Reports of Cases

JUDGMENT OF THE GENERAL COURT (Fourth Chamber)

13 January 2017*

(Access to documents — Regulation (EC) No 1049/2001 — Documents held by the ECHA containing information submitted by an undertaking in connection with its application for authorisation to use di-(2-ethylhexyl)phthalate (DEHP) — Decision to disclose certain information considered confidential by the applicant — Exception relating to the protection of commercial interests — Concept of private life — Right to property — Obligation to state reasons)

In Case T-189/14,

Deza, a.s., established in Valašské Meziříčí (Czech Republic), represented by P. Dejl, lawyer,

applicant,

v

European Chemicals Agency (ECHA), represented initially by A. Iber, T. Zbihlej and M. Heikkilä, acting as Agents, and subsequently by M. Heikkilä, C. Buchanan and W. Broere, acting as Agents, and by M. Mašková, lawyer,

defendant,

supported by

European Commission, represented by F. Clotuche-Duvieusart, P. Ondrůšek and K. Talabér-Ritz, acting as Agents,

and by

ClientEarth, established in London (United Kingdom),

European Environmental Bureau (EEB), established in Brussels (Belgium),

Vereniging Health Care Without Harm Europe, established in Rijswijk (Netherlands),

represented by B. Kloostra, lawyer,

interveners,

APPLICATION pursuant to Article 263 TFEU seeking the annulment of the ECHA's decisions of 24 January 2014 concerning the disclosure of certain information submitted by the applicant in the course of the procedure relating to the application for authorisation to use di-(2-ethylhexyl)phthalate (DEHP),

* Language of the case: Czech.

THE GENERAL COURT (Fourth Chamber),

composed of M. Prek (Rapporteur), President, I. Labucka and V. Kreuschitz, Judges,

Registrar: S. Bukšek Tomac, Administrator,

having regard to the written part of the procedure and further to the hearing on 29 June 2016,

gives the following

Judgment

Background to the dispute

1 The substance di-(2-ethylhexyl)phthalate (DEHP) is used to soften polyvinyl chloride plastics (PVC). DEHP was included in Annex XIV to 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). The inclusion of this substance in that annex had the effect that, as from 21 February 2015, its use is now subject to an authorisation issued by the European Chemicals Agency (ECHA).

2 In order to be able to continue to produce DEHP without interruption beyond 21 February 2015, the applicant, Deza a.s., submitted an application for authorisation to the ECHA pursuant to Article 62 of Regulation No 1907/2006. In this regard, it attached to its application for authorisation a confidential version and a non-confidential version of the required documents, including a chemical safety report, an analysis of alternatives and a socio-economic analysis. Arkema France, Grupa Azoty Zakłady Azotowe Kędzierzyn SA and Vinyloop Ferrara SpA ('the former applicants') also applied for authorisation to continue producing DEHP.

3 From 13 November 2013 to 8 January 2014, the ECHA, pursuant to Article 64(2) of Regulation No 1907/2006, organised a public consultation in respect of the applications relating to DEHP. In this context, it made several documents relating to that substance publicly available.

4 On 5 December 2013, on the basis of Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ 2001 L 145, p. 43), ClientEarth and the European Environmental Bureau (EEB) made an application to the ECHA for access to the report on chemical safety and analysis of alternatives included in the application for authorisation to use DEHP, since they considered that the documents disclosed during the public consultation procedure were incomplete.

5 By letter dated 18 December 2013, the ECHA informed the applicant of ClientEarth and EEB's request for access to the report on chemical safety and the analysis of alternatives included in the application for authorisation. The ECHA also informed the applicant that it was sending it, by email, a redacted version of the abovementioned documents and invited it to identify clearly the information which it did not wish to be disclosed and the reasons for which that information fell within one of the exceptions referred to in Article 4 of Regulation No 1049/2001.

6 On 24 January 2014, the ECHA sent to the applicant a letter bearing the reference AFA-C-0000004274-77-09/F and to the former applicants the letters bearing the references AFA-C-0000004280-84-09/F, AFA-C-0000004275-75-09/F and AFA-C-0000004151-87-08/F, informing them of its decision to disclose a part of the documents requested within the meaning of Regulation No 1049/2001 ('the contested decisions').

7 By letter of 7 February 2014, the ECHA informed ClientEarth and EEB that it had decided to grant them partial access to the information requested but that the disclosure was suspended because proceedings had been instituted before the Court to prevent that disclosure. Attached to that letter, in an annex, was one of the letters of 24 January 2014, namely that addressed to Arkema France, which was similar to that sent to the applicant.

Procedure and forms of order sought

8 On 24 March 2014 the applicant and the former applicants brought an action for annulment pursuant to Article 263 TFEU against the contested decisions. By separate document of the same date they lodged an application for interim relief pursuant to Article 278 TFEU, seeking suspension of the operation of the contested decisions.

9 By letter of 8 April 2014, the former applicants informed the Court that they were discontinuing their action, of which the President of the Court took formal note by an order for partial removal of 11 April 2014.

10 By order of 25 July 2014, *Deza* v *ECHA* (T-189/14 R, not published, EU:T:2014:686), the operation of the decision bearing the reference AFA C-0000004274-77-09/F was suspended and the ECHA was ordered not to disclose the chemical safety reports and analyses of alternatives to DEHP submitted by the former applicants bearing the references AFA-C-0000004280-84-09/F, AFA-C-0000004275-75-09/F and AFA-C-0000004151-87-08/F.

11 By a document lodged at the Court Registry on 1 August 2014, ClientEarth, EEB and Vereniging Health Care Without Harm Europe ('HCWH Europe') applied to intervene in support of the ECHA. Furthermore, they primarily requested to be able to use English in the written and oral phases of the proceedings and, in the alternative, during the oral part of the proceedings.

12 The applications referred to above were served on the applicant and the ECHA, in accordance with Article 116(1) of the Rules of Procedure of the General Court of 2 May 1991.

13 By order of the President of the Fourth Chamber of the Court of 25 September 2014, the European Commission was granted leave to intervene in support of the form of order sought by the ECHA.

14 By document lodged at the Court Registry on 3 October 2014, the ECHA requested confidential treatment of Annex D1 to the rejoinder in respect of ClientEarth, EEB and HCWH Europe.

15 By document lodged at the Court Registry on 10 October 2014, the applicant submitted a request for confidential treatment in respect of ClientEarth, EEB and HCWH Europe, relating to certain data and information contained in the application.

16 By a document lodged at the Court Registry on 31 October 2014, the applicant corrected its request for confidential treatment of certain elements contained in the application and its annexes as well as in the decisions of the ECHA and their annexes and also requested the confidential treatment of Annex D1 to the rejoinder, in respect of ClientEarth, EEB and HCWH Europe.

17 By order of the President of the Fourth Chamber of the Court of 16 January 2015, ClientEarth, EEB and HCWH Europe were granted leave to intervene in support of the form of order sought by the ECHA. The request by the interveners for derogation from the language rules was rejected in so far as it concerned the written stage of the procedure and the decision on the request for derogation from the language rules for the oral phase of the procedure was reserved.

18 On 20 February 2015, ClientEarth, EEB and HCWH Europe objected to the request for confidential treatment of Annex D1 to the rejoinder.

19 On 14 April 2015, the Court adopted a measure of organisation of the procedure by which it asked the applicant questions about its corrected request for confidential treatment.

20 On 29 April 2015, the applicant replied to the questions put by the Court.

21 By order of the President of the Fourth Chamber of the Court of 12 June 2015, the application for confidential treatment in respect of ClientEarth, EEB and HCWH Europe was granted, in respect of, first, the chemical safety report data contained both in Annex 3 to the confidential version of the contested decisions (pages 941 to 1503 of the application) and pages 353 to 915 of Annex A.4.5 to the confidential version of the application and, second, the analysis of the alternatives contained in both Annex 4 to the confidential version of the contested decisions (pages 1504 to 1819 of the application) and pages 37 to 352 of Annex A.4.4 to the confidential version of the application. The remainder of the request for confidential treatment was dismissed.

22 The applicant claims that the Court should:

— annul the contested decisions;

— order the ECHA to pay the costs.

23 The ECHA, supported by the Commission and by ClientEarth, EEB and HCWH Europe, contends that the Court should:

— dismiss the action as inadmissible in so far as it concerns the decisions contained in the letters which were not addressed directly to the applicant;

— dismiss the application as to the remainder;

— order the applicant to pay the costs.

Law

24 In support of its action, the applicant relies on four pleas in law, alleging, first, infringement of Article 4(2) of Regulation No 1049/2001, read in conjunction with Article 118 of Regulation No 1907/2006, second, infringement of the Agreement on trade-related aspects of intellectual property rights (TRIPs) of 15 April 1994 (OJ 1994 L 336, p. 214, the 'TRIPs Agreement'), which constitutes Annex 1 C to the Agreement establishing the World Trade Organisation ('the WTO') (OJ 1994 L 336, p. 3), and in particular Article 39(2) thereof, third, infringement of Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 ('the ECHR'), Article 1 of the Additional Protocol to the ECHR and Article 17 of the Charter of Fundamental Rights of the European Union and, fourth, infringement of Article 4(3) of Regulation No 1049/2001.

25 The ECHA contests the arguments raised by the applicant in support of its application for the annulment of the contested decisions and pleads that the action is inadmissible in so far as it concerns the decisions contained in the letters bearing the references AFA-C-0000004280-84-09/F, AFA-C-0000004275-75-09/F and AFA-C-0000004151-87-08/F.

26 In the circumstances of the present case, the Court considers that proper administration of justice justifies dismissing the merits of the present action, as is clear from the following considerations, without giving a preliminary ruling on the plea of inadmissibility raised by the ECHA in its defence inasmuch as the action relates to the decisions referred to in paragraph 25 above (see, to that effect, judgments of 26 February 2002, *Council* v *Boehringer*, C-23/00 P, EU:C:2002:118, paragraphs 50 to 52; of 23 October 2007, *Poland* v *Council*, C-273/04, EU:C:2007:622, paragraph 33; and of 10 October 2014, *Marchiani* v *Parliament*, T-479/13, not published, EU:T:2014:866, paragraph 23).

27 As a preliminary point, it must be borne in mind that Regulation No 1907/2006 requires an applicant wishing to use certain chemical substances to carry out an analysis of the availability of alternatives, to examine the risks involved and to verify the technical and economic feasibility of their use. As part of its application for authorisation to use DEHP, the applicant submitted, inter alia, the following two documents, in a confidential version and a non-confidential version, to the ECHA: a report on chemical safety and an analysis of alternatives. Those documents, in their non-confidential version, were published on the ECHA website. Following a request for access to documents made by ClientEarth and EEB, the ECHA requested the applicant to reconsider its position and to re-examine the information which was to be regarded as confidential. The applicant transmitted a modified version of the confidential documents. However, the ECHA considered that some of the information which the applicant did not wish to be disclosed was not confidential and thus had to be transmitted to the applicants for access to the documents. Therefore, the ECHA prepared another version of the documents, several of which have had parts redacted so as to remain confidential and others which have been retained in order to be disclosed. The applicant considered that certain pieces of information (the 'information at issue') among those which the ECHA intended to disclose should remain confidential. In its action for annulment, it listed exhaustively the information at issue in the latest version of the documents prepared by the ECHA. Accordingly, it is the issue of access to the contested information which is the subject of the present dispute.

