



Reports of Cases

JUDGMENT OF THE GENERAL COURT (Fifth Chamber)

20 September 2019*

(REACH — Evaluation of substances — Benpat — Persistence — ECHA decision requesting further information — Article 51(6) of Regulation (EC) No 1907/2006 — Action brought before the Board of Appeal — Task of the Board of Appeal — Adversarial procedure — Nature of review — Intensity of review — Powers of the Board of Appeal — Article 93(3) of Regulation No 1907/2006 — Conferral of powers on EU agencies — Principle of conferral — Principle of subsidiarity — Proportionality — Obligation to state reasons)

In Case T-755/17,

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

applicant,

v

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

defendant,

supported by

European Commission, represented by M. Konstantinidis, R. Lindenthal and M. Noll-Ehlers, acting as Agents,

and by

Envigo Consulting Ltd, established in Huntingdon (United Kingdom),

Djchem Chemicals Poland S.A., established in Wołomin (Poland),

represented by R. Cana, É. Mullier and H. Widemann, lawyers,

interveners,

ACTION under Article 263 TFEU for the partial annulment of Decision A-026-2015 of the Board of Appeal of the ECHA of 8 September 2017, in so far as it partially annulled the decision of the ECHA of 1 October 2015 requiring the conduct of further testing concerning the substance benpat (CAS 68953-84-4),

* Language of the case: German.

THE GENERAL COURT (Fifth Chamber),

composed of D. Gratsias, President, I. Labucka and A. Dittrich (Rapporteur), Judges,

Registrar: E. Coulon,

gives the following

Judgment

I. Background to the dispute and the contested decision

- 1 Benpat (CAS 68953-84-4) is a multicomponent substance consisting of three very similar chemical substances. It is used as a stabiliser in industrial and consumer products made of rubber, such as tyres and pipes. It delays the alteration of the physical properties and appearance of rubber-based products caused by light and atmospheric oxygen.
- 2 The intervening companies, Envigo Consulting Ltd and Djchem Chemicals Poland S.A., are part of a consortium which, in 2010, registered benpat with the European Chemicals Agency (ECHA), for a tonnage of between 1 000 and 10 000 tonnes per year.
- 3 In 2013, benpat was included in the Community rolling action plan for evaluation within the meaning of Article 44 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, corrigendum OJ 2007 L 136, p. 3), due to grounds for concern relating to its persistent, bioaccumulative and toxic properties, and due to its wide dispersive use, in particular by consumers.
- 4 In accordance with Article 45 of Regulation No 1907/2006, the competent authority of the Federal Republic of Germany ('the designated authority') was appointed to conduct the evaluation of benpat.
- 5 In accordance with Article 46(1) of Regulation No 1907/2006, the designated authority established a draft decision, providing for requests for further information about benpat. That draft was forwarded to the ECHA on 20 June 2014.
- 6 On 28 August 2014, in accordance with Article 50(1) of Regulation No 1907/2006, the draft decision was notified to the registrants, including the intervening companies.
- 7 On 6 October 2014, the registrants submitted their observations on the draft decision.
- 8 The designated authority took those observations into account and notified a revised draft decision to the competent authorities of the other Member States and to the ECHA on 5 March 2015.
- 9 Three competent authorities of other Member States and the ECHA submitted proposals for amendment, pursuant to Article 51(2) of Regulation No 1907/2006, applicable *mutatis mutandis* in accordance with Article 52(2) of that regulation.
- 10 The designated authority examined those proposals and amended the draft decision. On 20 April 2015, the revised draft decision was sent to the Member State Committee.

- 11 On 8 May 2015, the registrants were heard with regard to the proposals of the Member States.
- 12 At the meeting which was held from 8 to 11 June 2015, the Member State Committee reached unanimous agreement for the purposes of Article 51(6) of Regulation No 1907/2006, applicable *mutatis mutandis* in accordance with Article 52(2) of that regulation, with regard to a revised proposal for a decision.
- 13 On 1 October 2015, on the basis of Article 51(6) of Regulation No 1907/2006, applicable *mutatis mutandis* in accordance with Article 52(2) of that regulation, the ECHA adopted a decision as part of the evaluation of benpat ('the ECHA decision').
- 14 By its decision, the ECHA requests the registrants to submit in particular the following information:
- simulation testing on ultimate degradation in surface water (testing method: aerobic mineralisation in surface water — simulation testing of biodegradation, EU C.25/OECD 309 ['method No 309']) as specified by point III.3 of that decision, using the R-898 constituent instead of benpat;
 - in the event that testing conducted according to method No 309 does not allow it to be determined whether benpat was persistent or very persistent in accordance with paragraphs 1.1.1 and 1.2.1 of Regulation No 1907/2006, further simulation testing of biodegradation in sediments (testing method: aerobic and anaerobic transformation in aquatic sediment systems, EU C.24/OECD 308 ['method No 308']), as specified by point III.4 of that decision, using the R-898 constituent instead of benpat.
- 15 In the ECHA decision, the deadline for providing the information requested was fixed as 8 April 2018.
- 16 On 23 December 2015, the intervening companies brought an action against the ECHA decision before the Board of Appeal of that agency, pursuant to Article 51(8) of Regulation No 1907/2006, applicable *mutatis mutandis* in accordance with Article 52(2) of that regulation, and Article 91(1) of that regulation.
- 17 In accordance with Article 91(2) of Regulation No 1907/2006, the action brought against the ECHA decision has suspensive effect.
- 18 On 8 March 2016, the ECHA lodged its defence before the Board of Appeal.
- 19 On 13 April 2016, the designated authority was granted leave to intervene before the Board of Appeal in support of the form of order sought by the ECHA.
- 20 On 2 June 2016, the intervening companies submitted their reply to the Board of Appeal. On 8 July 2016, the ECHA submitted its observations on that reply.
- 21 On 20 June 2016, the designated authority submitted the statement in intervention to the Board of Appeal. On 31 October 2016, the ECHA and the intervening companies submitted their observations on that statement.
- 22 On 27 April 2017, a hearing took place before the Board of Appeal.
- 23 Before the Board of Appeal, the intervening companies, in particular, requested that board to annul the ECHA decision in so far as it requested the conduct of testing in accordance with method No 309 and testing in accordance with method No 308, and in so far as, in its statement of reasons, it had been stated that benpat was bioaccumulative in accordance with Annex XIII to Regulation No 1907/2006.

- 24 For its part, the ECHA, supported by the designated authority, applied for the action before the Board of Appeal to be dismissed.
- 25 On 8 September 2017, the Board of Appeal adopted decision A-026-2015 ('the contested decision'). By that decision, it:
- annulled the ECHA decision in so far as it requested the registrants:
 - to identify, in the context of testing conducted in accordance with method No 309, metabolites of benpat;
 - to conduct testing conducted in accordance with method No 308;
 - decided that the claim concerning bioaccumulation in the grounds for that decision should be deleted;
 - dismissed the action before it as to the remainder; and
 - fixed 15 March 2020 as the deadline for the production of the remaining information derived from testing conducted in accordance with method No 309 required by that decision.

II. Procedure before the Court and forms of order sought by the parties

- 26 By application lodged at the Court Registry on 20 November 2017, the Federal Republic of Germany brought the present action.
- 27 On 8 March 2018, the ECHA filed its statement of defence.
- 28 By document lodged at the Court Registry on 21 March 2018, the European Commission sought leave to intervene in the present proceedings in support of the form of order sought by the ECHA. By decision of the President of the Chamber of 23 April 2018, it was granted leave to intervene.
- 29 By document lodged at the Court Registry on 21 March 2018, the intervening companies sought leave to intervene in the present proceedings in support of the form of order sought by the ECHA. By order of the President of the Chamber of 7 May 2018, they were granted leave to intervene.
- 30 On 24 April 2018, the Federal Republic of Germany lodged its reply.
- 31 On 18 June 2018, the ECHA lodged the rejoinder.
- 32 On 9 July 2018, the Commission lodged its statement in intervention. On 10 July 2018, the intervening companies lodged their statement in intervention. On 31 October 2018, the Federal Republic of Germany and the ECHA submitted their observations on those statements in intervention.
- 33 In the absence of a request for a hearing by the main parties within 3 weeks after service on the parties of notification of the close of the written part of the procedure, considering that it had sufficient information available to it from the material in the file, the Court (Fifth Chamber) decided to rule on the action without an oral part of the procedure in accordance with Article 106(3) of its Rules of Procedure.
- 34 The Federal Republic of Germany claims that the Court should:
- annul the contested decision, in so far as the Board of Appeal

- partially annulled the ECHA decision, and
- decided that the claim relating to bioaccumulation should be deleted from the grounds for that decision;
- order the ECHA to pay the costs.

35 The ECHA, the Commission and the intervening companies contend that the Court should:

- dismiss the action;
- order the Federal Republic of Germany to pay the costs.

III. Law

36 In support of the action, the Federal Republic of Germany puts forward six pleas. The first plea alleges that, by examining the pleas relating to the evaluation of benpat, the Board of Appeal acted outside the framework of its powers. In the context of the second plea, that Member State claims that, by acting that way, that board did not respect the case-law (judgments of 13 June 1958, *Meroni v High Authority*, 9/56, EU:C:1958:7, and of 13 June 1958, *Meroni v High Authority*, 10/56, EU:C:1958:8). By the third plea, it claims that, since European Union law does not contain a legal basis allowing that board to conduct such an examination, the latter infringed the rights of the Member States institutionalised through their decision-making power within the ECHA's Member State Committee and thus infringed the principle of subsidiarity and the principle of limited conferral of powers. The fourth plea alleges an infringement of the provisions of Regulation No 1907/2006 and is divided into two parts. The first seeks to demonstrate that the Board of Appeal was not competent to examine the pleas in the action before it concerning the substantive assessments relating to the evaluation of benpat and the second to demonstrate that, in the context of the assessment of the pleas concerning the substantive assessments relating to the evaluation of benpat, the Board of Appeal committed errors. In the context of the fifth plea, the Federal Republic of Germany claims that that board violated the duty to state reasons by failing to establish its alleged power of review. In the context of the sixth plea, it claims that the Board of Appeal's assessments at issue are wrong.

37 As a first step, it is necessary to examine the first to third pleas, and the first part of the fourth plea, which seek to demonstrate that the Board of Appeal was not competent to examine the pleas in the action before it concerning substantive assessments relating to the evaluation of benpat.

38 As a second step, the fifth plea, alleging that the Board of Appeal infringed the obligation to state reasons by not establishing its power of review will be examined.

39 As a third step, the second part of the fourth plea and the sixth plea will be examined, by which the Federal Republic of Germany alleges that, in the context of the examination of the pleas concerning substantive assessments relating to the evaluation of benpat, the Board of Appeal committed errors.

A. The first to third pleas, and the first part of the fourth plea, seeking to demonstrate that the Board of Appeal was not competent to examine the pleas in the action before it concerning substantive assessments relating to the evaluation of benpat

40 In the context of the first to third pleas and the first part of the fourth plea, the Federal Republic of Germany claims that the Board of Appeal should have dismissed the action before it as inadmissible in so far as the intervening companies had put forward pleas seeking to have the ECHA decision

reviewed to the extent that it contained substantive assessments relating to the evaluation of benpat. According to it, that board was not competent to rule on such pleas, but solely to review the existence of formal errors vitiating that decision.

- 41 The ECHA, the Commission and the intervening companies dispute those arguments. They maintain that the Board of Appeal is competent to examine the pleas in the action before it seeking to contest the merits of a decision taken as part of the evaluation of a substance. That examination is however not a new evaluation of the substance at issue.
- 42 As a first step, it is necessary to examine the Federal Republic of Germany's arguments relating to the respective roles of the Member State Committee, the ECHA and of the Board of Appeal. As a second step, the other arguments put forward by the Federal Republic of Germany will be examined.

1. The Federal Republic of Germany's arguments relating to the respective roles of the Member State Committee, the ECHA and the Board of Appeal

- 43 In the context of the first plea and the first part of the fourth plea, the Federal Republic of Germany claims that, under Article 51(3) or (6) of Regulation No 1907/2006, as applicable *mutatis mutandis* in accordance with Article 52(2) of that regulation, it is the Member States or the Member State Committee which are competent concerning the substantive assessments contained in a decision taken as part of the evaluation of a substance. The substance evaluation procedure is characterised in particular by the important role of Member States and of that committee within the ECHA. That committee is a genuine group of experts. Even if it involved an ECHA body, it would nevertheless be functionally independent from that agency. The Member States directly appoint the members of the committee in question and each Member State could give instructions to members appointed by it. That committee serves to involve the Member States at European Union level, by combining the competences of the Member States and of the Union. Representatives of the ECHA and of the Commission could assist at the meetings of the committee at issue, but only as observers. The importance of such a committee is apparent from Article 76(1)(e) of that regulation. The importance of collective agreement within that committee is apparent from recital 67 of that regulation. Such a committee should thus not be regarded as a decision-making body separate from the Member States, capable of replacing them, but as an instrument designed to encourage agreement between the latter.
- 44 Under Article 51(6) of Regulation No 1907/2006, as applicable *mutatis mutandis* in accordance with Article 52(2) of that regulation, the role of the ECHA is limited to ensuring coordination between the procedure and the work preparing and monitoring the decision-making and to formally adopting the decision, the contents of which are determined by the Member State Committee. That role is limited to ensuring respect for the procedural rules. That agency is bound by the agreement of the Member States and has no discretion in that regard. In the absence of unanimous agreement between the Member States or within the Member State Committee, it loses any decision-making power in favour of the Commission.
- 45 According to the Federal Republic of Germany, the particular role of the Member States or of the Member State Committee within the ECHA in the context of the substance evaluation procedure should not be circumvented in the appeal proceedings. In the context of an action against a decision taken as part of the evaluation of a substance, the Board of Appeal does not have more powers than the ECHA. The latter have parallel competences. That board, which is part of that agency, is also bound by the agreement of the Member States and has only the power to adopt a decision in conformity with the agreement reached by the Member States. It does not, in the case of decisions taken as part of the evaluation of a substance, have autonomous legitimacy identical to or even equivalent to that enjoyed by the ECHA as a whole thanks to the participation of the Member States in the agreement process. It cannot disregard an agreement between all the Member States. It is thus solely competent to review aspects other than the substantive assessments relating to the evaluation of

a substance, namely in particular potential breaches of the rules of procedure. It is not competent to take a decision on the merits of a decision adopted as part of the evaluation of a substance in the context of its examination of an action against such a decision. That interpretation is not called into question by Article 93(3) of Regulation No 1907/2006. That provision should be read in conjunction with Article 51 of that regulation, which provides for a ‘dualism’ between the ECHA and the Member States (outside of or within the Member State Committee).

