Reports of Cases

JUDGMENT OF THE GENERAL COURT (Fifth Chamber)

4 April 2019*

(REACH — Regulation (EC) No 1907/2006 — Bis(2-ethylhexyl) phthalate (DEHP) — Request for internal review of a decision on marketing authorisation rejected as unfounded — Error of law — Manifest error of assessment — Article 10 of Regulation (EC) No 1367/2006)

In Case T-108/17,

ClientEarth, established in London (United Kingdom), represented by A. Jones, Barrister,

applicant,

v

European Commission, represented by G. Gattinara, R. Lindenthal and K. Mifsud-Bonnici, acting as Agents,

defendant,

supported by

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

intervener,

APPLICATION pursuant to Article 263 TFEU seeking the annulment of the letter of the Commission of 7 December 2016 by which that institution rejected a request for internal review of 2 August 2016 against Commission Implementing Decision C(2016) 3549 final of 16 June 2016, granting an authorisation for uses of bis(2-ethylhexyl) phthalate (DEHP) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council,

THE GENERAL COURT (Fifth Chamber),

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

Registrar: F. Oller, Administrator,

having regard to the written part of the procedure and further to the hearing on 6 September 2018,

gives the following

* Language of the case: English.

Judgment

Background to the dispute

1 In adopting Commission Regulation (EU) No 143/2011 of 17 February 2011 amending 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) (OJ 2011 L 44, p. 2), the European Commission included bis(2-ethylhexyl) phthalate, an organic compound essentially used to soften polyvinyl chloride (PVC) plastics, 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) because of the reproductive toxicity of that substance within the meaning of Article 57(c) of that regulation.

2 On 13 August 2013, three waste recycling companies ('the authorisation applicants') jointly submitted an application for authorisation under Article 62 of Regulation No 1907/2006, read in conjunction with Article 60(2) of that regulation, with a view to the placing on the market of DEHP for the following 'uses':

– 'the formulation of recycled soft poly(vinyl chloride) (PVC) containing DEHP in compounds and dry-blends;

– the industrial use of recycled soft PVC containing DEHP in polymer

processing by calendaring, extrusion, compression and injection moulding to produce PVC articles'.

3 In the analysis of the alternatives accompanying the application for authorisation, the authorisation applicants indicated the following:

'DEHP is a plasticiser that has been used in the softening of PVC for the manufacture of plasticised or flexible PVC over several decades. ...

DEHP is therefore added to PVC before the plastic is converted into plastic articles and before those plastic articles become waste, i.e. a potentially valuable commodity for the [authorisation] applicants. Therefore, in the strictest sense, DEHP does not play any specific functional role for the [authorisation] applicants; it is merely present as a (largely unwanted) impurity in the waste that is collected, sorted, processed and then placed on the market in the form of recyclate. Nevertheless, the limited presence of DEHP (or other plasticisers) in the recyclate could theoretically be of some benefit to downstream users (the PVC converters):

– it may facilitate the processing of the recyclate material into new PVC articles; and

– it may allow the PVC converters to reduce the amount of neat (or "virgin") DEHP (or other plasticiser) that they must add to their compounds before new flexible PVC articles are produced.'

4 In the application for authorisation, the authorisation applicants also stated that 'DEHP d[id] not have a specific functional role for [them]'. That substance is merely present as a (largely unwanted) impurity in the waste that is collected, sorted, processed and then placed on the market in the form of recyclate. It is also apparent from that application for authorisation that the limited presence of DEHP in the

recyclate may facilitate its processing into new PVC articles by reducing the amount of pure or virgin DEHP or other plasticisers that can be added to the compounds before new flexible PVC articles are produced.

5 On 10 October 2014, the Committee for Risk Assessment and the Committee for Socio-economic Analysis of the European Chemicals Agency (ECHA) produced their opinions on the application for authorisation. According to the Committee for Risk Assessment, the authorisation applicants had not demonstrated that the risks to the health of workers resulting from the two requested 'uses' were adequately controlled within the meaning of Article 60(2) of Regulation No 1907/2006. The Committee for Socio-economic Analysis, for its part, concluded that the authorisation could be granted in the present case, notwithstanding the existence of certain deficiencies in the analysis submitted by the authorisation applicants to demonstrate the socio-economic benefits resulting from the 'uses' for which the application for authorisation had been submitted, on the one hand, and on the basis of a 'qualitative analysis' including the relevant uncertainties, on the other.

6 On 22 October 2014, the Committee for Risk Assessment and the Committee for Socio-economic Analysis of the ECHA prepared a document containing a joint and consolidated version of their opinions. That document, which bears the reference 'ECHA/RAC/SEAC Opinion No AFA-O-0000004151-87-17/D', is entitled 'Opinion on an Application for Authorisation for Bis(2-ethylhexyl) phthalate (DEHP) use: Formulation of recycled soft PVC containing DEHP in compounds and dry-blends'. On 24 October 2014, ECHA sent those opinions to the Commission.

7 On 12 December 2014, ECHA updated and supplemented the existing entry for DEHP in the 'candidate list for eventual inclusion in Annex XIV' referred to in Article 59(1) of Regulation No 1907/2006 ('the candidate list') by identifying it as a substance with endocrine-disrupting properties for which there was scientific evidence of probable serious effects on the environment which gave rise to an equivalent level of concern to that of other substances listed in Article 57(a) to (e) of Regulation No 1907/2006, all within the meaning of Article 57(f) of that regulation.

8 The application for authorisation was also discussed within the committee provided for in Article 133 of Regulation No 1907/2006.

9 On 16 June 2016, the Commission adopted Implementing Decision C(2016) 3549 final granting an authorisation for uses of bis(2-ethylhexyl) phthalate (DEHP) under Regulation No 1907/2006 ('the authorisation decision'). By Article 1 of that decision, the Commission granted authorisation for the following 'uses':

– 'the formulation of recycled soft poly(vinyl chloride) (PVC) containing DEHP in compounds and dry-blends;

– industrial use of recycled soft PVC containing DEHP in polymer processing by calendaring, extrusion, compression and injection moulding to produce PVC articles, except: toys and childcare articles; erasers; adult toys (sex toys and other articles for adults with intensive contact with mucous membranes); household articles smaller than 10 cm that children can suck or chew on; consumer textiles/clothing intended to be worn against the bare skin; cosmetics and food contact materials regulated under sector-specific Union legislation'.

10 According to Article 1 of the authorisation decision, in essence, authorisation was granted 'in accordance with Article 60(4) of Regulation No 1907/2006, subject to full application of the risk management measures and operational conditions described in the chemical safety report submitted pursuant to Article 62(4)(d) of that Regulation, corresponding to each respective use and under the condition that the content of DEHP in recycled soft PVC in compounds and dry-blends authorised by this decision does not exceed 20% w/w'.

11 In Article 2 of the authorisation decision, the Commission fixed the review period for authorisation referred to in Article 60(9)(e) of Regulation No 1907/2006 at four years from the date of expiry laid down in Annex XIV to Regulation No 1907/2006, namely, 21 February 2019. In Article 3 of the authorisation decision, the Commission imposed monitoring arrangements within the meaning of Regulation No 1907/2006.

12 In Article 4 of the authorisation decision, the Commission stated that that decision was addressed to the authorisation applicants.

13 In recital 8 of the authorisation decision, the Commission declared that Regulation No 1907/2006 'd[id] not apply to waste as defined in Directive 2008/98/EC of the European Parliament and of the Council', and that, accordingly, 'the authorisation to place on the market and use recycled soft PVC compounds and dry-blends containing DEHP in accordance with Article 64 of [Regulation No 1907/2006] applie[d] to the extent that those compounds and dry-blends ha[d] ceased to be waste in accordance with Article 6 of that Directive'.

14 By letter of 2 August 2016 ('the request for internal review'), the applicant, ClientEarth, which is a not-for-profit organisation whose purpose is inter alia the protection of the environment, requested that the Commission carry out an internal review of the authorisation decision under Article 10 of Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (OJ 2006 L 264, p. 13).

15 By decision C(2016) 8454 final of 7 December 2016 ('the decision on the request for internal review'), the Commission rejected the request for internal review, in essence, on the ground that it was unfounded.

Procedure and forms of order sought by the parties

16 By application lodged at the Registry of the General Court on 17 February 2017, the applicant brought the present action.

17 The defence was lodged at the Court Registry 4 May 2017.

18 By document lodged at the Court Registry on 29 May 2017, ECHA applied for leave to intervene in support of the form of order sought by the Commission. By decision of the President of the Fifth Chamber of the General Court of 29 June 2017, the application to intervene was granted.

19 The reply and the rejoinder were lodged at the Court Registry on 22 June and 21 August 2017, respectively.

20 On 21 August 2017, ECHA lodged its statement in intervention at the Court Registry.

21 The applicant claims that the Court should:

– declare the application admissible and well founded;

– annul the decision on the request for internal review;

– annul the authorisation decision;

– order the Commission to pay the costs;

– ‘order any other measure deemed appropriate’.

22 The Commission contends that the Court should:

– dismiss the application;

– order the applicant to pay the costs.

23 ECHA contends that the Court should:

– dismiss the application;

– order the applicant to pay the costs.

Law

Application for the annulment of the authorisation decision

24 Without formally raising an objection of inadmissibility under Article 130 of the Rules of Procedure of the General Court, the Commission, supported by ECHA, partially contests the admissibility of the present action, in so far as the applicant seeks, by its third head of claim, the annulment of the authorisation decision.

25 In essence, first, according to the Commission, the authorisation decision is not the subject matter of the present action for annulment. Second, the applicant does not have standing to challenge the authorisation decision under Article 263 TFEU.

26 During the hearing, the applicant stated that it was not directly challenging the authorisation decision as it did not regard itself as having the necessary standing to bring an action based on Article 263 TFEU directed against that decision. It must therefore be held that the authorisation decision is not the subject of the present action in so far as it is based on Article 263 TFEU.

27 However, according to the applicant, first of all, the logical consequence of annulment of the decision on the request for internal review is that the authorisation decision must itself also be annulled.

28 In that regard, it should be noted that the system of judicial review provided for by the Treaties does not provide for the possibility, for the General Court, to annul a decision which is not the subject of a direct action for annulment based on Article 263 TFEU.

29 Second, the applicant adds that, in any event, in view of the first paragraph of Article 266 TFEU, the General Court has the power to require, as a measure necessary to give effect to the judgment in the present proceedings, that the Commission ‘revoke’ the authorisation decision. For that reason, the applicant indicated at the hearing that it wished to maintain the third head of claim.

30 To the extent that the applicant claims that the Court has the power, apparently provided for in the first paragraph of Article 266 TFEU, to request the Commission to ‘revoke’ the authorisation decision, it should be stated that the applicant misconstrues that provision. On the one hand, annulment by the Court of the authorisation decision, as is requested by the applicant under the third head of claim, has nothing to do with a possible revocation by the Commission of that decision. On the other hand, that provision does not confer on the Court any power that would go beyond the jurisdiction expressly laid down in the Treaties. Contrary to what the applicant seems to suggest, the first paragraph of Article 266 TFEU expressly addresses the obligation of the institution whose act has been declared

void by the judicature of the European Union to take the necessary measures to comply with the annulling judgment. According to the case-law, the Courts of the European Union are not entitled, when exercising judicial review of legality, to issue directions to the institutions or to assume the role assigned to them (see judgment of 30 May 2013, *Omnis Group* v *Commission*, T-74/11, not published, EU:T:2013:283, paragraph 26 and the case-law cited). Thus, in the case at hand, the Court is not entitled to issue directions to the Commission, in the event of annulment of the decision on the request for internal review, or to effect the revocation of the authorisation decision.

31 In the light of all the foregoing, it must be held that the third head of claim is manifestly inadmissible and must therefore be rejected.

The application for the annulment of the decision on the request for internal review

32 To the extent that, as is apparent from the second head of claim, the action seeks the annulment of the decision on the request for internal review, the applicant puts forward four pleas.

33 The first plea alleges that the decision on the request for internal review is vitiated by errors of law and manifest errors of assessment concerning the conformity of the application for authorisation with Article 62 and Article 60(7) of Regulation No 1907/2006. By its second plea, the applicant claims that the decision on the request for internal review is vitiated by errors of law and manifest errors of assessment concerning the socio-economic assessment based on Article 60(4) of Regulation No 1907/2006. The third plea alleges that the decision on the request for internal review is vitiated by manifest errors of assessment concerning the analysis of alternatives based on Article 60(4) and (5) of Regulation No 1907/2006. By the fourth plea, the applicant claims that the decision on the request for internal review is vitiated by errors of law and manifest errors of assessment as regards the application of the precautionary principle in the context of the authorisation process provided for in Regulation No 1907/2006.

The first plea, alleging errors of law and of assessment concerning the conformity of the application for authorisation with Article 62 and Article 60(7) of Regulation No 1907/2006

34 The first plea is subdivided into four parts aimed at demonstrating the existence, in the decision on the request for internal review, of errors of law and manifest errors of assessment as regards the conformity of the authorisation decision with Article 62 and Article 60(7) of Regulation No 1907/2006, first, in the interpretation of the concept of 'use' in Article 62(4)(c) of Regulation No 1907/2006, second, in connection with the existence of alleged deficiencies in the chemical safety report, third, in connection with the existence of alleged deficiencies in the assessment of appropriate alternatives, and fourth, in the interpretation of Article 60(7) and Article 64(3) of Regulation No 1907/2006.

– The first part, alleging errors of law and of assessment in the interpretation of the concept of 'use' in Article 56(1)(a) and Article 62(4)(c) of Regulation No 1907/2006

35 In the first place, the applicant claims that the authorisation applicants failed to define the 'use(s) of that substance' as required under Article 56(1)(a) of Regulation No 1907/2006. The Commission also misinterpreted the concept of 'use' referred to in Article 56(1)(a) of Regulation No 1907/2006 and in Article 62(4)(c) of that regulation.

36 First, according to the applicant, that concept covers cases in which authorisation is sought actively to deploy or introduce a substance 'in or into an industrial process'. The concepts of active deployment and introduction of a substance in or into an industrial process correspond to a concept of intentional use. The antithesis of that concept of active deployment is a situation in which a substance is merely

present as an incidental element of a pre-existing process. According to the applicant, however, the continued incidental presence of a substance in a pre-existing process cannot be described as 'use' properly so called.

37 In the present case, the application for authorisation was submitted for 'uses of recycled PVC containing DEHP'. In the light of the information contained in the application for authorisation, as well as the information contained in the analysis of alternatives drawn up by the authorisation applicants, it may be concluded that the authorisation applicants did not seek authorisation actively to deploy or introduce DEHP in or into an 'industrial process' carried out by them. The application for authorisation relates to the mere unintentional presence of a substance in a pre-existing process and not to a 'use' within the meaning of Regulation No 1907/2006. Rather, the authorisation applicants envisaged only a process of collection, processing and placing on the market of waste plastic containing a certain proportion of DEHP as an incidental ingredient. In other words, the present case involves uses of recycled PVC containing DEHP, that is to say the 'processing of waste plastic', as opposed to the processing of DEHP per se.