28 However, in the context of the second plea in law, the applicant, in essence, defends a position whereby general presumptions that access to documents is to be refused applies to certain categories of documents also applies to the information at issue presented in the context of the authorisation procedure provided for by Regulation No 1907/2006 and accordingly, the disclosure of those documents would in principle undermine commercial interests. The Court considers that this complaint constitutes a plea in its own right which must be examined first.

1. The distinct plea alleging that there is a general presumption of confidentiality concerning the information submitted in connection with the authorisation procedure provided for in Regulation No 1907/2006

29 In the context of that plea, the applicant, in essence, submits that all the information at issue in its entirety is a commercial secret.

30 The ECHA submits that this approach by the applicant does not correspond to the approach taken by it during the third-party consultation procedure, since it did not put forward any argument that it was necessary to deal with the information at issue in its entirety; on the contrary the applicant put forward, in support of its request for non-disclosure of the information at issue, a few specific grounds which did not relate to one another. As to the substance, the ECHA disputes the fact that the information at issue enjoys a general presumption of confidentiality.

31 It should be pointed out at the outset that, assuming that the approach advocated by the applicant does not correspond, as alleged by the ECHA, to the approach which it adopted during the administrative procedure, that does not imply, however, that that plea could not be raised by the applicant.

32 The applicant, in essence, defends a position of principle according to which the general presumptions of refusal of access applying to certain categories of documents also apply to the information at issue presented in the framework of the authorisation procedure provided for in Regulation No 1907/2006 and, accordingly, the disclosure of those documents would, in principle, undermine commercial interests. As this is a question of interpretation of Regulation No 1049/2001 and Regulation No 1907/2006, it can therefore be legitimately raised before the Court even if it has not been invoked, nor, a fortiori, examined, at the stage of the administrative procedure. It is therefore appropriate to examine it.

33 Under Article 2(3) of Regulation No 1049/2001, the provisions on public access to ECHA documents apply to all documents held by that agency, that is to say, all documents drawn up or received by it and in its possession in all areas of activity of the European Union. Although that regulation is intended to give the fullest possible effect to the right of public access to documents of the institutions, that right is subject to certain limitations based on grounds of public or private interest (see, to that effect, judgment of 27 February 2014, *Commission* v *EnBW*, C-365/12 P, EU:C:2014:112, paragraph 85).

34 It must also be noted that the Court has recognised that it is open to the institutions and agencies concerned to base their decisions in that regard on general presumptions which apply to certain categories of documents, as considerations of a generally similar kind are likely to apply to requests for disclosure relating to documents of the same nature (see, to that effect, judgment of 1 July 2008, *Sweden and Turco* v *Council*, C-39/05 P and C-52/05 P, EU:C:2008:374, paragraph 50).

35 Accordingly, the Court of Justice and the General Court have recognised the existence of general presumptions justifying refusal of access to documents in several cases such as, in particular, the administrative file concerning a procedure for reviewing State aid, documents exchanged in connection with a merger control proceedings, documents in the context of proceedings under Article 101 TFEU and documents drawn up in the context of impact assessments by the Commission, relating to a decision-making process in environmental matters.

36 First, it is apparent from the case-law that, in order for a general presumption to be validly relied upon against a person requesting access to documents on the basis of Regulation No 1049/2001, it is necessary that the documents requested belong to the same category of documents or be documents of the same nature (see, to that effect, judgments of 1 July 2008, *Sweden and Turco* v *Council*, C-39/05 P and C-52/05 P, EU:C:2008:374, paragraph 50, and of 17 October 2013, *Council* v *Access Info Europe*, C-280/11 P, EU:C:2013:671, paragraph 72).

37 Second, it follows from that case-law that the application of general presumptions is essentially dictated by the overriding need to ensure that the procedures at issue operate correctly and to guarantee that their objectives are not jeopardised. Accordingly, a general presumption may be recognised on the basis that access to the documents involved in certain procedures is incompatible with the proper conduct of such procedures and the risk that those procedures could be undermined, on the understanding that general presumptions ensure that the integrity of the conduct of the procedure can be preserved by limiting intervention by third parties (see, to that effect, Opinion of Advocate General Wathelet in *LPN and Finland* v *Commission*, C-514/11 P and C-605/11 P, EU:C:2013:528, points 66, 68, 74 and 76). The application of specific rules provided for by a legal measure relating to a procedure conducted before an EU institution for the purposes of which the documents requested were produced is one of the criteria for recognising a general presumption (see,

to that effect, judgment of 11 June 2015, *McCullough* v *Cedefop*, T-496/13, not published, EU:T:2015:374, paragraph 91, and Opinion of Advocate General Cruz Villalón in *Council* v *Access Info Europe*, C-280/11 P, EU:C:2013:325, point 75).

38 The Court of the European Union have considered that the exceptions to the right of access to documents contained in Article 4 of Regulation No 1049/2001 cannot be interpreted without taking account of the specific rules governing access to those documents, which are laid down in the relevant regulations. Accordingly, the Court of Justice has pointed out that, under a procedure for the application of Article 101 TFEU, certain provisions of Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles [101 TFEU and 102 TFEU] (OJ 2003 L 1, p. 1) and Commission Regulation (EC) No 773/2004 of 7 April 2004 relating to the conduct of proceedings by the Commission pursuant to Articles [101 TFEU and 102 TFEU] (OJ 2004 L 123, p 18) laid down restrictive rules for the use of documents in the file relating to that procedure, since they provided that the parties to a proceeding under Article 101 TFEU did not enjoy an unlimited right of access to the documents in the Commission's file and that third parties, with the exception of complainants, did not, under such proceedings, have the right of access to the documents in the Commission's file. The Court of Justice has held that allowing generalised access, on the basis of Regulation No 1049/2001, to the documents in a file relating to a proceeding under Article 101 TFEU would jeopardise the balance which the EU legislature sought to ensure in Regulations No 1/2003 and No 773/2004 between the obligation on the undertakings concerned to submit to the Commission possibly sensitive commercial information to enable it to ascertain whether a concerted practice was in existence and to determine whether that practice was compatible with Article 101 TFEU, on the one hand, and the guarantee of increased protection, by virtue of the requirement of professional secrecy and business secrecy, for the information so provided to the Commission, on the other. The Court of Justice concluded from this that the Commission, for the purpose of applying the exceptions provided for in the first and third indents of Article 4(2) of Regulation No 1049/2001, was entitled to presume, without carrying out a specific, individual examination of each of the documents in a file relating to a proceeding under Article 101 TFEU, that disclosure of those documents would, in principle, undermine the protection of the commercial interests of the undertakings involved in such proceedings (see, to that effect, judgment of 27 February 2014, *Commission* v *EnBW*, C-365/12 P, EU:C:2014:112, paragraphs 86, 87, 90 and 93).

39 However, unlike the situations in which the Court of Justice and the General Court have accepted that the general presumptions justifying refusal of access to documents apply, Regulation No 1907/2006 expressly governs the relationship between that regulation and Regulation No 1049/2001. Article 118 of Regulation No 1907/2006 provides that Regulation No 1049/2001 applies to documents held by the ECHA. It does not restrict the use of the documents in the file relating to an authorisation procedure for the use of a chemical substance. That regulation does not in fact provide for the limitation on access to the file to the 'parties concerned' or to the 'complainants'. At the most, Article 118(2) precisely identifies certain information whose disclosure undermines the commercial interests of the person concerned. By contrast, Article 119(1) of that regulation lists other information which is to be made publicly available over the internet.

40 No general presumption can therefore be inferred from the provisions of Regulation No 1907/2006. It cannot therefore be accepted that, in the context of an authorisation procedure provided for by Regulation No 1907/2006, the documents communicated to the ECHA are to be regarded as being, in their entirety, clearly covered by the exception relating to the protection of the commercial interests of applicants for authorisation.

41 Although that exception is, where relevant, applicable to some of the documents sent to the ECHA, that is not necessarily the case with regard to all of the documents or to those documents in their entirety. The ECHA is, at the very least, under a duty to satisfy itself that the exception does apply, by means of a proper, specific examination of each document, as required by the first indent of Article 4(2) of Regulation No 1049/2001.

42 In that context, it must be held that the ECHA carried out a proper, specific examination of each document in accordance with the respective provisions of Regulation No 1049/2001 and Regulation No 1907/2006.

43 It follows from the foregoing that the plea alleging that there is a general presumption of confidentiality of the information submitted in connection with the authorisation procedure provided for by Regulation No 1907/2006 must be rejected.

2. The first plea in law, alleging infringement of Article 4(2) of Regulation No 1049/2001

44 In the context of its first plea, alleging infringement of Article 4(2) of Regulation No 1049/2001, read in conjunction with Article 118 of Regulation No 1907/2006, the applicant, in essence, raises four complaints. By its first complaint, the applicant maintains that the information at issue is confidential, since it concerns the applicant's know-how and commercial secrets. In the second complaint, the applicant relies on Article 39(2) of the TRIPs Agreement, which is binding on the EU, to maintain that the disclosure of the information at issue to a third party would undermine the protection of its commercial interests and that of its intellectual property rights, namely the protection of its commercial secrets. The third complaint is based on the fact that the 'overriding public interest' justifying the disclosure of the information at issue cannot be regarded either as significant or as being pursued by that disclosure. Moreover, the ECHA did not indicate in a clear and concrete manner the public interest which would justify the disclosure of the information at issue. The fourth complaint alleges infringement of Article 296 TFEU; the applicant criticises the ECHA for not stating the reasons whether or not the information at issue constituted commercial secrets within the meaning of Article 39(2) of the TRIPs Agreement and, a fortiori, for failing to mention the possible overriding public interest justifying its decision to disclose that confidential information.

The first complaint, alleging confidentiality of the information at issue on account of its commercial nature and the fact that it relates to the applicant's know-how

45 By its first plea, the applicant maintains that the information at issue is confidential since it is of a commercial interest within the meaning of Article 4(2) of Regulation No 1049/2001.

46 In support of that complaint, in the first place, it submits that that information concerns its know-how and commercial secrets, since that information is not readily accessible, is potentially commercially profitable and required considerable financial expense and efforts to collect and organise in such a way as to make it possible to obtain authorisation for the placing on the market and the subsequent use of DEHP.

47 Second, it disputes the fact that the data relating to the threshold values compared with the exposure and concentration values which, if not reached, do not trigger adverse effects on human health (DNEL) or on the environment (PNEC) ('DNEL and PNEC values') to which the applicant refers can be regarded as public within the meaning of Article 119(1)(f) of Regulation No 1907/2006.