- 46 Moreover, the Federal Republic of Germany states that, according to the approach it advocates, effective legal protection is ensured. There is a link between the Board of Appeal’s decision and the decision taken as part of the evaluation of a substance. Therefore, even if the merits of the latter decision could not be reviewed by the Board of Appeal, the EU Courts could, in the context of an action against a decision of the Board of Appeal, review the pleas relating to that evaluation, since a decision of that board upholding a decision taken as part of the evaluation of a substance would reproduce the findings of the latter decision on the merits.
- 47 The ECHA, the Commission and the intervening companies dispute those arguments.
- 48 First of all, it should be noted that, in accordance with Article 51(8) of Regulation No 1907/2006, applicable *mutatis mutandis* in accordance with Article 52(2) of that regulation, and in accordance with Article 91(1) of that regulation, ECHA decisions taken as part of the evaluation of a substance may be subject to an action before the Board of Appeal.
- 49 Moreover, neither the provisions of Regulation No 1907/2006, nor those of Commission Regulation (EC) No 771/2008 of 1 August 2008 laying down the rules of organisation and procedure of the Board of Appeal of the ECHA (OJ 2008 L 206, p. 5) contain express rules providing that that board is not competent to examine pleas seeking to demonstrate the existence of substantive errors vitiating an ECHA decision.
- 50 On the contrary, in the light of the elements examined in paragraphs 51 to 63 below, it is necessary to establish the Board of Appeal’s competence to examine pleas seeking to demonstrate the existence of substantive errors vitiating an ECHA decision.
- 51 In the first place, it should be noted that, under the first indent of the second sentence of Article 89(3) of Regulation No 1907/2006, the Chairperson of the Board of Appeal, its other members and its alternate members are appointed on the basis of the experience and expertise they possess in the field of chemical safety, natural sciences or regulatory and judicial procedures. Furthermore, under the second paragraph of Article 1(1) of Regulation No 771/2008, at least one member is to be legally qualified and at least one member is to be technically qualified in accordance with Commission Regulation (EC) No 1238/2007 of 23 October 2007 on laying down rules on the qualifications of the members of the Board of Appeal of the ECHA (OJ 2007 L 280, p. 10). Under Article 1(2) of the latter regulation, the technically qualified members and their alternates are to hold a university degree or an equivalent qualification and are to have substantial professional experience in hazard assessment, exposure assessment or risk management with regard to human health or environment risks of chemical substances or in related fields. That board thus has the necessary expertise at its disposal in order to itself carry out assessments of scientific evidence.
- 52 As is apparent in particular from recital 3 of Regulation No 771/2008, the Board of Appeal’s expertise seeks to ensure that a balanced assessment of both legal and technical aspects can be carried out by that board.
- 53 In the second place, in so far as the Federal Republic of Germany’s arguments relate to the particular characteristics of the procedure provided for the adoption of decisions as part of the evaluation of a substance, it must be noted that neither Regulation No 1907/2006 nor Regulation No 771/2008 provide for special rules concerning actions against such decisions.

- 54 In the third place, the objectives pursued by the possibility of bringing an action before the Board of Appeal against an ECHA decision plead in favour of an approach in accordance with which that board is competent to examine pleas seeking to demonstrate the existence of substantive errors vitiating such a decision.
- 55 Firstly, as is apparent from recital 3 of Regulation No 771/2008, one of the objectives pursued by the possibility to bring an action against ECHA decisions, in particular those adopted as part of the evaluation of substances, is to allow the addressees of such decisions to review those decisions not only concerning legal aspects, but also concerning technical aspects. Concerning those technical aspects, as a result of the competences of the members of the Board of Appeal, the intensity of the review conducted by that board is greater than that of a review carried out by the EU Courts.
- 56 Secondly, a limitation on the powers of the Board of Appeal such as that envisaged by the Federal Republic of Germany would have the result that that board could not fully perform its function, which is to limit litigation before the EU Courts, whilst guaranteeing a right to an effective remedy. In that context, it should also be noted that, as is apparent from recital 4 of Regulation (EU, Euratom) 2019/629 of the European Parliament and of the Council of 17 April 2019 amending Protocol No 3 on the Statute of the Court of Justice of the European Union (OJ 2019 L 111, p. 1), the introduction of rules concerning the admission of appeals in cases which have already been considered twice is based on the consideration that, in cases concerning decisions of the Board of Appeal of the ECHA, it is possible for them to be considered twice, namely initially by that board and, subsequently, by the Court.
- 57 In the fourth place, it should be noted that an approach in accordance with which the Board of Appeal is not competent to examine pleas which seek to demonstrate the existence of substantive errors vitiating an ECHA decision is not capable of ensuring an effective remedy for the purposes of Article 47(1) of the Charter of Fundamental Rights of the European Union.
- 58 It should be noted that, in accordance with the fifth paragraph of Article 263 TFEU, acts setting up bodies, offices and agencies of the Union may lay down specific conditions and arrangements concerning actions brought by natural or legal persons against acts of those bodies, offices or agencies intended to produce legal effects in relation to them. Article 94(1) of Regulation No 1907/2006 provides that, where there is a right of appeal before the Board of Appeal, the EU Courts could only rule on an action for annulment of the decision of that board.
- 59 An action for annulment of a Board of Appeal decision relates therefore to the lawfulness of such a decision.
- 60 In the context of an action against an ECHA decision requesting further information as part of the evaluation of a substance, the Board of Appeal is limited to examining, in adversarial proceedings, whether the arguments put forward before it are capable of demonstrating the existence of an error vitiating that decision (see, to that effect, judgment delivered today, *BASF Grenzach v ECHA*, T-125/17, paragraphs 59 to 86).
- 61 Contrary to what is claimed by the Federal Republic of Germany, it cannot be considered that, in so far as the Board of Appeal did not rule on the findings in the ECHA decision, those findings are an integral part of that board's decision and could thus be reviewed in the context of an action against that decision before the EU Courts.
- 62 It follows that, if the approach according to which the Board of Appeal is not competent to review pleas seeking to demonstrate the existence of substantive errors vitiating an ECHA decision were adopted, such pleas could not be usefully invoked in the context of an action against a decision of that board brought before the Court. Firstly, it would not be possible, before the Court, to validly

criticise that board for failing to examine pleas, the examination of which lay outside its competence. Secondly, even assuming that the ECHA decision is vitiated by a substantive error, such an error is not capable of calling into question the lawfulness of the decision of the board at issue.

- 63 In any event, even assuming that, as the Federal Republic of Germany claims, considerations included in the ECHA decision and on which the Board of Appeal has not ruled form an integral part of that board's decision, the approach advocated by that Member State could have the result that unnecessary actions must be brought before that board. As is apparent from the fifth paragraph of Article 263 TFEU and Article 94(1) of Regulation No 1907/2006, where it is possible to bring an action against an ECHA decision before the Board of Appeal, an action against that decision before the Court is inadmissible. Therefore, where an applicant wishes to have an ECHA decision annulled solely for reasons relating to substantive errors vitiating that decision, it would only have the option of bringing an action before the Board of Appeal, although such an action would, in such a case, be bound to fail.
- 64 In the light of the above considerations, it must be concluded that, contrary to what is claimed by the Federal Republic of Germany, the Board of Appeal was competent, in the present case, to examine the pleas seeking to demonstrate the existence of substantive errors vitiating the ECHA decision.

2. The other arguments put forward by the Federal Republic of Germany

- 65 It is by taking account of the considerations developed in paragraphs 48 to 64 above that it is necessary to examine the other arguments put forward by the Federal Republic of Germany.
- 66 In the first place, in the context of the first part of the fourth plea, the Federal Republic of Germany claims that, in the context of the procedure leading to the adoption of a decision as part of the evaluation of a substance, the Member States or the Member State Committee play a prominent role. By contrast, the ECHA's role is limited. In that context, the ECHA is limited to responding to legal questions or simple scientific questions. Since the ECHA is bound by the agreement between the Member States or within the Member State Committee, the Board of Appeal is not competent to review that agreement, but must respect it. Otherwise, the special role of the Member States or of the Member State Committee within the ECHA in the context of the procedure for evaluating substances would be undermined.
- 67 The ECHA, the Commission and the intervening companies dispute those arguments.
- 68 In that context, firstly, it should be noted that, where the designated authority considers that further information is not necessary, in accordance with Article 46(1) of Regulation No 1907/2006, it is to establish a draft decision within 12 months of the publication of the Community rolling action plan on the ECHA website for substances to be evaluated that year. The decision is then taken in accordance with the procedure set out in Articles 50 and 52 of that regulation.
- 69 Article 50 of Regulation No 1907/2006 governs the rights of registrants and of downstream users. Article 50(1) thereof provides that the ECHA is to notify the draft decision to the registrants or to the downstream users concerned. If the registrants or the downstream users concerned wish to submit comments, they are to send them to the ECHA within 30 days of the receipt. The latter in turn is to immediately inform the designated authority about the communication of comments. That authority is to take into account any comments received and may amend the draft decision accordingly.
- 70 In accordance with Article 52(1) of Regulation No 1907/2006, the designated authority is to circulate its draft decision, as well as the comments presented by the registrant or downstream user to the ECHA and to the competent authorities of the Member States.

- 71 According to Article 52(2) of Regulation No 1907/2006, the provisions of Article 51(2) to (8) of that regulation, relating to the adoption of decisions under dossier evaluation, are applicable *mutatis mutandis* to the adoption of decisions as part of the evaluation of a substance.
- 72 In accordance with Article 51(2) of Regulation No 1907/2006, the Member States may submit proposals for amendments to the draft decision within 30 days of circulation. If no proposal for amendment is sent to the designated authority, in accordance with Article 51(3) of that regulation, as applicable under Article 52(2) of that regulation, the ECHA is to take the decision in the version notified.
- 73 Where the designated authority receives proposals for amendments, it may amend the draft decision in accordance with the first sentence of Article 51(4) of Regulation No 1907/2006, as applicable in accordance with Article 52(2) of that regulation. Within 15 days of the end of the period of 30 days for the submission of comments, that authority is to refer a draft decision, together with any amendments proposed, to the Member State Committee and to the ECHA, in accordance with the second sentence of Article 51(4) of that regulation, as applicable in accordance with Article 52(2) of that regulation. Under Article 51(5) of the regulation at issue, as applicable in accordance with Article 52(2) of that regulation, it is to send it also to the registrants and downstream users concerned, who may submit their comments. If, within 60 days of the referral of the draft decision, the Member State Committee reaches unanimous agreement on that decision, in accordance with Article 51(6) of the regulation at issue, as applicable in accordance with Article 52(2) of the regulation at issue, the ECHA is to take the decision accordingly.
- 74 On the contrary, if the Member State Committee does not reach unanimous agreement, in accordance with Article 51(7) of Regulation No 1907/2006, as applicable under Article 52(2) of that regulation, the Commission is to prepare a draft decision to be taken in accordance with the procedure referred to in Article 133(3) of that regulation.
- 75 The Federal Republic of Germany thus correctly claims that the Member States and the Member State Committee play an important role in the context of the procedure for the adoption of a decision as part of the evaluation of a substance.
- 76 However, although the Member States and the Member State Committee intervene in the context of the procedure leading to the adoption of a decision as part of the evaluation of a substance, it must be noted that that decision is adopted by the ECHA. Such a decision, which was adopted under Article 51(3) or (6) of Regulation No 1907/2006, applicable *mutatis mutandis* in accordance with Article 52(2) of that regulation, is thus neither a Member State decision nor a decision of the Member State Committee.
- 77 Secondly, it must be noted that the subject matter of an action before the Board of Appeal is an ECHA decision and not solely the measures taken by the director of the ECHA or his secretariat in the context of the procedure which led to the adoption of that decision.
- 78 In the context of an action against an ECHA decision, the Board of Appeal's review does not therefore relate solely to the measures taken by the director of the ECHA or by his secretariat, but may, on the contrary, relate to all the elements of that decision.
- 79 Therefore, contrary to what is claimed by the Federal Republic of Germany, in the context of an action against a decision taken as part of the evaluation of a substance, nothing prevents the Board of Appeal from examining pleas calling into question the findings in that decision and in respect of which unanimous agreement was found within the Member State Committee and which, under Article 51(6) of Regulation No 1907/2006, applicable *mutatis mutandis* in accordance with Article 52(2) of that regulation, constitutes the substantive basis of that decision. As is apparent from Article 76(1)(e) of that regulation, in that context, the Member State Committee intervenes as a body of the ECHA.

- 80 Those considerations are not called into question by the Federal Republic of Germany's arguments concerning the relationship between the Member States and their members within the Member State Committee, alleging the importance of that committee and that, under Article 76(1)(e) of Regulation No 1907/2006, that committee is tasked with resolving possible divergences of opinions on draft decisions proposed in accordance with Title VI of that regulation.
- 81 In the light of the foregoing, it is necessary to reject the Federal Republic of Germany's arguments relating to the important role played by the Member States and the Member State Committee during the procedure leading to the adoption of a decision as part of the evaluation of a substance.
- 82 Thirdly, it is necessary to examine the Federal Republic of Germany's arguments alleging that the procedure provided for the adoption of decisions as part of the evaluation of substances, which confers an important role on the Member States outside of or within the Member State Committee, would risk being circumvented if the Board of Appeal was competent to review the findings in an ECHA decision which are based on unanimous agreement for the purposes of Article 51(3) or (6) of Regulation No 1907/2006 applicable *mutatis mutandis* in accordance with Article 52(2) of that regulation.
- 83 In that context, the Federal Republic of Germany claims that Article 93(3) of Regulation No 1907/2006 cannot call into question either the functional 'dualism' between the ECHA, on the one hand, and the Member States or the Member State Committee, on the other hand, or the substantive limitation of the ECHA's decision-making powers concerning evaluation procedures. It claims that, given that the ECHA is not competent to adopt decisions in the absence of the agreement of the Member States or contrary to that agreement, that also applies to the Board of Appeal. In that regard, a comparison with the other EU agencies is not relevant, since no other agency has similar procedural rules and a similar Member State Committee, which would involve the Member States in the decision-making process to such a significant extent, by making the decision-making power itself dependent on their will.
- 84 Firstly, it is necessary to reject the argument put forward by the Federal Republic of Germany alleging that, if the Board of Appeal could examine the merits of pleas seeking to demonstrate the existence of substantive errors vitiating an ECHA decision, the role of the Member States or of the Member State Committee in the context of the procedure provided for the adoption of decisions as part of the evaluation of a substance would risk being called into question.
- 85 In that context, it should be noted that, when ruling on an action against a decision taken as part of the evaluation of a substance, the Board of Appeal does not itself conduct an evaluation of that substance, but is limited to reviewing whether that decision is vitiated by an error.
- 86 Moreover, where the Board of Appeal reviews an ECHA decision, it does not conduct an examination similar to that carried out by the competent bodies of that agency during the procedure leading to the adoption of that decision and does not apply the same rules of procedure as those applicable where the ECHA rules at first instance, but is limited to examining, in the context of adversarial proceedings, whether that decision is vitiated by an error (see, to that effect, judgment delivered today, *BASF Grenzach v ECHA*, T-125/17, paragraphs 59 to 86).
- 87 By contrast, for the reasons set out in paragraphs 48 to 64 above, it cannot be deduced from the relevant provisions that the intention of the EU legislature was that the Board of Appeal not be competent to examine the merits of pleas which seek to demonstrate the existence of substantive errors vitiating an ECHA decision.

