French Republic consider that the Board of Appeal of ECHA fell into error in applying the case-law of the General Court on confirmatory acts to the 'statements of non-compliance'.
- 47 More specifically, according to the Federal Republic of Germany, the submission by a registrant of information in response to a decision, such as that of 6 November 2012, merely executes the request contained in such a decision requiring additional information to be submitted, and cannot be interpreted as calling the decision into question. According to the French Republic, a 'statement of non-compliance' cannot be regarded as confirming a request for additional information by ECHA, in the sense that it is a fresh request for that additional information. A 'statement of non-compliance' is sent to the competent national authority with the single aim of informing that authority that the request for additional information was not complied with by the registrant, in order that it draws from that the consequences that it considers it must draw, where necessary by exercising its powers to impose sanctions.
- 48 The applicant contests the arguments advanced by ECHA, the Federal Republic of Germany and the French Republic.
- 49 As a preliminary point, as regards the questions of whether the contested act is open to challenge, it must be recalled that any measures adopted by the institutions, whatever their form, which are intended to have binding legal effects are regarded as acts open to challenge, within the meaning of Article 263 TFEU (judgments of 31 March 1971, *Commission v Council*, 22/70, EU:C:1971:32, paragraph 42; of 2 March 1994, *Parliament v Council*, C-316/91, EU:C:1994:76, paragraph 8; and of 13 October 2011, *Deutsche Post and Germany v Commission*, C-463/10 P and C-475/10 P, EU:C:2011:656, paragraph 36).
- 50 On the other hand, any act not producing binding legal effects, such as preparatory acts, confirmatory measures and implementing measures, mere recommendations and opinions and, in principle, internal instructions, falls outside the scope of the judicial review provided for in Article 263 TFEU (order of 14 May 2012, *Sepracor Pharmaceuticals (Ireland) v Commission*, C-477/11 P, not published, EU:C:2012:292, paragraph 52; see also, to that effect, the judgment of 12 September 2006, *Reynolds Tobacco and Others v Commission*, C-131/03 P, EU:C:2006:541, paragraph 55 and the case-law cited).

- 51 The capacity of a measure to produce binding legal effects and, therefore, be open to challenge pursuant to Article 263 TFEU must be assessed in accordance with objective criteria, such as the contents of that measure, taking into account, as appropriate, the context in which it was adopted and the powers of the institution which adopted the measure (see, judgment of 13 February 2014, *Hungary v Commission*, C-31/13 P, EU:C:2014:70, paragraph 55 and the case-law cited). The assessment of the content of a contested act consists in examining its substance (judgment of 11 November 1981, *IBM v Commission*, 60/81, EU:C:1981:264, paragraph 9), whilst also taking into account its wording (see, to that effect, the judgment of 20 March 1997, *France v Commission*, C-57/95, EU:C:1997:164, paragraphs 9 to 23). It is possible to have regard also to subjective criteria, such as the intention of the author of the act in question (see, to that effect, the judgments of 17 July 2008, *Athinaïki Techniki v Commission*, C-521/06 P, EU:C:2008:422, paragraph 42, and of 26 January 2010, *Internationaler Hilfsfonds v Commission*, C-362/08 P, EU:C:2010:40, paragraph 52).
- 52 The assessment of whether the contested act may be the subject of an action for annulment must be made in the light of those principles.
- 53 In that regard, it must be recalled that, in accordance with Article 6(1) of Regulation No 1907/2006, any manufacturer or importer of a substance, whether on its own or in one or more preparations, in quantities of 1 tonne or more per year, is required to submit a registration to ECHA except where the regulation provides otherwise. According to Article 10 of the regulation, each dossier comprises a technical dossier and a chemical safety report. The same provision defines the categories of information that the technical dossier and report in question must contain.
- 54 Furthermore, under Article 41(1) of Regulation No 1907/2006, in the context of the evaluation of the registration dossiers, ECHA checks the compliance of those registrations. In that context, ECHA may examine any registration in order to check whether the conditions relating, inter alia, to information contained in the technical dossiers, to adaptations of the standard information requirements and to chemical safety comply with the rules relating to them. For that purpose, ECHA is required under Article 41(5) of Regulation No 1907/2006 to select a minimum percentage of dossiers for compliance checking, giving priority to dossiers that have certain features described in that provision.
- 55 Thus, under Article 41(3) of Regulation No 1907/2006, ECHA may prepare a draft decision inviting the registrant(s) to submit any information needed to bring the registration into compliance with the relevant information requirements. That same provision provides that the final decision in the matter, which must also specify adequate time limits for the submission of the further information regarded as necessary, is to be taken in accordance with the procedure laid down in Articles 50 and 51 of Regulation No 1907/2006.
- 56 Article 41(4) of Regulation No 1907/2006 provides that the registrant must submit the information required to ECHA by the deadline set.
- 57 As regards the next part of the procedure, Article 42(1) of Regulation No 1907/2006 provides that ECHA is to examine any information submitted in consequence of a decision taken under Article 41 of the regulation and that it is to draft any appropriate decisions in accordance with that provision.
- 58 Once the evaluation of the dossier is completed, ECHA is to notify the European Commission and the competent authorities of the Member States of the information obtained and any conclusions made. That information is used for the purposes of the evaluation of substances, the identification of substances to be included in Annex XIV of Regulation No 1907/2006 and any restriction procedure regarding a substance (Article 42(2) of Regulation No 1907/2006).
- 59 Furthermore, Article 126 of Regulation No 1907/2006 requires Member States to lay down provisions on the penalties applicable for infringement of the provisions of that regulation and to take all measures necessary to ensure that they are implemented.