38 By following, in its decision on the request for internal review, the interpretation advocated by the authorisation applicants regarding the concept of 'use', the Commission committed a 'manifest' error of law. In so doing, the Commission actually — and wrongly — authorised a 'process as a whole', namely, the recycling of 'materials containing an SVHC' (substance of very high concern), whereas Regulation No 1907/2006 allows only the authorisation of an intentional use of a substance of very high concern for the purposes of Article 57 of Regulation 1907/2006 within an industrial process.

39 In response to one of the Commission's arguments, according to which the authorisation decision was granted for a substance, as contained 'in a mixture', the applicant maintains that it follows from the words 'in a mixture' used in Article 56(1)(a) of Regulation No 1907/2006 that the appropriate interpretation should be concerned rather with the use of the 'individual substance within the context of the mixture' and not the use 'of the mixture as a whole'. According to the applicant, while the use of the mixture is relevant to understanding the added value and the function of the substance in the mixture, the application for authorisation should have been framed around the specific use of the substance itself in that mixture. That did not happen in the present case, however.

40 Moreover, one of the reasons why it is important for the applicant for an authorisation under Regulation 1907/2006 to take into account the use of the 'substance of very high concern … in a mixture', rather than the 'use of the mixture', is that a proper analysis of alternatives and a proper socio-economic assessment depends on the definition of the use. In the present case, in their analysis of alternatives, the authorisation applicants did not examine alternative substances or technologies for the use of DEHP in the mixture. Rather, the application for authorisation covered only alternative ways to obtain a mixture that would not contain DEHP, that is to say PVC free from DEHP either by segregation or elimination or from other sources.

41 Last, the Commission wrongly maintains that the arguments of the applicant, mentioned in paragraphs 36 to 38 above, were not raised in the request for internal review. In the request for internal review, the applicant explained that the definition of the term 'use' should be interpreted as referring to a 'technical function' of the substance concerned in contrast to the statement made by the authorisation applicants that DEHP 'is not used per se … [but] is merely present as a (largely unwanted) impurity …'. The applicant states that, even though it did not use the adjective 'active' in that context, it did indicate, in paragraph 49 of its request for internal review, that the authorisation did not grant permission 'to continue to use DEHP on its own or in a mixture'. In other words, it noted that the authorisation decision did not permit the active use or deployment of DEHP.

42 Second, the Commission attempted to identify a use of DEHP compliant with Regulation No 1907/2006 by imposing upon the application for authorisation an identified use of DEHP which runs contrary to Regulation No 1907/2006.

43 Indeed, in the decision on the request for internal review, the Commission explained that it had been necessary to make a distinction between the 'presence of DEHP in the waste ... and the function that the substance has in the recovered material that ceased to be waste'. According to the Commission, the relevant function of DEHP in the recovered material is to 'reduc[e] the amount of plasticisers that needs to be added in the production of soft PVC articles made out of the recycled soft PVC material'.

44 On the one hand, however, that function was not indicated as such in the application for authorisation. On the contrary, the authorisation applicants expressly stated that 'DEHP [did] not play any specific functional role for [them]'. The function of DEHP that the Commission analysed does not, therefore, reflect the application for authorisation.

45 On the other hand and more importantly, reducing the amount of a virgin substance of very high concern used as a plasticiser by means of a recycled substance of very high concern cannot be qualified as a 'function' which could be authorised pursuant to Regulation 1907/2006.

46 According to the applicant, applying that reasoning beyond this case, any substance of very high concern in recycled material would thus have such a function, namely, reducing the amount of virgin substance of very high concern in the material. The effect of that reasoning is that any use of a substance of very high concern in recovered material would be authorised merely by virtue of the fact that a recycled material was involved. That would have the consequence that all applications for authorisation for use of recycled materials must necessarily be granted. Authorising the 'recycling of materials containing an SVHC' is directly at odds with the purpose of Regulation No 1907/2006, however. That regulation is intended not to promote the recycling of materials containing substances of very high concern, but rather progressively to replace them or faze them out, wherever they occur and however long their history in certain applications.

47 Moreover, if reducing the amount of virgin plasticisers was a function 'in line with Article 62 [of Regulation No 1907/2006]', the analysis of alternatives would, in the applicant's view, have had to be framed around that function. It would then have been necessary to determine whether there were alternatives to using recycled DEHP enabling the amount of virgin DEHP needed in the production of PVC articles to be reduced. In other words, if the definition of the terms 'use' and 'function' by the Commission were correct, the analysis of alternatives provided by the authorisation applicants should have provided other ways of reducing the amount of plasticisers in the virgin PVC, which that analysis failed to do.

48 Moreover, the Commission commits a further error in arguing that it was only at the stage of the application that the applicant presented the arguments relating to the existence of authorisation for a 'process as a whole', namely, the recycling of a mixture of waste PVC containing DEHP as opposed to authorisation for a specific use of DEHP within that process or that mixture. Contrary to what the Commission claims, the applicant already indicated, at the stage of its request for internal review, that it had in fact 'focused on substituting [a] waste stream'. The Commission considered the alternatives to recycled waste 'as a whole' and the applicant criticised the Commission for failing to analyse actual alternative substances capable of fulfilling the function of DEHP itself.

49 In the second place, the Commission's interpretation of the concept of 'use' in the present case could wrongly interfere with the system of regulation of waste.

50 In the absence of criteria for determining when a substance has obtained 'end-of-waste' status, there is a risk that, if an authorisation has been granted under Regulation No 1907/2006 for waste, undertakings could rely on that authorisation as evidence of the positive assessment of the effects on the environment or on human health when seeking to establish that waste must obtain 'end-of-waste' status. Thus, recycling undertakings could use the granting of authorisation under Regulation

No 1907/2006 for old waste in order to obtain 'end-of-waste' status, within the meaning of Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ 2008 L 312, p. 3; 'the Waste Framework Directive').

51 Last, contrary to what the Commission contends, the applicant's arguments, mentioned in paragraphs 49 and 50 above, had already been raised, in substance, in the request for internal review. In paragraphs 117 and 118 thereof, the applicant clearly stated that the relationship between Regulation No 1907/2006 and the Waste Framework Directive should not be disrupted.

52 The Commission disputes that line of argument.

53 As a preliminary point, it should be pointed out that, unlike what the applicant appears to argue in certain paragraphs of the application, the present action can concern only the legality of the decision on the request for internal review and not the sufficiency or otherwise of the application for authorisation. The pleas raised in the application should therefore seek to show any errors of law or of assessment committed by the Commission in the decision on the request for internal review and not any errors committed by the authorisation applicants.

54 Accordingly, the line of argument purporting to contend that (i) the authorisation applicants themselves failed to define correctly the 'use(s) of that substance' within the meaning of Article 56(1)(a) of Regulation No 1907/2006 (see paragraph 35 above), that (ii) according to the information contained in the application for authorisation, the authorisation applicants did not seek authorisation actively to deploy or introduce DEHP in or into an 'industrial process', but the application for authorisation relates instead to the mere unintentional presence of a substance in a mixture (see paragraph 37 above) and that (iii) the authorisation applicants envisaged only a process of collection, processing and placing on the market of waste plastic containing DEHP (see paragraph 37 above) could have a bearing on the present action only if the Commission had, in the decision on the request for internal review, endorsed the elements contained in the application for authorisation. The same applies to the argument that the application for authorisation does not indicate what function of DEHP the Commission adopted in its decision on the request for internal review (see paragraph 44 above).

55 Next, again as a preliminary remark, it should be noted that the pleas and arguments raised before the General Court in an action for annulment of a decision rejecting a request for internal review can be regarded as being admissible only in so far as those pleas and arguments have already been presented by the applicant in the request for internal review, and in such a way that the Commission has been able to respond (see, to that effect, judgment of 15 December 2016, *TestBioTech and Others* v *Commission*, T-177/13, not published, under appeal, EU:T:2016:736, paragraph 68).

56 That conclusion is evident in the light of the wording of Article 10(1) of Regulation No 1367/2006. It is apparent from that provision that a request for internal review of an administrative act adopted by an EU institution under environmental law must specify which act is being challenged and state the grounds for conducting the review. It follows from that obligation that the applicant for internal review has the right only to have the Commission state its position on the grounds it put forward in its request. However, it does not have any right to have the Commission state its position on matters that were not referred to, at the very least, in a reasonably recognisable manner in such a request.

57 In that regard, it should also be borne in mind that, in order to state the grounds for conducting the review in the manner required, a party requesting the internal review of an administrative act adopted under environmental law is required to put forward any facts and evidence or any legal arguments raising serious doubts about the assessment made in that act by the EU institution or body. A third party challenging a marketing authorisation must therefore adduce substantial evidence liable to raise serious doubts as to the lawfulness of the grant of that authorisation (see, to that effect, and by

analogy, judgments of 21 May 2015, *Schräder* v *CPVO*, C-546/12 P, EU:C:2015:332, paragraph 57, and of 15 December 2016, *TestBioTech and Others* v *Commission*, T-177/13, not published, under appeal, EU:T:2016:736, paragraphs 66 and 67).

58 The conclusion set out in paragraph 55 above also applies, in the light of the wording of the first sentence of Article 10(2) of Regulation No 1367/2006. According to that provision, the institution to which a request for internal review has been made is to consider any such request, unless it is clearly unsubstantiated. By virtue of that provision, it is thus for the Commission to examine carefully and impartially all the elements invoked in a request for internal review unless they are clearly unsubstantiated. On the one hand, it is not for the Commission to examine grounds other than those raised by the applicant for internal review. On the other hand, in order for the Commission to be able to respond satisfactorily to an applicant for internal review, that applicant must put the Commission in a position to know in a sufficiently precise manner the criticisms levelled against the administrative act at issue (see, to that effect, judgment of 15 December 2016, *TestBioTech and Others* v *Commission*, T-177/13, not published, under appeal, EU:T:2016:736, paragraphs 262 to 264).

59 In the case at hand, the Commission contends that the applicant's argument that the concept of 'use' consists of an 'active' deployment or introduction of a certain substance in or into an industrial process is a new argument in that it was not included in the request for internal review.

60 It is apparent from paragraph 49 of the request for internal review that, according to the applicant, first, the authorisation at issue in the present case relates to the use of a 'material containing DEHP that is incorporated as part of a plastic waste stream where DEHP does not have a technical function'. Second, it is also apparent from that paragraph of the request for internal review that, according to the applicant, 'the authorisation [at issue in the present case] therefore does not seek to allow the applicant to continue to use DEHP on its own, in a preparation or to incorporate [that substance] in an article'.

61 It must be pointed out, however, that, where, in the present action, the applicant argues that the concept of 'use' consists of an 'active' deployment or introduction of a certain substance into an industrial process, it formulates a complaint that was not indicated in a clear and specific manner or in a manner which is reasonably evident to the Commission in the request for internal review. Insisting, like the applicant does in the present action, that DEHP be used 'as a part of a ... waste stream' or requesting that that substance be used 'in a preparation', or incorporated 'in an article', on the one hand, and holding the view that only the active introduction or active deployment of a substance 'into an industrial process' corresponds to the concept of 'use', on the other, are two different things.

62 That being the case, it must be concluded that the applicant's argument that the concept of 'use' consists of an 'active' deployment or introduction of a certain substance into an 'industrial process' had not been submitted to the Commission in the request for internal review and is therefore inadmissible.

63 In the alternative, regarding the substance of that argument, that is to say, regarding the question as to which interpretation ought to be accorded to the concept of 'use' in Article 56(1)(a) and in Article 62(4)(c) of Regulation No 1907/2006, it should be noted that that concept is defined in Article 3(24) of that regulation. According to that provision, use means 'any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation'.

64 Contrary to what the applicant essentially claims (see paragraph 36 above), the concept of 'use' in Article 3(24) of Regulation 1907/2006 is not limited to the active introduction of a substance 'into an industrial process'. Moreover, nothing in that provision indicates that, to conclude that a substance is 'used', it must be intentionally introduced into such a process.

65 On the contrary, the wording of Article 3(24) of Regulation No 1907/2006 leads to the conclusion that it is also possible to speak of the 'use' of a substance where it is used in the composition of several substances, a composition which has, in turn, been subject to one of the operations referred to in Article 3(24) of Regulation No 1907/2006. In other words, when a composition of substances is, for example, processed, formulated, consumed or stored, all the substances used in that composition are 'used' within the meaning of Regulation No 1907/2006.

66 The use of the words 'any other utilisation' in Article 3(24) of Regulation No 1907/2006 makes the case for that interpretation. Those words, first, express the fact that operations other than those expressly provided for in that provision fall within the concept of 'use'. Second, those words also express the fact that the legislature adopted a broad interpretation whereby the active use of a composition of substances at the same time constitutes an active use of the substances that are constituents of the composition.

67 As a second step, the wording of Article 56(1)(a) of Regulation No 1907/2006 makes the case for such an interpretation. According to that provision, authorisation is necessary not only for the use of a substance on its own, but also for the use of a substance in a 'mixture'. It follows from Article 3(2) of the same regulation that a 'mixture' within the meaning of that regulation is a 'mixture or solution composed of two or more substances'.

68 Last, as the Commission has rightly argued, it is also implicit in Article 56(6) of Regulation No 1907/2006, which exempts from the authorisation requirement the 'use of substances when they are present in mixtures' below given concentration levels, that authorisation is required to use substances referred to in Annex XIV to that regulation as present 'in mixtures'. The underlying position behind that provision is, again, that a substance making up a composition is used each time that composition is used.

69 Contrary to what the applicant claims (see paragraph 39 above), it is not only when it is demonstrated that a substance has a specific function 'within the context of the mixture' — as opposed to the use of the 'mixture as a whole' — that a substance in a mixture should be considered to be used.

70 In that regard, it should be noted that a mixture may include substances which have a specific function within the mixture and substances the function of which is apparent only at the time the mixture itself is used. Next, there may also be mixtures in which the entirety of the components perform a function only because of the use of the mixture as such. The words 'any other utilisation' used in Article 3(24) of Regulation No 1907/2006, however, support the conclusion that, in both cases, the use of a mixture involves the use of all the substances within it.