- 88 Secondly, it should be noted that, in accordance with Article 93(3) of Regulation No 1907/2006, where the action before it is well founded, the Board of Appeal may, admittedly, exercise any power which lies within the competency of the ECHA or remit the case to the competent body of that agency with a view to the continuation of the action.
- 89 However, Article 93(3) of Regulation No 1907/2006 confers discretionary power on the Board of Appeal (judgment delivered today, *BASF Grenzach v ECHA*, T-125/17, paragraph 119). In the exercise of that discretionary power, that board must not only examine whether, following the examination of the action, it has at its disposal evidence allowing it to adopt its own decision, but it must also take into account the rules governing the procedure provided for the adoption of the ECHA decision where that agency rules at first instance. Therefore, if that procedure confers an important role on certain actors, such as the role provided for the Member States and the Member State Committee by the procedure for the adoption of decisions as part of the evaluation of dossiers and substances (see paragraphs 68 to 74 above), the Board of Appeal must raise the question whether the adoption of such a final decision at its level is compatible with the objectives pursued by Regulation No 1907/2006 or whether compliance with the rules governing the procedure before the ECHA where that agency rules at first instance and with the objectives pursued by them requires the case to be referred to the competent body of that agency. In that context, it must also take into account recital 67 of that regulation, from which it follows that the procedure provided for the evaluation of substances and dossiers is based on the principle that a collective agreement between Member States or within the Member State Committee concerning draft decisions should provide the basis for an efficient system that respects the principle of subsidiarity (see, to that effect, judgment delivered today, *BASF Grenzach v ECHA*, T-125/17, paragraph 115 to 120).
- 90 It follows that, contrary to what is claimed by the Federal Republic of Germany, an approach according to which the Board of Appeal is competent to review the findings in an ECHA decision where that agency rules at first instance which are based on unanimous agreement for the purposes of Article 51(3) or (6) of Regulation No 1907/2006, applicable *mutatis mutandis* in accordance with Article 52(2) of that regulation, is not capable of calling into question the important role that those provisions confer on the Member States or the Member State Committee in the context of the adoption of decisions as part of the evaluation of substances.
- 91 In the second place, in the context of the first plea, the Federal Republic of Germany claims that any amendment of a decision adopted as part of the evaluation of a substance amounts to a new draft of the decision, since even an amendment or an annulment of certain parts of that decision would modify the ‘overall strategy’ of the evaluation. Any amendment of such a decision would thus require a decision to be taken by the Member States since, under Article 76(1)(e) of Regulation No 1907/2006, the Member State Committee is responsible for resolving differences of opinion between Member States during the evaluation procedure. The Board of Appeal could not amend the ‘testing strategy’ envisaged by the Member States or the Member State Committee.
- 92 The ECHA, the Commission and the intervening companies dispute those arguments.
- 93 In that regard, firstly, it must be borne in mind, as was stated in paragraphs 84 to 87 above, that in the context of an action against a decision taken as part of the evaluation of a substance, the Board of Appeal does not carry out an evaluation of the substance at issue, but merely reviews whether that decision is vitiated by an error.
- 94 Secondly, as a result of the considerations developed in paragraphs 48 to 64 above, it cannot be concluded that the intention of the EU legislature was that the Board of Appeal not be able to examine pleas relating to errors vitiating the merits of a decision taken as part of the evaluation of a substance. It follows that that board is entitled to annul such a decision in so far as it is vitiated by such errors, even if that calls into question, partially or completely, the overall strategy pursued by Member State Committee in the context of that evaluation. Moreover, nothing prevents that board

from limiting the scope of the annulment of such a decision where one of the requests for information included in it is severable from the others. That applies also to elements of a request for further information the annulment of which does not amend the substance of that request.

- 95 Thirdly, as regards the consequences of the annulment of a decision taken as part of the evaluation of a substance, firstly, where, in accordance with Article 93(3) of Regulation No 1907/2006, the Board of Appeal refers the case to the competent body of the ECHA for the continuation of the action, it is for that body to decide whether a new decision must be adopted. In that case, the role of the Member States or of the Member State Committee provided for in Article 51(3) or (6) of that regulation is thus not called into question, subject to compliance with the obligation arising from Article 18 of Regulation No 771/2008, according to which that body is bound by the reasoning of that board's decision, except where there is a change in the circumstances of the case. That obligation constitutes merely the consequence of the Board of Appeal's competence to examine pleas relating to errors vitiating the merits of a decision taken as part of the evaluation of a substance.
- 96 Secondly, as regards the possibility provided for by Article 93(3) of Regulation No 1907/2006, for the Board of Appeal to itself adopt a final decision, by exercising the powers within the ECHA's competence, it should be noted that, as was stated in paragraph 89 above, in the context of the exercise of the discretionary power conferred on it by Article 93(3) of that regulation, that board must take into account the rules governing the procedure provided for the adoption of an ECHA decision where that agency rules at first instance, the role that that procedure grants to the various bodies and recital 67 of that regulation, from which it is apparent that the procedure provided for the evaluation of substances and dossiers is based on the principle that a collective agreement between the Member States concerning draft decisions should constitute the basis of an efficient system which complies with the principle of subsidiarity.
- 97 In the light of those considerations, it is necessary to reject the Federal Republic of Germany's argument alleging that any amendment of a decision adopted as part of the evaluation of a substance amounts to a new draft of that decision, which is not compatible with the provisions of Regulation No 1907/2006.
- 98 In the third place, in the context of the first part of the fourth plea, the Federal Republic of Germany claims that the quorum which must be reached before the Board of Appeal is much lower than that which must be reached in order to adopt a decision as part of the evaluation of substances under Article 51(3) or (6) of Regulation No 1907/2006. It adds that, according to the second paragraph of Article 20 of Regulation No 771/2008, that board's decision is to be taken by a simple majority of its members. In order to adopt a decision, that board should thus reach a much lower quorum in order to take its decision than that provided for a decision taken as part of the evaluation of a substance. Moreover, it is a matter of concern that two persons authorised to take a decision who have no technical qualifications may substitute their lay decision for the opinion of experts expressed within the Member State Committee.
- 99 The ECHA, the Commission and the intervening companies dispute those arguments.
- 100 In that regard, it should be noted that, in accordance with the second paragraph of Article 20 of Regulation No 771/2008, Board of Appeal decisions are taken by majority vote.
- 101 However, contrary to what is claimed by the Federal Republic of Germany, the fact that a decision taken as part of the evaluation of a substance can be adopted at the level of the ECHA only where there is unanimous agreement for the purposes of Article 51(3) or (6) of Regulation No 1907/2006, whereas the Board of Appeal decides on a majority of votes, does not justify a limitation to the competence of that board concerning the pleas relating to errors vitiating the merits of such a decision.

- 102 For the reasons set out in paragraphs 82 to 89 above, it cannot be considered that the role of the Member States in the context of the procedure leading to the adoption of a decision as part of the evaluation of a substance risks being called into question in the context of an action before the Board of Appeal.
- 103 In the light of those considerations, the argument relating to differences concerning the quorum which must be reached during a procedure before the ECHA and that which must be reached during a procedure before the Board of Appeal must be rejected.
- 104 In the fourth place, in the context of the first part of the fourth plea, the Federal Republic of Germany claims that the resources of the Board of Appeal are limited and that only one member of that board is technically qualified. In accordance with Article 89 of Regulation No 1907/2006 and Article 1(1) of Regulation No 771/2008, that board consists of three members, at least one member being legally qualified and at least one member technically qualified.
- 105 The ECHA, the Commission and the intervening companies dispute those arguments.
- 106 In that regard, firstly, it should be borne in mind that, in the context of an action against a decision taken as part of the evaluation of a substance, it is not for the Board of Appeal to carry out a new evaluation of that substance. It must also be noted that it is not for that board, in conducting its own evaluation, to examine itself whether it is necessary to request further information about that substance. In the context of such an action, that board is limited to examining whether the arguments developed by the applicant are capable of demonstrating the existence of an error vitiating that decision.
- 107 The Board of Appeal's workload can therefore not be compared to that of the designated national authority in the context of the evaluation of a substance.
- 108 Secondly, it must be borne in mind that, as a result of the considerations developed in paragraphs 48 to 64 above, it cannot be deduced from the provisions applicable to actions before the Board of Appeal that the intention of the EU legislature was to limit the competence of that board as regards pleas relating to errors vitiating the merits of a decision taken as part of the evaluation of a substance. By contrast, it should be noted that although, under Article 89(1) of Regulation No 1907/2006, in principle, that board consists of three members, it follows from the second subparagraph of Article 89(3) thereof that the management board of the ECHA may appoint additional members and their alternates upon recommendation of the executive director, if that is necessary in order to guarantee that an action is dealt with within a reasonable time frame. Moreover, there is nothing to prevent several Boards of Appeal from being set up, as is the case with other EU agencies.
- 109 In the light of those elements, it should be concluded that the argument relating to the limited character of the Board of Appeal's resources is not capable of calling into question the fact that that board is competent to examine pleas relating to errors vitiating the merits of a decision taken as part of the evaluation of a substance. Therefore, that argument of the Federal Republic of Germany must also be rejected.
- 110 In the fifth place, in the context of the first part of the fourth plea, the Federal Republic of Germany claims that, under Article 91(2) of Regulation No 1907/2006, actions before the Board of Appeal have suspensive effect. An approach allowing that board to conduct a substantial review of the assessments included in the ECHA decision prior to the review carried out by the court would thus cause unnecessary delays and disruptions, which would be compatible neither with the objectives of protecting human health and the environment pursued by that regulation under Article 1(1) of that regulation, nor with the precautionary principle mentioned in Article 1(3) of that regulation. The possibility for the ECHA to adopt decisions as part of the evaluation of substances at the ECHA level is intended to streamline and accelerate the decision-making process. Those decisions are only a

preliminary stage. To allow that board to review the substance of an ECHA decision would undermine that objective since the time limit would be longer where the decision at issue is adopted by the Commission. Articles 3(1) and 41(1) of the Charter of Fundamental Rights also preclude an excessive length of appeal proceedings.

- 111 The ECHA, the Commission and the intervening companies dispute those arguments.
- 112 In that regard, firstly, it should be noted that, as a result of the considerations developed in paragraphs 48 to 64 above, it cannot be considered that the intention of the EU legislature was that the Board of Appeal not be able to find errors vitiating the merits of a decision taken as part of the evaluation of a substance.
- 113 Secondly, as regards the objectives pursued by Regulation No 1907/2006, it should be noted that, admittedly, as follows in particular from Article 1(1) of that regulation, it aims to ensure a high level of protection of human health and the environment. However, at issue are not solely the objectives pursued by that regulation. It refers also to the promotion of alternative methods for the assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. Moreover, as can be deduced in particular from recital 47 of that regulation, the latter aims to avoid animal testing. In addition, the possibility of bringing an action before the Board of Appeal against certain decisions of the ECHA, with suspensive effect, aims also to avoid any impediment to the freedom to conduct a business for the purposes of Article 16 of the Charter of Fundamental Rights which is linked with erroneous decisions. As regards more specifically decisions taken as part of the evaluation of a substance, in which further information is requested, such a suspensive effect thus has the objective of avoiding studies being conducted which would incur costs for the registrants and which could involve animal testing, although the ECHA was not entitled to request them.
- 114 Thirdly, as regards the Federal Republic of Germany's argument alleging that the objective of the possibility granted to the ECHA to adopt decisions as part of the evaluation of a substance was to streamline and accelerate the decision-making process, it should be noted that it is apparent from Article 94(1) of Regulation No 1907/2006 that certain ECHA acts cannot be contested before the Board of Appeal. Thus, the procedure which is provided for the identification of candidate substances in accordance with Articles 57 and 59 of that regulation provides also that such a decision can be adopted at ECHA level where there is agreement between the Member States or within the Member State Committee and that, otherwise, the decision is to be adopted at Commission level. However, contrary to what is provided in relation to decisions taken as part of the evaluation of a substance, an action may not be brought which has automatic suspensive effect against such an act before the Board of Appeal. By contrast, under Article 94(1) of that regulation, it is before the Court that such acts may be contested and an action before that court does not have automatic suspensive effect.
- 115 In the light of those elements, it must be concluded that at issue is a deliberate choice on the part of the EU legislature to have provided for the possibility to bring an action before the Board of Appeal with automatic suspensive effect against certain acts of the ECHA and not for others.
- 116 Fourthly, in that context, it should also be noted that, under the second subparagraph of Article 89(3) of Regulation No 1907/2006, additional members may be appointed by the Board of Appeal if that is necessary to ensure that the action is dealt with within a reasonable time frame (see paragraph 108 above).
- 117 In the light of those elements, it must be concluded that the argument relating to potential delays caused by the automatic suspensive effect of actions before the Board of Appeal is not capable of calling into question the fact that that board is competent to examine pleas relating to errors vitiating the merits of a decision taken as part of the evaluation of a substance. Therefore, that argument of the Federal Republic of Germany must also be rejected.

- 118 In the sixth place, in the context of the first part of the fourth plea, the Federal Republic of Germany claims that the possibility of a review, by the Board of Appeal, of the ECHA's substantive assessments produces inconsistent outcomes concerning the review conducted by the EU Courts. Firstly, where the Board of Appeal reviews an ECHA decision, judicial protection is limited. The ECHA could not contest a decision by lodging an appeal or in another way. For their part, the Member States should content themselves with the review relating to the existence of errors of assessment conducted by that board. Secondly, where a decision is adopted by the Commission, the review is conducted by the Court.
- 119 The ECHA, the Commission and the intervening companies dispute those arguments.
- 120 In that regard, firstly, it should be noted that the intensity of the review conducted by the EU Courts of a decision of the Board of Appeal concerning an action against a decision taken as part of the evaluation of a substance does not differ from that conducted by it of a Commission decision as part of the evaluation of a substance. It concerns a review of lawfulness. According to the case-law, that review is limited where it concerns highly complex scientific and technical facts. Concerning such assessments, the EU Courts are limited to checking whether they are vitiated by a manifest error, a misuse of powers or whether the decision-maker manifestly exceeded the limits of its power of review (see judgment of 21 July 2011, *Etimine*, C-15/10, EU:C:2011:504, paragraph 60 and the case-law cited).
- 121 Secondly, it is true that, where the Court reviews a Commission decision taken as part of the evaluation of a substance, it conducts a direct review of the decision adopted as part of the evaluation of a substance, although, in the context of an action against a decision of the Board of Appeal, it is limited to reviewing the decision of that board. As stated in paragraphs 60 to 62 above, the Court's review relates therefore to the review conducted by that board.
- 122 However, as follows from Articles 91(1) and Article 94(1) of Regulation No 1907/2006, that is the result of a deliberate choice of the EU legislature. As was stated in paragraphs 114 and 115 above, certain acts of the ECHA may be contested directly before the EU Courts. Contrary to what is claimed by the Federal Republic of Germany, such a deliberate choice cannot be considered to be an inconsistent outcome capable of justifying a limitation to the competence of the Board of Appeal concerning the examination of pleas relating to errors vitiating the merits of a decision taken as part of the evaluation of a substance.
- 123 In the light of those considerations, those arguments must also be rejected.
- 124 In the seventh place, it is necessary also to reject the argument, put forward by the Federal Republic of Germany in the context of the first part of the fourth plea, alleging that the review relating to the existence of errors of assessment is a task reserved to the courts. Firstly, as was stated in paragraphs 54 to 56 above, the EU legislature provided that, with respect to certain ECHA decisions, such as decisions taken as part of the evaluation of a substance, an action before the Board of Appeal is possible, in the context of which that board examines whether the arguments put forward by the applicant are capable of demonstrating the existence of an error vitiating that agency's decision where the latter rules at first instance. Secondly, it must be noted that none of the Federal Republic of Germany's arguments is capable of substantiating its claim that the review of the existence of errors of assessment should be reserved to the courts.
- 125 In the eighth place, in the context of the third plea, the Federal Republic of Germany claims that, according to recital 67 of Regulation No 1907/2006, a decision taken as part of the evaluation of a substance is based on a collective agreement of the Member States or within the Member State Committee concerning their draft decisions. The ECHA's role is limited to coordinating and supporting the Member States' decision-making process. By adopting an autonomous decision instead of the ECHA concerning the substance of the evaluation, the Board of Appeal breached the principle of subsidiarity and the principle of conferral. In particular, concerning the latter principle, the Federal Republic of Germany claims firstly that, if the EU legislature had wanted to confer that power on the

ECHA, it would have expressly delegated the responsibility to it, as it would have done in particular with respect to the definitive rejection of a registration. Next, Article 51(3) and (6) of Regulation No 1907/2006 determine the ECHA's powers. Finally, the wording of Article 93(3) of that regulation does not allow it to be considered that the Board of Appeal possesses broader powers. In so far as it permits that board to exercise any power which lies within the competency of the ECHA, it concerns limited competences provided for in Article 51 of that regulation. That board also has the possibility to refer a case to the competent body of that agency for the purposes of the pursuit of the action.

126 The ECHA, the Commission and the intervening companies dispute those arguments.

127 Firstly, it is necessary to reject the Federal Republic of Germany's argument alleging a breach of the principle of conferral within the meaning of Article 5(1) and (2) TEU, in accordance with which the Union is to act only within the limits of the competences conferred upon it by the Member States in the Treaties to attain the objectives set out therein and according to which competences not conferred upon the Union in the Treaties remain with the Member States.

128 Regulation No 1907/2006 was adopted on the basis of Article 95 EC (Article 114 TFEU) and Regulation No 771/2008 on the basis of Article 93(4) and Article 132 of Regulation No 1907/2006.