- 60 It is clear from those provisions, first, that ECHA is only competent to initiate the compliance check of a registration dossier. That check can lead to the adoption of a number of decisions. If ECHA considers that the dossier under examination does not comply with the requirements as regards information relating to it, it is required to initiate the procedure laid down in Article 41(3) of Regulation No 1907/2006. In that regard, the reference that provision makes to Article 51 of Regulation No 1907/2001, as to the adoption of the decision formalising the requirement of bringing the registration dossier into compliance, means that that decision is taken by ECHA if the Member States reach a unanimous agreement on the draft, and by the Commission if the Member States do not reach such an agreement (Article 51(6) and (7) of Regulation No 1907/2006). Whoever is the author of that decision, it is, under the present version of Regulation No 1907/2006, once again for ECHA, in the context of the competence attributed expressly to it by Article 42(1) of the regulation, to examine all information submitted in accordance with it and to prepare, where necessary, any appropriate new decision.
- 61 It follows from those provisions, secondly and consequently, that, contrary to the submissions made by ECHA and the interveners, Article 126 of Regulation No 1907/2006 (see paragraph 59 above) cannot be interpreted as meaning that it is for Member States to assess whether the registrant has complied with the requirements imposed under the first decision requiring it to bring its registration dossier into compliance. Such an interpretation would call into question Article 42(1) of Regulation No 1907/2006 which provides that it is for ECHA to examine any information submitted in consequence of a decision taken under Article 41 of the same regulation. That latter provision reflects the reality that the compliance check of registrations in the context of the evaluation of the dossiers is a single procedure which may include the adoption of a decision requiring the registrant to bring the dossier into compliance. Article 126 of Regulation No 1907/2006, read in conjunction with Article 42(1) of the same regulation, means, in such a context, that it is for Member States to impose appropriate sanctions on registrants who have been held, in accordance with the latter provision, to have infringed their obligations. It must be added in that respect that, even if, as ECHA and the interveners submit, a registrant may always bring its dossier into compliance after the adoption of a decision finding that it did not comply, pursuant to Article 42(1) of Regulation No 1907/2006, the role of the Member States under Article 126 of the same regulation is to assess whether it is necessary, having regard to the facts of each case, to impose sanctions that are effective, proportionate and dissuasive for the period during which the registrant was in breach of its obligations under Article 41(4) of Regulation No 1907/2006.
- 62 Having regard to the fact that the check carried out by ECHA following a first decision requiring the registrant to bring the dossier into compliance, is merely the continuation of the same, single procedure, it must be held that, if the registrant completely fails to provide the information requested, no new assessment of the compliance of the dossier and therefore no new decision within the meaning of Article 42(1) of Regulation No 1907/2006 is required. On the other hand, where, in response to the decision requiring the registration dossier to be rendered compliant, the registrant avails itself of the possibility, laid down in Annex XI of Regulation No 1907/2006, of adapting the standard testing regime and the submissions in that regard are not manifestly unreasonable, having regard to the requirements of that annex, and do not therefore amount to an abuse of procedure, it must be held that, as Annex XI provides, ECHA is to assess those adaptations. It also follows from the foregoing that the evaluation in question is to be made pursuant to Article 42(1) of Regulation No 1907/2006, which refers to Article 41 of the same regulation as regards the decision-making procedure.
- 63 In that regard, it must be added that ECHA evaluates whether the adaptations in issue comply with the conditions laid down in Annex XI of Regulation No 1907/2006 irrespective of whether the adaptations in question rest on substantial and new facts that were not known at the time when the first decision requiring the dossier to be brought into compliance was taken under Article 41(3) of the regulation. It is clear from Article 13(1) and (2) of Regulation 1907/2006 that the objective of reducing tests on vertebrate animals and the number of animals used in those tests justifies the use of alternative methods to those laid down, for standard information, in Annexes VII to X of Regulation No 1907/2006, provided that the requirements set out in Annex XI thereof are complied with and the