71 In the case at hand, in order to justify its conclusion that the authorisation decision concerned a 'use' of DEHP, the Commission noted, in the decision on the application for internal review, first, that the authorisation had been requested for DEHP as a substance 'present as a (largely unwanted) impurity in the waste that is collected, sorted, processed and then placed on the market in the form of recyclate'. Second, consistent with that approach and in accordance with Article 2(2) of Regulation No 1907/2006, the Commission indicated that, as waste was not a substance, the requirements laid down in Regulation No 1907/2006 started applying, in case at hand, only once the waste containing DEHP was no longer waste. In that regard, that is an additional clarification aimed at highlighting the distinction between PVC waste, on the one hand, and PVC recyclate, on the other, namely, PVC waste that has lost its waste status and can therefore be placed on the market. It follows from the decision on the request for internal review that the authorisation applies only to the latter scenario. Third, it follows expressly from the latter decision that, when DEHP is present in recyclate, it has a precise 'technical' function: it 'reduces the amount of plasticisers that needs to be added in the production of soft PVC articles made out of the recycled soft PVC material'. Fourth, it must be stated that, in all the descriptions of the functions of DEHP, the Commission proceeded from the premiss, which was already stated in the application for authorisation, that DEHP generally has the function of plasticiser

(see paragraph 3 above). In summary, according to the decision on the request for internal review, the authorisation was granted for DEHP in its capacity as plasticiser in the PVC recyclate placed on the market after PVC lost its waste status. In other words, the Commission identified certain functions of DEHP that are activated at the latest when the PVC recyclate containing that substance is used.

72 Given those circumstances, it must be held that the Commission did not commit any error of law in considering, in essence, in the decision on the request for internal review, that the authorisation decision had been granted for a 'use' of DEHP within the meaning of Article 3(24), Article 56(1)(a), Article 60 and Article 62(4)(c) of Regulation No 1907/2006.

73 The applicant's other arguments are not such as to call that conclusion into question.

74 In the first place, the applicant's argument, according to which the Commission in fact authorised a 'process as a whole', namely, the 'recycling of materials containing an SVHC' (see paragraphs 38 and 48 above), is bound to fail.

75 First, as the Commission rightly submits, that is an argument which was not included in the request for internal review and which is, therefore, inadmissible.

76 Second and in any event, on the merits, as has already been noted in paragraph 71 above, the Commission explained in the decision on the request for internal review that authorisation had been granted for the use of DEHP as contained in a mixture, namely, DEHP as contained in recycled PVC, and not for the 'recycling of materials containing an SVHC' or for a 'process as a whole'. Moreover, the use of a mixture containing DEHP was expressly described in the application for authorisation. As the Commission has rightly argued, however, it does not mean that the authorisation pertains to a mixture, but rather to a substance contained in a mixture.

77 In the second place, as regards the applicant's argument that, first, the indication that the function of DEHP of 'reduc[ing] the amount of plasticisers that needs to be added in the production of soft PVC articles made out of the recycled soft PVC material', as identified by the Commission in the decision on the request for internal review, was included in the application for authorisation was given for the first time in that decision, and that, second, that function runs counter to the objective of Regulation No 1907/2006 progressively to replace substances of very high concern (see paragraphs 44 and 46 above), the following should be noted.

78 First, that function was not attributed to DEHP by the Commission in the decision on the request for internal review. In that regard, the first part of the first plea is based on a misreading by the applicant of the documents that the authorisation applicants had submitted to the Commission. Already at the stage of the application for authorisation, they had indicated that the plasticising function of DEHP was relevant for recycled soft PVC in that the presence of that substance in that material contributes to its flexibility, which reduces the amount of plasticisers to be added during its processing into a soft PVC article (see paragraphs 3 and 4 above). In addition, it is apparent from paragraph 51 of the request for internal review that the applicant was well aware that the authorisation applicants had referred to the function of DEHP in the application for authorisation.

79 Second, the function of DEHP referred to by the Commission in the decision on the request for internal review does not run counter to the objective of progressively substituting or replacing substances of very high concern referred to, in particular, in recital 70 and Article 55 of Regulation No 1907/2006. In that regard, it should be noted that the aim of those provisions is 'progressively' to replace substances of very high concern with suitable substances. The term 'progressively' is of particular importance in this context. Using DEHP that already exists in recycled PVC makes it possible to avoid producing new quantities of DEHP. A measure aimed in particular at reducing, gradually, the production of virgin DEHP therefore cannot run counter to the objective of 'progressively' replacing substances of very high concern.

80 Moreover, the applicant has not demonstrated which 'suitable' substance or technology within the meaning of Article 60(4) and (5) of Regulation 1907/2006, read in conjunction with recital 73 of that regulation, could replace DEHP in PVC employed for the uses referred to in paragraph 9 above.

81 In the third place, the applicant's argument that the effect of the Commission's reasoning relating to a function such as that examined by that institution in the decision on the request for internal review is that any use of a substance of very high concern in recovered material would be authorised merely by virtue of the fact that a recycled material was involved and that, therefore, all applications for authorisation for use of recycled materials must necessarily be granted is unconvincing (see paragraph 46 above).

82 In that regard, it should be noted that, as the Commission has rightly argued, that interpretation of the concept of 'use', set out in Regulation No 1907/2006, does not mean that all applications for authorisation for use of recycled materials must necessarily be granted. Indeed, in order for an authorisation to be granted, it is still necessary that all the conditions laid down in Article 60(2) or (4) of Regulation No 1907/2006 be fulfilled.

83 In the fourth place, in the light of all the applicant's arguments on the grant of authorisation at issue in the present case for alleged 'processing of waste' and on an alleged discrepancy between that authorisation and the EU waste legislation regime (see paragraphs 37 and 50 above), the following must be noted.

84 First of all, the applicant's argument that, in essence, authorisation was granted for 'processing of waste plastic', which it claims is not in conformity with legislation (see paragraph 37 above), can only be rejected.

85 It is true that, in paragraphs 117 and 118 of the request for internal review, the applicant invoked in a relatively imprecise manner an alleged discrepancy between the authorisation decision and waste legislation, with the result that that argument cannot be considered to have been raised for the first time in the present action and is therefore inadmissible.

86 However, that argument is unfounded. It should be noted that, as the Commission highlighted, in essence, in point 1.1 of the decision on the request for internal review, it follows from Article 2(2) of Regulation No 1907/2006 that waste as defined in the Waste Framework Directive is not a substance, mixture or article within the meaning of that regulation. Next, as essentially follows from the same paragraph of that decision, where a PVC mixture containing DEHP is used without that mixture having lost its waste status, the authorisation at issue in the case at hand is not applicable to that mixture. There is therefore no discrepancy between the authorisation decision and waste legislation.

87 Second, to the extent that the applicant refers to 'end-of-waste' status (see paragraph 50 above), it must, however, be stated that that complaint was raised neither specifically nor in a reasonably evident manner in the request for internal review. That argument was therefore raised only at the stage of the application. Accordingly, in the light of the considerations set out in paragraphs 55 to 58 above, it must be rejected as inadmissible.

88 In any event, regarding the merits, as the Commission has rightly argued, the applicant's concerns relating to the alleged fact that, in the absence of criteria derived from EU law or practice for establishing 'end-of-waste' status, the grant of authorisation 'for a waste substance' would prevent recycled soft PVC containing DEHP from leaving 'the waste stage' are unfounded.

89 In that regard, apart from the fact that that argument is speculative in that it is based on scenarios that are not certain to have already occurred or to be able still to occur in the Member States, it should be noted that, as is apparent from Article 6(4) of the Waste Framework Directive, it is for the Member States to decide whether waste has ceased to be waste. That decision must be taken on a case-by-case

basis, in the light of relevant EU case-law. Even if a Member State had opted, in order to adopt such a decision, taken in the context of applying the concept of 'end-of-waste' status, to rely on an authorisation decision granted under Regulation No 1907/2006, such as the one at issue, that could not have been a ground for refusal for the authorisation decision. Indeed, a decision on 'end-of-waste' status does not fall within the scope of Regulation 1907/2006 or that of the authorisation decision.

90 In the fifth place, the applicant's argument that, if reducing the amount of virgin plasticisers was a function 'in line with Article 62 Regulation No 1907/2006', the analysis of alternatives carried out by the Commission would have had to be framed around that function (see paragraph 47 above) is unconvincing.

91 It is true that the question as to which interpretation ought to be accorded to the concept of 'use' may have a bearing on the scope of the analysis of the different conditions set out in Article 60(2) and (4) of Regulation No 1907/2006. Nevertheless, as is apparent from the previous considerations, it is possible to speak of 'use' also where, as in the present case, there is a substance in a mixture and the characteristics of the substance have a certain function in that mixture, in this case that of plasticiser, and a function which only appears at the time of the use of the mixture, such as, in the case at hand, the function associated with the progressive reduction of virgin DEHP production. In such a context, it is not incorrect to consider as possible alternatives other mixtures which do not at all contain the substance or other processes in which the function provided by the substance can be met by other means. In particular and in any event, the Commission was not required to verify the extent to which the authorised use would reduce the presence of the substance of very high concern on the market.

92 In the light of the foregoing, the first part of the plea must be rejected as inadmissible and, in any event, as unfounded.

– The second part, alleging the existence of errors of law and of assessment in connection with deficiencies in the chemical safety report

93 According to the applicant, the assessments made by the Commission in the decision on the request for review regarding the chemical safety report are vitiated by errors of law and manifest errors of assessment.

94 In the first place, the application for authorisation is not consistent with Article 62(4)(d) of Regulation No 1907/2006. The failure to comply with that provision constitutes an error vitiating not only the application of Article 60(7) of that regulation in the context of the authorisation decision, but also the Commission's assessments concerning the application of that latter provision, as set out in the decision on the request for internal review.

95 The chemical safety report annexed to the application for authorisation did not adequately address the risks to the health of an entire class of relevant persons, namely workers exposed to DEHP. The data provided in the application for authorisation with respect to the exposure of workers comprised only minimal biomonitoring and air measurements. However, those data were inadequate for a proper assessment of the health risks to workers. Both the Committee for Risk Assessment and the Committee for Socio-economic Analysis noted the inadequacy of the chemical safety report in that respect. In particular, the Committee for Risk Assessment considered that the information provided in that report was of 'limited informative value' and that the presented exposure assessment for the worker population was not representative for that application for authorisation. In the authorisation decision, the Commission also noted that the Committee for Socio-economic Analysis had 'recognised the deficiencies in the workplace exposure assessment identified by the [Committee for Risk Assessment] and the lack of a health impact assessment in the socio-economic analysis'.

96 In response to the complaints submitted by the applicant in its request for internal review alleging that, on the one hand, the application for authorisation does not contain a chemical safety report adequately examining the risks to human health and the environment or to both and that, on the other hand, accordingly, the authorisation decision is incorrect, the Commission merely stated in the decision on the request for internal review that the Committee for Risk Assessment had noted deficiencies in the DEHP risk assessment, albeit without itself taking, after a thorough review of conflicting evidence, a reasoned view as to the conformity of the chemical safety report.

97 The Commission failed even to see the inconsistency in the opinion of the Committee for Risk Assessment, which had declared, on the one hand, that the application for authorisation was in conformity with the requirements of Regulation No 1907/2006, while clearly acknowledging gaps in the information submitted, on the other hand.

98 Far from remedying the obvious deficiency in the chemical safety report, the Commission, in point 1.2 of the decision on the request for internal review, noted that, ultimately, 'whereas indeed the [Committee for Risk Assessment] considered in its opinion that the exposure assessment had some deficiencies, it considered that the application included the necessary information … and the Commission considered the application in conformity with Article 62 [of Regulation No 1907/2006]'.

99 However, according to the applicant, that reasoning is clearly incorrect. According to the applicant, the decision on the request for internal review relies on the opinion of the Committee for Risk Assessment as if it constituted persuasive evidence. The mere fact that the Committee for Risk Assessment stated in its opinion that the application was in conformity does not bind the Commission. The reasoning of that institution consisting in relying solely on the conclusion of the Committee for Risk Assessment regarding the conformity, or even lawfulness, of the application for authorisation as persuasive evidence is manifestly inadequate. Moreover, in referring to the same reasoning in the decision on the request for internal review, the Commission demonstrates that it relied on the fact that the authorisation decision had considered the application for authorisation in conformity with Regulation No 1907/2006. In other words, the Commission relied on the authorisation decision as evidence of its conformity in fact. The decision on the request for internal review therefore presumes the very thing — the adequacy of the decision-making process at the authorisation stage — which the Commission was supposed to investigate at the internal review stage.

100 In the second place, it should be held that there were 'manifest' errors of law in the interpretation of Article 61 of Regulation No 1907/2006 on the review of authorisation, read in conjunction with Article 60(7) of that regulation. In its decision on the request for internal review, the Commission stated that it had acknowledged the conclusion of the Committee for Risk Assessment on the deficiencies in the application for authorisation by, on the one hand, setting a very short review period for the authorisation, expiring on 21 February 2019, and, on the other hand, by imposing monitoring arrangements on the holders of the authorisation. That reasoning would suggest that deficiencies in an application for authorisation, even deficiencies as serious as those identified by the Committee for Risk Assessment, can be remedied by the imposition of a 'very short review period'. In the applicant's view, Article 60(7) of Regulation No 1907/2006 does not confer on the Commission a 'remedial power' to the effect that a non-conforming application may be granted on restricted terms, whether by imposing a short review period or by other means. The objective of a review is not to give an undertaking an opportunity to fill the gaps in a previous application for authorisation, but to provide an opportunity for an undertaking to 'update' its initial application in the light of changes in circumstances, and in particular information on available alternatives.

101 Last, along the lines of that reasoning, the applicant submits that, when it indicated that the authorisation decision would expire on 21 February 2019, the Commission misinterpreted the legal implications of granting a short review period. Article 61 of Regulation No 1907/2006 stipulates that authorisations 'shall be regarded as valid until the Commission decides to amend or withdraw the

authorisation in the context of a review'. By considering that the deficiencies in the application for authorisation were duly taken into account in granting a very short review period, the Commission committed a 'manifest' error of law rendering its conclusion implausible.

102 The Commission disputes that line of argument.

103 As a preliminary point, it should be noted that the arguments put forward by the applicant under the second part of the first plea concern the existence of errors of law and manifest errors of assessment which, in its view, vitiate the application of Article 60(7) of Regulation No 1907/2006 for reasons connected with a reading of that article in conjunction with two different provisions. More specifically, the first complaint of that part seeks to show a misapplication of Article 60(7) of Regulation No 1907/2006 read in conjunction with Article 62(4)(d) of Regulation No 1907/2006, whereas the second complaint of that part concerns an interpretation of Article 60(7) of Regulation No 1907/2006 read in conjunction with Article 61 of that regulation.

104 With regard to the first complaint mentioned in paragraph 103 above, it should be borne in mind that the aim of Article 60(7) of Regulation No 1907/2006 is to enable the Commission to verify whether an application for authorisation is in conformity with the requirements of Article 62 of that regulation from a formal point of view. More specifically, the Commission is required to verify whether the elements mentioned in Article 62(4)(a) to (f) of Regulation No 1907/2006 are indeed contained in the application for authorisation or not. It is true that the documents submitted by applicants for authorisation so as to conform with Article 62(4) of Regulation 1907/2006 must be verifiable. In particular, the chemical safety report is to be prepared in accordance with the modalities set out in Annex I to the same regulation. Nevertheless, Article 60(7) of Regulation No 1907/2006 puts the Commission under a formal and procedural obligation and not under the obligation to examine the merits of the elements referred to in Article 62(4) of Regulation No 1907/2006.