129 As stated in paragraphs 48 to 124 above, the Federal Republic of Germany did not put forward any arguments capable of demonstrating that, by examining pleas alleging errors vitiating the merits of a decision as part of the evaluation of a substance, the Board of Appeal acted outside the powers conferred on it by Regulation No 1907/2006 and Regulation No 771/2008.

130 In the light of those considerations, the argument relating to the principle of conferral must also be rejected.

131 Secondly, it is necessary to reject the Federal Republic of Germany's argument alleging that the Board of Appeal infringed the principle of subsidiarity.

132 Firstly, in so far as that argument relates to recital 67 of Regulation No 1907/2006, it should be noted that it follows from that recital that the EU legislature considered that the scheme established by that regulation, according to which decisions taken as part of the evaluation of a substance adopted at the level of the ECHA are based on a collective agreement within the Member State Committee, was compatible with the principle of subsidiarity.

133 As was stated in particular in paragraphs 82 to 103 above, the Board of Appeal's competence to examine pleas calling into question the merits of the evaluation decision is compatible with recital 67 of Regulation No 1907/2006. Therefore, that argument must be rejected in so far as it relates to that recital.

134 Secondly, in so far as the Federal Republic of Germany's argument relates to the principle of subsidiarity for the purposes of Article 5(1) and (3) TEU, it should be noted that, in accordance with that principle, in areas where it does not have exclusive competence, the Union is to act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level.

135 It must be noted that the Federal Republic of Germany does not develop any detailed arguments capable of demonstrating that the principle of subsidiarity for the purposes of Article 5(1) and (3) TEU was not respected. Therefore, it is necessary to reject the argument relating to that principle and, consequently, all of the arguments alleging an infringement of the principle of subsidiarity.

136 In the ninth place, in the context of the second plea, the Federal Republic of Germany claims that the Board of Appeal breached the principles developed by the Court in the case-law according to which the Commission may not delegate discretionary decision-making powers to Union agencies (judgments of 13 June 1958, *Meroni v High Authority*, 9/56, EU:C:1958:7, and of 13 June 1958, *Meroni v High Authority*, 10/56, EU:C:1958:8). According to that case-law, any delegation of Commission powers to agencies should be limited and comply with objective requirements. That case-law should be taken into account during the application of Regulation No 1907/2006 in relation to the delegation of Commission powers to the ECHA regarding decisions taken as part of the evaluation. That delegation of powers relates not only to technical questions, but also to questions concerning the margin of discretion for the purposes of the case-law at issue. In that regulation, the EU legislature took into account the prohibition on delegation and the absence of a priori classification of decisions in relation to the evaluation of substances, by providing that substance evaluation decisions adopted at the level of the ECHA must be based on unanimous agreement between the competent Member State specialists regarding the necessity to conduct a particular evaluation for a substance. An agreement could take place only in two scenarios. In a first scenario, it would concern a related decision where the decision is obvious in the light of the situation at issue. In a second scenario, it would concern a discretionary decision where the scientific and technical situation is a little less clear, but could clearly be resolved in the light of technical concerns of a political, economic or social nature. In that case, formal agreement between the Member States would ensure the substantive correctness of the decision and provide, at the same time, broad legitimation to the ECHA via the Member State representatives who would be bound by instructions and democratically legitimised. The unanimous nature of the agreement would also allow it to be assumed that the Commission, in addition, could take that decision together with the Member States quickly and without difficulty in the context of a committee procedure. The fact of involving the Commission is thus merely a formality. In the absence of such an agreement, the ECHA would be deprived of its decision-making power and in that case the normal Commission decision-making procedure would apply in accordance with Articles 51(7) and 133(3) of that regulation. If the Board of Appeal could replace a discretionary decision based on unanimous agreement within the Member State Committee with its own decision, it would upset the complex institutional balance existing between the Member States, the ECHA and the Commission. In that scenario, contrary to the abovementioned case-law, an agency would adopt a discretionary decision autonomously and with the exclusion of any formal guarantees.

137 The ECHA, the Commission and the intervening companies dispute those arguments.

138 In the first place, in so far as the Federal Republic of Germany refers to the judgments of 13 June 1958, *Meroni v High Authority* (9/56, EU:C:1958:7), and of 13 June 1958, *Meroni v High Authority* (10/56, EU:C:1958:8), it should be noted that those judgments relate to a situation in which the Commission had delegated its powers. That case-law cannot therefore apply directly in the present case. Firstly, the powers of the ECHA and of its Board of Appeal which are at issue in the present case were not granted to them by way of a delegation by the Commission. They are powers granted by the EU legislature in the context of Regulation No 1907/2006. Secondly, the ECHA is not a body governed by private law, but a body of the Union created by that legislature.

139 In the second place, it must be noted that, as regards an EU entity created by the EU legislature, it has been stated in the case-law that a grant of powers to such an entity is compatible with the requirements of the Treaties, if it does not concern acts having the force of law and if the powers granted are precisely delineated and amenable to judicial review (see, to that effect, judgment of 22 January 2014, *United Kingdom v Parliament and Council*, C-270/12, EU:C:2014:18, paragraphs 41 to 55 and 63 to 68).

140 In that context, it should be noted that the Federal Republic of Germany does not put forward arguments seeking to demonstrate that granting the ECHA the power to adopt decisions as part of the evaluation of a substance in the conditions established by Article 51(3) or (6) of Regulation

No 1907/2006, did not respect those principles. The Federal Republic of Germany merely claims that, by examining the pleas relating to errors vitiating the substance of the evaluation of benpat, the Board of Appeal infringed the principles referred to above.

141 Moreover, in so far as the Federal Republic of Germany's arguments refer to the Board of Appeal, it should be noted that both the Member State Committee and the Board of Appeal are part of the ECHA. Contrary to what is claimed by the Federal Republic of Germany, by annulling an ECHA decision due to substantive errors affecting that decision, that board does therefore not exceed the powers granted to the ECHA as an agency.

142 In that context, it must also be noted that, as follows from Article 94(1) of Regulation No 1907/2006, decisions of the Board of Appeal may be subject to judicial review before the Court.

143 In the third place, in so far as the Federal Republic of Germany's arguments seeking to demonstrate that the Board of Appeal encroached on the competences of the Member State Committee, firstly, it must be recalled that, as was stated in paragraphs 85 and 86 above, in the context of the examination of the merits of an action before it, the Board of Appeal is limited to examining whether the decision contested before it is vitiated by error. It therefore checks whether the ECHA committed an error in the application of provisions governing the adoption of decisions as part of the evaluation of a substance.

144 Secondly, as regards the powers enjoyed by the Board of Appeal in accordance with Article 93(3) of Regulation No 1907/2006 where an action before it is well founded, it cannot be considered that that board misused its powers when it remits the case to the competent body of the ECHA.

145 Next, where the Board of Appeal decides to exercise itself any power which lies within the competence of the ECHA, in accordance with Article 93(3) of Regulation No 1907/2006, it should be noted that, as was stated in paragraph 89 above, in the context of the exercise of discretionary powers conferred on it by that provision, it must take account of the rules governing the procedure provided for the adoption of an ECHA decision where the latter rules at first instance, of the role that that procedure confers on the various bodies and of recital 67 of that regulation, from which it follows that the procedure provided for the evaluation of a substance and of the dossier is based on the principle that a collective agreement between Member States or within the Member State Committee concerning draft decisions should constitute the basis for an effective system which respects the principle of subsidiarity.

146 Finally, in so far as by its arguments, the Federal Republic of Germany again claims that the examination of the pleas relating to the merits of a decision taken as part of the evaluation of a substance is not compatible with recital 67 of Regulation No 1907/2006, with the principle of conferral or the principle of subsidiarity, it is necessary to reject them for the same reasons as those set out in paragraphs 89 and 125 to 135 above.

147 Therefore, those arguments of the Federal Republic of Germany must also be rejected.

148 In the light of the foregoing considerations, it is necessary to reject all of the arguments developed by the Federal Republic of Germany in the context of the first to third pleas, as well as the first part of the fourth plea.

B. The fifth plea, alleging an infringement of the duty to state reasons

149 The Federal Republic of Germany maintains that, in the contested decision, the Board of Appeal did not fulfil the obligation to state reasons. According to it, in the light of the unclear division of competences between the various organs of the ECHA and of the potential disruption to the balance prescribed in the scheme of Regulation No 1907/2006, that board should have set out in detail its

powers to review the merits of decisions taken as part of the evaluation. That obligation to state reasons cannot be fulfilled by referring to judgments of the EU Courts concerning their own powers in various situations.

150 The ECHA, the Commission and the intervening companies dispute those arguments.

151 According to the second paragraph of Article 296 TFEU, legal acts are to state the reasons on which they are based and are to refer to any proposals, initiatives, recommendations, requests or opinions required by the Treaties. As regards, more specifically, decisions taken under Regulation No 1907/2006, Article 130 of that regulation provides that the reasons for them must be stated.

152 It follows from the case-law that the statement of reasons required by Article 296 TFEU must be adapted to the nature of the measure in question and must disclose in a clear and unequivocal fashion the reasoning followed by the institution which adopted the measure in such a way as to make the persons concerned aware of the reasons for the measure and to enable the Court to exercise its power of review. However, it is not necessary for the reasoning to go into all the relevant facts and points of law. It is settled case-law that the question whether the statement of the grounds for a decision meets the requirements of Article 296 TFEU must be assessed with regard not only to its wording but also to its context and all the legal rules governing the matter in question (see judgment of 15 September 2016, *Crosfield Italia v ECHA*, T-587/14, EU:T:2016:475, paragraph 31 and the case-law cited).

153 As regards the grounds for the contested decision, firstly, it should be noted that it is clearly apparent from that decision that the Board of Appeal considered that it was competent to examine the pleas in the action before it relating to errors vitiating the substance of the evaluation of benpat. Secondly, in the light of the provisions referred to in paragraphs 43 to 148 above, the reasons why that board has such competence are clearly apparent from the provisions of Regulation No 1907/2006 and of Regulation No 771/2008 which apply to it. Thirdly, it must be stated that the Federal Republic of Germany does not claim that, during the procedure before the Board of Appeal, the latter failed to sufficiently respond to certain of the arguments concerning the competence of the Board of Appeal.

154 In the light of those elements, it must be concluded that the grounds of the contested decision allowed the Federal Republic of Germany to know the justifications for the contested decision and allowed the Court to exercise its review and were therefore sufficient.

155 Consequently, the fifth plea must be rejected.

C. The second part of the fourth plea and the sixth plea, seeking to demonstrate that the Board of Appeal committed errors in the context of the examination of pleas put forward before it

156 In the context of the second part of the fourth plea and of the sixth plea, the Federal Republic of Germany claims that, in the context of the examination of pleas concerning matters of substance relating to the evaluation procedure, the Board of Appeal committed errors.

157 In particular, the Federal Republic of Germany invokes errors vitiating the Board of Appeal's findings in the examination of the first to third pleas in the action before that board and in point 3 of the operative part of the contested decision.

158 It is necessary to examine, as a first step, the arguments relating to the examination of the first plea in the action before the Board of Appeal, as a second step, those relating to the examination of the second plea in that action and, as a third step, those relating to the examination of the third plea in that action and point 3 of the operative part of the contested decision.

1. The arguments relating to the examination of the first plea in the action before the Board of Appeal

- 159 In paragraphs 24 to 155 of the contested decision, the Board of Appeal examined the first plea in the action before it, which had alleged that the requests to conduct testing in accordance with method No 309 and method No 308 were not compatible with the principle of proportionality.
- 160 The first plea in the action before the Board of Appeal is divided into four parts. The first had alleged that it was not necessary to carry out further testing concerning the persistent character of benpat, the second that the testing to be conducted in accordance with method No 309 was not appropriate in order to attain the objective pursued, the third that the testing conducted in accordance with method No 308 was not appropriate in order to attain the objective pursued and the fourth that that testing constituted neither the most appropriate option nor the least onerous option.
- 161 In the context of the second part of the fourth plea and of the sixth plea in the present action, the Federal Republic of Germany raises arguments calling into question the Board of Appeal's findings developed in the context of the examination of the first three parts of the first plea in the action before the Board of Appeal.

(a) The arguments relating to the examination of the first part of the first plea before the Board of Appeal

- 162 In paragraphs 39 to 88 of the contested decision, the Board of Appeal examined and rejected the first part of the first plea in the action before it, alleging that, as regards the persistent character of benpat, it was not necessary to conduct further testing. After the examination of arguments put forward by the intervening companies in that regard, it concluded that the latter were not capable of demonstrating the erroneous nature of the ECHA's conclusion that the requests for further information concerning the persistent character of benpat were justified in the light of the potential risk posed by that substance to human health and the environment.
- 163 In the context of the second part of the fourth plea, the Federal Republic of Germany claims that, in paragraph 41 of the contested decision, the Board of Appeal committed an error by conducting a review which was too intense. According to it, that board should have contented itself with reviewing the scientific limits of the findings in the ECHA decision. That board encroached on the role of the Member State Committee and thus exceeded the limits of its power of review.
- 164 The ECHA, the Commission and the intervening companies dispute those arguments.
- 165 Those arguments must be rejected as ineffective. As is apparent from paragraph 34 above, the Federal Republic of Germany requests the annulment of the contested decision in so far as the Board of Appeal partially annulled the ECHA decision. However, paragraph 41 of the contested decision is in a part of that decision in which that board rejected the first part of the first plea raised before it.
- 166 Therefore, all of the Federal Republic of Germany's arguments relating to the examination of the first part of the first plea before the Board of Appeal must be rejected.

(b) The arguments relating to the examination of the second and third parts of the first plea in the action before the Board of Appeal

- 167 In the context of the second part of the fourth plea and the sixth plea in the present action, the Federal Republic of Germany puts forward arguments calling into question the examination, by the Board of Appeal, of the second and third parts of the first plea in the action before that board.

168 As a first step, the Federal Republic of Germany's arguments relating to the examination of the second part of the first plea in the action before the Board of Appeal and, as a second step, its arguments relating to the examination of the third part of the first plea in that action will be examined.

(1) The arguments relating to the examination of the second part of the first plea in the action before the Board of Appeal

169 In its decision, the ECHA requested the registrants to conduct simulation testing on ultimate degradation in surface water in accordance with method No 309 by using the R-898 constituent of benpat, as specified in section III.3 of the statement of reasons for that decision. In the context of that statement of reasons, on pages 8 to 10 of that decision, it stated that, during the organisation of that testing, it was important that metabolites be identified in order to show that degradation in the testing system have been observed. According to it, for that purpose, it was necessary to satisfy certain conditions. One of those conditions was that metabolites representing crucial steps of pathways for transformation (key metabolites) should be detected and identified by means of 'quantitative structure-activity relationships' and that standard solutions should guarantee that the detection and quantification of those key metabolites was possible.

170 In the context of the second part of the first plea in the action before the Board of Appeal, the intervening companies maintained that the testing to be conducted in accordance with method No 309 was not appropriate in order to obtain the results pursued. In the context of the third complaint of that part, they claimed in particular that the weak solubility in water of benpat has the consequence that such testing produces metabolites in such small quantities that it is not possible to identify them.

171 In paragraphs 118 to 125 of the contested decision, the Board of Appeal examined that complaint.

172 In paragraph 119 of the contested decision, the Board of Appeal held that, in its decision, the ECHA had required not only that testing be conducted in accordance with method No 309 in order to determine the half-life of benpat in pelagic waters, but also that metabolites derived from benpat be identified during that testing.

173 In paragraph 121 of the contested decision, the Board of Appeal stated that it followed from Organisation for Economic Cooperation and Development (OECD) Guidelines 309 for the Testing of Chemicals that, as a result of analytical limits, it was often impossible to measure the concentration of the test substance with the required precision, where the test substance was applied at a concentration less than or equal to 100 µg/l. It follows also from those guidelines that higher concentrations of the test substance (greater than 100 µg/l and sometimes than 1 mg/l) could be used for the identification and quantification of the major transformation products or where no specific method of analysis with a weak detection limit was available. According to those guidelines, where high concentrations of the test substance are tested, it may not be possible to use the results to estimate the first order degradation constant and half-life, as the degradation will probably not follow first order kinetics.

