Reports of Cases

JUDGMENT OF THE COURT (Third Chamber)

21 January 2021*

[Text rectified by order of 4 March 2021]

(Appeal – Registration, evaluation and authorisation of chemicals – Regulation (EC) No 1907/2006 (REACH) – Articles 5 and 6 – General obligation to register substances – Articles 41 and 42 – Evaluation of registration dossiers and compliance check of information submitted by registrants – Declaration of non-compliance – Actionable measure – Interest in bringing proceedings – *Locus standi* – Respective competences of the European Chemicals Agency (ECHA) and national authorities – Obligation on ECHA to check the compliance of additional information submitted by registrants at its request – ECHA's power to take an appropriate decision – Article 1 – Objective of protecting human health and the environment – Articles 13 and 25 – Use of animal testing – Promotion of alternative methods)

In Case C-471/18 P,

APPEAL under Article 56 of the Statute of the Court of Justice of the European Union, brought on 18 July 2018,

Federal Republic of Germany, represented initially by T. Henze and D. Klebs, and subsequently by D. Klebs and J. Möller, acting as Agents,

appellant,

the other parties to the proceedings being:

Esso Raffinage, established in Courbevoie (France), represented initially by H. Estreicher, Rechtsanwalt, and N. Navin-Jones, Solicitor, subsequently by H. Estreicher, Rechtsanwalt, A. Kołtunowska, adwokat, K. Merten-Lentz, avocate, and N. Navin-Jones, Solicitor, and finally by H. Estreicher, Rechtsanwalt, A. Kołtunowska, adwokat, and K. Merten-Lentz, avocate,

applicant at first instance,

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

defendant at first instance,

French Republic, represented initially by D. Colas, J. Traband and A.-L. Desjonquères, and subsequently by E. Leclerc, J. Traband, W. Zemamta and A.-L. Desjonquères, acting as Agents,

* Language of the case: English.

Kingdom of the Netherlands, represented by K. Bulterman and L. Noort, acting as Agents,

interveners at first instance,

[As rectified by order of 4 March 2021] **European Coalition to End Animal Experiments**, established in London (United Kingdom), represented by D. Thomas, Solicitor,

Higher Olefins and Poly Alpha Olefins REACH Consortium, established in Brussels (Belgium),

Higher Olefins & Poly Alpha Olefins vzw, established in Brussels, represented initially by E. Vermulst, advocaat, and subsequently by P. Kugel, advocaat,

interveners,

THE COURT (Third Chamber),

composed of A. Prechal (Rapporteur), President of the Chamber, K. Lenaerts, President of the Court, acting as Judge of the Third Chamber, N. Wahl, F. Biltgen and L.S. Rossi, Judges,

Advocate General: E. Tanchev,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after hearing the Opinion of the Advocate General at the sitting on 24 September 2020,

gives the following

Judgment

1 By its appeal, the Federal Republic of Germany seeks to have set aside the judgment of the General Court of the European Union of 8 May 2018, *Esso Raffinage* v *ECHA* (T-283/15, 'the judgment under appeal', EU:T:2018:263), by which the General Court annulled the letter of the European Chemicals Agency (ECHA) of 1 April 2015, which was addressed to the ministère de l'Écologie, du Développement durable, des Transports et du Logement (Ministry of Ecology, Sustainable Development, Transport and Housing, France) and entitled 'Statement of Non-Compliance following a Dossier Evaluation Decision under Regulation (EC) No 1907/2006' ('the letter at issue').

Legal context

2 Recitals 15, 18 to 20, 44, 47, 66, 121 and 122 of 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), as amended by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 (OJ 2008 L 353, p. 1) ('the REACH Regulation'), provide as follows:

'(15) There is a need to ensure effective management of the technical, scientific and administrative aspects of this Regulation at [Union] level. A central entity should therefore be created to fulfil this role. A feasibility study on the resource requirements for this central entity concluded that an independent central entity offered a number of long-term advantages over other options. A European Chemicals Agency (hereinafter referred to as "[ECHA]") should therefore be established.

…

(18) Responsibility for the management of the risks of substances should lie with the natural or legal persons that manufacture, import, place on the market or use these substances. …

(19) Therefore, the registration provisions should require manufacturers and importers to generate data on the substances they manufacture or import, to use these data to assess the risks related to these substances and to develop and recommend appropriate risk management measures. To ensure that they actually meet these obligations, as well as for transparency reasons, registration should require them to submit a dossier containing all this information to [ECHA] …

(20) The evaluation provisions should provide for follow-up to registration, by allowing for checks on whether registrations are in compliance with the requirements of this Regulation and if necessary by allowing for generation of more information on the properties of substances. If [ECHA] in cooperation with the Member States considers that there are grounds for considering that a substance constitutes a risk to human health or the environment, [ECHA] should, after having included the substance in the Community rolling action plan for substance evaluation, relying on the competent authorities of Member States, ensure that this substance is evaluated.

…

(44) In order to provide a harmonised, simple system, all registrations should be submitted to [ECHA]. To ensure a consistent approach and efficient use of resources, it should perform a completeness check on all registrations and take responsibility for any final rejections of registrations.

…

(47) In accordance with [Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (OJ 1986 L 358, p. 1)], it is necessary to replace, reduce or refine testing on vertebrate animals. Implementation of this Regulation should be based on the use of alternative test methods, suitable for the assessment of health and environmental hazards of chemicals, wherever possible. The use of animals should be avoided by recourse to alternative methods validated by the Commission or international bodies, or recognised by the Commission or [ECHA] as appropriate to meet the information requirements under this Regulation.

…

(66) [ECHA] should also be empowered to require further information from manufacturers, importers or downstream users on substances suspected of posing a risk to health or the environment, … on the basis of evaluations performed. Based on the criteria for prioritising substances developed

by [ECHA] in cooperation with the Member States a Community rolling action plan for substance evaluation should be established, relying on Member State competent authorities to evaluate substances included therein.

…

(121) In order to ensure compliance with this Regulation, Member States should put in place effective monitoring and control measures. The necessary inspections should be planned, carried out and their results should be reported.

(122) In order to ensure transparency, impartiality and consistency in the level of enforcement activities by Member States, it is necessary for Member States to set up an appropriate framework for penalties with a view to imposing effective, proportionate and dissuasive penalties for non-compliance, as non-compliance can result in damage to human health and the environment.'

3 Article 1 of the REACH Regulation, headed 'Aim and scope', provides in paragraph 1:

'The purpose of this Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.'

4 Title II of the REACH Regulation, headed 'Registration of Substances', contains, inter alia, Articles 5, 6, 13, 20 and 22.

5 As set out in Article 5 of that regulation, headed 'No data, no market':

'Subject to Articles 6, 7, 21 and 23, substances on their own, in mixtures or in articles shall not be manufactured in the [Union] or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required.'

6 Article 6 of that regulation, headed 'General obligation to register substances on their own or in mixtures', states in paragraph 1:

'Save where this Regulation provides otherwise, any manufacturer or importer of a substance, either on its own or in one or more mixture(s), in quantities of one tonne or more per year shall submit a registration to [ECHA].'