105 Similarly, Article 62(4) of Regulation No 1907/2006, meanwhile, indicates the information that the applicant for authorisation must submit at the time of the submission of its application. In accordance with that provision, applications for authorisation, which are, moreover, as is apparent from Article 62(1) of the same regulation, submitted to ECHA, are accompanied, inter alia, by a chemical safety report and an analysis of alternatives. Article 62(4) of Regulation 1907/2006 is also formal and procedural in nature.

106 However, neither Article 60(7) of Regulation No 1907/2006 nor Article 62 of the same regulation concerns the material conditions for the grant of an authorisation or the obligations incumbent on the Commission when assessing the facts and evidence enabling authorisation to be granted. In particular, it is not on the basis of those provisions that the Commission must examine inter alia whether the chemical safety report concerning a substance draws the right conclusions with regard to the properties of a chemical substance or whether the Committee for Risk Assessment made errors when it examined that report in the context of the preparation of the opinion referred to in Article 60(4) and in Article 64(4)(a) of Regulation No 1907/2006.

107 In fact, such requirements fall on the Commission under Article 60(2), (4) and (5) of Regulation No 1907/2006.

108 During the hearing, the parties were heard on the findings of the General Court set out in paragraphs 104 to 107 above. In response to the Court's questions, the applicant stated that, in its view, there was, in the 'structure of the assessment process under [Regulation No 1907/2006]', first, a stage involving the Commission's examination of the conformity of the application for authorisation with the requirements of that regulation and, second, a stage involving the substantive assessment of the conditions for granting an authorisation. However, the first stage could not be just a formal

box-ticking exercise, because there were actual requirements as to the substance of the documents to be submitted, such as, for instance, those in Annex I to Regulation No 1907/2006. That annex sets out, for example, what must be included in a chemical safety report.

109 That argument must, however, be rejected as unfounded. Annex I to Regulation No 1907/2006 describes the elements that certain documents submitted by the applicant for authorisation must necessarily contain, such as a chemical safety report. However, while it provides for an obligation on the part of the applicant for authorisation to refer to certain specific elements in its application for authorisation and the documents relating to it, that annex, by its wording, does not oblige the Commission, in the context of the examination incumbent on that institution on the basis of Article 60(7) of Regulation No 1907/2006, read in conjunction with Article 62 thereof, to examine the substance of those elements.

110 Last, during the hearing, the applicant emphasised, in essence, that, in its view, in any event, the application for authorisation contained deficiencies infringing not only the assessment requirements incumbent on the Commission under Article 60(2) to (5) of Regulation No 1907/2006, but also the requirements of the examination of the conformity of the application under Article 62 of that regulation. In so doing, the applicant seems to acknowledge that Article 62(4) of that regulation lays down the formal conditions for granting an authorisation.

111 However, that argument, too, can only be rejected as unfounded. First, the applicant appears to proceed from the premiss that a preliminary assessment must be made as to whether an application for authorisation which contains all the elements mentioned in Article 62(4) of Regulation No 1907/2006 and in Annex I to that regulation contains deficiencies relating to the substance of the application of such a serious nature that it would be permissible to find that application not to be in conformity with Regulation No 1907/2006 again from a formal point of view. That kind of preliminary assessment is not, however, provided for in Regulation No 1907/2006. Second, in the event that the applicant does not proceed from that premiss, but rather from the assumption that it is the examination provided for in Article 62(4) of Regulation No 1907/2006 that is at issue, it should be noted that it does not indicate what might be the objective criterion for determining, in a precise manner — or at least in a meaningful and convincing manner — the deficiency threshold of an application for authorisation which could result in a breach of the formal conditions laid down in that latter provision.

112 In the present case, it is common ground that the application for authorisation was accompanied by all the elements referred to in Article 62 of Regulation No 1907/2006 and that the formal condition laid down in Article 60(7) of Regulation No 1907/2006, relating to the submission of a chemical safety report, was met. The condition that the documents referred to in Article 62(4) of Regulation No 1907/2006 must be verifiable was also met. Neither ECHA's committees nor the Commission have argued that the documents submitted by the authorisation applicants were not verifiable. Nor has the applicant argued concretely and by means of evidence that the documents which accompanied the application for authorisation were unverifiable. Moreover, it is common ground that, so far as concerns the chemical safety report, the authorisation applicants complied with the requirements of Annex I to Regulation No 1907/2006. None of the actors involved has argued that that report did not comply with the requirements of Annex I to Regulation No 1907/2006. The applicant also failed to provide evidence in its request for internal review that would allow a different conclusion to be reached in that respect.

113 Given those circumstances, it must be held that the applicant's arguments concerning the existence of alleged deficiencies in the opinion of the Committee for Risk Assessment and their impact on the grant of the authorisation at issue in the case at hand, on the one hand, and the fact that the Commission did not remedy those deficiencies, but merely relied on the opinion of that committee and on the authorisation decision as convincing evidence, on the other hand, have no bearing on the decision to be taken on whether or not the Commission failed to fulfil its obligation under Article 60(7) of

Regulation No 1907/2006, read in conjunction with Article 62 of that regulation. Those arguments deal with matters relating to the assessment of complex facts that served as a basis for the preparation of the opinion of the Committee for Risk Assessment and with the Commission's power to assess those complex facts and, consequently, with the substantive legality of the authorisation decision.

114 Therefore, to the extent that the applicant disputes the formal legality of the authorisation decision by putting forward arguments relating to the material conditions of its adoption, it must be held, by way of a first interim conclusion, that those arguments are ineffective.

115 Regarding the second complaint made under the second part of the first plea (see paragraph 103 above), it should be noted that Article 60(7) of Regulation No 1907/2006 does not refer to Article 61 of that regulation and has no connection to it.

116 As a second interim conclusion, therefore, it must be held that the argument of the applicant based on combining those two provisions in order to demonstrate an infringement of Article 60(7) of Regulation 1907/2006 is also ineffective.

117 What is more, the argument regarding the setting of a 'short review period' and the objective of a 'review' under Article 61 of Regulation No 1907/2006 (see paragraph 100 above) rather appears liable to be put forward to demonstrate the existence of a deficiency in the substantive legality of the authorisation decision. That is also the case for the applicant's argument relating to the alleged absence of a 'remedial power' of the Commission to remedy the content of the application for authorisation through the imposition of a short review period. As has already been noted in paragraphs 104 and 106 above, however, Article 60(7) of Regulation No 1907/2006 does not concern the substantive legality of an authorisation decision.

118 As a third interim conclusion, it must therefore be held that the argument based on the setting of a 'short review period', which is contrary to the objective of a 'review' under Article 61 of Regulation No 1907/2006, is not relevant to deciding whether or not the Commission breached the formal requirements of Article 60(7) of that regulation. That argument, too, is therefore inoperative.

119 The three interim conclusions referred to in paragraphs 114, 116 and 118 above could, in principle, suffice to reject the second part of the first plea.

120 However, the question arises as to whether the applicant's arguments referred to in paragraphs 94 to 101, 113 and 117 above can serve as a basis for substantiating complaints alleging infringement of provisions other than Article 60(7) of Regulation No 1907/2006, namely, Article 60(4) of that regulation, on the one hand, and Article 60(8) and (9) of the same regulation, read in conjunction with the first sentence of Article 61(1) of that regulation, on the other hand.

121 In that regard, it should be recalled that an authorisation under Regulation No 1907/2006 may be granted in accordance with a so-called 'adequate control' procedure, such as that referred to in Article 60(2) of Regulation No 1907/2006, or, in the alternative, in accordance with a 'socio-economic' procedure, such as that referred to in Article 60(4) of Regulation No 1907/2006. An 'adequate control' procedure differs from a 'socio-economic' procedure in that the latter is intended to apply only where it has not been shown that the risk to human health or the environment posed by the use of a substance due to its intrinsic properties, as referred to in Annex XIV to Regulation No 1907/2006, is adequately controlled in accordance with Article 60(2) of that regulation.

122 Next, it should be noted that, taking into account the right to an effective remedy, as provided for in Article 47(1) of the Charter of Fundamental Rights of the European Union, where an applicant has provided facts and arguments in order to demonstrate the infringement of a legal provision that has proved not to be relevant, but those facts and arguments are capable of substantiating the infringement of another provision, there is nothing to prevent the Court from placing those facts and

arguments into the relevant legal context. In other words, the Court is not precluded from regarding those facts and arguments as relating to the relevant provision. It is not necessary for a party expressly to indicate the provisions under which it is entitled to bring its legal proceedings or, more generally, under which it is basing the claims on which it is relying (see judgment of 13 June 2012, *XXXLutz Marken* v *OHIM — Meyer Manufacturing (CIRCON)*, T-542/10, not published, EU:T:2012:294, paragraph 21 and the case-law cited).

123 However, in the context of an action concerning a decision such as a decision on a request for internal review under Article 10 of Regulation 1367/2006, the interpretation whereby certain of the facts and arguments put forward by the applicant are placed into the relevant legal context can be accepted only in so far as there is no breach of the limits imposed on the Court by that Article 10, as described in paragraphs 55 to 58 above.

124 Last, such an interpretation cannot be made without the applicant being in agreement, at least implicitly, with that manner of proceeding.

125 In the case at hand, during the hearing, the parties to the dispute were heard by the Court on the ineffective nature of the applicant's arguments referred to in paragraphs 94 to 101, 113 and 117 above. In particular, the Court asked the applicant to which other plea of the application could its arguments be attached.

126 In response to that question, the applicant recalled that, under the second and third pleas, it had argued that there were manifest errors of assessment, amounting to an infringement of substantive law, namely, in particular, of Article 60(4) and (5) of Regulation No 1907/2006. Moreover, the applicant indicated, in essence, that, in the event that the arguments raised under the second part of the first plea are not successful under that part, they should be taken into account under the second and third pleas.

127 Given those circumstances, the argument of the applicant according to which, in essence, first, the Commission, in the decision on the request for internal review, failed itself to take, after a thorough review of conflicting evidence, a reasoned view as to the conformity of the chemical safety report, the data of which had been deemed inadequate as regards the exposure of workers to DEHP by the Committee for Risk Assessment (see paragraphs 94 to 97 above), and according to which, second, the Commission simply indicated in that decision, by way of convincing evidence, that that committee had noted 'deficiencies' in the DEHP risk assessment (see paragraphs 98 and 99 above) can be interpreted as a complaint alleging infringement of Article 60(4) of Regulation No 1907/2006.

128 Similarly, the argument relating to the imposition of a 'short review period' (see paragraphs 100 and 101 above) can be interpreted as a complaint alleging infringement of Article 60(8) and (9) of Regulation No 1907/2006, read in conjunction with the first sentence of Article 61(1) of that regulation.

129 In the first place, the applicant's arguments referred to in paragraphs 94 to 99 above must, however, be rejected, even after their being reinterpreted into arguments concerning Article 60(4) of Regulation No 1907/2006.

130 Where an assessment of the risk posed by the use of a substance to human health or to the environment contained in a chemical safety report is affected by uncertainties or deficiencies, it may be concluded that it has not been demonstrated that that risk is adequately controlled. Where that is the case, authorisation cannot be granted under the 'adequate control procedure' referred to in Article 60(2) of Regulation No 1907/2006.

131 However, that circumstance may be an opportunity to ask whether, on the basis of the facts and evidence available to the Commission, the authorisation is capable of being under Article 60(4) of Regulation No 1907/2006, in accordance with the 'socio-economic procedure'.

132 In the case at hand, in alleging, in essence, that the Commission, in the decision on the request for internal review, failed itself to take, after a thorough review of conflicting evidence, a reasoned view as to the conformity of the chemical safety report with the provisions of Regulation No 1907/2006 (see paragraphs 94 to 97 above), the applicant calls into question a matter which could have had an impact on the application of Article 60(2) of that regulation and not on the application of Article 60(4) of the same regulation.

133 That is also the case for the argument that the Commission merely indicated in its decisions, by way of convincing evidence, that the Committee for Risk Assessment had noted 'deficiencies' in the DEHP risk assessment (see paragraphs 98 and 99 above)

134 In so far as they rely, in essence, on the premiss that the existence of uncertainties as to the control of the risks arising from the use of DEHP constituted an obstacle as such to the application of Article 60(4) of Regulation No 1907/2006, the arguments referred to in paragraphs 94 to 99 above are ineffective.

135 Moreover, it should be pointed out that, as the Commission stated, without being specifically contradicted on that point by the applicant, the chemical safety report contained biomonitoring information from two Member States and air measurements information, corresponding to studies on worker exposure in the PVC industry using virgin PVC and DEHP, instead of recycled PVC. Those studies included data on workers from two Member States, including biomonitoring information, as well as data from Germany, France, the Netherlands and Finland on air monitoring. The companies to which the data relate are engaged in the formulation and processing of PVC. Although the information provided is not specific to the use of recycled PVC containing DEHP, it relates to activities involving virgin PVC to which virgin DEHP is added, and the subsequent processing of that substance. Furthermore, the authorisation applicants had modelled exposures of workers for the transfer of the recycled soft PVC from small or large bags, which is an activity specific to the use of recycled PVC that was not covered by the measurements collected from the studies related to virgin PVC.

136 As the Commission rightly argues, however, the fact that the Committee for Risk Assessment recognised that there were uncertainties in the exposure assessment to workers and that the information provided was not representative for all uses covered in the application for authorisation does not mean that no information on worker exposure had been presented or that no conclusions could be drawn from it.

137 The applicant has not specifically challenged that finding of the Commission. Beyond challenging in a general manner the chemical safety report, it does not demonstrate that no useful conclusion could be drawn from that report.

138 In the absence of such a challenge, the argument of the applicant consisting in criticising the Commission for having failed to take, after a thorough examination of the various pieces of evidence, a reasoned position on the chemical safety report is not sufficient to demonstrate an infringement of Article 60(4) of Regulation 1907/2006. It therefore cannot succeed. That is also the case for the other arguments mentioned in paragraphs 97 to 99 above.

139 In the second place, the argument relating to the setting of a 'short review period', which constitutes, according to the applicant, an attempt by the Commission to remedy the deficiencies in the chemical safety report (see paragraphs 100 and 101 above), is capable of substantiating an infringement of

Article 60(8) and (9) of Regulation No 1907/2006, read in conjunction with the first sentence of Article 61(1) of that regulation. In order to verify whether it is well founded, the following should be noted.

140 According to the first sentence of Article 60(8) of Regulation 1907/2006, authorisations are to be subject to a 'time-limited review without prejudice to any decision on a future review period'. According to Article 60(9)(e) of Regulation No 1907/2006, 'the time-limited review period' must be specified in the authorisation. Last, according to the first sentence of Article 61(1) of Regulation No 1907/2006, authorisations granted in accordance with that Article 60 are to be regarded as valid 'until the Commission decides to amend or withdraw the authorisation in the context of a review, provided that the holder of the authorisation submits a review report at least 18 months before the expiry of the time-limited review period'.