174 In paragraph 122 of the contested decision, the Board of Appeal examined whether it was realistic to identify metabolites during testing conducted in accordance with method No 309. It considered that it was not realistic to expect such testing to allow the identification of metabolites of the substance, since the latter had a maximum solubility of 45 µg/l, whereas the concentration required for the identification of the major transformation products was higher than 100 µg/l and sometimes higher than 1 mg/l. Moreover, in that paragraph, it noted that neither the ECHA nor the intervening companies had been able to identify an appropriate method for identifying the major transformation products which would probably be created during the conduct of testing in accordance with that method.

- 175 In paragraph 123 of the contested decision, the Board of Appeal noted that the ECHA and the designated authority had maintained that the intervening companies should attempt to identify formed metabolites in the study, although it is not certain that they are able to do so. It noted that those arguments did not demonstrate that the required method No 309 was appropriate to identify metabolites of benpat and that they sought to transfer to those interveners the responsibility for designing and evaluating the study so as to allow the identification of metabolites.
- 176 In paragraph 124 of the contested decision, the Board of Appeal concluded that the ECHA had not sufficiently demonstrated that testing to be conducted in accordance with method No 309 would be capable of attaining its objective, in so far as that agency obliged the intervening companies to identify metabolites of benpat in the context of that testing. Relying on that conclusion, it upheld the third complaint of the second part of the first plea in the action before it and annulled the ECHA decision in so far as it had requested those companies to identify metabolites of benpat during testing in accordance with that method.
- 177 In the context of the second part of the fourth plea and the first part of the sixth plea in the present action, the Federal Republic of Germany claims that those findings of the Board of Appeal are erroneous.
- 178 It is necessary to examine, as a first step, the Federal Republic of Germany's arguments seeking to demonstrate that the Board of Appeal should not have found the existence of an autonomous and independent decision relating to the identification of metabolites, as a second step, its arguments relating to that board's competence, as a third step, its arguments alleging that that board exceeded the limits of its powers of review, as a fourth step, its arguments seeking to demonstrate the incorrectness of that board's conclusion, according to which, contrary to the ECHA's findings, it was not impossible to identify metabolites of benpat, as a fifth step, its arguments alleging that the identification of metabolites is one of the elements of method No 309, as a sixth step, its argument alleging that that method can be further clarified, as a seventh step, its argument relating to the inconsistency of the contested decision, as an eighth step, its argument alleging a violation of the obligation to state reasons and, finally, as a ninth step, its argument alleging that the Board of Appeal failed to have regard to the relevant criterion relating to the principle of proportionality.

(i) The arguments seeking to demonstrate that the Board of Appeal should not have found the existence of an autonomous and independent decision relating to the identification of metabolites

- 179 In the context of the first part of the sixth plea, the Federal Republic of Germany claims that, contrary to the Board of Appeal's findings in paragraph 119 of the contested decision, the details included in the ECHA decision relating to the identification of metabolites did not constitute an autonomous decision which is independent of the request for testing which should be conducted in accordance with method No 309. In general, decisions taken in relation to the evaluation of a substance not only would indicate the testing to be conducted, but would give also details concerning the concrete conduct of that testing in order to ensure that the results are optimally employed in the light of the objective for providing information pursued. The mere fact of having described the different stages to be followed in order to reach the result suggests that the only obligation imposed was that everything possible be done to follow them. The OECD Guidelines 309 for the Testing of Chemicals thus clarified the efforts which should be made in order to identify transformation products. No obligation of result follows from the ECHA decision. According to the Federal Republic of Germany, if the ECHA had genuinely wished to impose an obligation of result, there would have been no sense in prescribing those steps, since the registrants would then have been required to take all types of step. The sentence in the ECHA decision, according to which in relation to benpat it is necessary to detect and identify metabolites, also does not permit an obligation of result to be inferred. Only the presentation of raw data was required, meaning that not only the potential results concerning metabolites, but also the available data which would have allowed them to be obtained, should have been provided. That information is

wide open to interpretation and could constitute an essential basis of arguments for the identification of benpat as a persistent substance, and that, even in the event that the testing fails, because the data could then be employed in order to request that further testing be conducted or in order to complement other information.

180 The ECHA, the Commission and the intervening companies dispute those arguments.

181 In that regard, in the first place, it should be noted that, in paragraph 119 of the contested decision, the Board of Appeal did not find that the identification of metabolites constitutes a decision which is autonomous and independent of the request to conduct testing in accordance with method No 309, but merely noted that, in its decision, the ECHA had required not only that that testing be conducted, in order to determine the half-life of benpat in pelagic waters, but also that metabolites derived from benpat be identified in the context of that testing.

182 In the second place, in so far as the Federal Republic of Germany's arguments seek to demonstrate that the ECHA decision did not oblige the addressees thereof to identify metabolites derived from benpat, firstly, it should be noted that, according to the operative part of that decision, the addressees thereof are required to conduct simulation testing on ultimate degradation in surface water following the specifications in point III.3 of that decision.

183 Secondly, as follows from point III.3 of the ECHA decision, in the context of the testing at issue, metabolites representing crucial steps in pathways for transformation (key metabolites) should be identified with the help of 'quantitative structure-activity relationships'. Moreover, in that point, it was stated that, concerning benpat, 'the detection and identification of metabolites should be provided'.

184 In light of the wording of the ECHA decision, the Board of Appeal cannot be criticised for having considered that, in that decision, that agency had not only limited itself to indicating the way in which testing to be conducted in accordance with method No 309 should be carried out, but had provided for an obligation for the addressees to identify metabolites derived from benpat.

185 Therefore, it is necessary to reject the Federal Republic of Germany's arguments seeking to demonstrate that the Board of Appeal's finding, in paragraph 119 of the contested decision, according to which, in its decision, the ECHA had required that metabolites derived from benpat be identified in the context of that testing to be conducted in accordance with method No 309, is erroneous.

(ii) The arguments relating to the Board of Appeal's competence

186 In the context of the first part of the fourth plea, the Federal Republic of Germany claims that the question whether a concentration of 45 µg/l of benpat is below the detection limit which is 100 µg/l is a technical question relating to chemistry which is beyond the competence of the Board of Appeal. The Member State Committee was convinced that the identification of metabolites was possible by adopting the prescribed testing method and would be the best means of reaching conclusive results. It was not for that board to review that conclusion.

187 Those arguments must be rejected for the same reasons as those set out in paragraphs 40 to 148 above.

(iii) The arguments seeking to demonstrate that the Board of Appeal exceeded the limits of its power of review

188 In the context of the second part of the fourth plea and the first part of the sixth plea in the present action, the Federal Republic of Germany claims that, in paragraph 122 of the contested decision, the Board of Appeal exceeded the limits of its power of review. According to it, in that paragraph, that

board decided to contradict the Member State expertise concerning the question whether the identification of metabolites was possible. It is necessary to grant the Member State Committee a broad discretion in the light of its task as an expert committee and of the fact that its members are bound by the instructions of their Member States. Therefore, that board has only a limited power of review, the intensity of which is similar to the review exercised by the courts of discretionary decisions.

189 The ECHA, the Commission and the intervening companies dispute those arguments.

190 In that regard, in the first place, it should be noted that, in the context of the second part of the first plea in the action before it, the Board of Appeal neither conducted an evaluation of benpat nor examined itself which further information should be requested in order to be able to conclude the evaluation of benpat concerning the potential risk that that substance could be persistent. It limited itself to examining whether the arguments put forward by the intervening companies were capable of demonstrating the existence of an error vitiating the ECHA decision.

191 In the second place, it is necessary to reject the Federal Republic of Germany's arguments alleging that the intensity of the control conducted by the Board of Appeal was excessive and according to which it should have limited itself to reviewing whether the ECHA's considerations were vitiated by a manifest error of assessment.

192 In that context, it should be noted that, admittedly, in the context of an action for annulment under Article 263 TFEU, the review conducted by the EU Courts is limited where it concerns the assessment of highly complex scientific and technical facts. As regards such assessments, the EU Courts are limited to reviewing whether they are vitiated by a manifest error, a misuse of powers or whether the decision-maker manifestly exceeded the limits of its discretion (see judgment of 21 July 2011, *Etimine*, C-15/10, EU:C:2011:504, paragraph 60 and the case-law cited).

193 However, that case-law is not applicable to the review conducted by the Board of Appeal of the ECHA. In that regard, regarding the members of that body, it should be noted that, under the second subparagraph of Article 1(1) of Regulation No 771/2008, at least one member is legally qualified and at least one member is technically qualified, in accordance with Regulation No 1238/2007. Under Article 1(2) of the latter regulation, the technically qualified members are to hold a university degree or an equivalent qualification and are to have substantial professional experience in hazard assessment, exposure assessment or risk management with regard to human health or environment risks of chemical substances or in related fields. It must be deduced from those provisions that the legislature intended to provide the Board of Appeal of the ECHA with the expertise necessary in order to allow it to itself carry out assessments of highly complex scientific and technical facts.

194 Therefore, the review, by the Board of Appeal, of scientific assessments included in an ECHA decision is not restricted to verifying the existence of manifest errors. On the contrary, in that regard, by relying on the legal and scientific competences of its members, that board must examine whether the arguments put forward by the applicant are capable of demonstrating that the considerations on which that decision is based are vitiated by error.

195 It follows that, in paragraph 122 of the contested decision, the Board of Appeal did not exceed the limits of its power of review.

196 None of the other arguments put forward by the Federal Republic of Germany in the context of the second part of the fourth plea and the first part of the sixth plea is capable of calling that conclusion into question.

- 197 Firstly, in the context of the second part of the fourth plea, the Federal Republic of Germany claims that the substantive restrictions of the ECHA's decision-making power derive from Article 51 of Regulation No 1907/2006 and that the intensity of the review conducted by the Board of Appeal could not have been modified by Regulation No 771/2008, which was adopted on the basis of Article 93(4) of Regulation No 1907/2006.
- 198 First of all, it should be noted that that argument is based on the premiss that it follows from the provisions of Regulation No 1907/2006 that the review that the Board of Appeal conducts in relation to decisions taken as part of the evaluation of substances is limited to a review of the manifest error.
- 199 In that regard, firstly, it should be noted that the provisions of Regulation No 1907/2006 concerning the procedure before the Board of Appeal do not provide for restrictions relating to the intensity of reviews conducted by the Board of Appeal.
- 200 Secondly, in so far as the Federal Republic of Germany invokes that the Board of Appeal's review is limited as regards decisions adopted on the basis of Article 51 of Regulation No 1907/2006, it suffices to note that the provisions governing appeal proceedings before the Board of Appeal do not provide for specific rules relating to decisions taken as part of the dossier evaluation or evaluation of a substance (see paragraph 53 above).
- 201 In the light of those considerations, it should be noted that the Federal Republic of Germany's premiss that it follows from the provisions of Regulation No 1907/2006 that the review that the Board of Appeal conducts in relation to decisions as part of the evaluation of substances is limited to a review of the manifest error is mistaken.
- 202 Therefore, the argument alleging that Regulation No 771/2008 could not modify the limited intensity of the review carried out by the Board of Appeal provided for by Regulation No 1907/2006 is based on that erroneous premiss and must therefore be rejected.
- 203 Secondly, in the context of the second part of the fourth plea and the first part of the sixth plea, the Federal Republic of Germany claims that the Boards of Appeal are composed of only three members and that, in general, only one of them possesses technical expertise. A Board of Appeal composed in such a way could not guarantee an examination equivalent to that carried out during the procedure leading to the adoption of a decision as part of the evaluation of a substance. The appeal procedure is not appropriate for decisions taken as part of the dossier or substance evaluation. The possibilities for detection depend on a multitude of factors which should be assessed on a case-by-case basis and carefully examined. A sole qualified member of that board would not be capable of studying and classifying the thousands of pages of a study. Firstly, that board does not dispose of the necessary scientific knowledge or of qualified staff in order to respond to complex technical questions. Secondly, it does not have at its disposal all of the scientific data, for example, information in the registration dossier and other information of the ECHA and the competent authorities concerning substances.
- 204 In that regard, first of all, it is necessary to refer to the considerations developed in paragraphs 104 to 109 above which oppose the approach according to which the intensity of the review that the Board of Appeal carried out with regard to pleas relating to errors vitiating the merits of the evaluation of benpat should have been limited to the review of the existence of a manifest error.
- 205 Next, it must be noted that, in the context of an action before it, the Board of Appeal must neither conduct itself an evaluation of the substance at issue, similar to that carried out by the designated authority, nor decide which further information is necessary in order to complete such an evaluation. In the context of such an action, it is limited to examining whether the arguments put forward by the applicant are capable of demonstrating that a decision taken as part of the evaluation of a substance is vitiated by an error.

- 206 Moreover, it must be noted that the Federal Republic of Germany merely invokes that the member or members of the Board of Appeal possessing technical expertise are not capable of conducting a review concerning the merits of an ECHA decision as part of the evaluation of a substance, but does not put forward any detailed arguments capable of demonstrating that, despite powers which must be enjoyed by those members under the first indent of the second sentence of Article 89(3) of Regulation No 1907/2006, the second subparagraph of Article 1(1) of Regulation No 771/2008 and Article 1(2) of Regulation No 1238/2007, they are unable to conduct a review of the technical findings included in an ECHA decision in the context of adversarial proceedings.
- 207 The Federal Republic of Germany in particular does not set out the reasons why the members of the Board of Appeal who adopted the contested decision did not have the necessary technical expertise allowing them to identify the errors vitiating the ECHA decision that they identified in the contested decision.
- 208 Moreover, it should be noted that, under the second subparagraph of Article 89(3) of Regulation No 1907/2006, additional members of the Board of Appeal may be appointed if that is necessary in order to ensure that the action is dealt with within a reasonable time frame.
- 209 Finally, it must be noted that the approach suggested by the Federal Republic of Germany is not compatible with recital 3 of Regulation No 771/2008, from which it follows that the Board of Appeal's expertise seeks to guarantee that a balanced evaluation from a legal and technical point of view can be carried out by that board.
- 210 In the light of those findings, the Federal Republic of Germany's arguments relating to the composition of the Board of Appeal must be rejected.
- 211 Thirdly, in so far as the Federal Republic of Germany claims that an increased intensity of review is likely to create delays in the procedure, it is necessary to reject that argument for the same reasons as those set out in paragraphs 110 to 117 above.
- 212 Fourthly, the Federal Republic of Germany's argument alleging that such an intensity of review would result in decisions taken as part of the evaluation of a substance being examined differently depending on whether they are adopted by the ECHA or by the Commission must be rejected for the same reasons as those set out in paragraphs 118 to 122 above.
- 213 Fifthly, the Federal Republic of Germany claims that the intensity of the review carried out by the Board of Appeal cannot depend on the pleas, arguments and evidence put forward by the applicant. It cannot be accepted that the applicant could decide the intensity of that review.
- 214 In that regard, it should be noted that, since, in the context of proceedings before it, the Board of Appeal merely examines whether the arguments put forward by the applicant are capable of demonstrating an error vitiating the ECHA decision, the scope of the review carried out by the Board of Appeal depends, admittedly, on the arguments put forward by the applicant in the context of the action.
- 215 It is however necessary to distinguish the scope of the review conducted by the Board of Appeal, on the one hand, and the intensity of that review, on the other hand. Contrary to what is claimed by the Federal Republic of Germany, the intensity of the review cannot be determined by the pleas, arguments and evidence put forward by the applicant.
- 216 In the light of the above considerations, it is necessary to reject the argument alleging that the intensity of the review could not depend on evidence put forward by the applicant and therefore all of the Federal Republic of Germany's arguments seeking to demonstrate that, in paragraph 122 of the contested decision, the Board of Appeal exceeded the limits of its power of review.