adaptations proposed pursue effectively the aim of reducing that type of test. It must be observed in that regard that Annex XI of Regulation No 1907/2006 does not make a distinction depending on whether the adaptation proposed in implementing the first decision requiring the dossiers to be rendered compliant was based on matters that were, or could have been, known to the registrant at the time that decision was taken. In that context, the absence of any reference in Regulation No 1907/2007 to the scientific matters supporting the adaptations proposed in response to a first decision requiring the dossier to be made compliant being new in order for ECHA to be required to examine them implies that, as the law currently stands, ECHA must perform its evaluation, required by Article 42(1) of the regulation, irrespective of whether they are new or not.

- 64 In the present case, first, ECHA states in the contested act that it analysed the information submitted in the updated dossier after the adoption of the decision of 6 November 2012. Secondly, following that analysis, it held that the dossier did not contain all the information required. The reasons supporting that determination are set out in the annex to the letter of 1 April 2015. Thirdly, for those reasons, ECHA ‘states’ that the applicant did not satisfy the obligations following from the decision of 6 November 2012, the registration dossier is not in compliance with Article 5 of Regulation No 1907/2006 and, finally, the applicant is in breach of Article 41(4) of the regulation. Having found that there was an infringement of the decision of 6 November 2012 and of Regulation No 1907/2006, ECHA invited the French Republic to exercise its competence as regards enforcement under Article 126 of Regulation No 1907/2006 (see paragraph 19 above).
- 65 As regards the reasons supporting ECHA’s findings and conclusions set out in paragraph 64 above, it is clear from the contested act, in particular the annex to the letter of 1 April 2015, that the information submitted following the decision of 6 November 2012 was regarded as compliant as regards eight matters. By contrast, the information submitted in response to the request to carry out a prenatal developmental toxicity study on rabbits, oral route, and a long-term toxicity testing in sediment organisms (see paragraph 12 above), were considered by ECHA not to be compliant.
- 66 In particular, as regards the adaptation proposed by the applicant regarding the prenatal developmental toxicity study on rabbits, oral route, ECHA concluded that the evidence, the cross-references and the matters regarding the explanations relied on did not satisfy the conditions in points 1.2, 1.5 and 3.2 of Annex XI of Regulation No 1907/2006. Similarly, ECHA concluded that the evidence in support of the adaptation proposed in respect of the long-term toxicity testing in sediment organisms did not in fact cover the information requested by the decision of 6 November 2012.
- 67 In those circumstances, it must be held that the effects of the contested act went beyond the mere communication of information to the French Ministry of Ecology. The contested act is more than simply a technical opinion or a detailed factual record of the reasons why the registrant did not satisfy the obligations under Regulation No 1907/2006.
- 68 The contested act, in particular the third paragraph of the letter of 1 April 2015 and the annex thereto, is a definitive analysis of the documentation submitted by the applicant on the basis of Article 13 and Annex XI of Regulation No 1907/2006.
- 69 ECHA set out, in imperative and definitive terms, the reasons why it considered that that information did not suffice to meet the requirements flowing from the decision of 6 November 2012. It is clear from a reading of the fourth paragraph of the letter of 1 April 2015 that ECHA found that this was a case in which the obligations under Article 41(4) of Regulation No 1907/2006 were infringed. The objective significance of the fourth paragraph of the letter of 1 April 2015 cannot be other than that it produces binding legal effects as regards the applicant’s legal situation.
- 70 Additionally, it is clear from paragraphs 6 to 8 of the letter of 1 April 2015 that ECHA asks the French competent authority to adopt the measures necessary for the enforcement of sanctions in accordance with Article 126 of Regulation No 1907/2006. By giving its view of the possible legal consequences of