7 Article 13 of the regulation, headed 'General requirements for generation of information on intrinsic properties of substances', provides in paragraph 1:

'Information on intrinsic properties of substances may be generated by means other than tests, provided that the conditions set out in Annex XI are met. In particular for human toxicity, information shall be generated whenever possible by means other than vertebrate animal tests, through the use of alternative methods, for example, *in vitro* methods or qualitative or quantitative structure-activity relationship models or from information from structurally related substances (grouping or read-across) …'

8 As provided in Article 20 of the REACH Regulation, headed 'Duties of [ECHA]':

'1. [ECHA] shall assign a submission number to each registration …

2. [ECHA] shall carry out a completeness check of each registration in order to ascertain that all the elements required … have been provided. The completeness check shall not include an assessment of the quality or the adequacy of any data or justifications submitted.

…

If a registration is incomplete, [ECHA] shall inform the registrant […] as to what further information is required in order for the registration to be complete, while setting a reasonable deadline for this. The registrant shall complete his registration and submit it to [ECHA] within the deadline set. [ECHA] … shall perform a further completeness check, considering the further information submitted.

[ECHA] shall reject the registration if the registrant fails to complete his registration within the deadline set …

3. Once the registration is complete, [ECHA] shall assign a registration number to the substance concerned …

5. An appeal may be brought, in accordance with Articles 91, 92 and 93, against [ECHA] decisions under paragraph 2 of this Article.

…'

9 Article 22 of the REACH Regulation, headed 'Further duties of registrants', provides in paragraphs 2 and 3:

'2. A registrant shall submit to [ECHA] an update of the registration containing the information required by the decision made in accordance with Articles 40, 41 or 46 …

3. [ECHA] shall undertake a completeness check according to Article 20(2) first and second subparagraphs of each updated registration …'

10 Title III of the REACH Regulation, headed 'Data Sharing and Avoidance of Unnecessary Testing', begins with Article 25, headed 'Objectives and General Rules', paragraph 1 of which states:

'In order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort …'

11 Title VI of the REACH Regulation, headed 'Evaluation', contains four chapters. Chapters 1, 2 and 4, headed 'Dossier evaluation', 'Substance evaluation' and 'Common provisions', comprise Articles 40 to 43, 44 to 48 and 50 to 54 of the regulation, respectively.

12 Article 41 of the REACH Regulation, headed 'Compliance check of registrations', provides:

'1. [ECHA] may examine any registration in order to verify any of the following:

(a) that the information in the technical dossier(s) … complies with the requirements of Articles 10, 12 and 13 and with Annexes III and VI to X;

(b) that the adaptations of the standard information requirements and the related justifications submitted in the technical dossier(s) comply with the rules governing such adaptations set out in Annexes VII to X and with the general rules set out in Annex XI;

…

3. On the basis of an examination made pursuant to paragraph 1, [ECHA] may, within 12 months of the start of the compliance check, prepare a draft decision requiring the registrant(s) to submit any information needed to bring the registration(s) into compliance with the relevant information requirements and specifying adequate time limits for the submission of further information. Such a decision shall be taken in accordance with the procedure laid down in Articles 50 and 51.

4. The registrant shall submit the information required to [ECHA] by the deadline set.

5. To ensure that registration dossiers comply with [the provisions of] this Regulation, [ECHA] shall select a percentage of those dossiers, no lower than 5% of the total received by [ECHA] for compliance checking …'

13 Article 42 of that regulation, headed 'Check of information submitted and follow-up to dossier evaluation', provides:

'1. [ECHA] shall examine any information submitted in consequence of a decision taken under Articles 40 or 41 and draft any appropriate decisions in accordance with these Articles, if necessary.

2. Once the dossier evaluation is completed, [ECHA] shall notify the Commission and the competent authorities of the Member States of the information obtained and any conclusions made. …'

14 Article 45 of that regulation, headed 'Competent authority', reads as follows:

'1. [ECHA] shall be responsible for coordinating the substance evaluation process and ensuring that substances on the [Union] rolling action plan are evaluated. In doing so, [ECHA] shall rely on the competent authorities of Member States. In carrying out an evaluation of a substance, the competent authorities may appoint another body to act on their behalf.

2. A Member State may choose (a) substance(s) from the draft [Union] rolling action plan, with the aim of becoming a competent authority …

3. In cases where two or more Member States have expressed an interest in evaluating the same substance and they cannot agree who should be the competent authority, the competent authority … shall be determined in accordance with the following procedure.

…

4. The competent authority identified in accordance with paragraphs 2 and 3 shall evaluate the allocated substances in accordance with this Chapter.

…'

15 Article 50 of that regulation, headed 'Registrants and downstream users' rights', provides in paragraph 1:

'[ECHA] shall notify any draft decision under Articles 40, 41 or 46 to the registrant(s) or downstream user(s) concerned, informing them of their right to comment within 30 days of receipt. If the concerned registrant(s) or downstream user(s) wish to comment, they shall provide their comments to [ECHA]. [ECHA] in turn shall inform the competent authority of the submission of the comments without delay. The competent authority (for decisions taken under Article 46) and [ECHA] (for decisions taken under Articles 40 and 41) shall take any comments received into account and may amend the draft decision accordingly.'

16 According to Article 51 of the REACH Regulation, headed 'Adoption of decisions under dossier evaluation':

'1. [ECHA] shall notify its draft decision in accordance with Articles 40 or 41, together with the comments of the registrant, to the competent authorities of the Member States.

2. Within 30 days of circulation, the Member States may propose amendments to the draft decision to [ECHA].

3. If [ECHA] does not receive any proposals, it shall take the decision in the version notified under paragraph 1.

4. If [ECHA] receives a proposal for amendment, it may modify the draft decision. [ECHA] shall refer a draft decision, together with any amendments proposed, to the Member State Committee within 15 days of the end of the 30-day period referred to in paragraph 2.

…

6. If, within 60 days of the referral, the Member State Committee reaches a unanimous agreement on the draft decision, [ECHA] shall take the decision accordingly.

7. If the Member State Committee fails to reach unanimous agreement, the Commission shall prepare a draft decision to be taken …

8. An appeal may be brought, in accordance with Articles 91, 92 and 93, against [ECHA] decisions under paragraphs 3 and 6 of this Article.'

17 Title X of the REACH Regulation, headed 'Agency', contains, inter alia, Articles 75 and 77 of the regulation.

18 Article 75 of the regulation, headed 'Establishment and review', provides in paragraph 1 that ECHA is established 'for the purposes of managing and in some cases carrying out the technical, scientific and administrative aspects of [that] Regulation and to ensure consistency at [Union] level in relation to these aspects'.

19 Article 77 of the regulation, headed 'Tasks', provides in paragraph 1 that ECHA 'shall provide the Member States and the institutions of the [Union] with the best possible scientific and technical advice on questions relating to chemicals which fall within its remit'.

20 Article 89 of the REACH Regulation establishes a ECHA Board of Appeal, Article 91 provides that certain categories of ECHA decisions may be appealed to that Board of Appeal and Article 94 states that an action may be brought before the General Court contesting a decision taken by a Board of Appeal or, in cases where no right of appeal lies before the Board, by the ECHA.

21 Title XIV of the REACH Regulation, headed 'Enforcement', contains, inter alia, Articles 125 and 126 of the regulation.

22 According to Article 125 of the regulation, headed 'Tasks of the Member States', Member States 'shall maintain a system of official controls and other activities as appropriate to the circumstances'.

23 Article 126 of the regulation, headed 'Penalties for non-compliance', provides in its first two sentences as follows:

'Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.'

Background to the dispute

24 The background to the dispute, as set out in paragraphs 1 to 19 of the judgment under appeal, can be summarised as follows.

25 On a date not specified by the General Court, Esso Raffinage ('Esso') submitted to ECHA an application for registration of a substance it manufactures ('the substance at issue'). The registration was subsequently declared complete under Article 20(3) of the REACH Regulation.