48 The ECHA rejects all of those arguments.

49 It should be recalled, at the outset, that Article 15(3) TFEU provides that any citizen of the Union, and any natural or legal person residing or having its registered office in a Member State, has a right of access to documents of the European Union's institutions, bodies, offices and agencies subject to the principles and the conditions defined in accordance with the ordinary legislative procedure. The purpose of Regulation No 1049/2001, as indicated in recital 4 and Article 1 thereof, is to give the public a right of access to documents of the institutions that is as wide as possible (judgments of 28 June 2012, *Commission* v *Éditions Odile Jacob*, C-404/10 P, EU:C:2012:393, paragraph 111; of

28 June 2012, *Commission* v *Agrofert Holding*, C-477/10 P, EU:C:2012:394, paragraph 53; and of 14 November 2013, *LPN and Finland* v *Commission*, C-514/11 P and C-605/11 P, EU:C:2013:738, paragraph 40).

50 Furthermore, the procedure for applying for authorisation is governed by Regulation No 1907/2006, which establishes an EU procedure for authorising the use of chemical substances. Article 118 of Regulation No 1907/2006 provides that Regulation No 1049/2001 applies to documents held by the ECHA. It follows that the principle that the public should have the widest possible access to the documents must in principle be respected with regard to the documents held by the ECHA.

51 The principle that the public should have the widest possible access to the documents is nonetheless subject to certain limits based on reasons of public or private interest. Regulation No 1049/2001, in particular in recital 11 and Article 4 thereof, provides for a system of exceptions requiring institutions and bodies not to disclose documents in the event that such disclosure would undermine one of these interests (see, to that effect, judgments of 28 June 2012, *Commission* v *Éditions Odile Jacob*, C-404/10 P, EU:C:2012:393, paragraph 111; of 28 June 2012, *Commission* v *Agrofert Holding*, C-477/10 P, EU:C:2012:394, paragraph 53; and of 14 November 2013, *LPN and Finland* v *Commission*, C-514/11 P and C-605/11 P, EU:C:2013:738, paragraph 40).

52 Since the exceptions provided for in Article 4 of Regulation No 1049/2001 derogate from the principle that the public should have the widest possible access to the documents, they must be interpreted and applied strictly (see, to that effect, judgment of 21 July 2011, *Sweden* v *MyTravel and Commission*, C-506/08 P, EU:C:2011:496, paragraph 75). In that regard, it must be shown that the access in question is likely specifically and actually to undermine the interest protected by the exception, and that the risk of that interest being undermined is reasonably foreseeable and not purely hypothetical (judgments of 13 April 2005, *Verein für Konsumenteninformation* v *Commission*, T-2/03, EU:T:2005:125, paragraph 69, and of 22 May 2012, *Sviluppo Globale* v *Commission*, T-6/10, not published, EU:T:2012:245, paragraph 64).

53 It must also be noted that the system of exceptions laid down in Article 4 of Regulation No 1049/2001, particularly in Article 4(2), is based on a weighing of the opposing interests in a given situation, that is to say, on the one hand, the interests which would be favoured by the disclosure of the documents in question and, on the other, those which would be jeopardised by such disclosure. The decision taken on a request for access to documents depends on which interest must prevail in the particular case (judgments of 14 November 2013, *LPN and Finland* v *Commission*, C-514/11 P and C-605/11 P, EU:C:2013:738, paragraph 42, and of 23 September 2015, *ClientEarth and International Chemical Secretariat* v *ECHA*, T-245/11, EU:T:2015:675, paragraph 168).

54 The Court points out that, in order to justify refusal of access to a document, it is not sufficient, in principle, for that document to fall within an activity or an interest, mentioned in Article 4 of Regulation No 1049/2001. The institution concerned must also supply explanations as to how access to that document could specifically and actually undermine the interest protected by an exception laid down in that article (judgments of 28 June 2012, *Commission* v *Éditions Odile Jacob*, C-404/10 P, EU:C:2012:393, paragraph 116; of 28 June 2012, *Commission* v *Agrofert* Holding, C-477/10 P, EU:C:2012:394, paragraph 57; and of 27 February 2014, *Commission* v *EnBW*, C-365/12 P, EU:C:2014:112, paragraph 64).

55 As regards the concept of commercial interests, it is apparent from the case-law that it is not possible to regard all information concerning a company and its business relations as requiring the protection which must be guaranteed to commercial interests under the first indent of Article 4(2) of Regulation No 1049/2001 without frustrating the application of the general principle of giving the public the widest possible access to documents held by the institutions (judgments of 15 December 2011, *CDC Hydrogene Peroxide* v *Commission*, T-437/08, EU:T:2011:752, paragraph 44, and of 9 September 2014, *MasterCard and Others* v *Commission*, T-516/11, not published, EU:T:2014:759, paragraph 81).

56 Consequently, in order to apply the exception provided for by the first indent of Article 4(2) of Regulation No 1049/2001, it must be shown that the documents at issue contain elements which may, if disclosed, seriously undermine the commercial interests of a legal person. That is the case, in particular, where the requested documents contain commercially sensitive information relating, in particular, to the business strategies of the undertakings concerned or to their commercial relations or where those documents contain information particular to that undertaking which reveal its expertise (judgment of 9 September 2014, *MasterCard and Others* v *Commission*, T-516/11, not published, EU:T:2014:759, paragraphs 82 to 84).

57 It is in the light of those elements that the applicant's arguments must be analysed.

The question of the infringement of the first indent of Article 4(2) of Regulation No 1049/2001

58 It must be examined whether, as the applicant submits, the ECHA infringed the first indent of Article 4(2) of Regulation No 1049/2001 by adopting the contested decisions allowing the disclosure of the information at issue.

59 First, as regards the chemical safety report, it must first be noted that the information at issue included in the report is as follows:

— reference to the name of scientific studies and an EU report — namely the risk assessment report for 2008 — and the content of these studies and of this report (points 5.5.2.2, 5.5.3, 5.6.2, 5.6.3, 5.7.3, 5.8.2, 5.8.3, 5.9.1.2, 5.9.2.2, 5.9.3, 5.10.1.1, 5.10.3 and 9.0.1 of the chemical safety report);

— Reference only to the name and date of certain scientific studies (points 5.1.1.2, 5.10.1.2 and Tables Nos 43, 45, 52 to 54, 59, 70 and 73 of the chemical safety report);

— the name of a study concerning the 'no observed adverse effect level' values, ('the NOAEL exposure values') (point 5.11.2 of the chemical safety report);

— certain data on DEHP exposure scenarios and risk characterisation (points 9.1.1, 9.2.1, 9.3.1, 10.1.1, 10.1.2, 10.2.1, 10.2.2, 10.3.1, 10.4.2 and Tables Nos 141, 143 to 154 and 177 to 179 of the chemical safety report).

60 First, as regards the disputed information relating to the scientific studies and the content thereof, it should first be pointed out that they relate to data which have been published and which are therefore accessible to the public. The same applies to the disputed information contained in the risk assessment report for 2008. This is an EU document which has also been published. The information at issue therefore constitutes a compilation of excerpts from the studies and reports mentioned above and describes their contents. It does not appear that the disclosure of the mere compilation of those descriptive data, which are publicly available, is sufficient to undermine the protection of the applicant's commercial interests. Moreover, the applicant has not shown how, in the present case, that compilation of scientific data would constitute sensitive commercial data and how, if disclosed, its commercial interests would be undermined. It is only if the assessments made by the applicant when compiling this information provided added value — consisting of, for example, new scientific conclusions or relating to an inventive strategy which gives the undertaking a commercial advantage over its competitors (see, to that effect, orders of 13 February 2014, *Luxembourg Pamol (Cyprus) and Luxembourg Industries* v *Commission*, T-578/13 R, not published, EU:T:2014:103, paragraph 60, and of 25 July 2014, *Deza* v *ECHA*, T-189/14 R, not published, EU:T:2014:686, paragraph 54) — that they would then have fallen within the scope of commercial interests protected by Article 4(2) of Regulation No 1049/2001.

61 Next, it should be noted that the ECHA indicated in the decision contained in the letter bearing the reference AFA-C-0000004274-77-09/F that such information could be disclosed 'without the detailed underlying assessment'. In concrete terms, it has specifically redacted the assessments made by the applicant in the light of those studies (see, in particular, the information redacted by the ECHA in points 5.7.3, 5.8.3, 5.9.1.2, 5.9.2.2, 5.9.3, 5.10.1.1 and 5.10.1.2). Thus, it made a distinction between information relating to the content of published studies and thus of an essentially descriptive nature — which could be the subject of disclosure — and that which was derived from a critical evaluation of those studies by the applicant and thus was not available as such to the public — which, a priori, fell within the scope of commercial interest and were hidden by the ECHA. In the present case, 'objective' information cannot a priori be regarded as data particular to the undertaking which would reveal its expertise within the meaning of the case-law cited in paragraph 56 above.

62 Moreover, the applicant has only provided vague and generic explanations showing that the information at issue consisting of excerpts from studies available to the public could produce the alleged consequent harm to its know-how and its commercial secrets. It would have been all the more necessary to adduce precise and proper explanations since, as has been pointed out in paragraph 52 above, the exceptions provided for in Article 4 of Regulation No 1049/2001 must be interpreted and applied strictly because they derogate from the principle that the public should have the widest possible access to the documents.

63 Nor can the applicant's argument, in this context, that those data allow competitors to know how it would direct its future commercial strategy with regard to the subsequent use of that substance or would decide on the future manufacture of products consisting of DEHP or its alternatives. The compilation of the objective data cannot, as such, be sufficient to reveal the content of the applicant's commercial strategy or future choices as regards the manufacture of DEHP.

64 Furthermore, the applicant's argument that part of the information at issue is based on confidential data pooled by it and third parties, in particular its suppliers and purchasers, must also be rejected. On the one hand, the applicant does not identify any of the documents in dispute which would be the result of such a pooling of information. On the other hand, it has not submitted any document certifying the existence of agreements concluded with third parties in which it has undertaken not to disclose documents in the future.

65 Lastly, the Court cannot accept the argument that the compilation of publicly available studies would have required the applicant to engage in research and reading work of an intellectual nature which would have a commercial value and which would therefore fall within the scope of the applicant's commercial interest. The confidential or non-confidential nature of information is not determined by the work involved in compiling the data contained in studies available to the public. Rather, it was for the applicant to demonstrate that the document which represented the result of the compilation of publicly available information contained assessments providing added value within the meaning of paragraph 60 above and that that information thus fell within the scope of the commercial interest referred to in Article 4(2) of Regulation No 1049/2001.

66 That does not mean, contrary to what the applicant, in essence, claims, that disclosure gives a competitor the right simply to refer, in its application for authorisation to use a chemical substance, to the dossier of the applicant containing the compilation of studies and thus gain a competitive advantage. Article 63(1) of Regulation No 1907/2006 provides 'if an application has been made for a use of a substance, a subsequent applicant may refer to the appropriate parts of the previous application …, provided that the subsequent applicant has permission from the previous applicant to refer to these parts of the application'. This provision thus protects the holder of a document against the use of the document in the event that the information contained therein is disclosed as a result of a request for access to the document. It prevents the information in question from being used in such a way as to compete unfairly with the holder of the document and thus to give its competitors an illegal competitive advantage.