the alleged inadequacies of the ‘alternative documentation’ of 6 November 2013, ECHA referred to the legal situation of the applicant. Furthermore, having regard to the terms used in the contested act and taking into account the division of competences in the matter, as set out in paragraphs 54 to 61 above, that document must be regarded as containing findings and conclusions from which the French competent authority could not depart unless there was a particular reason based on new elements, namely elements which had not been taken into consideration by ECHA during the follow-up provided for in Article 42(1) of Regulation No 1907/2006.

- 71 Moreover, neither the wording nor the nature of the reasons in relation to the adaptations held not to comply with the rules in Annex XI of Regulation No 1907/2006 makes it clear that ECHA considered the applicant’s arguments to be manifestly unreasonable as regards the requirements of that annex and that they therefore constitute an abuse of process.
- 72 In those circumstances, it must be held that, having regard to its content, the contested act corresponds to a decision that ECHA was required to prepare pursuant to Article 42(1) of Regulation No 1907/2006, and which should have been adopted on the basis of Article 41(3) of that regulation. The contested act must, therefore, be regarded as producing binding legal effects, both as regards the applicant and as regards the French Republic, and as therefore being an act against which an action for annulment may be brought.
- 73 The other arguments put forward by ECHA and the interveners do not make it possible to call that finding into question.
- 74 In the first place, as regards ECHA’s argument that it did not intend to adopt a provision producing binding legal effects (see paragraph 41 above), it must be observed that it is true that such an intention is not clear from the contested act. In addition, the document entitled ‘Follow up to dossier evaluation decisions’ that ECHA published on its website in October 2013 also does not contain elements to support the thesis that an act such as the contested act, namely a ‘statement of non-compliance’, could be binding in nature.
- 75 However, it cannot be deduced from those mere assertions that the contested act does not produce binding legal effects. The criterion of the intention of the body that issued the contested act is a criterion that is only of subsidiary importance and does not take precedence over the examination of objective criteria, referred to in paragraph 51 above, in particular the substance of the contested act.
- 76 In the second place, ECHA’s argument relating to the fact that, first, the contested act was drafted in the context of an informal system of cooperation with the Member States for the enforcement of decisions concerning a compliance check and, second, in essence, the contested act took account of the fact that, at the stage of the enforcement of a decision such as that of 6 November 2012 the competent national authorities are free to decide the outcome in accordance with information submitted by a registrant in response to a statement of non-compliance, is unconvincing.
- 77 The informal nature of the mechanism of cooperation between ECHA and the competent national authorities, as referred to in paragraph 42 above, does not call into question the division of competences established by Regulation No 1907/2006, as described in paragraphs 54 to 61 above.
- 78 By contrast, to interpret the system established by Regulation No 1907/2006 as leaving only to the national authorities the task of assessing whether a registrant has complied with the obligation imposed on it under a decision by ECHA adopted on the basis of Article 41 of the regulation would defeat a substantial part of the architecture as it was expressly intended to be by the EU legislature.
- 79 Consequently, the competence of the national authorities, provided for in Article 126 of Regulation No 1907/2006, concern, in a context such as that in the present case, the stages following the finding by ECHA of a case of failure to comply with obligations flowing from Article 41(4) of that regulation.