26 On 9 July 2010, ECHA initiated the examination of the dossier pertaining to that registration, pursuant to Article 41(1) of the REACH Regulation, in order to verify that the information in that dossier complied with the requirements laid down by that regulation.

27 On 6 November 2012, ECHA adopted, in accordance with the procedure laid down in Articles 50 and 51 of the REACH Regulation, a decision under Article 41(3) of that regulation ('the decision of 6 November 2012') in which it concluded that some of the information in the registration dossier was non-compliant and requested that Esso provide it with the information necessary to remedy the situation before the expiry of one year. The information requested included, inter alia, a 'prenatal developmental toxicity study in rabbits, oral route' in respect of the substance at issue.

28 On 6 November 2013, Esso submitted to ECHA, in place of the toxicity study requested by ECHA, documents containing information the preparation and compilation of which had not required testing on animals. Esso stated that the information submitted was alternative to that study.

29 On 1 April 2015, ECHA sent the letter at issue to the Ministry of Ecology, Sustainable Development, Transport and Housing, accompanied by a document headed 'Annex to the statement of non-compliance following a dossier evaluation decision under [the REACH] Regulation'.

30 That letter reads as follows:

'Pursuant to Article 41(3) of [the REACH] Regulation, [ECHA] has performed a compliance check on the dossier [on the substance at issue]. 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 [Esso] 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 …

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 …

On this basis ECHA states that:

1. [Esso] has not met the obligations following from [the decision of 6 November 2012];

2. The registration dossier is not in compliance with Article 5 of the REACH Regulation; and

3. [Esso] 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 action 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 is looking forward to receiving your feedback concerning national action taken on this case of non-compliance.'

31 In the annex to that letter, ECHA stated that it had not been convinced by Esso's argument that the evidence provided by Esso on 6 November 2013 was satisfactory alternative information to the toxicity study requested in the decision of 6 November 2012.

The action before the General Court and the judgment under appeal

32 By application lodged at the General Court Registry on 29 May 2015, Esso brought an action for annulment of the letter at issue.

33 By documents lodged at the General Court Registry on 5 and 24 November 2015, the Federal Republic of Germany and the Kingdom of the Netherlands, on the earlier date, and the French Republic, on the later date, applied for leave to intervene in support of the form of order sought by ECHA, applications which the President of the Fifth Chamber of the General Court granted by orders of 7 June 2016.

34 By the judgment under appeal, the General Court annulled the letter at issue.

35 First, in paragraphs 33 to 37 of that judgment, the General Court held that the letter at issue was not a decision that could be challenged before the Board of Appeal established under Article 89 of the REACH Regulation. The General Court concluded that, pursuant to Article 94(1) of that regulation, it had jurisdiction to hear at first instance Esso's action for annulment.

36 Second, in paragraphs 49 to 83 of the judgment under appeal, the General Court held that the letter at issue was an act open to challenge within the meaning of the first paragraph of Article 263 TFEU, on the ground that the analysis of its content, in the light of the applicable provisions and the powers which those provisions confer on ECHA, revealed that it was intended to produce binding legal effects in so far as it (i) contained a definitive analysis of Esso's registration dossier and, more specifically, of the information submitted by Esso in response to the decision of 6 November 2012; (ii) found that some of that information did not comply with the requirements of the REACH regulation and that Esso had therefore failed to comply with some of the obligations laid down by that regulation; and (iii) asked the French competent authority to adopt the measures required by that situation.

37 Third, in paragraphs 86 to 97 of the judgment under appeal, the General Court held that Esso should be regarded as having standing to apply for annulment of the letter at issue since that letter was of direct and individual concern to it, within the meaning of the first part of the fourth paragraph of Article 263 TFEU.

38 Fourth and finally, in paragraphs 101 to 117 of the judgment under appeal, the General Court examined the first of the eight pleas put forward by Esso in support of its action for annulment, in which it alleged that the letter at issue was ultra vires or in breach of the provisions of the REACH regulation applicable to its adoption. The General Court held, at the end of its examination, that that plea was well founded on the ground that ECHA had exercised its competences without complying with the detailed arrangements relating to them, as laid down in Articles 41 and 42 of the REACH Regulation, and concluded that the letter at issue should be annulled, without the need to examine the other pleas put forward by Esso in support of its action for annulment.

Procedure before the Court and forms of order sought

Procedure before the Court

39 By document lodged at the Court Registry on 13 December 2018 on the basis of the second paragraph of Article 40 of the Statute of the Court of Justice of the European Union, the European Coalition to End Animal Experiments ('ECEAE') applied for leave to intervene in support of the form of order sought by Esso.

40 By document lodged at the Court Registry on 17 December 2018 on the same basis, Higher Olefins and Poly Alpha Olefins REACH Consortium ('HOPA REACH') and Higher Olefins & Poly Alpha Olefins vzw ('HOPA') also applied for leave to intervene in support of the form of order sought by Esso.

41 By order of 12 March 2019, the President of the Court granted ECEAE, HOPA and HOPA REACH leave to intervene in the proceedings.

42 By letter of 28 February 2020, the Court informed the parties that it intended to hold a hearing and asked them to answer certain questions at that hearing.

43 By letter of 3 April 2020, the Court asked the parties to state whether they wished to forego the hearing in view of the health crisis.

44 By letter of 23 April 2020, the Court informed the parties that, since they had notified the Court of their wish to forego the hearing in view of the health crisis, it was decided to forego that hearing. The Court also asked the parties to reply in writing to questions put to them in preparation for that hearing, and the parties complied with that request within the time limit prescribed.

Forms of order sought by the parties

45 By its appeal, the Federal Republic of Germany, supported by the French Republic and the Kingdom of the Netherlands, claims that the Court should:

– set aside the judgment under appeal;

– give final judgment in the dispute by dismissing the action; and

– order Esso to pay the costs incurred at first instance and at the appeal stage.

46 Esso, supported by ECEAE, HOPA, HOPA REACH and ECHA, contends that the Court should dismiss the appeal and order the Federal Republic of Germany to pay the corresponding costs.

The appeal

47 In support of its claims, the Federal Republic of Germany, supported by the Kingdom of the Netherlands and the French Republic, relies on two grounds of appeal challenging, respectively, the General Court's assessments of the admissibility and the merits of Esso's action for annulment.

The first ground of appeal

Arguments of the parties

48 The Federal Republic of Germany, supported by the French Republic and the Kingdom of the Netherlands, submits that the General Court committed three sets of errors of law in declaring Esso's action for annulment admissible.

49 In the first place, the letter at issue was not an act against which an action for annulment could be brought, contrary to the General Court's finding in paragraph 72 of the judgment under appeal. Under this complaint, the Federal Republic of Germany states, first, that the General Court erred in law in failing to take sufficient account, in paragraphs 74, 75 and 80 of that judgment, of the fact that ECHA had not intended that letter to produce binding legal effects. Next, it claims that the title and wording of that letter, as examined in paragraphs 64 to 71 of the judgment under appeal, demonstrate that legally it is not binding on Esso or the French competent authority, with the result that, in holding otherwise, the General Court erred in its legal characterisation of the facts. Finally, it submits that, in any event, the relevant legal provisions of the REACH Regulation were misinterpreted by the General Court in paragraphs 53 to 63 of that judgment and that an examination of those provisions should have led the General Court to conclude that, whatever its terms, the letter at issue was not capable of producing binding legal effects.