67 Even if it were accepted that the applicant's work of systemising public information may have some commercial value, it must still be shown that the systematisation of that information was accompanied by assessments resulting in new scientific conclusions or relating to an inventive strategy which gives the undertaking a commercial advantage over its competitors and which would, as a result, clearly be of a confidential nature (see paragraph 60 above); the applicant was unable to do so. In this context, it is important to recall, first, that the chemical safety report must comply with the format laid down in point 7 of Annex I to Regulation No 1907/2006, which is designed to standardise the method of systemising information. Second, account should be taken that the way in which publicly available information is searched for is facilitated by IT tools such as search engines. These two findings qualify to a certain extent the commercial value of compiling publicly available information.

68 Second, with regard to points 5.1.1.2, 5.10.1.2 and Tables Nos 43, 45, 52 to 54, 59, 70 and 73, it should be recalled that they mention the name and date of several studies which the applicant considers to be confidential and which the ECHA wishes to disclose. However, the applicant does not explain how its disclosure would undermine its commercial interests and confer advantages on its competitors. It does not specify how the disclosure of these studies would be problematic, yet raises no objection to the disclosure of almost all the other studies cited in the same tables.

69 Third, with regard to the contested information in point 5.11.2 of the chemical safety report, the ECHA stated, in the contested decisions, that the NOAEL exposure values contained in the approaches, methods and reflections could not undermine the applicant's commercial interests. It stated that this type of information was essential for the public to have an indication of the risks associated with the use of DEHP and that there was therefore considerable public interest in the disclosure of that information. It must be held that the applicant has neither called that consideration into question nor, a fortiori, specified how the reference to the abovementioned information contained in the report on chemical safety would undermine its commercial interests.

70 Fourth, as regards the DEHP exposure scenario data and the risk characterisation referred to in the last indent of paragraph 59 above, it must be found that the applicant has not put forward any arguments showing that those data were confidential.

71 Furthermore, the file shows that the ECHA deleted the vast majority of the information relating to the exposure scenarios and that only the introductory data relating to those scenarios are mentioned. It was for the applicant to show how such data were confidential.

72 As regards information on the risk characterisation, the file reveals that this information concerns data relating to the DNEL value and those relating to the risk characterisation ratio (RCR). As the ECHA points out in the contested decisions, the data on the DNEL value must be published in accordance with Article 119(1) of Regulation No 1907/2006 and the data relating to the RCR — which is a combination of the DNEL and PNEC values and the exposure values — cannot undermine the commercial interest of the applicant and are essential for the public awareness of the risk associated with the use of DEHP.

73 Second, as regards the analysis of alternatives, it is first of all necessary to observe the following:

— the information at issue in Tables Nos 4.6, 4.7, 4.12, 4.13, 4.18, 4.19, 4.23, 4.24, 4.27, 4.28, 4.33, 4.34, 4.37, 4.38, 4.41, 4.42, 4.46, 4.47, 4.51, 4.52, 4.56 and 4.57 are figures in the framework of comparisons of DNEL and PNEC values of DEHP and those values of other chemical substances;

— Tables Nos 25 and 26 of the document entitled 'Hazard and Risk Assessment for DEHP Alternatives' contain a comparative assessment of hazards, respectively, to human health and to the environment. The information at issue contained in the tables relates to the names of the alternatives, the DNEL and PNEC values of each of them, as well as brief observations about some of those substances;

— the disputed information in Table No 27 of the abovementioned document concerns three figures representing the transfer rate, in saliva, of DEHP and another substance and the information at issue in table No 28 is a figure representing the transfer rate, in sweat, of DEHP;

— the information at issue in point 5.5 of the abovementioned document relating to general conclusions are consideration on the PNEC value in relation to another substance.

74 Next, it should be pointed out that, in its observations made during the third-party consultation procedure, the applicant claimed, as regards the tables referred to in the first indent of paragraph 73 above, that they contained information similar to that contained in the chemical safety report, in particular the DNEL and PNEC values, and that this information was the intellectual property of the applicant for authorisation. The applicant pointed out that the disclosure of such information would cause it commercial harm since it could have charged for that information. It pointed out that payment would have to have been made in exchange for access to the analysis of alternatives and that that analysis should therefore be the subject of negotiations in order to ensure that the costs are shared.

75 It must be recalled that, in the contested decisions, the ECHA considered that the DNEL and PNEC values, the results of the studies and the conclusions of the classification included in the analysis of alternatives were not regarded as confidential since those findings and conclusions by themselves, without the detailed underlying assessment, could not be considered as seriously undermining the commercial interest of the applicant or the former applicants or a third party. The ECHA also stated that this type of information must be published by the ECHA in accordance with Article 119(1)(c),(e) and (f) of Regulation No 1907/2006.

76 It must be held that the applicant has failed to demonstrate how the disclosure of the data contained in the analysis of alternatives, which were specifically covered by its request for non-disclosure, would undermine its commercial interest. They are objective figures, determined in the context of the comparisons of the DNEL and PNEC values of DEHP and those values of other chemicals, which are mainly derived from published studies. It cannot be held that those figures which are set out in published studies, fall within the scope of the applicant's commercial interest. As has been pointed out in paragraph 61 above, the ECHA has redacted the applicant's 'subjective' remarks on that data, which is also borne out by the contested decisions, stating that the results and conclusions as such, 'without the underlying detailed assessment', cannot be regarded as seriously undermining the commercial interests of the applicant or the former applicants.

77 In that context, as has been pointed out in paragraph 63 above, the compilation of objective data cannot, as such, reveal the content of the applicant's commercial strategy or future choices as regards the manufacture of DEHP and cannot be regarded either as information particular to that undertaking which would reveal its expertise within the meaning of the case-law cited in paragraph 56 above.

78 The same conclusions can be reached in respect of the information at issue in Tables Nos 25 to 28 of the document entitled 'Hazard and Risk Assessment for DEHP Alternatives'. Moreover, the applicant has not provided any explanation to justify why four out of the 11 figures contained in Tables Nos 27 and 28 should not have been disclosed.

79 As regards Table No 25, it should be pointed out that the ECHA included the column headed 'Remarks' in the information to be disclosed. It must be found that those remarks are descriptive. As regards the information included in the column entitled 'Remarks' in Table No 26, the applicant adduced no evidence to support the view that these are assessments providing added value within the meaning of paragraph 60 above.

80 As regards the information at issue in point 5.5 of the analysis of alternatives, the applicant has also failed to adduce any justification which would enable it to be found that its disclosure would undermine its commercial interest. It is all the more difficult to conceive of this information as confidential as it concerns the identification of other substances which would have environmental effects equivalent to or of greater concern than DEHP. It does not appear that such information is sufficient to reveal the substance of the applicant's commercial strategy and the direction of its research and developments in the field of chemical substances or that it forms part its know-how or reveals its expertise, within the meaning of the case-law cited in paragraph 56 above.

81 Third, the applicant claims that it submitted several items of information which it was not mandatory to submit when introducing the application for authorisation. Specifically, it points out that, given that in Regulation No 1907/2006 DEHP is described not as a substance which has an impact on the environment but as a substance which has possible toxic effects on humans, it was not under obligation to submit PNEC values. While acknowledging that PNEC values did not have to be submitted in this case, the ECHA states that this did not affect its obligation to disclose the data in its possession.

82 First of all, it must be borne in mind that, pursuant to Article 2(3) of Regulation No 1049/2001 and Article 118(1) of Regulation No 1907/2006, the scope of Regulation 1049/2001 extends to all documents held by the institutions and agencies, that is to say, drawn up or received by them and in their possession, in all activities of the European Union.

83 Accordingly, information submitted to an institution or an agency of the European Union in the framework of an administrative procedure such as a procedure to authorise the use of a chemical substance or the placing on the market of a medicinal product may in principle be disclosed even if it was not obligatory to submit that information in the procedure concerned, where that information has been voluntarily sent by its holder. The only exceptions to this disclosure are those provided for in Article 4 of Regulation No 1049/2001. None of those exceptions covers the information contained in the documents submitted voluntarily to the ECHA by the applicant.

84 It follows that the ECHA was correct to treat the information at issue which the applicant was not obliged to submit but submitted voluntarily identically to the information required by Regulation No 1907/2006 for the application for authorisation and to consider, consequently, that it was required to disclose that information.

85 Next, since the scope of Regulation No 1049/2001 is clearly defined, natural or legal persons who submit information are not entitled to claim that, according to the principle of protection of legitimate expectations, a document submitted voluntarily is not subject to disclosure pursuant to Regulation No 1049/2001. The applicant's arguments must therefore also be rejected on that point.

86 Furthermore, the applicant stated, at the hearing, that it had submitted that information with a view to presenting a complete dossier of alternatives which had no impact on humans or the environment. As a result, even if this information was not mandatory, it was presented in order to support the application for authorisation and thus increase the chances of obtaining authorisation from the Commission and the ECHA.

87 Finally, the applicant does not specify how the objective PNEC values mentioned in the analysis of the alternatives would undermine its commercial interests. In addition, since DEHP is not considered to be an environmentally dangerous substance, the applicant would have no commercial interest in hiding this information, which would attest to the fact that DEHP has no impact on the environment and which would thus be favourable to the applicant.

88 It follows that the ECHA did not infringe Article 4(2) of Regulation No 1907/2006.

The question of the obligation to disclose information pursuant to Article 119(1)(f) of Regulation No 1907/2006 or the already public nature of such information

89 The Court is required to examine the arguments put forward by the ECHA that the exceptions provided for in Article 4(2) of Regulation No 1049/2001 cannot be applied to information regarded as public under Article 119(1)(f) of Regulation No 1907/2006, on the one hand, and that already available to the public, on the other.

– The admissibility of the challenge based on an incorrect application of Article 119(1)(f) of Regulation No 1907/2006

90 It must be borne in mind that, in response to the first plea, the ECHA submits that certain information relating to the DNEL and PNEC values was public pursuant to Article 119(1)(f) of Regulation No 1907/2006. In the context of the reply the applicant submits that the ECHA committed an error of assessment in applying that provision to the data corresponding to the DNEL and PNEC values which are the subject of the authorisation procedure. The ECHA submits that that complaint is new and out of time and, therefore, inadmissible. It submits that the contested decisions clearly indicated that, in respect of the DNEL and PNEC values and the results of the studies, such information had to be disclosed in accordance with Article 119(1)(f) of Regulation No 1907/2006, and that the legal presumptions laid down in that provision therefore applied to that information.