- 80 In the third place, ECHA's argument that, in its reasons for the contested act, it had not intended to express a definitive position on the 'alternative documentation' provided by the applicant (see paragraph 42 above) must be rejected for the reasons set out in paragraphs 53 to 72 above.
- 81 In the fourth place, ECHA's argument that the contested act is a 'confirmatory act' also cannot succeed.
- 82 It is clear from the contested act, in particular from pages 3 to 6 and 10 to 12 of the letter of 1 April 2015, that ECHA examined the merits of the elements and arguments submitted by the applicant in reply to the decision of 6 November 2012, and that it made its assessments and conclusions in relation to them. A comparison with the grounds set out in pages 6 to 10 of the decision of 6 November 2012 shows that the grounds that are set out in the contested act are not a repetition of the assessments supporting the latter decision but provide new reasoning developed in relation to the elements and arguments relied on by the applicant in reply to the decision of 6 November 2012. That fact excludes the possibility of regarding the contested act as being an act that confirms the decision of 6 November 2012.
- 83 In those circumstances, the other arguments made by the Federal Republic of Germany and the French Republic as to the application, by the Board of Appeal, of the case-law on confirmatory acts in the Solutia case (see paragraphs 46 and 47 above) must also be rejected.

The applicant's locus standi

- 84 Both the Federal Republic of Germany and the French Republic take the view that the applicant does not have standing to challenge the contested act, because it is not directly concerned by the contested act within the meaning of the fourth paragraph of Article 263 TFEU. More specifically, according to the Federal Republic of Germany the French competent national authority has a discretion in deciding whether and how a decision adopted on the basis of Article 41(3) of Regulation No 1907/2006 must be enforced. In addition, enforcement measures rest exclusively on provisions of national law, such that enforcement does not proceed on the basis of provisions of EU law. According to the French Republic, the 'statement of non-compliance' in question leaves a wide margin of discretion to the competent national authority. It is clear from the wording itself of the letter of 1 April 2015 that the complaints could be the object of sanctions and that only the national authority was competent in the matter. Furthermore, Article 126 of Regulation No 1907/2006 itself leaves a wide margin of discretion to Member States to lay down provisions on the penalties applicable for infringement of the provisions of that regulation and to take all measures necessary to ensure that they are implemented.
- 85 The applicant contests the arguments advanced by the Federal Republic of Germany and the French Republic.
- 86 As a preliminary matter, it should be recalled that, under the terms of the fourth paragraph of Article 263 TFEU, any natural or legal person may, under the conditions laid down in the first and second paragraphs of that article, institute proceedings against an act addressed to that person or which is of direct and individual concern to them, and against a regulatory act which is of direct concern to them and does not entail implementing measures.
- 87 In the present case, it must be observed that the French Ecology Ministry is the only addressee of the contested act, whilst the applicant received only a copy thereof.