50 In the latter respect, the Federal Republic of Germany submits, in essence, that the letter at issue should be understood as an opinion meant for the French competent authority in which ECHA confined itself to making an informal assessment of the information provided by Esso, and not as a decision under Article 42 of the REACH Regulation that is legally binding on that authority and on Esso, as the General Court held. That article does not empower ECHA to carry out evaluations that produce binding legal effects for the economic operators concerned and the national competent authority. On the contrary, it is for the national competent authority exclusively to determine, in the light of ECHA's evaluation in a given case, whether it intends to adopt measures applicable to the economic operators concerned, and, if so, which, in accordance with Articles 125 and 126 of that regulation.

51 In the second place, the Federal Republic of Germany submits that Esso had no interest in bringing proceedings against the letter at issue since that letter imposed no new legal obligations on Esso besides those already resulting from the decision of 6 November 2012, contrary to what the General Court held in paragraphs 81 and 82 of the judgment under appeal. Under that decision, Esso was obliged to submit to ECHA, within a given time-frame, a set of information in order to bring its registration dossier into compliance with the requirements of the REACH Regulation. Furthermore, failure to comply with that obligation would, in itself, create a situation in which the provisions of that regulation were infringed, exposing Esso to the possibility that the French competent authority would adopt appropriate measures. Consequently, the declaration of non-compliance and the findings of infringements contained in the letter at issue did not in any way alter Esso's legal situation as already ensuing from the decision of 6 November 2012, irrespective of the fact that they were not binding on the French competent authority.

52 In the third and final place, the Federal Republic of Germany states that, if the letter at issue were to be classified as an act open to challenge against which Esso had an interest in bringing proceedings, the fact remains that Esso did not have standing to apply for the annulment of that letter since the letter was not of direct concern to it, within the meaning of the first part of the fourth paragraph of Article 263 TFEU, contrary to what the General Court held in paragraphs 91 to 94 of the judgment under appeal. Where ECHA decides to request information from an economic operator on the basis of Article 41(3) of the REACH Regulation and then finds that the information submitted does not comply with the requirements of that regulation, it is for the national competent authority alone, and therefore in the present case for the French authorities, to draw conclusions from that finding, in accordance with Articles 125 and 126 of that regulation.

53 In its answers to the questions put to it by the Court, the Federal Republic of Germany adds, in particular, that the adoption of a measure such as the letter at issue does not require a specific legal basis, since that measure is adopted as part of the advisory task which Article 77(1) of the REACH Regulation assigns to ECHA.

54 Esso, supported by ECEAE, HOPA and HOPA REACH, disputes, first, that the General Court's assessment that the letter at issue was intended to produce binding legal effects is vitiated by errors of law.

55 Secondly, Esso submits that the General Court was right to hold that those binding legal effects went beyond those produced by the decision of 6 November 2012.

56 Thirdly and finally, Esso denies the existence of an error of law relating to its standing and argues, in essence, that the letter at issue directly affects its legal situation in that it contains a finding of an infringement which is also binding on the French competent authority.

57 ECHA also contends that the ground of appeal should be rejected.

58 First, ECHA submits that it was on the basis of a correct analysis of the applicable legal framework and of ECHA's competences that the General Court found that the letter at issue produced binding legal effects.

59 Secondly, the General Court did not err in its approach or legal characterisation of the facts in holding, in the light of the content of that letter, that it was of direct concern to Esso.

60 Thirdly and finally, the General Court's analysis was consistent with the objectives pursued by the REACH Regulation.

Findings of the Court

61 As is apparent from paragraphs 48 to 52 above, the Federal Republic of Germany submits, in essence, that the General Court erred in law in holding, first, in paragraphs 49 to 80 of the judgment under appeal, that the letter at issue was an act against which an action for annulment could be brought, secondly, in paragraphs 81 and 82 of that judgment, that the letter was an act against which Esso had an interest in bringing proceedings and, thirdly, in paragraphs 91 to 94 of that judgment, that the letter was of direct concern to Esso.

62 It is necessary to examine those three complaints in turn.

– *The existence of an act open to challenge*

63 It follows from the settled case-law of the Court that an action for annulment may be brought, on the basis of the first paragraph of Article 263 TFEU, against any provision or measure adopted by the institutions, bodies, offices or agencies of the Union, whatever form it may take, which is intended to produce binding legal effects capable of affecting the interests of a natural or legal person by bringing about a distinct change in their legal position (judgments of 11 November 1981, *IBM* v *Commission*, 60/81, EU:C:1981:264, paragraph 9; of 12 September 2006, *Reynolds Tobacco and Others* v *Commission*, C-131/03 P, EU:C:2006:541, paragraph 54; and of 31 January 2019, *International Management Group* v *Commission*, C-183/17 P and C-184/17 P, EU:C:2019:78, paragraph 51).

64 Furthermore, in order to determine, in a given case, whether the contested act is intended to produce binding legal effects, it is necessary to examine the substance of the act and to assess its effects in the light of objective criteria, such as the content of the act in question, taking into account, as appropriate, the context in which it was adopted and the powers of the Union institution, body, office or agency which adopted it (judgments of 13 February 2014, *Hungary* v *Commission*, C-31/13 P, EU:C:2014:70, paragraph 55; and of 9 July 2020, *Czech Republic* v *Commission*, C-575/18 P, EU:C:2020:530, paragraph 47). Those powers should not be understood in the abstract, but should be regarded as factors that inform the specific analysis of the content of the act in question, which is central and indispensable (see, to that effect, judgment of 25 October 2017, *Romania* v *Commission*, C-599/15 P, EU:C:2017:801, paragraphs 49, 51 to 52 and 55).

65 Lastly, while it is clear from the Court's case-law that it is also possible to take into consideration a subjective criterion relating to the intention that led the institution, body, office or agency of the Union which drafted the contested act to adopt it (see, to that effect, 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), it follows from the preceding paragraph that that subjective criterion can play only a complementary role as compared with the objective criteria referred to in that paragraph and, therefore, cannot be given greater weight than those objective criteria, nor can it affect the assessment of the effects of the resulting contested act.

66 In the present case, having regard to the arguments of the Federal Republic of Germany referred to in paragraph 49 above, it should be noted, first, that it is clear from paragraphs 74, 75 and 80 of the judgment under appeal that the General Court took into consideration the intention that led ECHA to adopt the letter at issue, while giving that subjective criterion less weight than the objective criteria relating to the letter's content and the powers conferred on ECHA by the relevant provisions of the REACH Regulation, which the General Court had previously examined.

67 That assessment of those subjective and objective criteria cannot be regarded as vitiated by an error of law, in the light of the case-law cited in paragraph 65 above.

68 Secondly, the General Court held, in paragraphs 64 to 71 of the judgment under appeal, that, in view of its content, the letter at issue should be regarded as an act that was intended to produce binding legal effects as regards Esso. More specifically, the General Court found, in essence, that the letter was such as to bring about a distinct change in Esso's legal situation in that it contained, first, a definitive evaluation of Esso's registration dossier and a definitive compliance check of the information submitted to ECHA to complete it, next, a declaration that some of that information did not comply with the requirements of the REACH regulation and, finally, a number of findings that provisions of that regulation had been infringed by Esso. Furthermore, the General Court pointed out that that letter asked the French competent authority to take the measures required by that situation.