91 In that regard, it must be borne in mind that, under the first subparagraph of Article 48(2) of the Rules of Procedure of 2 May 1991, new pleas in law may not be introduced in the course of the proceedings unless they are based on matters of law or of fact which have come to light in the course of the procedure. A plea which amplifies a submission put forward previously, whether directly or by implication, and which is closely connected with that submission, will be declared admissible (judgments of 10 April 2003, *Travelex Global and Financial Services and Interpayment Services* v *Commission*, T-195/00, EU:T:2003:111, paragraphs 33 and 34, and of 24 May 2007, *Duales System Deutschland* v *Commission*, T-151/01, EU:T:2007:154, paragraph 71). Moreover, the prohibition laid down in Article 48(2) of the Rules of Procedure of 2 May 1991 concerns only new pleas in law and does not prevent the applicants submitting new arguments based on pleas already contained in the application (see, to that effect, judgment of 5 April 2001, *Wirtschaftsvereinigung Stahl and Others* v *Commission*, T-16/98, EU:T:2001:117, paragraph 49).

92 In the present case, it is apparent from paragraph 6 of the letters containing the contested decisions that, according to the ECHA, the information (values, study, results and the conclusions of the classification) concerning the DNEL and PNEC values could not be regarded as undermining the commercial interests of the applicant and that, therefore, the exception provided for in Article 4(2) of Regulation No 1049/2001 was not applicable to that type of information. The contested decisions state that that conclusion was also corroborated by the fact that such information had to be published pursuant to Article 119(1)(f) of Regulation No 1907/2006.

93 It is thus clear from the contested decisions that the findings that Article 119(1) of Regulation No 1907/2006 provided for the publication of information concerning the DNEL and PNEC values supported the main finding that that information could not seriously undermine the commercial interests of the applicant. It thus appears that, in contending that such information fell within the exception provided for by Article 4(2) of Regulation No 1049/2001, the applicant implicitly but indisputably contested the findings that such information had to be published pursuant to Article 119(1)(f) of Regulation No 1907/2006.

94 In the reply, the applicant merely responded to the ECHA's argument, which recalled the obligation, set out in the contested decision, to publish the information concerning the DNEL and PNEC values pursuant to Article 119(1) of Regulation No 1907/2006, corroborating the main finding relating to the lack of commercial interests.

95 It follows that the complaint alleging an incorrect application of Article 119(1)(f) of Regulation No 1907/2006 must be declared admissible.

– The existence of the obligation to publish certain information pursuant to Article 119(1)(f) of Regulation No 1907/2006 and the question of the already public nature of other information

96 First, it is necessary to consider whether, as the applicant maintains, Article 118 and Article 119(1)(f) of Regulation No 1907/2006 refer only to data corresponding to the values DNEL and PNEC which are the subject of the registration procedure referred to in Title II of the above regulation and not data relating to the practical application of the DNEL and PNEC values in the authorisation procedure provided for in Title VII of Regulation No 1907/2006.

97 As has been stated in paragraph 50 above, Article 118 of Regulation No 1907/2006 provides that Regulation No 1049/2001 applies to documents held by the ECHA. It follows that the principle that the public should have the widest possible access to the documents applies in principle to the documents which constitute the application for authorisation of a chemical substance. It is therefore immaterial whether the information is presented in the course of the proceedings by the applicant for authorisation or has already been presented in the context of another procedure, such as the registration procedure, provided for by Regulation No 1907/2006. Accordingly, there is nothing to suggest that the principle of access to documents laid down in Article 118 of Regulation No 1907/2006 and in Article 2 of Regulation No 1049/2001 read in conjunction would not apply in both cases.

98 Article 119(1)(f) of Regulation No 1907/2006 provides:

'The following information held by [the ECHA] on substances whether on their own, in mixtures or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 77(2)(e): … (f) any derived no-effect level (DNEL) or predicted no-effect concentration (PNEC) established in accordance with Annex I.'

99 Thus, Article 119(1) provides for a specific derogation from the rules governing access to documents laid down in Article 118(1) of Regulation No 1907/2006 and Article 2 of Regulation No 1049/2001, read together. In absolute terms, Article 119(1) of Regulation No 1907/2006 states that several types of information are to be made publicly available. The purpose of that provision is to provide the minimum information required to control adequately a substance, namely basic information on the hazards of the substance, guidance on safe use, the elements of the safety data sheet and the information needed to identify the substance (see Commission document COM(2003) 644 final of 23 October 2003). THE DNEL and PNEC values are among the information, cited in Article 119(1)(f) of Regulation No 1907/2006, that is to be made publicly available.

100 It should be noted that the DNEL value corresponds to the level of exposure to the substances — normally calculated on the basis of the dose descriptors available from animal studies — below which no harmful effect for humans is expected. The PNEC value corresponds to the concentration of substances below which there should be no adverse effect in the environmental sphere of concern. Therefore, any applicant for authorisation who can demonstrate that exposure to the effects of substances of very high concern on human health or the environment is less than the DNEL and PNEC values required, proves that no harmful effects on humans are expected to result from the use

of these substances, that no adverse effects should be expected to occur in the environmental sphere of concern and that the risk to human health or the environment is adequately controlled, in accordance with Article 60(2) of Regulation No 1907/2006.

101 First, Article 119(1)(f) of Regulation No 1907/2006 does not explicitly provide that the obligation to publish information over the internet is limited to the DNEL and PNEC values submitted in the context of the registration procedures and that it would therefore not cover the values to which the applicant refers in the context of an authorisation procedure.

102 Next, Article 64 of Regulation No 1907/2006, which concerns the procedure for the adoption of authorisation decisions, explicitly provides in paragraphs 2 and 6 thereof that the publication of the information on the ECHA website is to take account of Articles 118 and 119 of that regulation.

103 In addition, Annex I, to which Article 119(1)(f) of Regulation No 1907/2006 refers, states that a chemical safety assessment of a manufacturer must address the manufacture of a substance and all the identified uses. It also provides that the assessment is to cover all stages of the life cycle of the substance resulting from the manufacture and identified uses (see point 0.3 of that annex). For the determination of the DNEL value, it is specified that, depending on the exposure scenario(s), a single DNEL value may be sufficient or that it may be necessary to identify different DNEL values for each relevant human population (for example, workers, consumers, vulnerable populations) and for different routes of exposure. Annex I to Regulation No 1907/2006 provides that, if several exposure routes are probable, a DNEL value is to be established for each route and for all routes of exposure considered as a whole (see point 1.4.1 of that annex). Annex I to Regulation No 1907/2006 also indicates that the PNEC value is established for each environmental sphere of concern (see point 3.3.1 of that annex).

104 Annex I to Regulation No 1907/2006 also provides for a section dealing with risk characterisation, which consists in particular of a comparison between the exposure of the populations concerned and the relevant DNEL values and a comparison of the environmental concentrations foreseen in each environmental spheres and the PNEC values (see points 6.2 and 6.3 of that annex). Point 6.4 of Annex I indicates that, for any exposure scenario, the risk to humans and the environment can be considered to be adequately controlled, throughout the life cycle of the substance that results from manufacture or identified uses, if, in particular, the exposure levels estimated in the risk characterisation do not exceed the appropriate DNEL or PNEC values.

105 It is apparent both from Article 119(1)(f) of Regulation No 1907/2006 and from Annex I thereto that, given the importance of the data corresponding to the DNEL and PNEC values for the protection of public health and the environment, the chemical safety assessment of a substance and the resulting data should cover all identified uses and cover all stages of the substance's life cycle and the data must be published. Thus the distinction made by the applicant between the data corresponding to the DNEL and PNEC values relating to the 'registered substance' and the practical application of the data corresponding to the DNEL and PNEC values under the authorisation procedure provided for in Title VII of Regulation No 1907/2006 appears to be artificial. The obligation to publish provided for by the above provision does indeed apply to the DNEL and PNEC values contained in the chemical safety report attached to the application for authorisation. In this connection, it should be noted that the applicant did not call into question the arguments of the ECHA, ClientEarth, EEB and HCWH Europe according to which the DNEL and PNEC values remained in principle unchanged for a given substance and that the moment at which such a value is mentioned (the registration procedure or authorisation procedure) and the identity of the applicant who provided the values in connection with those proceedings mattered little. The applicant merely indicated, without further explanation, that the DNEL and PNEC values mentioned in the chemical safety report were different and had been arrived at through another method and for another purpose.

106 Lastly, the ECHA states that, in the context of an application for authorisation, it could be presented with DNEL and PNEC values different from the references values which the ECHA itself published. It states that, after having been examined by and approved by the Committee for Risk Assessment, those values could be recognised as the new reference values and henceforth be applicable to all future applicants for authorisation. It thus appears that those values must be made publicly available as a matter of course.

107 In that context, the applicant's argument that the ECHA has already fulfilled its obligation to provide information by publishing on its information portal the data corresponding to the relevant DNEL and PNEC values concerning the 'registered substance' or a document dated 12 April 2013 entitled 'Authorisation, establishing reference DNELs for DEHP. As the ECHA rightly points out, it was under no obligation to publish the reference DNEL or PNEC values for threshold substances. However, since these DNEL and PNEC values must be used in the same way by all applicants for authorisation, the ECHA considered it necessary, in the interests of transparency and equal treatment, to publish them in order to allow those applicants to understand the evaluation criteria. Such an approach by the ECHA cannot be criticised and cannot be regarded as mandatory. In any event, such publication of the reference values did not relieve the ECHA of its duty to publish, in accordance with Article 64(2) of Regulation No 1907/2006 and taking into account Articles 118 and 119 thereof, the broad information, sent by the applicant, relating to the uses in respect of which it applied for authorisation for DEHP.

108 As regards the scope of the obligation to publish the information referred to in Article 119(1)(f) of Regulation No 1907/2006, the Court endorses the ECHA's view that that obligation extends to the minimum information on the method of derivation or prediction of the DNEL and PNEC values and their correlation with other values. That minimum information is necessary in order to understand what the DNEL and PNEC values represent and to determine to what they relate. The Court must therefore accept, as the ECHA points out, that if the values alone were published without any explanation as to their meaning, the abovementioned provision would lose its effectiveness.

109 Second, as regards the statement that certain information was already publicly available, it is clear and, moreover, not disputed by the parties that the part of the information which was already available to the public could be disclosed. The question which must be examined is whether the compilation of known scientific data — and thus already available to the public — and secret scientific data must be disclosed. The applicant submits that such a combination produces a complex set of information which, as such, is not easily available and must therefore be treated as confidential.

110 It must be held that the applicant has not identified in the list of contested information those which would constitute secret scientific data grouped together with information already available to the public. Moreover, it is apparent from the analysis in paragraph 58 et seq. above that they are not regarded as commercial secrets.

111 It follows that the ECHA did not err by considering in the contested decisions that a part of the information at issue was already publicly available given that it had already been published and that another part had to be made publicly available pursuant to Article 119 of Regulation No 1907/2006.