- 88 In that regard, and in order to reply to the applicant's argument that it was an addressee of the contested act, it must be noted that the notion of an addressee of an act must be understood in a formal sense, as referring to the person designated by that act as being its addressee (judgment of 21 January 2016, *SACBO v Commission and INEA*, C-281/14 P, not published, EU:C:2016:46, paragraph 34).
- 89 The fact that ECHA sent a copy of the contested act to the applicant does not call that conclusion into question. The fact that a person other than the formal addressee could be covered by its content may, certainly, give rise to that person having *locus standi* if they demonstrate inter alia that, having regard to that content, that act directly concerns them but not as an addressee of the act (judgment of 21 January 2016, *SACBO v Commission and INEA*, C-281/14 P, not published, EU:C:2016:46, paragraph 34).
- 90 In those circumstances, the first and second heads of claim are inadmissible, under the fourth paragraph of Article 263 TFEU, unless the contested decision is of direct and individual concern to the applicants or if the contested decision is of direct concern to them and that decision constitutes a regulatory act which does not entail implementing measures.
- 91 With regard to whether the applicant is directly concerned, it must be recalled that the condition that a natural or legal person must be directly concerned by the decision being challenged, as provided for in the fourth paragraph of Article 263 TFEU, requires two cumulative criteria to be met, namely, (i) the contested measure must directly affect the legal situation of the individual, and (ii) it must leave no discretion to its addressees, who are entrusted with the task of implementing it, such implementation being purely automatic and resulting from EU rules without the application of other intermediate rules (order of 6 March 2014, *Northern Ireland Department of Agriculture and Rural Development v Commission*, C-248/12 P, not published, EU:C:2014:137, paragraph 21).
- 92 In the present case, as follows from the considerations set out in paragraphs 62 to 73 above, the contested act affects the legal situation of the applicant in that it sets out ECHA's assessment of whether the registration dossier was compliant having regard to the information submitted by the applicant in response to a first decision, taken in accordance with Article 41(3) of Regulation No 1907/2006, namely the decision of 6 November 2012.
- 93 Therefore, contrary to the submissions made by the French Republic and the Federal Republic of Germany, the discretion afforded to the Member States in the application of Article 126 of Regulation No 1907/2006 concerns the nature and quantum of possible sanctions that could be imposed as a result of the non-compliance of the registration dossier and, consequently, infringement of obligations arising under the decision of 6 November 2012 and of Article 41(4) of Regulation No 1907/2006. That discretion does not therefore concern the finding in itself of a failure to comply with the obligations.
- 94 In that context, as noted in paragraph 61 above, bringing the registration dossier into compliance after the adoption of a decision under Article 42(1) of Regulation No 1907/2006 finding that it was not compliant does not call into question the fact that the dossier was not compliant in that period, notwithstanding that the Member State concerned may use its powers under Article 126 of Regulation No 1907/2006 in regard to that period.
- 95 As for whether the applicant is individually concerned by the contested act, it should be recalled that, according to the case-law, persons other than those to whom a decision is addressed may claim to be individually concerned only if that act affects them by reason of certain attributes which are peculiar to them or by reason of circumstances in which they are differentiated from all other persons and, by virtue of those factors, distinguishes them individually just as in the case of the person addressed (judgment of 15 July 1963, *Plaumann v Commission*, 25/62, EU:C:1963:17, p. 223).

- 96 Since, on analysis, the contested act is an assessment by ECHA of the matters submitted by the applicant on 6 November 2013 to update the registration dossier on the registered substance following the decision of 3 November 2012 addressed to the applicant, it is of individual concern to the applicant. The fact that the applicant received a copy of the contested act confirms that conclusion.
- 97 Having regard to the foregoing considerations, it must be concluded that the contested act is of direct and individual concern to the applicant, such that the applicant has standing to bring proceedings against it.
- 98 In the light of all the foregoing considerations, it must be held that the first and second heads of claim are admissible.

Substance

- 99 The applicant's arguments are made through eight pleas in law.
- 100 By its first plea in law, the applicant submits that the contested act was ultra vires since ECHA did not have any legal basis for establishing, compiling, adopting or sending 'statements of non-conformity' such as the contested act. In particular, if there must be a legal basis for the contested act, such as Article 42(1) of Regulation No 1907/2006, it was drafted in breach of the procedural requirements of Articles 41 and 51 of Regulation No 1907/2006. The second and third pleas allege, respectively, a breach of the principle of proportionality and a breach of the principles of legal certainty and legitimate expectation. By its fourth and eighth pleas, the applicant alleges a breach of the right to be heard and the rights of the defence, the principle of good administration, the obligation to state reasons, the right to a fair trial and breach of the provisions concerning the request to provide a prenatal development toxicity study of the registered substance.
- 101 It is appropriate first of all to examine the first plea, which is divided into two branches.
- 102 By the first branch of its first plea in law, the applicant submits that the contested act was ultra vires since ECHA did not have any legal basis for establishing, compiling, adopting or sending 'statements of non-compliance'. In particular, Article 42(1) of Regulation No 1907/2006 does not authorise the issuing of a 'Statement of Non-Compliance' document under the guise of a formal decision intended to compel the French Competent Authority to take action. Moreover, the contested act was not an appropriate decision under Article 42(1) of Regulation No 1907/2006.
- 103 By the second branch of its first plea in law, the applicant submits that, while there must be a legal basis for the contested act, the delivery of such an act by ECHA could not be made except under Article 42(1) of Regulation No 1907/2006. According to the applicant, if ECHA had wished to rely on that provision as a 'legal authority' or legal basis for the contested act, it must be noted that the evaluation of the validity of the justifications provided in response to a decision ordering a study should only take place in the context of a new procedure for verifying conformity in accordance with the procedure laid down in Article 41 of Regulation No 1907/2006. The contested act was therefore drawn up in breach of the procedural requirements laid down in Articles 41 and 51 of Regulation No 1907/2006.
- 104 ECHA and the Federal Republic of Germany contest the applicant's arguments.
- 105 First, ECHA takes the view that it is not required to recommence the same procedure for taking a decision laid down in Articles 41 to 51 of Regulation No 1907/2006 for adaptations which are not only invalid but also based on information that was already available before the initial compliance check procedure. If that were the case, it would mean that registrants could repeatedly submit material in order to adapt the information required by a decision on a compliance check. The