141 In that regard, it should be emphasised at the outset that, as is apparent, for example, from the English and German versions of Regulation No 1907/2006, as well as from the context of those provisions, the terms 'réexamen' and 'révision' used in the French-language version of the three provisions mentioned in paragraph 140 above (which appears as 'review' in the English-language version) are synonymous.

142 Next, it should be emphasised that, in principle, irrespective of their content, the conditions imposed in accordance with Article 60(8) and (9)(d) and (e) of Regulation No 1907/2006 cannot, it is true, purport to remedy any shortcomings in an application for authorisation or in the analysis of alternatives submitted by an applicant for authorisation or any deficiencies in the Commission's examination of the conditions provided for in Article 60(4) of Regulation No 1907/2006.

143 In other words, the possibility of attaching certain conditions to an authorisation, as provided for in Article 60(8) and (9)(d) of Regulation No 1907/2006, cannot be interpreted as allowing the Commission to leave open the question of whether the conditions of Article 60 of Regulation No 1907/2006 have been met and to respond to that situation by attaching to that authorisation conditions purporting to remedy any deficiencies or gaps in the assessment incumbent on it under that latter provision.

144 In examining the conditions provided for in Article 60 of Regulation No 1907/2006, the Commission must establish whether all the relevant facts and the technical and economic assessments relating to them support the conclusion that the conditions provided for in that provision are indeed fulfilled. If that is not the case, the Commission is not entitled to grant an authorisation, even conditional.

145 Nevertheless, in the case at hand, contrary to what the applicant essentially maintains, it cannot be held that the review period set in the authorisation decision served as a vehicle for remedying, by virtue of a 'remedial of power' conferred on the Commission, the deficiencies contained in the chemical safety report submitted by the authorisation applicants.

146 At the time the Commission set a review period, a short one in this case, it was not necessary to remedy the deficiencies identified by the Committee for Risk Assessment.

147 On the one hand, the only consequence of the uncertainties surrounding the chemical safety report was that the legal basis for the authorisation decision was not that set out in Article 60(2) of Regulation No 1907/2006, but that provided for in Article 60(4) of that regulation. It was therefore not necessary to remedy the deficiencies in the chemical safety report in the light of Article 60(2) of Regulation 1907/2006.

148 On the other hand, it should be recalled that, in the context of its qualitative analysis, which included the uncertainties identified by the Committee for Risk Assessment, the Committee for Socio-economic Analysis had stated that, in its view, the authorisation could be granted in the present case, which indicates that the uncertainties surrounding the chemical safety report had ultimately been dispelled.

149 The applicant cannot, however, invoke the deficiencies in the safety report in isolation, without specifically challenging the assessment of the Committee for Socio-economic Analysis.

150 By the arguments raised under the second part of the first plea, the applicant has not demonstrated that the deficiencies in the chemical safety report had an impact on the application of the conditions of Article 60(4) of Regulation 1907/2006, so there is no reason to consider that the Commission attempted to remedy it by setting a review period. An infringement of Article 60(8) and (9)(e) of Regulation No 1907/2006 cannot therefore be accepted.

151 In the light of the foregoing, the second part must be rejected as unfounded.

– The third part, alleging the existence of errors of law and manifest errors of assessment in connection with deficiencies in the assessment of appropriate alternatives

152 According to the applicant, the Commission committed a manifest error of law in the interpretation of the notion of 'alternatives' under Article 62(4)(e) of Regulation No 1907/2006 and, consequently, a 'manifest error of assessment of the conformity under Article 60(7) [of the same regulation] of the application for authorisation'. Those errors render the Commission's conclusions in the decision on the request for internal review 'implausible'.

153 Indeed, in view of the wording of recital 74 of Regulation No 1907/2006 and in the light of both the role that the assessment of alternatives plays and the natural meaning of the term 'alternative', it is necessary to consider that an application for authorisation must contain an analysis of the substances or technologies which may be used in place of the substance of very high concern 'in the process — or "use"' — for which authorisation is sought. According to the applicant, the analysis of 'alternatives' is, in reality, intended to allow an examination of whether or not another substance or technology may be substituted for the substance of very high concern 'in the anticipated process' Moreover, alternatives should be assessed in the light of the function for which authorisation is sought. In particular, an alternative should be understood in relation to the function of the substance and also by comparison with a substance or technology that is less hazardous.

154 In the case at hand, the analysis of alternatives proposed in the application for authorisation was deficient. Because that application did not identify a function of DEHP, it did not provide alternatives capable of substituting that substance in its function.

155 It is true that the Commission stated in the decision on the request for internal review that DEHP had the function of 'reduc[ing] the amount of plasticiser that needs to be added in the production of articles made out of PVC'. Moreover, the Commission stated in the decision on the request for internal review that the application for authorisation actually contained an assessment of alternatives 'from the [authorisation] applicants' perspective', notably the alternative of using virgin PVC.

156 However, taking the view that using virgin PVC can be qualified as an 'alternative', even though the production of the virgin PVC also uses a substance of very high concern, amounts to a manifest error of law in the interpretation of the concept of 'alternative'.

157 In any event, the applicant states that, if, as the Commission noted in the decision on the request for internal review, the function of DEHP was to 'reduce the amount of plasticiser that needs to be added in the production of articles made out of PVC' and if that function truly was compatible with Regulation No 1907/2006, the Commission should have examined alternatives making it possible to reduce the amount of DEHP used in the production of PVC articles. That examination should have taken into account a much wider range of alternatives to DEHP in the manufacturing process for PVC articles, including, for example, the use of plasticisers which are not substances of very high concern.

158 In the present case, however, the analysis of alternatives annexed to the application for authorisation was not even consistent with the 'function' of DEHP accepted by the Commission in the decision on the request for internal review. Instead of indicating an alternative making it possible to 'reduce the amount of plasticiser that needs to be added in the production of articles made out of PVC', the application for authorisation provided information concerning three other processes for recycling PVC, that is to say one alternative consisting in separating and removing from the recycling process post-consumer waste that contains DEHP in quantities above a certain concentration (0.3% weight by weight); one alternative consisting in eliminating DEHP from the waste PVC, and one alternative involving the use of a different type of industrial waste PVC.

159 The Commission disputes that line of argument.

160 As a preliminary point, it should be recalled that, as has been noted in paragraphs 104 to 106 above, Article 60(7) and Article 62(4) of Regulation No 1907/2006 concern the question of whether the documents referred to were submitted in support of the application for authorisation. Those provisions relate to the formal aspects of the authorisation procedure.

161 In the case at hand, it is common ground that the application for authorisation was accompanied by a presentation of alternatives. Since it is also necessary that the documents to be submitted by applicants for authorisation in order to comply with Article 62(4) of Regulation No 1907/2006 must be verifiable, it is necessary to point out that the applicant has not demonstrated concretely and by means of evidence that the documents provided by the authorisation applicants did not meet that criterion (see paragraph 111 above).

162 On closer examination, the applicant's arguments aimed at asserting deficiencies in the alternatives concern the merits of the decision on the request for internal review. Those arguments are, therefore, ineffective in so far as they have been put forward in order to demonstrate errors of law or errors of assessment with regard to the application of Article 60(7) and Article 62(4) of Regulation No 1907/2006.

163 Admittedly, for the same reasons as those set out in paragraphs 122 to 124 above, those arguments can be interpreted as arguments put forward in support of the plea alleging infringement of Article 60(4) and (5) of Regulation No 1907/2006 by an incorrect assessment by the Commission of alternatives.

164 Under the third plea raised in the application, the applicant specifically alleges infringement of Article 60(4) and (5) of Regulation 1907/2006 by putting forward arguments based on an allegedly erroneous assessment of alternatives. Both the present part of the first plea and the third plea essentially concern an alleged error of law as regards the interpretation of the concept of 'alternatives'. In addition, the arguments put forward by the applicant under the present part of the first plea in the application and those put forward under the first complaint of the third plea partly overlap.

165 In that regard, it must be pointed out that, by the first part of the third plea, the applicant raises infringement of Article 60(4) and (5) of Regulation No 1907/2006 as regards the analysis of the alternatives in the light of the following two factors. First, the Commission, in the decision on the request for internal review, like the authorisation applicants in the application for authorisation, focused on the wrong 'frame of reference', namely 'substitution of a waste stream as opposed to substitution of the [substance of very high concern] in the process (production of PVC articles)'. Second, the Commission repeated that DEHP had the function of reducing the amount of plasticiser that needed to be added in the production of PVC articles (see paragraph 226 below). There is overlap, however, between the issue related to the wrong 'frame of reference' and whether the analysis of alternatives must focus on a substance of very high concern 'within a process', as mentioned by the applicant under the first part of the first plea. There is also overlap in the case of the complaint

relating to the existence of errors in the assessment of alternatives on account of a misinterpretation of the function of DEHP (see paragraph 233 below), on the one hand, and the criticisms of the applicant in its arguments set out in paragraphs 155 to 158 above, on the other hand.

166 Moreover, the conditions allowing the Court to interpret arguments so as to give them practical effect (see paragraphs 122 to 124 above) are satisfied. In particular, it should be stressed inter alia that the details provided by the applicant during the hearing as to the practicality of its arguments under Article 60(4) and (5) of Regulation No 1907/2006 — as opposed to their practicality under Article 60(7) and Article 62(4) of Regulation No 1907/2006 — also included arguments raised in support of the present part of the first plea. Last, the Commission was also heard in that regard.

167 Given those circumstances, it is necessary to address the arguments mentioned in paragraphs 152 to 158 above to supplement the arguments raised under the third plea.

– The fourth part, alleging an error of law in the interpretation of Article 60(7) and Article 64(3) of Regulation No 1907/2006

168 In support of the fourth part of the first plea, the applicant notes that the Committee for Risk Assessment of ECHA had requested additional information from the authorisation applicants when, according to that committee, the application for authorisation was already in conformity with the requirements of Article 62 of Regulation No 1907/2006. By proceeding in that manner, that committee committed a 'manifest' error of law, namely an infringement of the procedure laid down in Article 64(3) of Regulation No 1907/2006. To the extent that the Commission, in its decision on the request for internal review, endorsed that approach, that decision, too, is vitiated by a 'manifest' error of law. Last, the Commission itself infringed not only Article 64(3) of Regulation No 1907/2006, but also Article 60(7) of that regulation.

169 In the applicant's opinion, according to Article 64(3) of Regulation No 1907/2006, once an application is considered to be in conformity with the requirements of Article 62 of Regulation No 1907/2006, only the Committee for Socio-economic Analysis can request further information and can do so only in relation to alternatives. However, it follows from that provision that the Committee for Risk Assessment does not have the power to request additional information in respect of an application which has already been found to be in conformity with the requirements of Article 62 of Regulation No 1907/2006.

170 The Commission disputes that line of argument.

171 As a preliminary point, it should be pointed out that, as follows from the first sentence of Article 64(3) of Regulation No 1907/2006, the requests which the Committee for Risk Assessment and the Committee for Socio-economic Analysis may make to an applicant for authorisation under that provision concern the question of whether the application for authorisation includes all the relevant information specified in Article 62 of Regulation No 1907/2006 that is relevant to the remit of those committees relating to the drawing up of the opinions referred to in Article 64(1) of Regulation No 1907/2006. Pursuant to the second sentence of Article 64(3) of Regulation No 1907/2006, those committees, in consultation with each other, are to make a joint request to the applicant for additional information to bring the application into conformity with the requirements of Article 62. It thus follows from the first two sentences of Article 64(3) of Regulation No 1907/2006 that the joint application of those committees must concern the question of whether the application for authorisation is in conformity with Article 62 of Regulation No 1907/2006 from a formal perspective, that is to say, whether it is accompanied by all the documents and information referred to in that latter provision. In addition, the joint application of those committees may seek to obtain verifiable documents from the applicant for authorisation.

172 In addition to the first sentence of Article 64(3) of Regulation No 1907/2006, the Committee for Socio-economic Analysis may, on the basis of the third sentence of Article 64(3) of that Regulation, if it deems it necessary, require the applicant for authorisation or request third parties to submit, within a specified time period, additional information on possible alternative substances or technologies.

173 Unlike the request mentioned in the second sentence of Article 64(3) of Regulation No 1907/2006, the requirement or request mentioned in the third sentence of Article 64(3) of that regulation does not concern the question of whether the information referred to in Article 62 of Regulation No 1907/2006, as submitted by the applicant for authorisation, is complete or verifiable. The requirement or request mentioned in the third sentence of Article 64(3) of Regulation No 1907/2006 therefore does not concern a formal aspect of the application for authorisation in question. Rather, its objective is to obtain additional information necessary for the substantive appraisals of the Committee of Socio-economic Analysis on the substance at issue and on the assessment of alternatives. Such a request may be useful during the preparation by the Committee for Socio-economic Analysis of the opinion containing the elements specified in Article 64(4)(b) of Regulation No 1907/2006. In particular, where, for example, the analysis of alternatives submitted by the applicant for authorisation shows deficiencies or shortcomings which may be addressed by the applicant, a request made under the third sentence of Article 64(3) of Regulation No 1907/2006 may, in the event that the applicant for authorisation wished to submit the comments referred to in the first subparagraph of Article 64(5), prevent the Committee for Socio-economic Analysis from having to wait for that applicant to submit them, in accordance with the second sentence of the third subparagraph of Article 64(5) of that regulation.

174 In Regulation No 1907/2006, there is no analogous provision enabling the Committee for Risk Assessment to ask additional questions of the applicant for authorisation in order to obtain the elements necessary for a substantive assessment of the data that must be contained in its opinion, as mentioned in Article 64(1) of Regulation No 1907/2006.

175 However, when preparing the opinion of the Committee for Risk Assessment, it may also prove necessary to ask the applicant for authorisation for the additional information in order to address any deficiencies or shortcomings in a chemical safety report on a certain substance. The Committee for Risk Assessment must be able to send questions to the applicant for authorisation, not least in order to speed up the procedure for the preparation of its opinion and to avoid having to wait for the applicant for authorisation to submit comments, as referred to in the third subparagraph of Article 64(5) of Regulation No 1907/2006.

176 As part of its duty of care and in the interests of the proper administration of the dossier before it, the Committee for Risk Assessment may at any time alert the applicant to the existence of deficiencies in the chemical safety report concerning a substance. In addition, that committee may also opt to give the applicant for authorisation the possibility to submit any information necessary to enable it to supplement, or refine, the assessments it will have to carry out in the performance of its duties in the assessment of risks of the substance concerned, even if that option is not expressly provided for in Regulation No 1907/2006.

177 In the light of the foregoing, contrary to what the applicant maintains in the entirety of its arguments referred to in paragraphs 168 and 169 above, it cannot be concluded that the Committee for Risk Assessment infringed Article 64(3) of Regulation No 1907/2006 by asking additional questions on the substance of the application for authorisation, even though it had concluded that the application for authorisation was in conformity with the requirements of Article 62 of that regulation.