(iv) The arguments alleging that, contrary to the Board of Appeal's findings, it was not impossible to identify metabolites of benpat

- 217 The Federal Republic of Germany claims that the Board of Appeal's finding concerning the alleged impossibility of identifying metabolites is wrong. In the first place, that finding is based on OECD Guidelines 309 for the Testing of Chemicals. Those guidelines merely stated that, in general, it is necessary to use concentrations of 100 µg/l in order to be able to detect the presence of metabolites. They do not however exclude that that detection could be possible at a lower level of concentration. In the second place, the Board of Appeal overlooked the fact that that method was adopted in 2004 and that, since then, detection by analytical methods has been continuously improved. In the third place, the ECHA decision contains requirements relating to adapting tests, which seek precisely to enable the identification of a heightened probability of metabolites in a substance which is not very soluble. In the fourth place, the '2004 testing methods' could have been used with half the amount of the substance, namely a solubility of 45 µg/l instead of 100 µg/l. That is especially true in the light of current measurement methods.
- 218 The ECHA, the Commission and the intervening companies dispute those arguments.
- 219 In that regard, in the first place, it should be noted that, in the contested decision, the Board of Appeal did not exclude that, during testing to be conducted in accordance with method No 309, metabolites of benpat could potentially be identified. As is apparent from paragraph 123 of that decision, that board confined itself to noting that it was not sure that the addressees of the ECHA decision could succeed in identifying metabolites derived from benpat in the context of the conduct of the testing at issue. Therefore, contrary to what is claimed by the Federal Republic of Germany, in the contested decision, that board did not find that it was impossible for metabolites to be identified at a concentration below 100 µg/l.
- 220 In the second place, in the contested decision, the Board of Appeal did not call into question the obligation of the addressees of the ECHA decision to take into account metabolites of benpat in the event that metabolites could be identified in the context of testing to be conducted in accordance with method No 309. By contrast, as is apparent from paragraph 125 of the contested decision, it considered that, according to OECD Guidelines 309 for the Testing of Chemicals, in principle, those addressees were required to make all reasonable efforts to identify and quantify the major transformation products by conducting that testing and to record those efforts in the study report accordingly. It therefore restricted itself to calling into question the obligation of result concerning the identification of metabolites of benpat in the context of that testing.
- 221 In the third place, the Federal Republic of Germany claims that the Board of Appeal committed an error, due to the fact that OECD Guidelines 309 for the Testing of Chemicals did not exclude that detection of the presence of metabolites could be possible at a level of concentration below 100 µg/l.
- 222 In that regard, it should be noted that, in the contested decision, the Board of Appeal did not hold that it was impossible to identify the presence of metabolites at a concentration less than 100 µg/l. On the contrary, it upheld the ECHA decision in so far as it obliged the addressees of that decision to make all reasonable efforts to identify and quantify the major transformation products during the conduct of testing in accordance with method No 309 and to record those efforts in the study report accordingly.
- 223 By contrast, the Board of Appeal considered that, in so far as it was not certain that that identification is possible, an obligation of result concerning the identification of metabolites was not justified. The possibility that identification could be possible at a concentration of 45 µg/l is not capable of calling into question the merits of that finding.
- 224 Therefore, it is necessary to reject that argument of the Federal Republic of Germany.

- 225 In the fourth place, assuming that, by its arguments, the Federal Republic of Germany seeks to claim that the Board of Appeal's assessment according to which it was not certain that metabolites of benpat could be identified in the context of testing to be conducted in accordance with method No 309 was manifestly erroneous, they must be rejected.
- 226 In that context, it should be noted that, in paragraphs 121 to 123 of the contested decision, the Board of Appeal found, in essence, that it was apparent from OECD Guidelines 309 for the Testing of Chemicals that, as a result of analytical limits, if the test substance was applied at a concentration of 100 µg/l, it was not realistic to expect testing to allow metabolites of that substance to be identified, since that substance had a maximum solubility of 45 µg/l and neither the ECHA nor the intervening companies were able to identify the major transformation products which would probably be created during the conduct of that testing.
- 227 It should also be recalled that, in the context of an action for annulment under Article 263 TFEU, the review carried out by the EU Courts is limited where concerns the assessment of highly complex scientific and technical facts. As regards such assessments, the EU Courts are limited to reviewing whether they are vitiated by a manifest error or misuse of powers, or whether the decision-maker clearly exceeded the limits of its discretion (see judgment of 21 July 2011, *Etimine*, C-15/10, EU:C:2011:504, paragraph 60 and the case-law cited).
- 228 It is therefore necessary to examine whether the Federal Republic of Germany's arguments are capable of demonstrating that, as regards the assessment at issue, the Board of Appeal committed a manifest error, a misuse of powers, or whether it clearly exceeded the limits of its discretion.
- 229 Firstly, the Federal Republic of Germany claims that method No 309 was adopted in 2004 and that, since then, the detection by analytical methods has been continuously improved.
- 230 In that regard, it must be stated that, in paragraphs 121 to 123 of the contested decision, the Board of Appeal not only set out the reasons why it was not certain that metabolites of benpat could be identified in the context of testing to be conducted in accordance with method No 309, but also held that neither the intervening companies, nor the ECHA, nor the designated authority had been able to identify an appropriate method for identifying the major transformation products which would probably be created during the conduct of that testing.
- 231 In those circumstances, the unsubstantiated arguments of the Federal Republic of Germany relating to the continuously improving detection of methods of analysis are not capable of demonstrating that the Board of Appeal's assessment at issue is manifestly erroneous.
- 232 Secondly, the Federal Republic of Germany claims that the ECHA decision contained details relating to the adaptation of testing which seeks precisely to be able to identify with a high degree of probability metabolites of a substance with weak solubility.
- 233 In that regard, it should be noted that the Federal Republic of Germany merely refers to details in the ECHA decision, but does not indicate which details are at issue and does not state the reasons why such details are capable of demonstrating that the Board of Appeal's assessment set out in paragraph 226 above is manifestly erroneous.
- 234 In any event, it must be stated that the Federal Republic of Germany merely claims that the details in the ECHA decision sought to allow metabolites of a substance with weak solubility to be identified with a high degree of probability, but does not demonstrate that it is certain that those details allowed metabolites of benpat to be identified in the context of testing conducted in accordance with method No 309.

235 Therefore, that argument is not capable of demonstrating that the Board of Appeal's assessment at issue is manifestly erroneous.

236 Thirdly, the Federal Republic of Germany claims that its scientific staff assumes that the '2004 testing methods' could have been used with half the quantity of the substance, namely a solubility of 45 µg/l instead of 100 µg/l.

237 In that regard, it suffices to note that the Federal Republic of Germany merely makes an assumption. However, by its very nature, an assumption is not capable of demonstrating that the Board of Appeal's assessment at issue is manifestly erroneous.

238 In any event, it should be noted that the Federal Republic of Germany does not set out in detail the evidence on which that assumption is based.

239 Fourthly, the Federal Republic of Germany claims that the ECHA decision did not oblige the registrants to identify all of the metabolites formed, but only the major metabolites, namely the major degradation products. However, in itself, that argument is not capable of demonstrating the existence of a manifest error vitiating the Board of Appeal's assessment at issue.

240 Therefore, the Federal Republic of Germany's arguments alleging that, contrary to the Board of Appeal's findings, it was not impossible to identify metabolites of benpat must be rejected in their entirety.

(v) The arguments alleging that the identification of metabolites constitutes one of the elements of method No 309

241 The Federal Republic of Germany claims that the identification of metabolites constitutes one of the elements of method No 309, which is commonly laid down by OECD Guidelines 309 for the Testing of Chemicals, and by the corresponding transposition laid down in Council Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation No 1907/2006 (OJ 2008 L 142, p. 1), as amended for the purpose of its adaptation to technical progress by Commission Regulation (EC) No 761/2009 of 23 July 2009 (OJ 2009 L 220, p. 1). It is inherent to that method that it is not certain that testing can effectively identify the metabolites at issue and that the registrant is responsible for the detailed management of metabolites. It is not possible to clearly foresee either the result or the conduct of testing in accordance with that method and it is possible that, in the course of such testing, the person responsible for the evaluation must take and apply other decisions in order to better comply with the objectives of that evaluation. The specifications concerning testing conducted in accordance with that method cannot therefore be classified as disproportionate.

242 The ECHA, the Commission and the intervening companies dispute those arguments.

243 In that regard, it should be noted that it was stated in paragraph 219 above that, in the contested decision, the Board of Appeal did not annul the ECHA decision in so far as that decision provided for an obligation for its addressees to conduct testing in accordance with method No 309, but solely in so far as that decision provided for an obligation of result concerning the identification of metabolites in the context of the conduct of that testing.

244 Therefore, subject to the obligation of result concerning the identification of metabolites of benpat, the specifications concerning the conduct of testing to be carried out in accordance with method No 309 were not called into question by the Board of Appeal.

245 The Federal Republic of Germany's arguments alleging that the identification of metabolites constitutes one of the elements of method No 309 must be rejected.

(vi) The arguments alleging that method No 309 can be further clarified

246 The Federal Republic of Germany claims that a more precise clarification of method No 309 is possible. In the context of the evaluation of a substance, the testing methods provided for by the regulation could be specified, or partially modified, in order to be able to optimise the results, in specific cases, as a result of targeted adaptations. The identification of metabolites in the context of testing conducted in accordance with method No 309 is useful also for the purposes of preparing testing in accordance with method No 308. In that context, the Federal Republic of Germany claims also that the Board of Appeal should not have separated the request to conduct testing in accordance with method No 309 from the identification of metabolites. Firstly, the deletion of specifications relating to the identification of metabolites could result in artificial deadlines, which would delay unnecessarily the identification, and in increased expenditure in relation to the collection of necessary information. Secondly, that would have made the subsequent conduct and the success of testing in accordance with method No 308 more complicated.

247 The ECHA, the Commission and the intervening companies dispute those arguments.

248 The Federal Republic of Germany's arguments alleging that method No 309 can be further clarified must be rejected. They are not capable of calling into question the Board of Appeal's findings.

249 As was stated in paragraphs 243 and 244 above, in the contested decision, the Board of Appeal neither challenged the use of method No 309, nor the possibility of modifying that method. It merely annulled the ECHA decision in so far as it provided for an obligation of result concerning the identification of metabolites, as a result of the fact that it was not certain that the addressees of that decision are capable of identifying metabolites of benpat in accordance with that method.

(vii) The argument relating to the allegedly contradictory character of the contested decision

250 The Federal Republic of Germany claims that the contested decision is contradictory. Firstly, the Board of Appeal annulled the obligation to identify metabolites in paragraph 1 of that decision. Secondly, in the grounds for that decision, it acknowledged that it could not exclude that no useful results about metabolites are obtained and indicated that the addressees of the ECHA decision should make every effort to quantify the major transformation products during the conduct of testing in accordance with method No 309 and specify those efforts in the corresponding study report.

251 The ECHA, the Commission and the intervening companies dispute those arguments.

252 The Federal Republic of Germany's argument relating to the allegedly contradictory character of the contested decision must be rejected.

253 As stated in paragraphs 243 and 244 above, the Board of Appeal annulled the ECHA decision in so far as that decision provided for an obligation of result concerning the identification of metabolites. In that context, it did not rely on the finding that such identification was impossible, but solely on the finding that it was not certain that such identification is possible in relation to metabolites of benpat.

254 Therefore, contrary to what is claimed by the Federal Republic of Germany, the Board of Appeal's finding, in paragraph 125 of the contested decision, according to which, in the context of the conduct of testing in accordance with OECD Guidelines 309 for the Testing of Chemicals, the addressees of that decision remained obliged to make all reasonable efforts to identify and quantify the major transformation products and to record those efforts in the study report accordingly cannot be considered to be inconsistent with the annulment by the Board of Appeal of the ECHA decision in so far as that decision provided for an obligation of result with respect to the identification of metabolites.

(viii) The argument alleging infringement of the obligation to state reasons

255 The Federal Republic of Germany claims that the Board of Appeal infringed the obligation to state reasons. The reasons indicated in the contested decision do not justify the annulment of the requirement concerning the identification of metabolites, but rather the maintenance of that requirement.

256 The ECHA, supported by the Commission, and the intervening companies dispute that argument.

257 In that regard, firstly, it should be noted that the obligation to state reasons is an essential procedural requirement, which must be distinguished from the question whether the grounds given are correct, which goes to the substantive legality of the contested measure (judgment of 22 March 2001, *France v Commission*, C-17/99, EU:C:2001:178, paragraph 35). Therefore, it is necessary to reject the Federal Republic of Germany's arguments calling into question the merits of the Board of Appeal's findings in so far as those arguments are put forward in support of its argument alleging an infringement of the obligation to state reasons.

258 Secondly, in so far as, by its arguments, the Federal Republic of Germany claims, in essence, that the alleged contradictory nature of the Board of Appeal's reasoning does not allow it to understand whether the contested decision was well founded or possibly vitiated by an error, it suffices to note, by referring to paragraphs 252 to 254 above, that the Board of Appeal's findings developed in paragraphs 118 to 125 of the contested decision are not contradictory.

259 It follows that the Federal Republic of Germany's argument alleging an infringement of the obligation to state reasons must also be rejected.

(ix) The argument alleging that the Board of Appeal introduced a probability level which is substantively imprecise and not quantified

260 The Federal Republic of Germany claims that the Board of Appeal's approach disregards the relevant criterion relating to the principle of proportionality. The relevant question is whether, according to the state of regulatory toxicology, it seems appropriate and helpful to conduct testing. In other words, it is necessary to determine whether that testing is capable of identifying a risk, although its use in the actual case is not certain. In the contested decision, that board introduced a probability level which was substantively imprecise and not quantified.

261 The ECHA, supported by the Commission, and the intervening companies, dispute that argument.

262 In that regard, in the first place, it should be noted that the Board of Appeal, admittedly, considered that the ECHA was not entitled to provide for an obligation to identify metabolites of benpat if it was not certain that those metabolites could be identified during testing to be conducted in accordance with method No 309. However, that board cannot be criticised for having considered that the ECHA was not entitled to provide for an obligation of result for the addressees of its decision, although it was not certain that metabolites of benpat could be identified in accordance with that method.

263 In the second place, as regards the obligation to conduct testing in accordance with method No 309, it suffices to note that, in the contested decision, the Board of Appeal did not call that obligation into question. Therefore, in that decision, that board did not modify the probability level that had to be reached in order to justify a request to conduct that testing. By contrast, as is apparent from paragraph 125 of that decision, that board considered that, according to OECD Guidelines 309 for the Testing of Chemicals, the addressees of the ECHA decision were required to make all reasonable efforts to identify and quantify the main transformation products in the context of the conduct of that testing and to record those efforts in the study report accordingly.

264 Therefore, it is necessary to reject the Federal Republic of Germany's argument alleging that the Board of Appeal introduced a probability level which was substantively imprecise and not quantified and, therefore, all of the arguments relating to the examination of the second part of the first plea in the action before the Board of Appeal.

(2) The arguments relating to the examination of the third part of the first plea before the Board of Appeal

265 In its decision, the ECHA made provision for a request for further information in the event that testing conducted in accordance with method No 309 did not allow it to be determined whether benpat was persistent or very persistent for the purposes of points 1.1.1 and 1.2.1 of Annex XIII to Regulation No 1907/2006. In that case, it was provided that simulation testing on sediments conducted in accordance with method No 308 should be carried out with the R-898 constituent instead of benpat.

266 In the context of point III.4 of the reasons for its decision, the ECHA stated that sediments were also an environmental sphere of concern. Benpat was a strong absorbent and, consequently, it is absorbed quickly and extensively in sediments. According to it, it was also likely that a high level of non-extractable residues would be produced in the context of testing conducted in accordance with method No 308 and it would probably be difficult to separate the degradation from the processes of dissipation. In order to facilitate the interpretation of data, it is necessary to satisfy certain conditions. In order to evaluate the persistence of benpat, it is necessary to make a distinction between simple elimination and degradation. For that purpose, the detection and identification of metabolites are fundamental requirements. A high temperature encourages the vitality of inoculum, the likelihood that metabolites will be formed and the possibility of identifying metabolites as compared with a lower temperature. Consequently, the testing should be carried out at 20 °C, but that temperature should be reduced to 12 °C using the Arrhenius equation. R-898 should be used instead of benpat.