registrant would be able unduly to delay the submission of information which normally he would have had to provide in the initial registration, since, so long as the registrant provided an adaptation, enforcement could not take place. In such circumstances, ECHA would be required not to ask Member States to enforce a decision on a compliance check and to recommence the procedure laid down in Articles 41, 50 and 51 of Regulation No 1907/2006 every time. That would be an open door to dilatory measures by registrants, which would create, as ECHA fears, an ‘endless loop of new decisions’ or an ‘endless spiral of evaluations and adaptations’ at the stage of the procedure covered by Article 42 of Regulation No 1907/2006. For its part, the competent national authority would not be able to enforce a decision on a compliance check since each procedure undertaken in that respect could be suspended until ECHA took a decision on new information or adaptations submitted by the applicant. Therefore, the evaluation procedure would always remain suspended, as the stage of closing the evaluation procedure referred to in Article 42(2) of Regulation No 1907/2006 would never be reached.

- 106 Secondly, ECHA recalls that, by applying the approach adopted by the case-law of the EU courts on confirmatory decisions by analogy, one of its Boards of Appeal decided in the *Solutia* case that, where there is new information submitted by a registrant and taken into account in its scientific evaluation, it is appropriate to give an act, such as the contested act, the value of a decision adopted on the basis of Article 42(1) of Regulation No 1907/2006 where it does not confirm the decision on the initial compliance check. A decision should be adopted in accordance with the procedure laid down in Articles 41, 50 and 51 of Regulation No 1907/2006 and could be the object of an appeal before the Board of Appeal pursuant to Article 91 of Regulation No 1907/2006. In the present case, given that, in response to a decision by ECHA, the applicant submitted documentation different from the studies requested, it would be appropriate to determine whether the ‘alternative documentation’ in question is based on substantially new elements. However, according to ECHA, the ‘alternative documentation’ offered by the applicant on 6 November 2013 contained information which was neither new nor substantial. In those circumstances, given that the update of 6 November 2013 did not contain substantially new information, the contested act is, according to ECHA, a confirmatory act.
- 107 As a preliminary point, it is necessary to refer to the considerations set out in paragraphs 54 to 62 above concerning the allocation of competences as regards the evaluation of registration dossiers as established by Regulation No 1907/2006.
- 108 It is clear from the allocation of competences regarding the evaluation of dossiers that ECHA is to carry out that evaluation in accordance with the detailed arrangements laid down in Articles 41 and 42 of Regulation No 1907/2006. Those arrangements must be complied with by ECHA in the exercise of its competences, and ECHA may not act independently of that legal framework by having recourse to an instrument other than the decision laid down by Articles 41 and 42 of Regulation No 1907/2006. In those circumstances, it was held in paragraph 72 above that having regard to its content the contested act corresponds to a decision that ECHA was required to prepare pursuant to Article 42(1) of Regulation No 1907/2006, and which should have been adopted in accordance with Article 41(3) of that regulation.
- 109 Moreover, having regard to the fact that, first, Article 41(3) of Regulation No 1907/2006 provides for the adoption of a decision in accordance with the procedure laid down in Article 51 of Regulation No 1907/2006 and, secondly, that procedure was not followed in this case, it must be held that ECHA carried out its tasks without complying with the detailed rules relating to them.
- 110 None of the arguments raised by ECHA or the interveners is capable of calling that conclusion into question.