178 Accordingly, the Commission cannot be held to have committed any error of law in the adoption of the decision on the request for internal review, meaning that the fourth part of the first plea can only be rejected. The first plea must therefore be rejected in its entirety.

The second plea, alleging manifest errors of assessment vitiating the socio-economic assessment referred to in Article 60(4) of Regulation No 1907/2006

179 The second plea put forward by the applicant is intended to demonstrate the existence of manifest errors of assessment vitiating the socio-economic assessment, as provided for in Article 60(4) of Regulation No 1907/2006, on which the Commission relied to grant the authorisation and then to reject the request for internal review. This plea consists of three parts.

– The first part, alleging errors of law and manifest errors of assessment regarding the frame of reference in the socio-economic assessment

180 The applicant considers that the 'frame of reference' for the authorisation decision was the use of DEHP, as had been mentioned by the authorisation applicants in the application for authorisation.

181 In the case at hand, the alleged error of law vitiating that 'frame of reference', namely the error resulting from the interpretation, by the three authorisation applicants, of the concept of 'use' provided for in Article 56(1)(a) of Regulation No 1907/2006, raised under the first part of the first plea, also vitiates the Commission's assessment of the alleged benefits of the 'use' forming the subject matter of the application for authorisation. As the applicant explained in the request for internal review, no socio-economic benefit could result from the 'use' of a substance of very high concern that does not fulfil any function. In response to that argument, the Commission again considered in the decision on the request for internal review that the relevant function of DEHP was to 'reduce … the amount of plasticisers that needs to be added in the production of soft PVC articles'. In the applicant's view, however, 'reduc[ing] the amount of plasticisers that needs to be added in the production of soft PVC articles' is not a 'function' which is consistent with the requirements of Regulation No 1907/2006.

182 Moreover, by using the 'same elements' to describe the 'use' under Article 56(1)(a) of Regulation No 1907/2006, on the one hand, and to describe the socio-economic 'benefit' under Article 60(4)(b) of Regulation No 1907/2006, on the other hand, the Commission also erred in law in its interpretation of the concept of 'benefit'.

183 The Commission disputes that line of argument.

184 As a preliminary point, it must be pointed out that all the arguments the applicant puts forward in support of the first part of its second plea are based on the premiss set out by the applicant in the first part of the first plea, according to which the manner in which the Commission interpreted the concept of 'use', referred to in particular in Article 3(24), Article 56(1)(a) and Article 60 of Regulation No 1907/2006, constitutes an error of law.

185 As has been found in paragraphs 63 to 91 above, however, that institution committed no error of law in that regard.

186 Moreover, regarding the argument concerning the 'same elements' that the Commission allegedly used to describe the use at issue in the present case and the socio-economic advantages (see paragraph 182 above), the following distinction should be made.

187 In so far as, by that argument, the applicant seeks to restate its reasoning based on the assumption that the manner in which the Commission interpreted the concept of 'use' resulted in an error of law also so far as concerns the concept of 'advantage', that argument must be rejected, without it even being necessary to define 'advantage'. Indeed, as has been noted in paragraph 185 above, that institution committed no error of law in that regard.

188 If, on the other hand, the complaint relating to the 'same elements' that the Commission allegedly used to describe the use at issue in the case at hand and the socio-economic benefits (see paragraph 182 above) is to be understood as being an additional argument, it must be pointed out that the applicant does not specifically state what those 'same elements' comprise.

189 Given those circumstances, the first part of the second plea can only be rejected as unfounded.

– The second part, alleging a manifest error of assessment regarding the assessment of the balance between risks and benefits

190 According to the applicant, the existence of a manifest error of assessment under Article 60(4) of Regulation No 1907/2006 vitiating the decision on the request for internal review was established on the basis of the following information.

191 First of all, in view of the fact that, according to the Committee for Risk Assessment, the risk to the health of workers could not be quantified, neither the Committee for Socio-economic Analysis nor, in turn, the Commission could have had the requisite information upon which to make a judgment as to the socio-economic assessment. In the absence of a quantification of the risk to the health of workers, the underlying balancing of the risks and benefits referred to in Article 60(4) of Regulation No 1907/2006 could not have been carried out correctly. Therefore, the Commission's argument set out in the decision on the request for internal review, according to which, in essence, it was appropriate to follow the approach adopted by the Committee for Socio-economic Analysis, which had 'concluded that benefits of continued use outweigh the risks on the basis of a qualitative analysis of the available information', and that the socio-economic assessment was therefore satisfactory, is absurd. It is true that Article 60(4) of Regulation No 1907/2006 does not specify whether the risk must be quantified. However, according to paragraphs 6.1 to 6.5 of Annex I to Regulation No 1907/2006, the chemical safety report requires a quantification of the risk to human health, unless it is not possible to determine a derived no-effect level ('DNEL') and a predicted no-effect concentration ('PNEC'). In the present case, the application for authorisation considered DEHP to be a 'threshold substance', that is to say, a DNEL and a PNEC could be determined.

192 In a similar vein, the applicant states that the reason why the Committee for Risk Assessment could not quantify the risk was not that it was considered impossible with the current scientific knowledge (for example, because it was not possible to set a DNEL) but rather because the information on worker exposure scenarios was insufficient. However, 'such situation runs counter to the basic principle of authorisation', which requires that the applicant demonstrates that the risk from the use of the substance be adequately controlled, in accordance with Article 60(2) of Regulation No 1907/2006, or, when it cannot demonstrate adequate control, that the applicant for authorisation demonstrates that the benefits from the continued use of the substance outweigh the risks, as is provided in Article 60(4) of Regulation No 1907/2006. In the case at hand, in any event, the authorisation applicants had not provided all the necessary data to perform the assessment.

193 In response to the Commission, the applicant claims to have raised those arguments for the first time not in the present action, but in the request for internal review. The conclusions of the Committee for Risk Assessment and of the Committee for Socio-economic Analysis, which highlight the deficiency resulting from the absence of a full socio-economic analysis and the absence of any health impact assessment, were specifically quoted in the request for internal review.

194 The Commission disputes that line of argument.

195 As a preliminary point, it should be noted that, contrary to what the applicant claims, the argument aimed at demonstrating the existence of a manifest error of assessment by the Commission in the application of Article 60(4) of Regulation No 1907/2006, in that that institution endorsed, in the

decision on the request for internal review, the approach followed by the Committee for Socio-economic Analysis, which had, for its part, 'concluded that benefits of continued use outweigh the risks on the basis of a qualitative analysis of the available information' was not raised as such in the request for internal review.

196 The arguments relied on by the applicant involving the benefits and their balancing against the risks posed by DEHP to human health, as set out in paragraphs 93 to 100 of the request for internal review, did indeed concern some aspects that dealt with that issue. Those elements were summarised by the applicant in paragraph 99 of the request for internal review. According to that paragraph, '[o]verall, the Authorisation Applicants failed to demonstrate that the socio-economic benefits of the continued use of DEHP outweighed the risks within the meaning of Article 60(4), since (1) the substance d[id] not serve a function; (2) the Authorisation Applicants incorrectly claimed that there were no risks of using DEHP and (3) the SEA was narrowly focused on the impact of not granting the authorisation'.

197 However, no mention is made in the request for internal review of the argument on the question of what was or might be the actual or potential impact of the absence of quantification of the risk to workers' health, as identified by the Committee for Risk Assessment in its opinion under the second sentence Article 60(4) of Regulation 1907/2006, read in conjunction with Article 64(1) of that regulation, on the balancing between the risks and the socio-economic benefits of the use of DEHP.

198 In that regard and for the sake of completeness, it should be pointed out that the passage from the decision on the request for internal review cited by the applicant to demonstrate that the Commission effectively dealt with its argument concerning the impact of the absence of quantification of the risk to the health of workers on the balancing between the risks and the socio-economic benefits, namely the passage whereby the Committee for Socio-economic Analysis 'concluded that benefits of continued use outweigh the risks on the basis of a qualitative analysis of the available information' is shortened and taken out of context.

199 In that passage of the decision on the request for internal review, the Commission did not respond to the argument relating to the deficiencies of the chemical safety report concerning DEHP due to the absence of quantification of the health risks for workers exposed to that substance. In fact, by means of the wording mentioned in paragraph 193 above, the Commission responded to the argument of the applicant raised in paragraphs 95 and 99 of the request for internal review, according to which the socio-economic analysis submitted by the authorisation applicants did not demonstrate that the socio-economic benefits of DEHP outweighed the risks posed by that substance since that analysis was based on the false assumption that that substance posed no risk at all.

200 Given those circumstances, it must be considered that the argument of the applicant set out in paragraphs 190 to 192 above did not appear in the request for internal review. For the same reasons as those set out in paragraphs 55 to 58 above, that complaint must therefore be rejected as unfounded.

201 Moreover and in any event, as regards the substance, that argument is unfounded.

202 The applicant claims, in essence, that the balancing between the socio-economic benefits and the risks posed by the use of DEHP to human health, as carried out by the Commission in the decision on the request for internal review, was flawed as one of the factors, namely the risk posed by the use of DEHP to workers, could not be 'quantified', even though the Commission, which did not ignore that aspect, highlights that it endorsed the opinion of the Committee for Socio-economic Analysis, which had carried out a 'qualitative' analysis on that subject.

203 It is necessary to respond to that argument by stating that the balancing between the socio-economic benefits and the risks posed by the use of DEHP to human health should not be limited to taking into account quantitative elements. Moreover, where there are not enough elements to enable a risk to be 'quantified', the fact remains that that risk can also be evaluated using qualitative elements.

204 It follows from the foregoing that the second part of the second plea must be rejected as inadmissible and, in any event, as unfounded.

– The third part, alleging a manifest error of assessment based on the failure to take into account information in the context of the socio-economic assessment

205 According to the applicant, to the extent that, when applying Article 60(4)(d) of Regulation No 1907/2006, the Commission ignored the information as to the endocrine-disrupting qualities of DEHP, that institution committed a 'manifest error of law and assessment'.

206 The term 'available information' used in that provision should be understood as referring to all the information which was, as a matter of fact, available to the Commission at the time of the evaluation of the application for authorisation. As DEHP had been identified, in December 2014, by ECHA as a substance of very high concern within the meaning of Article 57(f) of Regulation No 1907/2006, because of its properties as an endocrine disruptor of very high concern (see paragraph 7 above), the Commission, in the case at hand, should have taken into account information relating to the properties of that substance as an endocrine disruptor under Article 60(4)(d) of Regulation No 1907/2006. In any event, the wording of that provision does not specify that only the information which is 'available to the applicants' may be examined.

207 According to the applicant, it is true that the Commission attempted to justify that latter approach by stating, in point 3.2 of the decision on the request for review, that '[o]ne could not have expected the [authorisation] applicants to anticipate the identification of an additional hazardous property of DEHP when preparing the application for authorisation, in the course of 2012-2013, [since] such properties were only identified [in December 2014, that is to say,] 15 months later'. However, the wording of Article 60(4)(d) of Regulation No 1907/2006 does not contain any provision stating that only information which is available to applicants may be examined. In fact, under Article 60(4) of that regulation, the Commission's duty of assessment is not subject to any limitation as to the type of hazards to human and environmental health which must be examined and is not subject to the limitation that only the evidence received from the authorisation applicants must be taken into account.

208 In the case at hand, it should be borne in mind that the relevant texts for the socio-economic assessment are Article 62(5)(a) and Annex XVI to Regulation No 1907/2006. That annex, however, is not limited to the 'benefits for human health and the environment' of a refusal of authorisation based on the hazards listed in Annex XIV to the same regulation. Accordingly, it should be concluded that information on hazardous properties that are not referred to in Annex XIV to Regulation No 1907/2006 must be taken into account when drawing up the socio-economic assessment submitted under Article 60(4) of that regulation.

209 The applicant is unconvinced by the argument which the Commission relies on its defence, according to which requiring authorisation applicants to submit information on the risk related to properties of very high concern which were not identified when they lodged the application for authorisation completely disregards the principle of legal certainty. That argument is contradicted by the established case-law on legitimate expectations, according to which economic operators are not justified in having a legitimate expectation that an existing situation which is capable of being altered by the EU institutions in the exercise of their discretionary power will be maintained. The authorisation

applicants could not legitimately expect that the substances which they use or manufacture would not raise 'very high concerns' additional to those already justifying their inclusion in the list referred to in Annex XIV to Regulation No 1907/2006.

210 The Commission disputes that line of argument.

211 As a preliminary point, it should be noted that, by virtue of Article 60(4)(d) of Regulation No 1907/2006, the authorisation decision is to be taken by the Commission after consideration of 'available information on the risks to human health or the environment of any alternative substances or technologies'.

212 However, contrary to what the applicant seems to suggest (see paragraphs 205 and 206 above), Article 60(4)(d) of Regulation No 1907/2006 is concerned neither expressly nor implicitly with the intrinsic properties of the substance of very high concern in question.

213 The same conclusion can be drawn not only from the wording of that provision, but also from its context. Indeed, under Article 60(4) of Regulation No 1907/2006, the intrinsic properties of substances of very high concern are implicitly referred to in the first sentence and in point (a) of the second sentence of that provision.

214 Therefore, the fact that the Commission did not take into account the intrinsic properties of DEHP as an endocrine disruptor could constitute, at most, an infringement of Article 60(4), first sentence and point (a) of the second sentence of Regulation No 1907/2006.

215 However, an infringement of Article 60(4)(d) of Regulation No 1907/2006 cannot be accepted.

216 Furthermore, in the alternative, it should be noted that, in the context of the answer to be given to the question of whether it is demonstrated that the socio-economic benefits outweigh the risk to human health and the environment arising from the use of the substance of very high concern, such risks being expressly mentioned in the first sentence of Article 60(4) of Regulation No 1907/2006 and implicitly referred to in the second sentence of Article 60(4)(a) of that regulation, the Commission is, admittedly, required to examine of its own motion all the relevant information available to it at the time of the adoption of the authorisation decision, without the risk assessment being limited to examining the information provided in the application for authorisation. Indeed, the role of the Commission in a risk assessment is not that of an arbitrator whose competence only relates to the information and evidence provided by the applicant for authorisation.

217 It is true that it is not directly apparent from the wording of the first sentence of Article 60(4) of Regulation No 1907/2006 that the risk assessment to be carried out by the Commission must be based solely on information concerning the intrinsic properties of the substance under examination, as referred to in Annex XIV to Regulation No 1907/2006, or whether, in that regard, the Commission is rather obliged to take into account also the properties of a substance not included in that annex, but in the candidate list.

218 In that regard, it should be recalled that, according to Article 60(2) of Regulation No 1907/2006, an authorisation is to be granted if the risk to human health or the environment from the use of a substance 'arising from the intrinsic properties specified in Annex XIV [to that regulation]' is adequately controlled in accordance with Section 6.4 of Annex I to the same regulation and as documented in the applicant's chemical safety report.