112 It is clear from all the foregoing that the first complaint must be rejected.

The second complaint, alleging infringement of the protection of intellectual property rights, justifying the application of Article 4(2) of Regulation No 1049/2001

113 The applicant submits that the ECHA unjustifiably infringes its right to confidential treatment of the information which constitutes its intellectual property, which is covered by its commercial secrets. It refers in this respect to the definition of commercial secrets set out in Article 39(2) of the TRIPs Agreement.

114 The ECHA challenges that complaint.

115 First of all, Article 39(2) of the TRIPs Agreement provides as follows:

'Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information:

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) has commercial value because it is secret; …'

116 It must be pointed out, as a preliminary point, that the provisions of the TRIPs Agreement, which is part of the WTO Agreement, signed by the European Community and subsequently approved by Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994) (OJ 1994 L 336, p. 1), constitute an integral part of the European Union legal order. Where there are EU rules in a sphere concerned by the TRIPs Agreement, EU law will apply, which will mean that it is necessary, as far as possible, to adopt an interpretation in keeping with the TRIPs Agreement, although no direct effect may be given to the provision of that agreement at issue (see judgment of 11 September 2007, *Merck Genéricos — Produtos Farmacêuticos*, C-431/05, EU:C:2007:496, paragraph 35 and the case-law cited). It follows that Article 39(2) of the TRIPs Agreement cannot be invoked, as such, to invalidate the contested decisions.

117 In so far as the applicant's argument is to be understood as meaning that there is a principle, based on the definition in Article 39(2) of the TRIPs Agreement, according to which the mere fact that a person who has submitted a document has an intellectual property right over that document would suffice for the exception provided for in Article 4(2) of Regulation No 1907/2006 to apply, it must be rejected.

118 Such an approach is not consistent with the content of Article 39(2) of the TRIPs Agreement on which the applicant relies. This provision provides that, in order for it not to be disclosed, the information concerned must be 'secret'. The fact that it has commercial value does not make that information secret.

119 Similarly, the applicant's approach is tantamount to arguing that the protection afforded to intellectual property rights systematically takes precedence over the presumption in favour of the disclosure of information laid down in Regulation No 1049/2001 and Article 118(1) of Regulation No 1907/2006. As the ECHA points out, Article 4(2) of Regulation No 1907/2006 cannot be interpreted as meaning that the fact that a copyright protects a document implies that it is a commercial secret and that the proprietor may thus rely on the exception provided for by that provision.

120 In that regard, it must be borne in mind that Article 16 of Regulation No 1049/2001 provides that 'that Regulation shall be without prejudice to any existing rules on copyright which may limit a third party's right to reproduce or exploit released documents'. Similarly, as was pointed out in paragraph 66 above, Article 63(1) of Regulation No 1907/2006 provides that the subsequent applicant for the use of a substance must obtain authorisation from the applicant to refer to the appropriate parts of the previous application. These provisions thus protect the holder of a document from copyright infringement and the commercial value of the document in the event that the information contained therein is disclosed as a result of a request for access to that document. These provisions prevent the information in question from being used for commercial purposes by the competitors and thus giving them a competitive advantage.

121 It follows that the second complaint must be rejected.

The third complaint, alleging that there was no clear indication as to the public interest justifying the disclosure of the information at issue

122 By its third complaint, the applicant maintains that the 'overriding public interest' justifying the disclosure of the information at issue cannot be regarded either as significant or as being pursued by that disclosure. It considers that the interest in protecting its fundamental rights (or its commercial interests) outweighs the public interest justifying the disclosure of the information at issue and adds that the ECHA did not explain what the public interest would be in disclosing the information at issue.

123 It must be recalled that the final sentence of Article 4(2) of Regulation No 1049/2001 provides that EU institutions must not refuse access to a document where its disclosure is justified by an overriding public interest, even if it could undermine, the protection of a particular natural or legal person's commercial interests or the protection of the purpose of inspections, investigations and audits of the institutions of the European Union (judgment of 7 October 2014, *Schenker* v *Commission*, T-534/11, EU:T:2014:854, paragraph 74). In that respect, it is necessary to weigh, on the one hand, the particular interest to be protected by non-disclosure of the document concerned against, on the other hand, inter alia, the public interest in the document being made accessible, having regard to the advantages of increased openness, as described in recital 2 of Regulation No 1049/2001, in so far as it enables citizens to participate more closely in the decision-making process and guarantees that the administration enjoys greater legitimacy and is more effective and more accountable to the citizen in a democratic system (judgment of 21 October 2010, *Agapiou Joséphidès* v *Commission and EACEA*, T-439/08, not published, EU:T:2010:442, paragraph 136).

124 Although an overriding public interest capable of justifying the disclosure of a document must not necessarily be distinct from the principles which underlie Regulation No 1049/2001 (judgment of 14 November 2013, *LPN and Finland* v *Commission*, C-514/11 P and C-605/11 P, EU:C:2013:738, paragraph 92), it is nonetheless apparent from the case-law that general considerations alone cannot provide an appropriate basis for establishing that the principle of transparency is of particularly pressing concern and capable of prevailing over the reasons justifying the refusal to disclose the documents in question, and that it is the task of the party requesting information to make specific reference to circumstances showing that there is an overriding public interest to justify the disclosure of the documents concerned (see, to that effect, judgments of 14 November 2013, *LPN and Finland* v *Commission*, C-514/11 P and C-605/11 P, EU:C:2013:738, paragraphs 93 and 94, and of 23 September 2015, *ClientEarth and International Chemical Secretariat* v *ECHA*, T-245/11, EU:T:2015:675, paragraph 193).

125 In the present case, as the ECHA points out, the latter did not conclude that the information at issue should be protected by an exception referred to in Article 4(2) of Regulation No 1049/2001. As a result, it was under no obligation to determine or assess the public interest in the disclosure of the information or to weigh it against the applicant's interest in keeping that information confidential.

126 It follows that the applicant's arguments are ineffective.

127 Furthermore, as regards the DNEL and PNEC values in the report on chemical safety and the analysis of alternatives, it should be borne in mind that, even if those values were regarded as falling within the commercial interest of the applicant, Article 119(1)(f) of Regulation No 1907/2006 provides that they are automatically available to the public. That obligation to have access to that information is justified in recital 117 of the same regulation by the need to give EU citizens information about the substances to which they may be exposed in order to allow them to make informed decisions about the use that they wish to make of those chemicals.

128 As the ECHA rightly points out, it is clear from Article 119(1) of Regulation No 1907/2006 and recital 117 thereof that the EU legislature considered that the disclosure was a matter of a significant interest. The legislature itself weighed the interests and concluded that the interest in the disclosure of the information relating to the DNEL and PNEC values mattered more that the applicant's interest in their non-disclosure, since this information concerned some of the most important interests that existed, namely those relating to human health and the environment. Those factors are capable of establishing that the principle of transparency is of particularly pressing concern and capable of prevailing over the reasons justifying the refusal to disclose the information at issue.

129 The same is true of the NOAEL exposure values — that is, those indicating the maximum no observed adverse effect level — contained in the approaches, methods and reflections. Even assuming that the disclosure could undermine the applicant's commercial interests — which the applicant has not been able to demonstrate — that information is in any event essential for the public to have an indication about the risks associated with the use of DEHP. Thus, the ECHA did not err in considering that there was a high public interest in the disclosure of that information.

130 As regards the applicant's claim that the ECHA did not indicate clearly and concretely the public interest justifying the disclosure of the information at issue, it must be rejected. As is clear from paragraphs 69, 92, 128 and 129 above, the existence of an overriding public interest for the disclosure of certain information at issue was supported by the reference to Article 119 of Regulation No 1907/2006 — which is based on recital 117 of that regulation — in respect of the references to the DNEL and PNEC values, on the one hand, and the grounds of the contested decisions themselves as regards the NOAEL exposure values, on the other.

131 Accordingly, the third complaint, alleging that there is no clear indication as to the public interest justifying the disclosure of the information at issue, must be rejected.

The fourth complaint, alleging infringement of the obligation to state reasons

132 The applicant submits that the ECHA infringed Article 296 TFEU by failing to indicate the reasons for determining whether the information at issue constituted commercial secrets within the meaning of Article 39(2) of the Agreement TRIPs Agreement and, a fortiori, not mentioning the possible overriding public interest justifying its decision to disclose this confidential information.

133 According to settled case-law, the statement of reasons required under Article 296 TFEU must be appropriate to the measure in question and must disclose in a clear and unequivocal fashion the reasoning followed by the institution which adopted that measure, in such a way as to enable the persons concerned to ascertain the reasons for the measure and to enable the competent court to

carry out its review. The requirements to be satisfied by the statement of reasons depend on the circumstances of each case, in particular the content of the measure in question, the nature of the reasons given and the interest which the addressees of the measure, or other parties to whom it is of direct and individual concern, may have in obtaining explanations. It is not necessary for the reasoning to go into all the relevant facts and points of law, since the question whether the statement of reasons meets the requirements of Article 296 TFEU must be assessed with regard not only to its wording but also to its context and to all the legal rules governing the matter in question (see judgment of 7 July 2011, *Valero Jordana* v *Commission*, T-161/04, not published, EU:T:2011:337, paragraph 48 and the case-law cited).

134 In the present case, the ECHA mentions, first of all, in the contested decisions that several pieces of information contained in the report on chemical safety must be disclosed on the ground that they are already publicly available, namely, information already available over the internet (for example, in Chapter 9.0.1, summary table of descriptive uses, already published on the ECHA website as general information on the uses required for the public consultation on alternatives), information from peer-reviewed publications (for example Chapter 5.10.1.2), summaries of studies and experimental ecotoxicological assessments published in peer-reviewed journals or chapters that have been adapted or copied directly from the 2008 risk assessment presented by the European Union (for example, Chapters 5.6.3, 5.7.3, 5.10.3 and pp. 141 to 142 and 168 to 175).

135 It must be held that the grounds on which the abovementioned information cannot fall within the exception provided for in the first indent of Article 4(2) of Regulation No 1049/2001 are clear from the contested decisions, namely that this information is already publicly available.

136 The ECHA then notes, as regards the analysis of alternatives and the chemical safety report, that the DNEL and PNEC values, the results of the studies and the conclusions of the classification are not considered to be confidential because these results and conclusions as such, without the detailed underlying assessment, cannot be regarded as seriously undermining the commercial interests of the applicant or of a third party. On the one hand, it is clear from that reasoning that the ECHA distinguished between 'objective' data and the simple conclusions which may be easily drawn from that data — considered as non-confidential — on the one hand, and, on the other hand, the detailed assessments made by the applicant made on the basis of those data — considered to be confidential. Second, the contested decisions also state that this type of information was to be published by the ECHA pursuant to Article 119(1)(c), (e) and (f) of Regulation No 1907/2006.

137 Consequently, as regards the information relating to the DNEL and PNEC values, it must be held that the ECHA gave adequate reasons why it considered that the disclosure of those values could not undermine the commercial interest of the applicant and why it was required to disclose the information, namely the existence of an obligation under Article 119(1)(c), (e) and Regulation No 1907/2006.