- 111 Firstly, ECHA's argument that the need to avoid a system in which every 'alternative documentation' must be treated following the 'onerous procedure' laid down in Articles 41, 50 and 51 of Regulation No 1907/2006, since such a system could lead to an endless procedure of new decisions which would paralyse the application of ECHA decisions, cannot succeed.
- 112 In that regard, first, as is clear from paragraph 62 above, an offer of adaptation based on Article XI of Regulation No 1907/2006 in support of which manifestly unreasonable elements are relied on with regard to the requirements of that annex and constituting therefore an abuse of process are equivalent to the complete failure to respond to the first decision requiring the registrant to bring the registration dossier into compliance. Since Article 42(1) of Regulation No 1907/2006 does not provide that ECHA must prepare, in the context of the follow-up to registration dossier evaluation, a decision in every case but only 'if necessary', it must be held that, in such a case, ECHA is in a position to find that the dossier was not compliant by means of a simple information to the Member State concerned and the interested party.
- 113 As has been observed in paragraph 71 above, it is not clear either from the wording or the nature of the reasons in relation to the adaptations held not to comply with the rules in Annex XI of Regulation No 1907/2006 that ECHA considered the applicant's arguments to be manifestly unreasonable were therefore an abuse of process.
- 114 Second, it must be held that, as is clear from Article 41(4) of Regulation No 1907/2006, if a decision is adopted, under Article 42(1) of the regulation, finding that the registration dossier is non-compliant, that lack of compliance relates, at the least, to the end of the time limit granted under the first decision requesting the dossier be brought into compliance, adopted on the basis of Article 41(3) of the same regulation. Consequently, as has been held in paragraph 61 above, on such a hypothesis, it would be for the Member State concerned to exercise the power reserved to it under Article 126 of Regulation No 1907/2006 for the period during which the registration dossier was not compliant.
- 115 Finally, ECHA's argument that the situation is analogous to that in the case-law on confirmatory acts and based on the fact that the information provided by the applicant on 6 November 2013 was neither new nor substantial must be rejected for the reasons set out in paragraph 84 above.
- 116 Furthermore, in the contested act, ECHA restricted itself to checking the information submitted by the applicant on 6 November 2013, without stating whether it was new or substantial information. ECHA cannot successfully invoke, in the context of this dispute, arguments on which it did not base its evaluation that preceded the contested act being sent.
- 117 In those circumstances, it must be concluded that the first plea is well founded and that, therefore, the action must be upheld, without it being necessary to examine the other pleas raised by the applicant.

Costs

- 118 Under Article 134(3) of the Rules of Procedure, where each party succeeds on some and fails on other heads, the parties are to bear their own costs. In the present case, the applicant having been unsuccessful in its third and fifth heads of claim, it is necessary to decide that the applicant and ECHA shall each bear their own costs.
- 119 Under Article 138(1) and (2) of the Rules of Procedure, the Member States, and States other than the Member States which are parties to the Agreement on the European Economic Area (EEA) which intervened in the proceedings must bear their own costs. It is appropriate to apply those provisions to the Federal Republic of Germany, the French Republic and the Kingdom of the Netherlands.

On those grounds,

THE GENERAL COURT (Fifth Chamber)

hereby:

- 1. Annuls the letter of the European Chemicals Agency (ECHA) of 1 April 2015 addressed to the French Ministère de l'écologie du développement durable, des transports et du logement (Ministry of Ecology, Sustainable Development, Transport and Housing) and entitled 'Statement of Non-Compliance following a Dossier Evaluation Decision under Regulation (EC) No 1907/2006' and the annex thereto;**
- 2. Orders Esso Raffinage and ECHA each to bear their own costs;**
- 3. Orders the Federal Republic of Germany, The French Republic and the Kingdom of the Netherlands each to bear their own costs.**

Gratsias

Dittrich

Xuereb

Delivered in open court in Luxembourg on 8 May 2018.

E. Coulon
Registrar

D. Gratsias
President