267 In the context of the third part of the first plea in the action before the Board of Appeal, the intervening companies claimed, in essence, that, as a result of the properties of benpat, testing conducted in accordance with method No 308 was not appropriate for the purposes of examining its persistence.

268 In paragraphs 133 to 142 of the contested decision, the Board of Appeal examined those arguments.

269 In paragraph 136 of the contested decision, the Board of Appeal found that benpat posed particular difficulties in the context of the conduct of testing according to method No 308. Not only is benpat liable to move from the aqueous phase to the solid phase of the testing system, but it is also likely to form non-extractable residues in the solid phase. As the two parties before it confirmed during the hearing, it is currently not certain that it is possible to identify and quantify non-extractable residues formed by the substance in the context of testing conducted in accordance with that method. According to that board, it was not certain that that testing would allow in practice the absorption or decomposition of the substance at issue to be measured.

270 In paragraph 137 of the contested decision, the Board of Appeal notes that a European Chemical Industry Council (CEFIC) initiative for long-term research report raised a number of questions relating to the appropriateness of method No 308 for the evaluation of substances such as benpat. It also stated that the designated authority and the ECHA had confirmed during the hearing before it that there currently existed no generally accepted approach to include non-extractable residues in the environmental evaluation of a substance.

- 271 In paragraph 138 of the contested decision, the Board of Appeal concluded that, on the basis of the evidence and arguments presented before it, at that time there was no scientific consensus as to the way in which the results of testing conducted in accordance with method No 308 should be evaluated concerning the identity and the properties of non-extractable residues.
- 272 In paragraph 139 of the contested decision, the Board of Appeal held that the ECHA decision required testing to be conducted in accordance with method No 308 solely where testing to be conducted in accordance with method No 309, including the identification of metabolites, does not allow the persistence of benpat to be demonstrated. Given that the obligation to measure metabolites formed in the context of the latter testing had been annulled, that identification was uncertain. It also indicated that, as soon as information relating to metabolites is available, that new information should be evaluated and the conduct of a study in accordance with method No 308 could be required where appropriate.
- 273 In paragraph 140 of the contested decision, the Board of Appeal reached the conclusion that the ECHA had not demonstrated that testing to be conducted in accordance with method No 308 was appropriate for the purposes of determining the persistence of benpat.
- 274 In paragraph 141 of the contested decision, the Board of Appeal did not exclude that it could be possible that testing conducted in accordance with method No 308 allows the persistence of benpat to be determined. It notes that the ECHA could be able to establish at a later point in time that a study conducted in accordance with that method was appropriate for the purposes of studying the persistence of benpat, including a method providing for the examination of the identity and properties of its metabolites. However, according to it, the justification by the ECHA of such a study should take account of all other relevant and newly available information such as the results of testing which must be conducted in accordance with method No 309.
- 275 In paragraph 142 of the contested decision, the Board of Appeal concluded that, for those reasons, the third part of the first plea in the action before it should be upheld and the ECHA decision annulled in so far as that decision requested the conduct of testing in accordance with method No 308.
- 276 In the context of the second part of the fourth plea and the second part of the sixth plea in the present action, the Federal Republic of Germany claims that those findings of the Board of Appeal are vitiated by an error.
- 277 As a first step, it is necessary to rule on the Federal Republic of Germany's argument alleging that the Board of Appeal exceeded the limits of its power of review. As a second step, the arguments calling into question the merits of that board's findings will be examined.

(i) The arguments seeking to demonstrate that the Board of Appeal exceeded the limits of its power of review

- 278 In the context of the second part of the fourth plea and the second part of the sixth plea in the action before the Court, the Federal Republic of Germany claims that, in paragraph 136 of the contested decision, the Board of Appeal exceeded the limits of its power of review. According to it, in that paragraph, that board contradicted the expertise of the Member States concerning the question whether testing to be conducted in accordance with method No 308 was appropriate. However, it is necessary to grant the Member State Committee a wide discretion in the light of its function as an expert committee and of the fact that it is composed of members bound by the instructions of their Member States. Therefore, that board has only a limited power of review, the intensity of which is similar to the review exercised by courts of discretionary decisions.
- 279 The ECHA, the Commission and the intervening companies dispute those arguments.

280 The Federal Republic of Germany's arguments seeking to demonstrate that the Board of Appeal exceeded the limits of its power of review must be rejected for the same reasons as those set out in paragraphs 190 to 216 above.

(ii) The arguments calling into question the merits of the Board of Appeal's findings

281 In the context of the second part of the sixth plea, the Federal Republic of Germany puts forward arguments calling into question the merits of the considerations on which the Board of Appeal based its conclusion that it was not established that the sediment simulation testing conducted in accordance with method No 308 and requested by the ECHA in its decision was not appropriate. It acknowledges that a part of benpat is irreversibly connected with environmental media and thus cannot be detected in those media, which could create difficulties in performing an experimental assessment of the distribution of the substance in the testing system and of the percentage of degradation to be indicated. Nevertheless, according to it, the Member State Committee correctly considered that there existed a genuine chance that the testing conducted in accordance with method No 308 would provide realistic and useful results despite the problems connected with non-extractable residues.

282 In the first place, the Federal Republic of Germany claims that the Board of Appeal's approach disregards the relevant criterion relating to the principle of proportionality. The relevant question is whether, according to the state of regulatory toxicology, it seems appropriate and helpful to conduct testing. In other words, it is necessary to determine whether that testing is capable of identifying a risk, although its use in the specific case is uncertain. The requests for further information have no direct impact upon the commercial value of benpat, but constitute merely an intermediate step prior to potential risk management measures. In the light of the objective of Regulation No 1907/2006 which is to guarantee a high level of protection for human health and the environment and of the precautionary principle, the identification of risks should be particularly easy and entirely possible. A too high probability cannot therefore be required in relation to the possibility of tests to identify a specific property because, otherwise, only tests whose results are relatively foreseeable will be authorised. It is however only in entirely exceptional cases that it could be predicted before the conduct of a test that it would indeed allow the information sought to be produced or whether other tests will be necessary in order to identify the existing risk. According to the Federal Republic of Germany, that board should have limited itself to verifying whether the measure pursued the end intended and whether it was capable of attaining it, by examining whether the findings of the Member State Committee were manifestly wrong.

283 The testing strategy provided for by the ECHA decision satisfied that criterion. By contrast, that strategy, as modified by the Board of Appeal, did not satisfy that criterion. The modifications made by that board were based on the idea that testing may be required only if it can be expected with reasonable certainty that it will allow conclusive results to be obtained about the property being studied. By proceeding in that way, that board introduced a level of probability that was imprecise and not quantified. It is difficult to foresee to what extent testing will allow the presence or absence of the property being studied to be definitively evaluated. That level considerably reduces the possibilities of obtaining information by means of Regulation No 1907/2006. Such an approach is not compatible with the objectives pursued by that regulation. It is in particular not compatible with the precautionary principle, which requires all the information relating to the risks to be collected. The testing requests remaining after the contested decision are less capable of identifying the persistence criterion than the ECHA decision. Ultimately, that would have the result that the testing strategy, as modified in the contested decision, would undermine the objective of clarification.

284 The ECHA, the Commission and the intervening companies dispute those arguments.

- 285 In that regard, it should be noted that, in accordance with Article 1(1) of Regulation No 1907/2006, the latter seeks, admittedly, to ensure a high level of protection of human health and the environment and that, in accordance with the second sentence of Article 1(3) of that regulation, the provisions thereof are based on the precautionary principle.
- 286 However, Regulation No 1907/2006 cannot be interpreted solely in the light of the objective of ensuring a high level of protection of human health and the environment and of the precautionary principle. In accordance with Article 1(1) of that regulation, the latter also refers to 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. Moreover, account should also be taken of the freedom to conduct a business set out in Article 16 of the Charter of Fundamental Rights and, where appropriate, of the objective of avoiding testing on animals, which follows in particular from recital 47 of that regulation.
- 287 The relevant criterion relating to the principle of proportionality is the result of balancing the different objectives pursued by Regulation No 1907/2006 and the application of the precautionary principle. In accordance with that criterion, in order to justify a request to conduct testing, the ECHA must not only demonstrate the existence of a potential risk for human health and the environment, and the necessity to clarify that risk, but also establish that there is a realistic likelihood that the information requested would allow improved risk management measures to be taken.
- 288 In the light of those considerations, the Board of Appeal therefore cannot be criticised for having considered that a request to conduct testing provided for in a decision taken as part of the evaluation of a substance was appropriate where there was a realistic possibility that that testing would produce results which are relevant to that evaluation.
- 289 In the light of those considerations, the Board of Appeal cannot be criticised for having considered that, where, as a result of the particularities of a substance, there existed reasonable doubts concerning the question whether the testing method envisaged by the ECHA would allow results to be produced which are relevant for the evaluation of a substance, it was for the ECHA to establish that, despite those doubts, there was a realistic possibility that the method would allow relevant results to be produced.
- 290 In the light of those considerations, it is necessary to reject the Federal Republic of Germany's arguments alleging that the Board of Appeal disregarded the criterion relevant to the principle of proportionality by introducing a probability level that is too high.
- 291 In the second place, the Federal Republic of Germany puts forward arguments seeking to demonstrate the erroneous character of the Board of Appeal's assessment according to which the ECHA did not establish the existence of a realistic possibility that testing to be conducted in accordance with method No 308 would produce results which are relevant to the evaluation of benpat.
- 292 In that context, it should be noted that the assessment at issue is based on the assessment of highly complex scientific and technical facts and be borne in mind that, in the light of the limits to the review by the EU Courts in that regard, it is necessary to examine whether the arguments put forward by the Federal Republic of Germany are capable of demonstrating that, concerning that assessment, the Board of Appeal committed a manifest error or whether it manifestly exceeded the limits of its discretion (see paragraph 227 above).
- 293 Firstly, it is necessary to reject the Federal Republic of Germany's argument alleging that all of the Member States within the Member State Committee considered that there was a real chance that testing to be conducted in accordance with method No 308 would produce realistic and useful results despite problems connected with non-extractable residues of benpat. In itself, that argument is not capable of demonstrating the existence of a manifest error regarding the assessment at issue.

- 294 Secondly, the Federal Republic of Germany claims that the request to conduct testing in accordance with method No 308 decided upon in the ECHA decision corresponded to the state of regulatory toxicology concerning the procedure to be followed in order to evaluate the persistence criterion, as it was provided for by OECD Guidelines 308 for the Testing of Chemicals. The Board of Appeal's findings call that method itself into question and are thus not compatible with Regulation No 440/2008.
- 295 In that regard, firstly, it should be noted that, contrary to what is claimed by the Federal Republic of Germany, in the contested decision, the Board of Appeal did not call into question method No 308 as such. On the contrary, as is apparent from paragraph 141 of that decision, that board considered that testing conducted in accordance with that method could be appropriate to the extent that the ECHA is able to establish that, despite problems relating to non-extractable residues of benpat, such testing is capable of producing relevant results for the evaluation of the persistent character of benpat in the environment of sediments.
- 296 Secondly, in the light of the considerations developed in paragraphs 285 to 290 above, the Board of Appeal cannot be criticised for not restricting itself to examining in abstract terms whether method No 308 was appropriate for evaluating the persistence of substances in a sedimentary environment, and for having examined that question more concretely with respect to benpat, by taking into account the particularities of that substance.
- 297 Therefore, the Federal Republic of Germany's argument according to which the Board of Appeal's findings call into question method No 308 as such and are thus not compatible with Regulation No 440/2008 must be rejected.
- 298 Thirdly, the Federal Republic of Germany claims that the Board of Appeal does not call into question the fact that obtaining conclusive results in accordance with method No 308 is possible.
- 299 In that regard, it should be noted that, in paragraph 141 of the contested decision, the Board of Appeal, admittedly, did not exclude that, despite problems connected with non-extractable residues, method No 308 could produce realistic and useful results. However, in that paragraph, that board stated that, in order to establish that there existed a realistic possibility that testing conducted in accordance with that method could produce results which are relevant for the evaluation of benpat, it was for the ECHA to establish that, despite those problems, such a possibility was realistic.
- 300 In essence, although the Board of Appeal did not exclude that it could be demonstrated that there exists a realistic possibility that testing conducted in accordance with method No 308 could produce results which are relevant for the evaluation of benpat, despite problems connected with the formation of non-extractable residues, it considered that, at that stage, the ECHA had not demonstrated that possibility.
- 301 The Federal Republic of Germany's argument alleging that the Board of Appeal did not call into question the fact that obtaining conclusive results in accordance with method No 308 was possible must therefore be rejected.
- 302 Fourthly, the Federal Republic of Germany claims that the reasoning followed by the Board of Appeal in the contested decision is circular, in so far as that board justifies the lack of a prospect that testing conducted in accordance with method No 308 will be successful by the fact that that board deleted the specifications for the identification of metabolites in the context of testing to be conducted in accordance with method No 309. The purpose of the adopted testing strategy consisted precisely in ensuring that information about metabolites already obtained, as the case may be, during testing conducted in accordance with method No 309, could be used in testing conducted in accordance with method No 308, which would present difficulties in that regard. That therefore makes it very clear to

what extent declarations relating to the widest possible identification of metabolites in the context of testing conducted in accordance with method No 309 are essential to the success of strategies for the identification of the persistence criterion.

- 303 In that regard, first of all, it should be noted that the Board of Appeal, admittedly, annulled the obligation of result for the identification of metabolites in testing to be conducted in accordance with method No 309, as a result of the fact that it was not certain that such identification was possible. As was stated in paragraphs 169 to 264 above, none of the arguments put forward by the Federal Republic of Germany is capable of validly calling into question the Board of Appeal's findings justifying that decision.
- 304 Next, it should be noted that, as the Board of Appeal indicated in paragraph 125 of the contested decision, the annulment of the obligation of result concerning the identification of metabolites in testing to be conducted in accordance with method No 309 did not call into question the intervening companies' obligation to make all reasonable efforts to identify and quantify the main transformation products in the context of the conduct of that testing and to record those efforts in the study report accordingly. Therefore, it cannot be considered that that board unduly limited that testing and, therefore, it also cannot be criticised for having unduly limited the prospect that the testing in accordance with method No 308 would be successful.
- 305 Finally, it should be noted that the reason why the Board of Appeal annulled the ECHA's decision to conduct testing in accordance with method No 308 was that that agency had not established that, despite problems connected with the fact that benpat produced non-extractable residues, there was a realistic possibility that testing conducted in accordance with that method could produce results which are relevant for the evaluation of that substance.
- 306 In the light of those considerations, the Federal Republic of Germany's argument alleging circular reasoning on the part of the Board of Appeal in the contested decision must be rejected.
- 307 Fifthly, the Federal Republic of Germany claims that neither the fact that testing to be conducted in accordance with method No 308 is difficult to carry out, nor the fact that it is not certain that it allows sufficient information to be obtained about non-extractable residues and metabolites preclude the conduct of that testing from being requested. Otherwise, substances which are difficult to study could not be subject to any testing.
- 308 In that regard, firstly, it should be noted that the Board of Appeal did not rely on the finding that it was difficult to conduct testing in accordance with method No 308, but on the finding that the ECHA had not established that there was a realistic possibility that that testing could produce results which are relevant to the evaluation of benpat.
- 309 Secondly, it must be noted that, in paragraphs 136 and 138 of the contested decision, the Board of Appeal also did not rely on the uncertainty inherent to all experimental research. By contrast, it stated that, as regards benpat, there was a particular problem relating to the application of method No 308, which was linked to the fact that that substance is likely not only to move from the aqueous phase to the solid phase of the testing system, but also to form non-extractable residues in the solid phase. Moreover, it stated, in essence, that during the procedure before it, the ECHA had not been able to establish that, despite that problem, the conduct of testing in accordance with that method could allow the absorption and degradation of that substance to be measured. Therefore, in that decision, it relied on the finding according to which there existed justified doubts concerning the question whether, as a result of the specificities of that substance, there existed a realistic likelihood that testing conducted in accordance with method No 308 would allow conclusions to be drawn relating to the persistence of that substance in the environment of sediments. In the light of the considerations developed in paragraphs 282 to 290 above, such an approach cannot be regarded as manifestly wrong.