69 Having regard to the wording of the letter at issue and the document annexed thereto, as set out in paragraphs 29 to 31 above, the General Court's assessments relating to the letter's content cannot be regarded as vitiated by an error in the legal characterisation of the facts. The wording of the letter demonstrates that it was intended to produce not only binding legal effects such as to bring about a distinct change in Esso's legal situation, for the reasons rightly highlighted by the General Court, but also binding legal effects as regards the French competent authority, by asking it to adopt the measures that that legal situation required.

70 Thirdly and finally, the Federal Republic of Germany submits, in essence, that, whatever assessment might result from considering in isolation the content of the letter at issue, it should in fact be understood, having regard to the provisions of the REACH Regulation concerning ECHA's relevant powers, as an opinion addressed to the French competent authority and, as such, devoid of binding legal effects of any kind.

71 In that regard, the General Court held, in paragraph 72 of the judgment under appeal, that, in view of its content, as summarised in paragraph 68 above, the letter at issue corresponded to a decision that ECHA was required to prepare and adopt pursuant to Article 42(1) of the REACH Regulation, in the context of an evaluation carried out under Article 41 of that regulation.

72 As set out in paragraphs 54 to 58 and 60 to 61 of the judgment under appeal, the General Court held, in essence, that those two provisions are to be interpreted in the light of their context, in the sense that the EU legislature conferred on ECHA exclusive competence to evaluate the registration dossiers which Article 6 of the REACH Regulation requires manufacturers and importers of substances in quantities of one tonne or more per year to submit. Furthermore, the General Court held that, for the purposes of exercising that competence, ECHA has the power not only to check the compliance with the requirements of the REACH Regulation of the information submitted by registrants, but also to draw legally binding conclusions from that evaluation and compliance check. Finally, the General Court stated that such legally binding conclusions may take the form of, first, a declaration of non-compliance of all or part of the information submitted by the registrant, secondly, findings that the registrant has infringed relevant requirements of the REACH Regulation and, thirdly, a request made to the competent national authority to adopt the measures required by that situation.

73 Accordingly, the General Court stated, in paragraphs 59 and 61 of the judgment under appeal, that those provisions do not confer on the Member States any competence to assess the compliance of registration dossiers, and that the Member States are empowered, under Articles 125 and 126 of the REACH Regulation, only to carry out checks and impose penalties in order to ensure compliance with declarations of non-compliance and findings that provisions of that regulation have been infringed previously made by ECHA.

74 In that regard, it follows from Article 41(1) of the REACH Regulation that ECHA is competent to evaluate registration dossiers for substances which must be submitted to it by manufacturers or importers of those substances, as the General Court rightly pointed out in paragraphs 53 and 54 of the judgment under appeal.

75 In particular, as is clear from subparagraphs (a) and (b) of that provision, such an evaluation is intended to cover, inter alia, whether the information in registration dossiers complies with the requirements of that regulation and, where the registrant has submitted alternative information to that prescribed, referred to as 'adaptations', whether the adaptations comply with the rules governing them.

76 In the event that that evaluation leads ECHA to find that some of the information in the registration dossier does not comply with the requirements of the REACH Regulation, ECHA is empowered to take a decision under Article 41(3) of that regulation, requiring the registrant to submit specified information to ECHA, by the deadline set, in order to bring the registration dossier into compliance, as rightly stated in paragraphs 55 and 56 of the judgment under appeal.

77 As regards the next part of the procedure, Article 42(1) of the REACH Regulation provides that ECHA is to examine any information submitted by the registrant in consequence of such a decision and that, if necessary, it is to draft any appropriate decisions, as pointed out by the General Court in paragraph 57 of the judgment under appeal.

78 It follows from the clear wording of that provision that ECHA has not only the power but also the obligation to examine any information submitted by the registrant in consequence of a decision taken under Article 41(3) of the REACH Regulation.

79 It is also clear from Article 42(1) of that regulation that, following such an examination, ECHA is empowered to 'draft any appropriate decisions in accordance with [Articles 40 and 41 of that regulation], if necessary'.

80 However, neither Article 42(1) of the REACH Regulation nor the articles to which that provision refers explicitly specify what is meant by 'appropriate decisions'.

81 Therefore, in accordance with the settled case-law of the Court, in interpreting the provision in question, it is necessary to consider not only its wording but also the context in which it occurs and the objectives pursued by the rules of which it is part (judgments of 7 June 2005, *VEMW and Others*, C-17/03, EU:C:2005:362, paragraph 41; and of 4 February 2016, *C & J Clark International and Puma*, C-659/13 and C-34/14, EU:C:2016:74, paragraph 124), as informed, where necessary, by the preparatory work for those rules (see, by analogy, judgments of 9 December 2019, *Nederlands Uitgeversverbond and Groep Algemene Uitgevers*, C-263/18, EU:C:2019:1111, paragraph 56; and of 11 March 2020, *Baltic Cable*, C-454/18, EU:C:2020:189, paragraph 48).

82 In that regard, first, it is apparent from the expression 'any appropriate decisions' in Article 42(1) of the REACH Regulation that the EU legislature has conferred on ECHA the power to draw legally binding conclusions after examining the information submitted by a registrant who has been notified of a decision taken under Article 41(3) of that regulation, to the extent that those conclusions are deemed appropriate.

83 Where such a measure follows a decision requiring a registrant to bring the information in its registration dossier into compliance with the requirements of the REACH Regulation, as set out in paragraph 76 above, that measure is intended to determine, first of all, whether the information submitted complies with the requirements in question and, consequently, whether the registrant has complied with the corresponding obligations. As held by the General Court, those obligations are not limited to the obligation to comply with the decision requiring the submission of that information, but ultimately also include the obligation on manufacturers and importers of substances in quantities of one tonne or more per year to comply with all the requirements applicable to the registration of those substances under Article 5 and Article 6(1) of that regulation. As the Court has previously held, the EU legislature introduced the registration and evaluation system laid down by that regulation in order to allow ECHA to determine that industry is meeting its obligations (see, to that effect, judgments of 10 September 2015, *FCD and FMB*, C-106/14, EU:C:2015:576, paragraph 32; and of 17 March 2016, *Canadian Oil Company Sweden and Rantén*, C-472/14, EU:C:2016:171, paragraph 25), chief among them being the obligation set out in Article 5, the infringement of which renders the economic operators concerned liable to penalties, in accordance with Article 126 of that regulation (see, to that effect, judgment of 27 April 2017, *Pinckernelle*, C-535/15, EU:C:2017:315, paragraph 46).

84 Next, an examination of the context of Article 42(1) of the REACH Regulation reveals that, if ECHA declares that information submitted in consequence of a decision taken under Article 41(3) of that regulation does not comply with the requirements of the regulation and finds that the registrant

concerned has infringed the relevant provisions, such a declaration and finding are binding not only on the registrant but also on the competent national authority, contrary to the submission made by the Federal Republic of Germany.

85 First, Article 42(2) of the REACH Regulation states that once the dossier evaluation is completed, ECHA is to notify the Commission and the national competent authority of the information obtained and 'any conclusions made', which include that declaration and finding. In the present case, ECHA notified the French competent authority by sending it the letter at issue, as the General Court rightly noted in paragraphs 64, 67 and 70 of the judgment under appeal.

86 Second, Articles 125 and 126 of the REACH Regulation, which are to be construed in the light of recitals 121 and 122 of that regulation, require the Member States to establish a system of penalties 'applicable for infringements of the provisions' of that regulation and to take the measures necessary to ensure that they are implemented. Such implementation in a given case necessarily presupposes a finding that those provisions have been infringed, which, as pointed out above, falls within the exclusive competence of ECHA, except in cases where that competence is transferred to the Commission, as provided for in Article 51 of that regulation and referred to by the General Court in paragraph 60 of the judgment under appeal.