219 In line with Article 60(2) of Regulation No 1907/2006, Article 62(4)(d) of Regulation No 1907/2006 provides that an application for authorisation is to include, inter alia, unless already submitted as part of the registration, a chemical safety report in accordance with Annex I to that regulation covering the risks to human health or the environment from the use of the substance or substances 'arising from the intrinsic properties specified in Annex XIV [to the same regulation]'.

220 Given those circumstances, in the light of Article 60(2) and Article 62(4)(d) of Regulation No 1907/2006, it should be concluded that only data relating to the intrinsic properties of a substance that have been included in Annex XIV to Regulation No 1907/2006 are relevant for the risk assessment referred to in the first sentence of Article 60(4) of Regulation No 1907/2006.

221 On the contrary, any information on the intrinsic properties of a substance that has not been included in that Annex XIV should not be taken into account during the evaluation, even if those intrinsic properties have already been included in the candidate list provided for in Article 59(1) of Regulation No 1907/2006.

222 The inclusion of a substance in the candidate list, first, and the inclusion in Annex XIV to Regulation No 1907/2006, second, constitute two different stages of the authorisation procedure laid down in Regulation No 1907/2006, which are governed by their own rules, concern objectives which only partly overlap and are based, in part, on different assessment criteria.

223 Moreover, as follows from the word 'may' used in Article 57 of Regulation No 1907/2006, the mere inclusion of certain intrinsic properties of a substance in the candidate list does not necessarily or automatically lead to the inclusion of those properties in Annex XIV to Regulation No 1907/2006. On the contrary, as is clear from Article 58 of Regulation No 1907/2006, a decision must also be taken in that respect in accordance with all the conditions referred to in that latter provision. The decision to include a substance in Annex XIV to Regulation No 1907/2006 is adopted by the Commission on the basis of a recommendation prepared by ECHA which takes into account the prior opinion of its Member State Committee and comments — in particular concerning uses which should be exempted from the authorisation requirement under Article 58(2) of that regulation — supplied by the interested parties in the context of a public consultation provided for in the second subparagraph of Article 58(4) of the same regulation (judgment of 25 September 2015, *VECCO and Others* v *Commission*, T-360/13, EU:T:2015:695, paragraph 30).

224 In the light of the foregoing, the applicant's arguments in support of the third part of the second plea and set out in paragraphs 205 to 209 above must be rejected as unfounded. Accordingly, as the three parts of the second plea in law have been rejected, the second plea must be rejected in its entirety.

The third plea, alleging errors of law and manifest errors of assessment under Article 60(4) and Article 60(5) of Regulation No 1907/2006 regarding the analysis of alternatives

225 The third plea relied on by the applicant consists of two complaints which seek to establish the existence of errors of law and manifest errors of assessment vitiating the application by the Commission of Article 60(4) and (5) of Regulation No 1907/2006 in the case at hand, in particular in the light of the Commission's assessment of the economic feasibility for the authorisation applicants of alternatives to DEHP.

226 In the first place, the analysis provided by the authorisation applicants focused on the wrong 'frame of reference', namely the substitution of a waste stream as opposed to the substitution of DEHP in an industrial process, and led to a misinterpretation by the authorisation applicants of the concepts of 'use' and 'alternative', given in the authorisation decision. In response to that argument of the applicant raised in its request for internal review, the Commission, in the decision on the request for internal review, repeated its assessment concerning the function of DEHP as a substance to 'reduce

the amount of plasticiser that needs to be added in the production of articles made out of PVC'. Those errors of law are alleged to have had an effect on the decision on the request for internal review as regards the analysis of alternatives and to have led to that latter decision being vitiated by an error of law.

227 In the second place, the applicant claims that the decision on the request for internal review approved an interpretation of the concept of 'assessment' of alternatives which is contrary to Article 60(5) of Regulation No 1907/2006.

228 First, the applicant states that, in view of the fact that the authorisation applicants had provided a quick calculation containing confidential costs information and because the Committee for Socio-economic Analysis had been unable to find adequate information in the public domain, that committee could not check the 'price range of these waste streams'. The Commission, for its part, referred to that element in the decision on the request for review. In that regard, it added that 'since the public consultation did not yield contradictory information regarding the figures put forward by the applicant the [Committee for Socio-economic Analysis] concluded that they were realistic'.

229 In so doing, the Commission actually considered that it was lawful for the Committee for Socio-economic Analysis to presume the reliability of the information provided by the applicants until that information was directly contradicted by third party submissions. That approach, however, runs counter to the Commission's obligation to assess all relevant aspects of the alternatives, including their economic feasibility, an obligation incumbent on the Commission under Article 60(4) and Article 60(5)(b) of Regulation No 1907/2006. In that regard, it is a manifest error for which there is no plausible justification. According to the applicant, the task of assessment of 'all relevant aspects' of alternatives, including their 'economic feasibility', would only have meaning if it constituted a proper scrutiny of independently verifiable information. Applying a 'procedural rule' presuming reliability is a short-cut to avoid that assessment. It therefore does not constitute an economic assessment at all.

230 Second, in the applicant's view, an approach which consists in presuming that the information provided by the applicants is reliable unless third parties prove otherwise undermines the effectiveness of the authorisation process, as it encourages applicants to conceal information which would be contrary to their interests. Moreover, given that economic information may also be subject to commercial confidentiality restrictions, it is not reasonable to rely on that information being discovered and communicated by third parties during the consultation procedure.

231 Third, the applicant states that the Commission, in point 5.2 of the decision on the request for review, attempted to justify that approach by stating that 'requiring the Committee [for Socio-economic Analysis] to undertake an independent search for this specific data would be disproportionately burdensome on the procedure'. However, those grounds are manifestly erroneous. In a case such as the present one, the 'obvious solution' is simply to require that the authorisation applicants provide an adequate corpus of reliable, verifiable, evidence.

232 The Commission disputes that line of argument.

233 As a preliminary point, it must be recalled that, as has been noted in paragraph 167 above, the applicant's arguments under the third part of the first plea (see paragraphs 152 to 158 above) must be regarded as being raised in support of the present plea and will be addressed in the context of the examination of it. Indeed, to the extent that they seek to establish the existence of an error of law by the Commission in its interpretation of the term 'alternative' (see paragraphs 153 to 156 above), those arguments essentially constitute a complement to the first complaint raised under the present plea. However, the other arguments articulated by the applicant in support of the third part of the first plea are intended to support the existence of manifest errors of assessment (see paragraph 157 and 158 above).

234 In the first place, it is appropriate at the outset to reject as inadmissible the applicant's argument that the analysis of alternatives proposed in the application for authorisation was deficient since, in its view, that application did not specify the function of DEHP (see paragraph 154 above).

235 The present action can pertain only to the legality of the decision on the request for internal review and not to whether the request for an authorisation is deficient or not. The general aim of the third plea in law should therefore be to demonstrate the existence of any errors committed by the Commission and not any errors committed by the authorisation applicants in the application for authorisation.

236 However, in so far as it is intended to illustrate the existence of errors in the decision on the request for internal review, namely, in the event that it was appropriate to conclude that the decision restates and endorses the elements contained in the application for authorisation, the argument set out in paragraph 233 above must be rejected as unfounded. Irrespective of what the applicants for the authorisation did or did not indicate in the application for authorisation, the Commission expressly identified a function of DEHP for the purposes of the authorisation at issue in the present case.

237 In the second place, regarding the reasoning used by the applicant to demonstrate that the analysis of alternatives must be an assessment of the substances or technologies that may be substituted for the substance of very high concern 'within a process' (see paragraph 165 above), it must be pointed out that that reasoning shares a link with the argument put forward under the present plea, according to which the analysis provided by the authorisation applicants focused on the wrong incorrect 'frame of reference', namely, 'the substitution of a waste stream as opposed to the substitution of DEHP in an industrial process', which led to a misinterpretation by the authorisation applicants of the concepts of 'use' and 'alternative', in the application for authorisation (see paragraph 226 above). In addition, that reasoning shares a link with the argument consisting in contending that the Commission claimed that DEHP has a function which is unacceptable under Regulation 1907/2006, such that, ultimately, the misinterpretation of the notions of 'use' and 'alternative', appearing both in the application for authorisation and in the authorisation decision, had an impact as an error of law on the decision on the request for internal review (see paragraph 226 above).

238 As has been noted in the assessments relating to the first part of the first plea, however, for the reasons set out in paragraphs 63 to 91 above, it is possible to speak of the 'use' of a substance even if it is not actively introduced 'in or into an industrial process'. The Commission therefore did not err in concluding that, in the present case, it was a 'use' of the substance at issue, as contained 'in a mixture'. In that context, it is without error of law that the Commission found that one of the functions of DEHP was to 'reduce the amount of plasticiser that needs to be added in the production of articles made out of PVC'. It is also without error of law that the Commission proceeded from the premiss, already stated in the application for authorisation, that DEHP generally has a function of plasticiser. Those functions, which are activated at the latest when the PVC recyclate containing that substance is used (see paragraph 71 above), have supported the conclusion that the authorisation decision could be granted for a 'use' within the meaning of Article 3(24), Article 56(1)(a) and Article 60 of Regulation No 1907/2006.

239 Given those circumstances, as the Commission has rightly argued, the assessment of the alternatives could, in the case at hand, focus on the mixture rather than on the substance contained in the mixture. However, contrary to what the applicant claims, the analysis of alternatives should not be an evaluation of the substances or technologies that can replace DEHP 'in or into an industrial process'.

240 Therefore, the argument relating to the analysis of alternatives to the substances or technologies that may be substituted for the substance of very high concern 'in or into an industrial process' is bound to be rejected, just like the claims related to the function of DEHP identified by the Commission.

241 In the third place, the argument that it is incorrect to consider that using virgin PVC can be qualified as an 'alternative' must also be rejected, since the production of virgin PVC also uses a substance of very high concern (see paragraph 156 above).

242 First, the decision on the request for internal review indicates, in essence, that, according to the Commission, reducing the amount of a virgin substance of very high concern used as a plasticiser by means of a recycled substance of very high concern may constitute a function in conformity with Regulation 1907/2006. It is in view of that function that the Commission examined alternatives. However, contrary to what the applicant seems to suggest, the Commission did not, in the decision on the request for internal review, consider either expressly or implicitly that the use of virgin PVC corresponded to an alternative as such.

243 Second, a use that makes it possible to reduce the amount of DEHP, whether pure or virgin, that has to be added to compounds in order to produce new flexible PVC articles does not contravene the express requirements or the objectives of Regulation No 1907/2006.

244 Indeed, the objective referred to in Article 55 of Regulation No 1907/2006 does not preclude that. The aim of that provision is not to replace substances of very high concern with suitable alternative substances or technologies in an unconditional, unilateral and immediate manner. On the contrary, as is clear from the wording of that article, its objective is 'progressively' to replace substances of very high concern with suitable alternative substances or technologies 'where these are economically and technically viable'. Moreover, that objective is repeated in almost identical terms in recital 70 of Regulation No 1907/2006.

245 In the fourth place, as regards the arguments concerning the existence of a manifest error of assessment on the ground that, even if the function alleged by the Commission were to be accepted, that institution did not, in any event, examine the existence of alternatives enabling the amount of DEHP in the manufacture of PVC articles to be reduced by taking into account a large number of solutions, including the use of plasticisers that are not substances of very high concern (see paragraph 157 above), the following elements should be noted.

246 According to the case-law, in order to establish that that institution committed a manifest error in assessing complex facts such as to justify the annulment of that act, the evidence adduced by the applicant must be sufficient to make the factual assessments used in the act implausible. Subject to that review of plausibility, it is not the Court's role to substitute its assessment of complex facts for that made by the institution which adopted the decision (see judgment of 9 September 2011, *France* v *Commission*, T-257/07, EU:T:2011:444, paragraph 86 and the case-law cited). Consequently, a plea alleging the existence of a manifest error must be rejected if, despite the evidence adduced by the applicant, the contested assessment may still be accepted as true or valid. That is particularly so where the decision at issue is vitiated by errors of assessment which, taken together, are of only minor significance unlikely to have influenced the administration (see judgment of 9 September 2011, *France* v *Commission*, T-257/07, EU:T:2011:444, paragraph 87 and the case-law cited).

247 In the case at hand, it must be pointed out, on the one hand, that the authorisation applicants had alleged a lack of availability of alternatives in the application for authorisation. In that regard, alternatives for the downstream converters of the recycled soft PVC were discussed, such as the use of virgin PVC containing plasticisers which are not substances of very high concern. Although that prospect was not presented as an alternative by the applicants for authorisation, that alternative was regarded by the Committee for Socio-economic Analysis as being unsuitable and, in particular, as not being economically feasible for the downstream users of the products of the applicants for authorisation, or at least for some of those users.

248 Contrary to what is incumbent on an applicant, which invokes a manifest error of assessment in accordance with the rules established by the EU Courts, as set out in paragraph 246 above, to prove, the applicant has not provided any evidence that would render the factual assessments used in the decision on the request for internal review implausible as regards the lack of availability of alternatives.

249 First, the applicant does not explain on the basis of which elements other than those indicated by the authorisation applicants, by the third parties during the public consultation referred to in Article 64(2) of Regulation No 1907/2006 and by the Member States which stated their positions on the outcome of the application for authorisation during the discussions of the Committee provided for in Article 133 of the same regulation, the Commission could, at the stage of the adoption of the decision on the request for internal review, have reached an outcome other than that contained in the opinion of the Committee for Socio-economic Analysis concerning alternatives based on plasticisers that are not substances of very high concern. Indeed, the applicant does not indicate which other substance that is not a substance of very high concern could have been taken into account by the Commission.

250 Second and in any event, the applicant did not specifically dispute, in its request for internal review, the overall conclusion reached by the Commission on the lack of availability of alternatives.

251 Moreover, it should be underlined that requiring, as has just been noted in paragraphs 249 and 250 above, the applicant to specify the factors that might call into question the Commission's conclusion as to the lack of availability of alternatives in the context of the present action, or in the context of the request for internal review, does not amount to reversing the burden of proof on the applicant for authorisation, as referred to in Article 60(4) of Regulation No 1907/2006, read in conjunction with recital 69 thereof. On the contrary, those are, on the one hand, requirements related to the need that, in an action for annulment, the arguments and pleas of the action be indicated clearly such that the Court can analyse them properly, without having to speculate as to what the applicant wishes and without having to substitute its own reasoning. On the other hand, those are requirements of precision such as those stemming from Article 10 of Regulation No 1367/2006 (see paragraph 56 and 57 above).

252 Given those circumstances, the argument set out in paragraph 244 above must be dismissed as unfounded.

253 In the fifth place, the applicant's argument that, in essence, the Commission presumed the reliability of the price data, as indicated by the authorisation applicants in their analysis of alternatives and as accepted by the Committee for Socio-economic Analysis, without the latter having itself carried out an independent assessment of their reliability, which ultimately amounted to an interpretation of the notion of 'assessment' of alternatives that is contrary to Article 60(5) of Regulation No 1907/2006, must also be rejected as unfounded.