310 It follows that it is necessary to reject the Federal Republic of Germany's argument alleging that neither the fact that testing to be conducted in accordance with method No 308 is difficult to carry out, nor the fact that it is not certain that it will allow sufficient information to be obtained about non-extractable residues and metabolites preclude the conduct of that testing being requested.

311 Therefore, it is necessary to reject all the arguments calling into question the merits of the Board of Appeal's findings and, therefore, all of the arguments relating to the examination of the third part of the first plea before the Board of Appeal.

2. The arguments relating to the examination of the second plea in the action before the Board of Appeal

312 In paragraphs 156 to 161 of the contested decision, the Board of Appeal examined and rejected the second plea in the action before it.

313 In the context of the second part of the fourth plea in the present action, the Federal Republic of Germany claims that, in that part of the contested decision, the Board of Appeal committed an error. According to it, in paragraph 159 of that decision, that board conducted an excessively intensive review and encroached on the role of the Member State Committee.

314 The ECHA, the Commission and the intervening companies dispute those arguments.

315 The Federal Republic of Germany's arguments alleging an error vitiating paragraphs 156 to 161 of the contested decision must be rejected as ineffective. As is apparent from paragraph 34 above, the Federal Republic of Germany requests the annulment of that decision in so far as the Board of Appeal partially annulled the ECHA decision. However, paragraph 159 of the contested decision is in a part of that decision in which that board rejected the second plea in the action raised before it.

316 Therefore, the Federal Republic of Germany's arguments relating to the examination of the second plea before the Board of Appeal must be rejected.

3. The arguments relating to the third plea before the Board of Appeal and point 3 of the operative part of the contested decision

317 On page 7 of its decision, the ECHA stated that there existed evidence showing that benpat was bioaccumulative and toxic and that, since the criteria for bioaccumulation and toxicity were fulfilled, it was necessary to evaluate the criterion of persistence.

318 In the context of the third plea in the action before the Board of Appeal, the intervening companies claimed that the ECHA's findings concerning the bioaccumulative character of benpat were vitiated by errors.

319 In paragraphs 166 to 171 of the contested decision, the Board of Appeal examined those arguments.

320 In paragraph 166 of the contested decision, the Board of Appeal held that those considerations of the ECHA were included in a part of its decision, in which it had set out the reasons justifying the requests for further information concerning the persistent character of benpat. According to it, in that context, the information on the bioaccumulative character of that substance was not relevant.

321 In paragraphs 167 to 169 of the contested decision, the Board of Appeal held that the ECHA's finding, according to which benpat was bioaccumulative, should not have been included in that decision. Firstly, the intervening companies were not heard on that point, because that finding was added to the modified draft decision following those companies' comments on the draft decision and no

proposals for modification were submitted in that regard. Secondly, the finding at issue was not relevant in the context of the reasoning followed by the ECHA in order to justify its request for further information concerning the potential risk that benpat could be persistent.

322 In paragraphs 169 to 171 of the contested decision, the Board of Appeal stated that it was necessary to delete the ECHA's finding at issue from its decision. However, according to it, that error had no impact on the operative part of the ECHA decision, was ineffective and therefore did not justify an annulment of that decision.

323 In point 3 of the operative part of the contested decision, the Board of Appeal 'decided' that the claim concerning bioaccumulation in the reasons for the ECHA decision should be deleted from that decision.

324 In the context of the third part of the sixth plea, the Federal Republic of Germany claims that the Board of Appeal should not have decided, in point 3 of the operative part of the contested decision, that the finding relating to bioaccumulation in the grounds for the ECHA decision should be deleted. On the contrary, that board should have rejected the third plea in the action before it. In the first place, it is necessary to distinguish the grounds for that decision, which reflect the opinion of the Member State authorities, from the operative part of that decision. In themselves, those grounds do not prejudice the procedure under Article 59 of Regulation No 1907/2006, in which the existence of persistent, bioaccumulative and toxic properties of the substance are evaluated and the registrants are again heard and involved. The ECHA's position relating to bioaccumulation is not binding. A legally binding finding concerning the bioaccumulative nature of benpat is only possible in the context of another procedure, for example a procedure in accordance with Article 59 of that regulation. That claim could not have been misunderstood by the addressees of the ECHA decision. Moreover, the ECHA is not subject to any legal obligation to limit the reasoning of its decisions to what is strictly necessary. In the second place, the contested decision remains vague. That operative part does not provide for the annulment of the ECHA decision, but recommends that part of the statement of reasons be deleted, without clearly indicating how or by whom that should be done. In the third place, the Board of Appeal's finding according to which deleting the ECHA's finding concerning the bioaccumulative nature of benpat was justified because the intervening companies had not been heard on that issue, is unfounded. In the context of the procedure before the ECHA, those companies put forward an argument alleging that the requests for further information relating to the persistence criterion were disproportionate, on the ground that the bioaccumulation criterion has not yet been definitively defined. The finding at issue responded to that argument.

325 The ECHA, supported by the Commission, disputes those arguments. It maintains that the contention, in the ECHA decision, according to which benpat was bioaccumulative was inappropriate and that there was a risk that, in other contexts, such as in national procedures or subsequent procedures seeking to define substances of very high concern for the purposes of Title VII of Regulation No 1907/2006, reference could be made to that contention. Therefore, the intervening companies should have had the possibility to dispute such a contention. Moreover, if the contention at issue did not have an effect on the rest of the ECHA decision, as is maintained by the Federal Republic of Germany, then an annulment of the contested decision by the Court in that regard would also have no effect on the rest of that decision.

326 For their part, in the first place, the intervening companies claim that the ECHA's contention that benpat was bioaccumulative, was based on errors of appraisal. In the second place, they claim that it was justified to delete the finding at issue. They maintain that they had had the right to request the annulment of that part of the ECHA decision. They state that, without that deletion, they would not have had the possibility to effectively make their point of view known regarding the bioaccumulation criterion which had no place in that decision. They claim in the third place that, assuming that the

declaration relating to bioaccumulation in the initial decision is not final, the annulment thereof would have no consequence. The Federal Republic of Germany thus has no interest in the annulment of that part of the contested decision.

327 In the first place, it should be noted that the Federal Republic of Germany does not put forward any arguments capable of demonstrating the erroneous character of the Board of Appeal's conclusion, in paragraph 169 of the contested decision, according to which the claim that benpat was bioaccumulative should not have been included on page 7 of the ECHA decision.

328 The Federal Republic of Germany's arguments are not capable of validly calling into question the Board of Appeal's finding, in paragraph 166 of the contested decision, according to which the claim concerning the bioaccumulative character of benpat was moved to the part of the statement of reasons for the ECHA decision where that agency had set out the reasons why a request for further information about the persistent character of benpat was justified.

329 The Federal Republic of Germany's arguments are also not such as to validly call into question the Board of Appeal's finding, in paragraph 168 of the contested decision, according to which, in the context of the adoption of a decision taken as part of the evaluation of a substance, it is not necessary to reach a definitive conclusion concerning the bioaccumulative nature of that substance. Although, in order to identify a substance as a substance to be included in Annex XIV in accordance with Articles 57 and 59 of Regulation No 1907/2006, it is necessary to reach a definitive conclusion concerning the criterion justifying that inclusion, such as the persistent, bioaccumulative, toxic, very bioaccumulative or very toxic character of that substance, that is not necessary in the context of the evaluation of a substance in order to justify a request for further information about a substance. In that context, it is sufficient to establish a potential risk.

330 In the second place, it should be noted that, in the contested decision, the Board of Appeal did not confine itself to stating, in the context of the statement of reasons, that the ECHA should not have maintained in its decision that benpat was bioaccumulative. As is apparent from the wording of point 3 of the operative part of that decision, the Board of Appeal 'decided' that the claim concerning bioaccumulation should be deleted from the ECHA decision. In that context, it is also necessary to point out that, in the other points of that operative part, that board partially annulled the ECHA decision, dismissed the action as to the remainder, fixed the date on which the information requested should be submitted and ruled on the costs.

331 Firstly, in light of the wording of paragraph 3 of the contested decision and its context, that paragraph cannot be considered to be an element of the reasons for that decision, but must be considered to be a part of the operative part of that decision.

332 Secondly, it cannot be considered that a potential upholding of the Federal Republic of Germany's arguments alleging that the Board of Appeal should not have decided, in point 3 of the operative part of the contested decision, that the grounds of the ECHA decision should be deleted, would have no effect. Since that point is part of the operative part of the contested decision, if those arguments were upheld, it would be necessary to partially annul the contested decision.

333 Thirdly, it is necessary to reject the intervening companies' argument alleging that the Federal Republic of Germany does not have an interest in bringing an action as regards the partial annulment of the contested decision.

334 In that regard, it suffices to note that Article 263 TFEU draws a distinction between the right of Union institutions and Member States, on the one hand, to bring an action for annulment and the right of natural and legal persons, on the other hand, to do so, in that the second paragraph of that article gives all Member States the right to contest the legality of decisions of an agency of the Union by means of an action for annulment without having to establish any legal interest in bringing

proceedings. A Member State need not therefore prove that an act of an agency which it is contesting produces legal effects with regard to it in order for its action to be admissible (see, to that effect, judgment of 10 April 2008, *Netherlands v Commission*, T-233/04, EU:T:2008:102, paragraph 37 and the case-law cited).

- 335 Fourthly, it is necessary to uphold the arguments of the Federal Republic of Germany which allege that the Board of Appeal should not have decided, in point 3 of the operative part of the contested decision, that the finding relating to bioaccumulation included in the reasons for the ECHA decision should be deleted. As that board stated in paragraph 170 of the contested decision, the errors which it had identified in paragraphs 166 to 169 of the ECHA decision were not capable of calling into question the operative part of that decision and the third plea in the action before it was thus ineffective. In those circumstances, in the operative part of the contested decision, that board should have limited itself to dismissing that plea.
- 336 That conclusion is not called into question by the ECHA's argument alleging that the intervening companies should have had the possibility to contest that agency's finding concerning bioaccumulation, in view of the risk that reference could be made to it in other proceedings.
- 337 Firstly, since the ECHA decision related solely to the requests for further information which that agency considered to be necessary in order to complete the evaluation of benpat concerning the potential risk that that substance could be persistent, the finding concerning the bioaccumulative character of benpat was not a ground of that decision on which the operative part of that decision was based. In those circumstances, nothing prevents that ground being called into question in a subsequent procedure. Therefore, in the event that the ECHA or the Commission rely on the finding at issue in such a procedure, for example, a procedure in order to identify benpat as a bioaccumulative substance, in accordance with Articles 57 and 59 of Regulation No 1907/2006, nothing prevents the intervening companies from contesting that finding in the context of that procedure or, as the case may be, in an action before the Board of Appeal or before the EU Courts. That would also be the case in procedures before the national authorities.
- 338 Secondly, it must be noted that nothing precludes that, in the context of the statement of reasons for a decision, the Board of Appeal rules on arguments put forward before it. However, where those arguments are ineffective, that cannot have an impact on the operative part of its decision.
- 339 It follows that it is necessary to uphold the third part of the sixth plea, without it being necessary to rule on the Federal Republic of Germany's arguments seeking to demonstrate that, in paragraph 167 of the contested decision, the Board of Appeal should not have held that the rights of defence of the intervening companies had been infringed.
- 340 Therefore, it is necessary to annul point 3 of the operative part of the contested decision and to dismiss the action as to the remainder.

IV. Costs

- 341 Under Article 134(1) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings.
- 342 In the present case, point 3 of the operative part of the contested decision must, admittedly, be annulled for the reasons set out in paragraphs 330 to 340 above. However, as was stated in paragraphs 327 to 329 above, the Board of Appeal was entitled to hold, in the statement of reasons for that decision, that the ECHA should not have claimed that benpat was bioaccumulative. In those circumstances, the annulment of point 3 of that operative part cannot be considered to be significant

for the purposes of the allocation of the costs. Since the Federal Republic of Germany has been largely unsuccessful, it must be ordered to pay the costs incurred by the ECHA and by the intervening companies, in accordance with the form of order sought by them.

³⁴³ In accordance with Article 138(1) of the Rules of Procedure, the institutions which have intervened in the proceedings are to bear their own costs. Consequently, the Commission is to bear its own costs.

On those grounds,

THE GENERAL COURT (Fifth Chamber)

hereby:

- 1. Annuls Decision A-026-2015 of the Board of Appeal of the European Chemicals Agency (ECHA) of 8 September 2017, in so far as, in point 3 of the operative part of that decision, the Board of Appeal decided that the claim concerning bioaccumulation in the statement of reasons for the ECHA decision of 1 October 2015 requiring additional testing concerning the substance benpat (CAS 68953-84-4) should be deleted;**
- 2. Dismisses the action as to the remainder;**
- 3. Orders the Federal Republic of Germany to bear its own costs, the costs incurred by the ECHA, and those incurred by Envigo Consulting Ltd and Djchem Chemicals Poland S.A.;**
- 4. Orders the European Commission to pay its own costs.**

Gratsias

Labucka

Dittrich

Delivered in open court in Luxembourg on 20 September 2019.

[Signatures]

Table of contents

I. Background to the dispute and the contested decision	2
II. Procedure before the Court and forms of order sought by the parties	4
III. Law	5
A. The first to third pleas, and the first part of the fourth plea, seeking to demonstrate that the Board of Appeal was not competent to examine the pleas in the action before it concerning substantive assessments relating to the evaluation of benpat	5
1. The Federal Republic of Germany's arguments relating to the respective roles of the Member State Committee, the ECHA and the Board of Appeal	6
2. The other arguments put forward by the Federal Republic of Germany	9
B. The fifth plea, alleging an infringement of the duty to state reasons	19
C. The second part of the fourth plea and the sixth plea, seeking to demonstrate that the Board of Appeal committed errors in the context of the examination of pleas put forward before it	20
1. The arguments relating to the examination of the first plea in the action before the Board of Appeal	21
(a) The arguments relating to the examination of the first part of the first plea before the Board of Appeal	21
(b) The arguments relating to the examination of the second and third parts of the first plea in the action before the Board of Appeal	21
(1) The arguments relating to the examination of the second part of the first plea in the action before the Board of Appeal	22
(i) The arguments seeking to demonstrate that the Board of Appeal should not have found the existence of an autonomous and independent decision relating to the identification of metabolites	23
(ii) The arguments relating to the Board of Appeal's competence	24
(iii) The arguments seeking to demonstrate that the Board of Appeal exceeded the limits of its power of review	24
(iv) The arguments alleging that, contrary to the Board of Appeal's findings, it was not impossible to identify metabolites of benpat	28
(v) The arguments alleging that the identification of metabolites constitutes one of the elements of method No 309	30
(vi) The arguments alleging that method No 309 can be further clarified	31
(vii) The argument relating to the allegedly contradictory character of the contested decision	31
(viii) The argument alleging infringement of the obligation to state reasons	32

(ix) The argument alleging that the Board of Appeal introduced a probability level which is substantively imprecise and not quantified	32
(2) The arguments relating to the examination of the third part of the first plea before the Board of Appeal	33
(i) The arguments seeking to demonstrate that the Board of Appeal exceeded the limits of its power of review	34
(ii) The arguments calling into question the merits of the Board of Appeal's findings	35
2. The arguments relating to the examination of the second plea in the action before the Board of Appeal	39
3. The arguments relating to the third plea before the Board of Appeal and point 3 of the operative part of the contested decision	39
IV. Costs	42