87 Accordingly, an examination of the wording of Article 42(1) of the REACH Regulation, construed in the light of its context, reveals that it confers on ECHA, and not on the national authorities responsible for ensuring compliance with that regulation, the power to adopt a decision such as that contained in the letter at issue, as the General Court rightly held in the judgment under appeal.

88 Finally, as regards the objectives pursued by the REACH Regulation, to which the General Court did not refer in that judgment, the Court has previously pointed out that they include, as follows from Article 1(1) of that regulation, that of ensuring a high level of protection of human health and the environment by means of an integrated system for monitoring manufactured chemical substances, imported or placed on the market in the Union, based on the registration, evaluation and authorisation of those substances and possible restrictions on their use (judgments of 10 September 2015, *FCD and FMB*, C-106/14, EU:C:2015:576, paragraphs 31 and 32; of 17 March 2016, *Canadian Oil Company Sweden and Rantén*, C-472/14, EU:C:2016:171, paragraphs 24 and 25; and of 15 March 2017, *Polynt* v *ECHA*, C-323/15 P, EU:C:2017:207, paragraph 20).

89 As is apparent from Article 75 and recital 15 of the REACH Regulation, one of the essential elements of that system is the establishment, as a Union body, of a central and independent entity responsible for ensuring the efficient management of certain administrative, technical and scientific aspects of that regulation.

90 In particular, as is apparent from Articles 6, 20, 22, 41 and 42 of the REACH Regulation and from recitals 19, 20 and 44 of that regulation, in the light of which those articles are to be construed, it is on ECHA that the EU legislature has conferred the competence, first, to receive applications for registration of substances and updates to those applications, secondly, to check that they are complete and to reject them if they are incomplete and, finally, to check the compliance of the information they contain with the relevant requirements, if necessary after they are completed.

91 That centralised procedure for the registration of substances and the evaluation of the corresponding dossiers, which is under the exclusive responsibility of ECHA, differs from the evaluation of the substances themselves, primary responsibility for which lies with the Member States, as is clear from Article 45 and recitals 20 and 66 of the REACH Regulation, without prejudice to the coordinating role which that article assigns to ECHA, as an independent body, and the powers attached to it.

92 As the Advocate General noted, in essence, in point 92 of his Opinion, that distribution of roles and the ensuing allocation of competences and powers are the result of a choice by the EU legislature, as demonstrated by the preparatory work for the REACH Regulation.

93 Accordingly, the objectives pursued by the REACH Regulation support the interpretation of Article 42(1) of that regulation set out in paragraph 87 above.

94 It follows that, having regard to ECHA's powers under the REACH Regulation, construed in the light of their context and the objectives pursued by that regulation, the General Court was correct to conclude, in paragraph 72 of the judgment under appeal, that, in view of its content, the letter at issue corresponded to a decision implementing Article 42(1) of that regulation and, as such, was intended to produce binding legal effects capable of bringing about a distinct change in Esso's legal situation.

95 Consequently, that letter cannot be regarded as an opinion addressed to the French competent authority, issued as part of the advisory task which Article 77(1) of the REACH Regulation assigns to ECHA.

96 Accordingly, the arguments of the Federal Republic of Germany seeking to call in question the existence of an act open to challenge must be dismissed as unfounded.

– *The existence of an interest in bringing proceedings*

97 It should be noted at the outset that, although the Federal Republic of Germany expressly criticises the General Court for having erred in law in finding, in paragraphs 81 and 82 of the judgment under appeal, that Esso had an interest in bringing proceedings, no position is taken in those paragraphs on that issue. The General Court merely states, in essence, that the letter at issue is an act against which an action may be brought since it contains new matters of fact and law as compared with the decision of 6 November 2012 and therefore cannot be described as a 'confirmatory act' in respect of that decision.

98 In those circumstances, it should be pointed out that, first, in so far as the Federal Republic of Germany seeks to argue that the General Court should have classified the letter at issue as an act confirming the decision of 6 November 2012, it follows from the Court's case-law that a measure is to be regarded as such when it contains no new factual or legal elements as compared with the earlier measure (judgment of 31 January 2019, *International Management Group* v *Commission*, C-183/17 P and C-184/17 P, EU:C:2019:78, paragraph 67 and the case-law cited).

99 In the present case, as the General Court stated in paragraphs 81 and 82 of the judgment under appeal, the letter at issue contained new assessments and conclusions made by ECHA that were arrived at after it had examined the information submitted to it by Esso in reply to the decision of 6 November 2012.

100 Those new matters of fact and law show that the letter at issue could not be regarded as an act confirming the decision of 6 November 2012.

101 Second, in so far as the Federal Republic of Germany seeks to argue that Esso had no interest in bringing proceedings, it follows from the Court's case-law that any action for annulment brought by a natural or legal person must be based on an interest on the part of the applicant in bringing proceedings (see, to that effect, order of 24 September 1987, *Vlachou* v *Court of Auditors*, 134/87, EU:C:1987:388, paragraph 8) and that non-compliance with that essential prerequisite, which it is for that natural or legal person to prove, constitutes an absolute bar to proceeding with a case, which the EU judicature may raise of its own motion at any time (see, to that effect, orders of 7 October 1987, *G. d. M.* v. *Council and ETUC*, 108/86, EU:C:1987:426, paragraph 10; and of 21 July 2020, *Abaco Energy*

and Others v *Commission*, C-436/19 P, not published, EU:C:2020:606, paragraph 80), as well as the conditions of admissibility laid down in Article 263 TFEU (order of 15 April 2010, *Makhteshim-Agan Holding and Others* v *Commission*, C-517/08 P, not published EU:C:2010:190, paragraph 54 and the case-law cited).

102 Consequently, the Federal Republic of Germany is entitled to claim before the Court that Esso had no interest in bringing proceedings before the General Court against the letter at issue.

103 It also follows from the Court's case-law that the existence of an interest in bringing proceedings presupposes that annulment of the contested act must be capable of procuring an advantage for the natural or legal person who brought the action (see, to that effect, judgments of 17 September 2009, *Commission* v *Koninklijke FrieslandCampina*, C-519/07 P, EU:C:2009:556, paragraph 63; and of 31 January 2019, *Islamic Republic of Iran Shipping Lines and Others* v *Council*, C-225/17 P, EU:C:2019:82, paragraph 30).

104 In the present case, it follows from paragraphs 68 and 69 above that the letter at issue, which was adopted on the basis of Article 42(1) of the REACH Regulation, produced binding legal effects as regards Esso, in that ECHA considered that the information submitted to it by that company did not comply with the requirements of that regulation and therefore imputed to Esso a series of infringements of the relevant provisions of that regulation.

105 It follows that the annulment of that letter, in view of the legally binding declaration and findings it contains, is, in itself, capable of procuring an advantage for Esso.

106 Accordingly, the Federal Republic of Germany's claim that Esso had no interest in bringing proceedings is unfounded.

– *The existence of* locus standi

107 As regards the question whether the General Court erred in law in holding that the letter at issue was of direct concern to Esso, within the meaning of the first part of the fourth paragraph of Article 263 TFEU, it is settled case-law that the requirement that a Union measure be of direct concern to the natural or legal person challenging it requires the fulfilment of two cumulative criteria, namely that the measure must, first, directly affect the legal situation of the individual and, secondly, leave no discretion to the addressees of that measure who are entrusted with the task of implementing it, such implementation being purely automatic and resulting solely from EU rules alone without the application of other intermediate rules (judgments of 5 May 1998, *Dreyfus* v *Commission*, C-386/96 P, EU:C:1998:193, paragraph 43, and of 3 December 2019, *Iccrea Banca*, C-414/18, EU:C:2019:1036, paragraph 66).