138 Furthermore, the contested decisions state that the NOAEL exposure values contained in the approaches, methods and reflections could not undermine the commercial interests of the applicant and that, accordingly, the disclosure of the risk characterisation ratio (RCR) — which is a combination of the DNEL and PNEC values and the exposure values — could not undermine that commercial interest either. The ECHA states that the exception provided for in the first indent of Article 4(2) of Regulation No 1049/2001 cannot be applied to this type of information. It notes that this type of information is essential for the public to have an indication of the risks associated with the use of DEHP and that there is therefore a high interest for the public in having this information disclosed.

139 It follows from this that the ECHA made clear the grounds on which the information in question must, in its view, be made public, the grounds for which it rejected the applicant's arguments for applying the exceptions provided for in Article 4(2) of Regulation No 1049/2001 and the grounds for which it considered that certain information could not be disclosed.

140 Lastly, the contested decisions state that the names of the authors of unpublished study reports were not disclosed, pursuant to Article 4(1) (b) of Regulation No 1049/2001, but that no exception was applicable in respect of the date and title of the studies.

141 Again, it must be held that the contested decisions stated the reasons why only the date and title of the studies which were not yet publicly available could be disclosed.

142 Accordingly, the complaint alleging infringement of the obligation to state reasons must be rejected, since the ECHA gave sufficient grounds for the contested decisions.

143 It follows from all of the above that the first plea, alleging infringement of Article 4(2) of Regulation No 1049/2001, must be rejected.

3. The second and third pleas in law, alleging, on the one hand, in respect of the second plea, infringement of the Union's commitments under the TRIPs Agreement and infringement of the right to protection of confidential information (commercial secrets) and, on the other hand, in respect of the third plea, infringement of the Union's commitments under Article 8 of the ECHR and Article 17 of the Charter of Fundamental Rights and infringement of the right to property and to the protection of property

144 The Court considers that the second and third pleas in law, alleging, on the one hand, in respect of the second plea, infringement of the European Union's commitments under the TRIPs Agreement and infringement of the right to protection of confidential information (commercial secrets) and, on the other hand, in respect of the third plea, infringement of the European Union's commitments under Article 8 of the ECHR and Article 17 of the Charter of Fundamental Rights and infringement of the right to property and to the protection of property, should be examined together.

145 As a preliminary point, as recalled in paragraph 116 above, the provisions of the TRIPs Agreement constitute an integral part of the European Union legal order but no direct effect may be given to them. It follows that Article 39(2) of the TRIPs Agreement cannot be invoked, as such, to invalidate the contested decisions.

146 In the first place, the Court must examine the ECHA's argument that, in order to argue that the contested decisions are in breach of the ECHR, the Charter of Fundamental Rights and the TRIPS Agreement, the applicant should have pleaded that the provisions of Regulation No 1907/2006 — namely Article 119(1)(c), (e) and (f) of that regulation, which provides for legal presumptions of non-confidentiality — are incompatible with the primary law of the European Union or with the legally higher-ranking provisions of those conventions.

147 As regards the assertion that the ECHR and the Charter of Fundamental Rights have been infringed, the Court points out that the applicant relies on a fundamental right to protection of confidential information, which is enshrined in Article 339 TFEU. It should also be borne in mind that, according to the case-law, the protection of commercial secrets is recognised as a general principle (see, to that effect, judgments of 24 June 1986, *AKZO Chemie and AKZO Chemie UK* v *Commission*, 53/85, EU:C:1986:256, paragraph 28; of 19 May 1994, *SEP* v *Commission*, C-36/92 P, EU:C:1994:205, paragraph 37; and of 14 February 2008, *Varec*, C-450/06, EU:C:2008:91, paragraph 49). The question therefore arises whether Article 119 of Regulation No 1907/2006 was not interpreted in such a way that, by applying it, the ECHA infringed the fundamental right to protection of information. Thus, as the applicant submits in essence, its argument is directed not against that particular provision of Regulation No 1907/2006 but against the way in which the ECHA interpreted that provision and, consequently, applied it. The applicant cannot therefore be criticised for not having invoked, under Article 277 TFEU, the inapplicability of the regulation on the ground that it was allegedly incompatible with the primary law of the European Union.

148 As regards the argument alleging an infringement of the TRIPs Agreement, for the reasons set out in paragraph 145 above, the ECHA's argument that the applicant should have raised a plea of illegality of the relevant provisions of the regulations concerned in relation to the TRIPs Agreement is irrelevant.

149 Second, the Court must examine the second plea in law, alleging infringement of the European Union's commitments under the TRIPs Agreement and the resulting infringement of the right to the protection of commercial secrets. The applicant submits that the information at issue constitutes commercial secrets (confidential information) within the meaning of Article 39(2) of the TRIPs Agreement meaning that, in its entirety or in the exact configuration and assembly of its elements, that information is generally not known by those within the circles of people who normally deal with the type of information in question or is not easily available to them.

150 As was pointed out in paragraph 116 above, it is clear from the case-law that where EU rules exist in an area covered by the TRIPs Agreement, EU law applies, which means that it is necessary, as far as possible, to adopt an interpretation in conformity with that agreement.

151 Regulation No 1049/2001 and Regulation No 1907/2006 must therefore be interpreted in such a way as to ensure that they comply with the content of Article 39(2) and (3) of the TRIPs Agreement. However, that provision cannot imply that the protection afforded to intellectual property rights takes precedence over the presumption in favour of the disclosure of information submitted in connection with an application for authorisation for the use of a chemical substance. In that sense, the approach advanced by the applicant amounts to disapplying Article 119 of Regulation No 1907/2006. Such an approach must be rejected, since, in reality, it challenges the legality of that provision in the light of Article 39(2) and (3) of the TRIPs Agreement (see, to that effect and by analogy, judgment of 17 September 2007, *Microsoft* v *Commission*, T-201/04, EU:T:2007:289, paragraph 800).

152 In the present case, it does not appear that the ECHA applied Regulation No 1049/2001 and Regulation No 1907/2006 in a way which is inconsistent with Article 39(2) and (3) of the TRIPs Agreement.

153 As is apparent from paragraphs 60 to 67 above, the published studies — and hence already available to the public — could be disclosed. This is all the more true as the ECHA has redacted the conclusions drawn by the applicant in the light of those studies which are not publicly available and which it considered, in essence, to have added value within the meaning of paragraph 60 above. These conclusions are accordingly different from the objective content of the studies as well as from the simple conclusions that could be drawn from these studies by any expert in the field concerned.

154 The ECHA's distinction between the objective content of the studies and the simple conclusions which can be drawn from them, on the one hand, and individual and personal assessments which have added value, on the other hand, is based on an application of Regulations No 1049/2001 and No 1907/2006 which is consistent with Article 39(2) and (3) of the TRIPs Agreement.

155 As regards the studies referred to in paragraph 68 above, it should be borne in mind that the applicant has not submitted any information explaining how their disclosure would be unlawful. It must therefore be held that it also failed to demonstrate how the ECHA did not apply EU law in line with Article 39(2) and (3) of the TRIPs Agreement.

156 Lastly, as regards the DNEL and PNEC values and the NOAEL exposure values, it has been pointed out, in particular in paragraphs 129 and 151 above, that the consistent application of Regulations No 1049/2001 and No 1907/2006 and Article 39(2) and (3) of the TRIPs Agreement could not lead to Article 119 of Regulation No 1907/2006 being disapplied or to the public interest being disregarded. It must be added that Article 39 of the TRIPs Agreement itself provides, in paragraph 3 thereof, for the possibility of disclosure where it is necessary to protect the public.

157 Consequently, the second plea is unfounded.

158 As regards the third plea, it should be pointed out, as recalled in paragraph 147 above, that the applicant does not plead that the particular provisions of Regulation No 1907/2006 — namely Article 119(1)(c), (e) and (f) of that regulation, which provides for legal presumptions of non-confidentiality — are incompatible with primary EU law or the legally higher-ranking provisions of the conventions, but argues that the manner in which the ECHA interpreted these provisions and, therefore, the manner in which it applied them were not in conformity with Article 8 of the ECHR, Article 1 of the Additional Protocol to the ECHR and Article 17 of the Charter of Fundamental Rights.

159 It should be noted that Article 8 of the ECHR, whilst laying down in paragraph 1 the principle that public authorities shall not interfere with the exercise of the right to private life, does acknowledge, in paragraph 2, that such interference is possible in so far as it 'is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others'.

160 In its pleadings, the applicant is mistaken as to the scope of Article 8 of the ECHR by stating that that provision protects its right to property. It makes no specific submissions to demonstrate that the principle that public authorities may not interfere in the exercise of the right to respect for private life as enshrined in that provision has been infringed. The fact remains that, notwithstanding this mistake and the absence of any arguments, its complaint remains intelligible. In that regard, as the Court acknowledged in its judgment of 14 February 2008, *Varec* (C-450/06, EU:C:2008:91, paragraphs 47 and 48), referring to the case-law of the European Court of Human Rights, that it may be necessary to prohibit the disclosure of information which is classified as confidential, in order to protect the fundamental right of an undertaking to respect for 'private life', enshrined in Article 8 of the ECHR and Article 7 of the Charter of Fundamental Rights, it being stated that the concept of 'private life' must not be interpreted as excluding the commercial activity of a legal person.

161 Pursuant to Article 17(1) of the Charter of Fundamental Rights of the European Union, everyone has the right to own, use, dispose of and bequeath his or her lawfully acquired possessions. No one may be deprived of his or her possessions, except in the public interest and in the cases and under the conditions provided for by law, subject to fair compensation being paid in good time for their loss. The use of property may be regulated by law in so far as is necessary for the general interest. According to case-law, the protection granted by that provision applies to rights with an asset value creating an established legal position under the legal system, enabling the holder to exercise those rights autonomously and for his benefit (see, to that effect, judgment of 22 January 2013, *Sky Österreich*, C-283/11, EU:C:2013:28, paragraph 34).

162 It is also clear from the case-law that the right to protection of privacy as enshrined in Article 8 of the ECHR is an integral part of the general principles of law whose observance is ensured by the Courts of the European Union. That principle is not, however, absolute, but must be viewed in relation to its function in society. Restrictions may be involved provided that those restrictions in fact correspond to objectives of general interest pursued by the European Union and do not constitute disproportionate and intolerable interference, impairing the very substance of the rights guaranteed (judgments of 5 October 1994, *X* v *Commission*, C-404/92 P, EU:C:1994:361, paragraphs 17 and 18, and of 24 September 2008, *M* v *European Ombudsman*, T-412/05, not published, EU:T:2008:397, paragraph 126). The same applies to case-law as regards the right of property as enshrined in Article 17 of the Charter of Fundamental Rights (judgment of 12 July 2005, *Alliance for Natural Health and Others*, C-154/04 and C-155/04, EU:C:2005:449, paragraph 126).