108 In the present case, the General Court held, first, that the letter at issue directly affected Esso's legal situation by finding that Esso had infringed some of its obligations under the REACH Regulation by submitting to ECHA information that did not comply with the requirements of that regulation, as is apparent from paragraph 92 of the judgment under appeal and the paragraphs referred to therein.

109 That finding is untainted by any error of law, as follows from paragraphs 104 and 105 above.

110 Furthermore, the General Court stated, in paragraph 93 of the judgment under appeal, that ECHA's finding was binding on the French competent authority, which had discretion only as regards the nature and quantum of the penalties that could be imposed on Esso for the infringements of the REACH Regulation that were imputed to it.

111 As follows from paragraphs 84 to 87 above, that assessment is consistent with the allocation of competences between ECHA and national authorities under the REACH Regulation. A decision such as the letter at issue is binding, automatically and without the application of other intermediate rules, on the Member State to which it is addressed and, within that Member State, on the competent national authority, which is exclusively called upon to adopt measures to ensure compliance with it, in accordance with Articles 125 and 126 of that regulation.

112 Accordingly, the arguments of the Federal Republic of Germany that the General Court erred in law in holding that the letter at issue was of direct concern to Esso, within the meaning of the first part of the fourth paragraph of Article 263 TFEU, must be rejected as unfounded.

113 It follows that the first ground of appeal must be dismissed in its entirety as unfounded.

The second ground of appeal

Arguments of the parties

114 The Federal Republic of Germany, supported by the French Republic and the Kingdom of the Netherlands, submits that the General Court misapplied Article 42(1) of the REACH Regulation. It refers, in this context, to paragraphs 57, 58, 60 to 63, 71, 78, 108 and 112 of the judgment under appeal.

115 First, it submits that the General Court was wrong to hold that Article 42(1) of the REACH Regulation was applicable in the present case, on the basis of a misinterpretation of that provision according to which that provision requires ECHA, in principle, to carry out, by way of a decision, a compliance check of all the information submitted to it by economic operators in consequence of a decision taken under Article 41(3) of that regulation, unless that information is manifestly unreasonable. It should be inferred from the wording of those provisions, inter alia, that where ECHA notifies an economic operator of a decision asking it to submit specific information and that operator provides ECHA with alternative information, ECHA may confine itself to declaring that the person concerned has not complied with its decision, without the need to carry out any compliance check of the alternative information in question. In the present case, the General Court expressly found that Esso had not submitted to ECHA the information requested by the decision of 6 November 2012, but instead had submitted alternative information, and the General Court omitted to draw from that finding the legal conclusion that there was no need for a compliance check.

116 Secondly, the interpretation adopted by the General Court is also incompatible with the objective of protecting human health and the environment pursued by the REACH Regulation and with the legislative context of Article 42(1) of that regulation. That interpretation would require ECHA to carry out a compliance check of the information submitted to it by economic operators, even if that information is different from the information that was specifically requested, by means of a lengthy procedure that would lead to long delays during which substances potentially dangerous to human health could continue to be manufactured, imported or placed on the market in the Union. In addition, the provisions of the REACH Regulation do not allow economic operators which have been specifically requested to produce a study involving animal testing, by means of a decision taken under Article 41(3) of that Regulation, to submit alternative information to ECHA.

117 Thirdly, general EU administrative law precludes a requirement that ECHA check the compliance of information submitted to it by economic operators where that information is different from the information specifically requested by means of a decision taken under Article 41(3) of the REACH Regulation, as the General Court required ECHA to do. That requirement is tantamount to calling in question such a decision.

118 Fourthly and finally, the interpretation adopted by the General Court is liable indefinitely to prolong the processing of registration dossiers which ECHA is to select under Article 41(5) of the REACH Regulation in order to check their compliance with the requirements of that regulation. Furthermore, it is liable to hinder the exercise of the competences conferred on national authorities by Articles 125 and 126 of that regulation.

119 Esso and ECHA, supported by ECEAE, HOPA and HOPA REACH, state, in essence, that the interpretation of Article 42(1) of the REACH Regulation proposed by the Federal Republic of Germany is contrary to the title and wording of that provision, its context and the objectives pursued by that regulation.

120 In addition, they state that the arguments of the Federal Republic of Germany based on general EU administrative law and the need to ensure the effectiveness of the registration dossier evaluation procedure established by the REACH Regulation are unfounded.

Findings of the Court

121 The Federal Republic of Germany submits, in essence, that even if Esso's action is admissible, the General Court erred in law in upholding Esso's first plea alleging that ECHA had not complied with the detailed arrangements relating to the exercise of the decision-making competence provided for in Article 42(1) of the REACH Regulation and, consequently, in annulling the letter at issue.

122 It takes the view that, where ECHA takes a decision under Article 41(3) of the REACH Regulation asking an economic operator to submit to it a study involving animal testing, and the person concerned submits alternative information to such a study, ECHA must confine itself to finding that the information submitted is not that requested and cannot check that it complies with the requirements of that regulation.

123 In that regard, as pointed out in paragraphs 78 and 79 above, it follows from Article 42(1) of the REACH Regulation that, where ECHA has taken a decision under Article 41(3) of that Regulation requesting a registrant to submit information to it, it must, first, 'examine any information submitted' by that registrant in consequence of that decision in order to check that it complies with the relevant requirements of that regulation and, secondly, 'draft any appropriate decision' on the matter 'if necessary'.

124 While the first of those obligations is of a general nature, in that it applies to 'any information submitted' to ECHA, the wording of Article 42(1) of the REACH Regulation does not rule out that that provision may be interpreted, as the Federal Republic of Germany maintains, to mean that such a general obligation applies only where the information submitted by the registrant corresponds to that requested by ECHA and not, therefore, where ECHA has specifically requested a study involving animal testing and, in reply, the registrant has provided information alternative to such a study.

125 In those circumstances, and in accordance with the case-law cited in paragraph 81 above, that provision should be construed in the light of its context and the objectives pursued by the REACH Regulation.

126 As regards, first, the context of Article 42(1) of the REACH Regulation, it should be noted that, pursuant to Article 41(1)(a) and (b) of that regulation, the obligation on ECHA to evaluate substance registration dossiers that are submitted to it and to check the compliance of the information contained therein relates not only to the question whether that information complies with the 'requirements' laid down by the relevant provisions of that regulation, but also, if a registrant has

submitted 'adaptations of the standard information requirements and the related justifications', whether those adaptations and the related justifications comply with the rules governing them, as set out in the annexes to that regulation.

127 That obligation to evaluate and check reflects the possibility that all registrants have, under those annexes, to submit with their registration dossier alternative information, referred to as 'adaptations' to the 'standard information' prescribed by the relevant provisions of the REACH Regulation, subject to compliance with the requirements governing such adaptations. As is apparent from recitals 18 and 19 of that regulation, that possibility itself reflects the EU legislature's decision to establish a system for the registration and evaluation of chemical substances in which responsibility for the risks associated with those substances and the obligation to submit all the information necessary for their registration and evaluation lies with the natural or legal persons that manufacture, import or place those substances on the market in the Union.

128 Next, it is true that no specific provision of the REACH Regulation stipulates whether the possibility thus given to registrants to have recourse to 'adaptations' at the initial stage of the procedure for the registration and evaluation of substances that involves the submission of a registration dossier to ECHA also applies to subsequent stages of that procedure, in particular where ECHA has taken a decision under Article 41(3) of that regulation requiring a registrant to complete its registration dossier with a study involving animal testing.

129 Nevertheless, that possibility arises from the relevant general provisions of the REACH Regulation and from the guiding principle of limiting animal testing which those general provisions reflect, as the Advocate General noted in point 153 of his Opinion.

130 In particular, Article 13 of that regulation, headed 'General requirements for generation of information on intrinsic properties of substances', expressly provides in paragraph 1 that 'information on intrinsic properties of substances may be generated by means other than [animal] tests, provided that the conditions set out in Annex XI [to that regulation] are met'. In addition, that provision states that, 'in particular for human toxicity, information shall be generated whenever possible by means other than vertebrate animal tests, through the use of alternative methods, for example, in vitro methods or qualitative or quantitative structure-activity relationship models or from information from structurally related substances (grouping or read-across)'.

131 Similarly, Article 25 of the REACH Regulation, headed 'Objectives and general rules', states in paragraph 1 that 'in order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort'.

132 It follows from those general provisions, which are to be construed in the light of recital 47 of the REACH Regulation, according to which 'it is necessary to replace, reduce or refine testing on vertebrate animals', that a registrant has, generally and therefore especially where ECHA issues it with a decision asking it to complete its registration dossier with a study involving animal testing, not simply the possibility but the obligation to generate information obtained by means other than animal testing 'whenever possible' and to undertake such testing 'only as a last resort'.

133 As regards, secondly, the objectives pursued by the REACH Regulation, they include, inter alia, the objective of ensuring a high level of protection of human health and the environment, including the promotion of alternative methods for the assessment of hazards of substances, as is clear from Article 1(1) of that regulation.

134 That provision reveals that the use of alternative methods to animal testing is one of the means favoured by the REACH Regulation for evaluating the toxicity of substances in humans (see, to that effect, judgment of 21 July 2011, *Etimine*, C-15/10, EU:C:2011:504, paragraph 108) and that such use contributes, on that basis, to the attainment of the objective of protecting human health and the

environment which underlies the entire registration and evaluation procedure established by that regulation (see, to that effect, judgment of 7 July 2009, *S.P.C.M. and Others*, C-558/07, EU:C:2009:430, paragraphs 45 to 47).

135 In the light of all of those factors, the General Court was right to refer, in paragraph 62 of the judgment under appeal, to the possibility available to a registrant which has been asked by ECHA to supplement its registration dossier with a study involving animal testing to comply with the obligation under Articles 13 and 25 of the REACH Regulation by submitting, in reply to that request, alternative information to such a study.

136 Similarly, the General Court was right to conclude, in paragraphs 62 and 63 of the judgment under appeal and, by reference, in paragraph 108 of that judgment, that ECHA is under a corresponding obligation to check the compliance of such alternative information with the applicable requirements and, more specifically, to determine whether it is to be classified as adaptations in accordance with the rules laid down in the relevant annexes to the REACH Regulation.

137 Finally, the General Court was right to hold, in paragraphs 108, 109 and 112 of the judgment under appeal, that ECHA is required, where it is 'necessary' to prepare a decision pursuant to Article 42(1) of the REACH Regulation, to comply with the applicable requirements, as laid down in Articles 50 and 51 of that regulation.

138 Accordingly, the Federal Republic of Germany is not justified in maintaining that the General Court erred in law in interpreting Article 42(1) of the REACH Regulation in a manner incompatible with the context of that provision and the objectives of that regulation and in holding, on the basis of that interpretation, that the first plea put forward by Esso was well founded.

139 In the light of the arguments of the Federal Republic of Germany summarised in paragraphs 117 and 118 above, it should be added, first, that that interpretation also does not infringe general EU administrative law. Since it follows from the REACH Regulation that a registrant is generally obliged to use animal testing only as a last resort and that it may, where ECHA has decided to request a study involving such testing, comply with that obligation by providing alternative information, making use of that possibility cannot be regarded as calling in question that decision. On the contrary, the registrant remains obliged under that decision to submit the required study within the time limit prescribed, unless it can produce information which, while alternative, meets the requirements such that it can be classified as an 'adaptation', within the meaning of the relevant annexes to the REACH Regulation.

140 Secondly, the interpretation in question does not have the effect of prolonging indefinitely the processing of registration dossiers selected by ECHA under Article 41(5) of the REACH Regulation in order to check their compliance with the requirements of that regulation, or of hindering the exercise of the competences conferred on national authorities by Articles 125 and 126 of that regulation.

141 As follows from paragraphs 79, 82 and 83 above, ECHA has the power, after carrying out that check, not only to make a definitive finding that the information submitted to it does not comply with the applicable requirements, but also to decide that the registrant has thereby infringed certain of its obligations under the REACH Regulation, in particular its obligation to register, in accordance with those requirements, the substance which it manufactures, imports or places on the market in the Union. As is clear from Article 5 of that regulation, compliance with that obligation is a precondition for the continued manufacture, import or placing on the market in the Union of the substance in question.

142 That is, moreover, what ECHA did in adopting the letter at issue.

143 For their part, the national authorities have, in accordance with Articles 125 and 126 of the REACH Regulation, the duty to ensure that that decision is enforced and complied with and, to that end, inter alia, to carry out checks and impose effective, proportionate and dissuasive penalties (see, to that effect, judgment of 27 April 2017, *Pinckernelle*, C-535/15, EU:C:2017:315, paragraph 46).

144 In the light of all of the foregoing, the second ground of appeal is unfounded.

145 Accordingly, the appeal must be dismissed in its entirety.

Costs

146 Article 184(2) of the Rules of Procedure of the Court of Justice provides, inter alia, that where an appeal is unfounded, the Court is to make a decision as to costs.

147 Article 138(1) of the Rules of Procedure, which is applicable to appeal proceedings by virtue of Article 184(1) thereof, provides that the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings.

148 In the present case, since Esso and ECHA have applied for costs against the Federal Republic of Germany and the latter has been unsuccessful, it must be ordered to pay the costs incurred by those two parties.

149 Under Article 184(4) of the Rules of Procedure, the Court may decide that an intervener at first instance who takes part in the appeal proceedings is to bear its own costs.

150 In the present case, the French Republic and the Kingdom of the Netherlands must be ordered to bear their own costs.

151 Article 140(3) of the Rules of Procedure, which is applicable to appeal proceedings by virtue of Article 184(1) of the Rules of Procedure, provides, inter alia, that the Court may order interveners other than Member States or institutions to bear their own costs.

152 In the present case, ECEAE, HOPA and HOPA REACH must be ordered to bear their own costs.

On those grounds, the Court (Third Chamber) hereby:

1. **Dismisses the appeal.**

2. **Orders the Federal Republic of Germany to bear its own costs and to pay those incurred by Esso Raffinage and the European Chemicals Agency (ECHA).**

3. **Orders the French Republic, the Kingdom of the Netherlands, the European Coalition to End Animal Experiments, Higher Olefins and Poly Alpha Olefins REACH Consortium and Higher Olefins & Poly Alpha Olefins vzw to bear their own costs.**

Prechal Lenaerts Wahl

Biltgen Rossi

Delivered in open court in Luxembourg on 21 January 2021.

A. Calot Escobar
Registrar

A. Prechal
President of the Third Chamber