163 It follows that Article 8 of the ECHR and Article 17 of the Charter of Fundamental Rights cannot be interpreted as laying down an automatic exception to the principle of disclosure for documents drawn up in the course of a private entity's commercial activity. In the case of a request for access made by a third party to such documents, a proper and specific examination of each of them is required, except in cases where the Court of Justice and the General Court have accepted a general presumption of refusal of access to the documents in question. As has been stated in paragraphs 33 to 42 above, there is no general presumption of refusal of access to documents submitted in connection with the authorisation procedure provided for in Regulation No 1907/2006.

164 In the present case, the ECHA therefore carried out a proper examination of the various data concerned by the request for access to documents. It should be noted that that examination was carried out in accordance with the right of property and the right to privacy.

165 First, as is apparent from paragraph 60 et seq. above, it is important to note that several pieces of the information at issue constitute a compilation of studies available to the public, but that the fact that the report bringing that intellectual endeavour to fruition has a financial value does not imply that all the information contained therein is to be regarded as having a commercial interest and that the disclosure of that information would automatically undermine that interest. The infringement of the protection of the commercial interests of a person as referred to in Article 4(2) of Regulation No 1049/2001 is not necessarily determined by reference to the financial value of the information subject to disclosure.

166 Next, as regards the information relating to the DNEL and PNEC values, it should be held that their disclosure would not infringe the right to privacy and to the right to property. The ECHA's interference with the exercise of those rights is permissible since it is provided for by Article 119 of Regulation No 1907/2006 and is necessary for the protection of health and the environment.

167 Finally, as regards the NOAEL exposure values, their disclosure is also essential for the public to have an indication of the risks associated with the use of DEHP. There is therefore considerable public interest in the disclosure of that information. Even assuming that the disclosure of that information constitutes a restriction on the right to privacy and the right to property — which the applicant has not shown in the present case — that disclosure corresponds in any event to objectives of general interest pursued by the Union and in no way constitutes, in relation to the aim pursued, a disproportionate and intolerable interference, impairing the very substance of the rights guaranteed.

168 In the light of all the foregoing, the second and third pleas must be rejected.

4. The fourth plea in law, alleging infringement of Article 4(3) of Regulation No 1049/2001

169 The applicant raises a fourth plea in law, alleging infringement of Article 4(3) of Regulation No 1049/2001, which protects the Union institutions' decision-making process against external, unjustified and unlawful harm and influence. First, it submits that the failure to disclose information relating to the proceedings which have not yet given rise to a decision by the institution concerned constitutes a principle and follows the logic of Regulation No 1049/2001. By disclosing the documents, the ECHA would thus seriously undermine that process. It then points out that, when giving their opinion, the Committee for Risk Assessment and the Committee for Socio-economic Analysis are likely to be influenced by the possible disclosure of the information at issue, since they also allow those requesting access to documents to participate in their deliberations. Conversely, the applicant for authorisation does not have access to the meetings of those committees and does not have the right to be heard at all stages of the procedure. Finally, the applicant points out that no overriding public interest justifies the disclosure of the information in question.

170 The ECHA disputes those arguments.

171 It must be recalled that recital 11 of Regulation No 1049/2001 states that the institutions should be entitled to protect their internal consultations and deliberations where necessary to safeguard their ability to carry out their tasks. To that end, the first subparagraph of Article 4(3) of Regulation No 1049/2001 provides that, 'access to a document, drawn up by an institution for internal use or received by an institution, which relates to a matter where the decision has not been taken by the institution, shall be refused if disclosure of the document would seriously undermine the institution's decision-making process, unless there is an overriding public interest in disclosure'.

172 According to the case-law, the application of that exception requires it to be established that access to the document in question drawn up by the institution for its internal use in question was likely, specifically and actually, to undermine the interest protected by the exception, and that the risk of that interest being undermined was reasonably foreseeable and not purely hypothetical (judgment of 18 December 2008, *Muñiz* v *Commission*, T-144/05, not published, EU:T:2008:596, paragraph 74).

173 In addition, in order to be covered by the exception in the first subparagraph of Article 4(3) of Regulation No 1049/2001, the decision-making process must be seriously undermined. That is the case, in particular, where the disclosure of the documents in question has a substantial impact on the decision-making process. The assessment of that serious nature depends on all of the circumstances of the case including, inter alia, the negative effects on the decision-making process relied on by the institution (judgments of 18 December 2008, *Muñiz* v *Commission*, T-144/05, not published, EU:T:2008:596, paragraph 75, and of 7 June 2011, *Toland* v *Parliament*, T-471/08, EU:T:2011:252, paragraph 71).

174 It is in the light of those considerations that the fourth plea must be examined.

175 First of all, the Court must reject the applicant's approach by which it seeks to establish that the exception to the disclosure provided for in Article 4(3) of Regulation No 1049/2001 creates a rule of principle. The principle of access to documents laid down in Article 2 of that regulation remains that applicable to information relating to proceedings which have not yet given rise to a decision by the institution concerned. The exceptions to that principle are defined in Article 4 of Regulation No 1049/2001, as interpreted by the case-law. There can therefore be no exception to the principle of access to documents under Article 4(3) of that regulation other than under the conditions determined by the case-law referred to in paragraphs 172 and 173 above.

176 Next, it is necessary to examine the question whether access to the information at issue could have seriously undermined the ECHA's decision-making process. The applicant, in essence, submits that applicants for authorisation do not have the guarantee of being heard at all stages of the decision-making process and do not have the opportunity to submit observations concerning irregularities or errors. In addition, the Committee for Risk Assessment and the Committee for Socio-economic Analysis allow applicants for access to the information to participate in their deliberations. Applicants for authorisation do not, however, have the right to participate in such deliberations.

177 First, it must be borne in mind that Article 64(5) of Regulation No 1907/2006 provides that the ECHA is to send the draft opinions of the Committee for Risk Assessment and the Committee for Socio-economic Analysis to the applicant for authorisation and that that applicant may provide written comments if he so wishes within two months of receipt of the draft opinion. This provision thus guarantees the applicant for authorisation the right to submit written arguments to the committees before the latter adopts a final opinion on the application for authorisation.

178 Second, the applicant does not show how applicants for access to the information to whom observer status may be granted could seriously undermine the ECHA's decision-making process.

179 Articles 6 of the Rules of Procedure for the Risk Assessment Committee and the Socio-Economic Analysis Committee (bearing the reference MB/09/2009 final, 'the Rules of Procedure of the Committees'), drafted in identical terms, provide that stakeholder representatives 'may' be admitted as observers to committee meetings, thus allowing the ECHA discretion in this respect. Moreover, their participation in ECHA meetings is strictly regulated. In accordance with Article 6(6) of those rules of procedure, observers are to adhere to the 'ECHA Code of Conduct for observers from stakeholder organisations at ECHA meetings' (reference ED/62/2008, the 'Code of Conduct'), adopted by a decision of the Executive Director of the ECHA on 9 October 2008.

180 The Code of Conduct provides that stakeholder organisations are to avoid nominating, as observers, persons who have a direct interest in the cases dealt with by the committees and, if such an interest arises, they should declare the interest at the beginning of the meeting (paragraph 6). It also states that observers are not to interfere in meetings in such a way which constitutes harassment or may hinder the work of the body (paragraph 7) and that their participation in meetings is at the discretion of the Chair (paragraph 8). The Code of Conduct also mentions that observers should normally inform the Chair in advance of the points on which they wish to intervene and at the latest at the start of the meeting and that their interventions should be brief and within the time allotted to them (paragraph 9). The Code of Conduct states that observers may submit documents, but the fact that they are distributed does not mean that the ECHA validates or approves their content (paragraph 15).

181 It follows from the foregoing that the applicant misunderstands the role of observers during committee meetings and that their role is strictly regulated to prevent them from seriously undermining the decision-making process.

182 Although it is not contested by the ECHA that an applicant for authorisation is not in principle entitled to participate in the meetings of committees on the same basis as observers and therefore does not have the right to express itself at those meetings, it must be noted, as has been pointed out in paragraph 177 above, that the third subparagraph of Article 64(5) of Regulation No 1907/2006 authorises it to submit detailed written arguments and grants it a period of two months from the date of receipt of the draft opinion to do so. It is at that point that the applicant will have the opportunity to respond to any comments made by the observers.

183 It is also important to note that in response to a written question from the Court to the parties on the role of observers, as provided for in the Code of Conduct, the ECHA referred to an approach paper of 14 December 2012 describing the approach taken by it in the context of an application for authorisation procedure ('the Approach Paper'). The ECHA states that the presence of observers and the absence of the applicants for authorisation may lead to a hearing which is unfair, since the former are the only ones authorised to make observations on the case. For this reason, it clarified in the Approach Paper that in this type of procedure observers have no speaking rights at committee meetings. It should be noted that this approach is in line with the Code of Conduct, which grants a margin of discretion to the ECHA by indicating that observers 'may' be admitted to participate in committee meetings and according to which the Chair enjoys discretion in how meetings are conducted. Similarly, the ECHA provided that observers, in order to ensure consistency with the Code of Conduct and Rules of Procedure of the Committees, do not have access to commercial information of a confidential nature and may not be present at meetings in which such information is being discussed.

184 Finally, the applicant has not adduced any concrete evidence to show that, in the present case, access to the information at issue relating to the application for authorisation for the use of DEHP would have a substantial impact on the ECHA's decision-making process and the Commission and thus seriously undermine that process.

185 Given the mechanism provided for by Regulation No 1907/2006, which is reflected in the Rules of Procedure of the Committees, the Code of Conduct and the Approach Paper, on the one hand, and the absence of any concrete evidence supporting the suspicion that in the present case access to the information at issue would have undermined the ECHA's decision-making process, it must be held that the disclosure of the information at issue cannot have adverse effects on the decision-making process to the point of seriously jeopardising it.

186 It follows from all the foregoing that the fourth plea, alleging infringement of Article 4(3) of Regulation No 1049/2001 must be rejected.

187 It follows from all of the foregoing that the action must be dismissed, without it being necessary to rule on the plea of inadmissibility raised in defence by the ECHA.

Costs

188 Under Article 134(1) of the Rules of Procedure of the General Court, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. In the present case, since the applicant has been unsuccessful, it must be ordered to pay the ECHA's costs, in accordance with the form of order sought by the latter, including those relating to the application for interim measures.

189 The Commission is to bear its own costs, in accordance with Article 138(1) of the Rules of Procedure.

190 ClientEarth, EEB and HCWH Europe are to bear their own costs, in accordance with Article 138(3) of the Rules of Procedure.

On those grounds,

THE GENERAL COURT (Fourth Chamber)

hereby:

1. **Dismisses the action;**

2. **Orders Deza, a.s. to bear its own costs and to pay those incurred by the European Chemicals Agency (ECHA), including those relating to the application for interim measures;**

3. **Orders the European Commission to bear its own costs;**

4. **Orders ClientEarth, European Environmental Bureau (EEB) and Vereniging Health Care Without Harm Europe to bear their own costs.**

Prek Labucka Kreuschitz

Delivered in open court in Luxembourg on 13 January 2017.

[Signatures]

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