254 In that regard, it should be noted, first, that, contrary to what the applicant suggests, when examining the economic feasibility of the alternatives proposed by the authorisation applicants under Article 60(5)(b) of Regulation No 1907/2006, the Commission did not 'presume' the accuracy of the price data submitted by those applicants.

255 In response to that argument of the applicant and without being contradicted by it on that point, the Commission noted in point 5.2 of the decision on the request for internal review that the authorisation applicants had provided prices which were not publicly available for post-industrial waste. The Committee for Socio-economic Analysis, for its part, carried out its assessment concerning the price data provided in the application for authorisation by trying to obtain additional information in the public domain and by checking any relevant information submitted in the public consultation referred to in Article 64(2) of Regulation No 1907/2006.

256 That approach of seeking additional information is an indication that the Committee for Socio-economic Analysis did indeed carry out an examination of the information submitted by the authorisation applicants.

257 When the Commission endorsed that examination of the Committee for Socio-economic Analysis, therefore, it did not presume the accuracy of that information, either. In addition, it is specifically because there was no evidence contradicting the accuracy of the data provided by the authorisation applicants that the Commission endorsed the assessments of that committee in respect of the prices for post-industrial waste.

258 Second, in the interests of precision, it should be stated that the applicant's criticism that the Commission 'presumed' that the economic data indicated by the authorisation applicants were correct does not concern a question of law.

259 According to Article 60(5) of Regulation No 1907/2006, when assessing whether suitable alternative substances or technologies are available, all relevant aspects are to be taken into account by the Commission, including, according to Article 60(5)(b) thereof, the technical and economic feasibility of alternatives for the applicant. However, Article 60(5) of Regulation No 1907/2006 does not define a particular method for implementing the 'assessment' referred to in that provision, which might be considered as a method required by law and which, in other words, is an integral part of the legal concept of 'assessment'.

260 On the contrary, the assessment of the availability of suitable alternative substances or technologies provided for in Article 60(5) of Regulation No 1907/2006 involves a process of assessing technical, economic and scientific issues, as well as complex facts, which is intended to verify all the relevant aspects of the matter, in particular the aspects referred to in Article 60(5)(a) and (b) of that regulation, on the basis of the information available to the Commission at the time when it adopted its authorisation decision.

261 In that vein, the applicant's criticism that the Commission 'presumed' that certain data specified by the authorisation applicants were accurate is actually directed against an infringement of Article 60(5)(b) of Regulation No 1907/2006 in terms of the existence of a possible (manifest) error of assessment rather than a breach of the concept of 'assessment' as an element of law, as the applicant claims.

262 In that regard, irrespective of the fact that the Commission did not 'presume' certain elements in the case but endorsed the results of an examination of the Committee for Socio-economic Analysis, after having stated that there was no evidence contradicting the information submitted by the authorisation applicants (see paragraph 257 above), it must be pointed out that the applicant does not put forward in the case at hand any argument capable of demonstrating which facts or evidence the Committee for Socio-economic Analysis or the Commission could have taken into account to verify — or invalidate following such a verification — the reliability of the data set out in the application for authorisation. Moreover, the applicant does not specify what could have been the particular technical, economic or scientific method that could have made it possible to remedy the existence of any doubts as to the reliability of the information submitted by the authorisation applicants on the prices for post-industrial waste.

263 Furthermore, as with what has been noted in paragraph 251 above regarding the lack of availability of alternatives, it should be stressed that requiring the applicant to specify the factors that might call into question the Commission's conclusions as to the reliability of the data contained in the application for authorisation does not amount to reversing the burden of proof on the applicant for the authorisation, as referred to in Article 60(4) of Regulation No 1907/2006, read in conjunction with recital 69 thereof. However, those are requirements relating to the case-law cited in paragraph 246 above.

264 Given those circumstances, simply criticising the Commission for having 'presumed' the accuracy of the data that had been specified by the authorisation applicants in the application for authorisation and subsequently accepted by the Committee for Socio-economic Analysis when preparing its opinion under Article 64(4)(b) of Regulation No 1907/2006 is not sufficient to substantiate the existence of a manifest error of assessment.

265 None of the arguments put forward by the applicant is capable of calling that conclusion into question.

266 Second, it is necessary to reject the argument that an approach which consists in presuming that the information provided by the applicants for an authorisation is reliable 'unless proven otherwise by third parties' undermines the effectiveness of the authorisation process, as it encourages applicants to conceal information which is contrary to their interests. The same is true of the argument that, given that economic information may also be subject to commercial confidentiality restrictions, it is not reasonable to rely on that information being discovered and communicated by third parties during the consultation procedure (see paragraph 230 above).

267 In that regard, it should be noted that it is indeed true that there is an interest that applicants for an authorisation not conceal the relevant information in an authorisation procedure, which they might be inclined to do if that information is contrary to their interests.

268 However, it should be noted again that the applicant does not identify the method that might best be suited for mitigating the risk of an applicant for authorisation concealing relevant information known only to it. On the one hand, neither the Commission nor the ECHA committees referred to in Article 64(1) of Regulation No 1907/2006 have powers similar to those of a competition authority or of a Member State's public prosecution service which would allow the accuracy of facts to be verified by means of coercive measures such as search and seizure. On the other hand, the solution described by the applicant as 'obvious', whereby it might simply be 'require[d] that the authorisation applicants provide an adequate corpus of reliable, verifiable, evidence' (see paragraph 231 above), is far from being one. The problem of the existence of confidential information known only to the applicant arises each time it is necessary to ask it to supplement or clarify information of which it is the sole holder.

269 Second, it is appropriate to reject the applicant's criticism of the argument raised by the Commission in point 5.2. of the decision on the request for internal review, according to which 'requiring the Committee [for Socio-economic Analysis] to undertake an independent search for this specific data would be disproportionately burdensome on the procedure' (see paragraph 231 above).

270 Leaving aside the issue of the 'disproportionate burden' on the procedure, as invoked by the Commission, the applicant does not show specifically what more the Committee for Socio-economic Analysis could have done in order to allay the concerns expressed by the applicant.

271 In the light of the foregoing, the third plea must be rejected as unfounded.

The fourth plea, alleging errors of law and manifest errors of assessment on account of a breach of the precautionary principle in the context of the authorisation procedure

272 By its fourth plea, the applicant alleges breach of the precautionary principle, as referred to in Article 191(2) TFEU.

273 In the first place, according to the applicant, a correct application of the precautionary principle requires that the burden of proving that a substance should be authorised rest with the applicant for authorisation. In the event that there remain uncertainties concerning the risks to human health or to

the environment even after the applicant has submitted its evidence, the Commission should conclude that the burden of proof has not been discharged and that the use of the substance cannot obtain authorisation.

274 In the present case, on the one hand, the Committee for Risk Assessment concluded that it 'could not quantify' the risks to the health of workers. On the other hand, the endocrine disrupting properties of DEHP were not taken into account in the decision-making process. Accordingly, the Commission failed to comply with the precautionary principle when it nevertheless decided to grant authorisation for the use of DEHP. That error also had an impact on the merits of the decision on the request for internal review.

275 Second, in view of the properties of DEHP as an endocrine disruptor of very high concern, which means that that substance raises concerns of a level equivalent to those which led to its inclusion in the list contained in Annex XIV to Regulation No 1907/2006, the applicant takes the view that the Commission should have requested that the authorisation applicants update the application for authorisation in accordance with the precautionary principle.

276 Third, in response to the argument put forward by the Commission in its defence, according to which taking into account in the risk assessment properties which had not been identified when submitting the application for authorisation disregards the principle of legal certainty, the applicant recalls that, according to the case-law of the EU judicature on the principle of the protection of legitimate expectations, which is a corollary of the principle of legal certainty, economic operators are not justified in having a legitimate expectation that an existing situation which is capable of being altered by the EU institutions in the exercise of their discretionary power will be maintained.

277 In the second place and irrespective of the foregoing, the Commission did not provide any explanation as to how it applied the precautionary principle in the present case.

278 The Commission disputes that line of argument.

279 In that regard and first of all, it should be recalled that, as is apparent from Article 191(1) and (2) TFEU, Union policy on the environment is to contribute to the pursuit of the objective of protecting human health and is to be based, in particular, on the precautionary principle. This principle applies when the EU institutions take measures to protect the environment. In addition, the precautionary principle applies where the institutions of the Union take measures to protect human health (see, to that effect, judgment 22 December 2010, *Gowan Comércio Internacional e Serviços*, C-77/09, EU:C:2010:803, paragraph 72).

280 In particular, it follows from Article 1(3) of Regulation No 1907/2006 that the provisions of that regulation are based on that principle.

281 It follows from the precautionary principle that, where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent (see judgment 22 December 2010, *Gowan Comércio Internacional e Serviços*, C-77/09, EU:C:2010:803, paragraph 73 and the case-law cited). A correct application of that principle presupposes, first, identification of the potentially negative consequences for health of the proposed use of the substance at issue, and, secondly, a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research (see judgment 22 December 2010, *Gowan Comércio Internacional e Serviços*, C-77/09, EU:C:2010:803, paragraph 75 and the case-law cited).

282 In that vein, according to the case-law, where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the

risk materialise, the precautionary principle justifies the adoption of restrictive measures (see judgment 22 December 2010, *Gowan Comércio Internacional e Serviços*, C-77/09, EU:C:2010:803, paragraph 76 and the case-law cited). When adopting a restrictive measure aimed at protecting the environment or human health, the competent institution in that regard is required to ensure a correct articulation between the precautionary principle and the principle of proportionality. That is the consequence of a reading of the case-law cited in paragraph 281 above in the light of the principle of proportionality which is enshrined in Article 5(4) TEU and which forms part of the general principles of EU law. That being the case, it must be held that the precautionary principle justifies the adoption of restrictive measures on condition that they are not only non-discriminatory and objective, but also proportionate (Opinion of Advocate General Bobek in *Confédération paysanne and Others*, C-528/16, EU:C:2018:20, point 51).

283 In the present case, the applicant argues, in essence, that, by virtue of the precautionary principle, the existence of uncertainties as to the risks to workers identified by the Committee for Risk Assessment precluded the grant of the authorisation issued by the Commission under Article 60(4) of Regulation No 1907/2006. In other words, in the applicant's view, the Commission should have totally refused to grant the authorisation at issue in the present case.

284 First, however, it must be noted that the precautionary principle, as laid down in Article 191(2) TFEU, is directed at action at EU level and cannot be interpreted as meaning that an EU institution is required, on the basis of that principle, to adopt a specific measure, such as the refusal of an authorisation envisaged by the applicant. That provision does no more than define the general environmental objectives of the European Union, since Article 192 TFEU confers on the European Parliament and the Council of the European Union, acting in accordance with the ordinary legislative procedure, responsibility for deciding what action is to be taken in order to attain those objectives Moreover, while it is true that that principle may warrant the adoption of a restrictive measure by an institution, it does not require it to do so.

285 Furthermore, it must be observed that Article 1(3) of Regulation No 1907/2006 cannot, on its own, support the applicant's argument that the Commission should have refused to grant the authorisation at issue.

286 Second, in the case at hand, contrary to what the applicant suggests (see paragraph 273 above), there were no uncertainties about the risks to human health. On the contrary, it was absolutely certain that DEHP posed risks to human health. As has been noted in paragraph 1 above, that substance has reproductive toxicity properties within the meaning of Article 57(c) of the same regulation. In the present case, the Committee for Risk Assessment drew the Commission's attention to the existence of uncertainties as to the allegations made by the authorisation applicants regarding the control of the risks arising from DEHP when workers are exposed to that substance. According to that committee, the authorisation applicants did not demonstrate that the risks to the health of workers resulting from the two requested 'uses' were adequately controlled within the meaning of Article 60(2) of Regulation No 1907/2006. That is essentially the reason why the Commission opted for the 'socio-economic procedure' provided for in Article 60(4) of Regulation No 1907/2006.

287 However, it cannot be considered that the choice of the Commission to apply the 'socio-economic procedure' of Article 60(4) of Regulation No 1907/2006 constitutes a breach of the precautionary principle. The authorisation procedure under that procedure was precisely conceived to enable undertakings to place on the market substances which pose in particular a risk to human health but whose socio-economic advantages prevail.

288 As follows from recital 69 of Regulation No 1907/2006, on the one hand, and from Article 60(4) of that regulation, on the other, where it has not been established that the risks to human health or the environment arising from the use of a substance are adequately controlled, an authorisation may be

granted if it can be shown that the socio-economic benefits from the use of the substance outweigh the risks connected with its use and there are no suitable alternative substances or technologies that are economically and technically viable.

289 In the present case, it must be recalled that, as follows from paragraphs 211 to 223 above, the applicant's claim that the properties of DEHP as an endocrine disruptor should have been taken into account in the risk assessment referred to in Article 60(4) of Regulation No 1907/2006 has had to be disregarded, in view of the literal interpretation of paragraphs 2 and 4 of that article. The precautionary principle cannot, however, be interpreted in such a way as to call into question the coherence between those two paragraphs of Article 60 of Regulation No 1907/2006.

290 Third, when adopting a restrictive measure aimed at protecting the environment or human health, the competent institution is required to ensure a correct articulation between the precautionary principle and the principle of proportionality (see paragraph 282 above).

291 According to settled case-law, the principle of proportionality, which is one of the general principles of EU law, requires that acts of the EU institutions be appropriate for attaining the legitimate objectives pursued by the legislation at issue and do not exceed the limits of what is necessary in order to achieve those objectives; when there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued (see judgment of 4 May 2016, *Pillbox 38*, C-477/14, EU:C:2016:324, paragraph 48 and the case-law cited).

292 In that regard, it should be pointed out that Article 60(4) of Regulation No 1907/2006 constitutes, in an abstract manner, the articulation between the precautionary principle and the principle of proportionality in the event that one of the conditions set out in Article 60(2) of that regulation is not fulfilled, in the case at hand that relating to evidence of control of the risk to human health or the environment posed by the use of a certain substance due to its intrinsic properties, as referred to in Annex XIV to Regulation No 1907/2006.

293 Indeed, in so far as it has permitted the grant of an authorisation in a situation where all the risks related to the use of a substance of very high concern are not adequately controlled, but the socio-economic benefits of using the substance outweigh the risks associated with its use and there are no suitable alternative substances or technologies that are economically and technically viable, the EU legislature struck a balance between, on the one hand, the protection of human health and the environment and, on the other, the interests of the applicant for authorisation, as well as the socio-economic benefits resulting from the use of the substance concerned.

294 Admittedly, in a case such as the present, the balancing, in a concrete manner, of the interests at issue can justify the imposition by the Commission of specific monitoring and a short review period. It nevertheless follows from Article 60(4) of Regulation No 1907/2006 that, if the conditions of that provision are fulfilled, the Commission cannot refuse an authorisation, if it is not to breach the principle of proportionality.

295 Given those circumstances, contrary to what the applicant claims, the precautionary principle cannot be interpreted as allowing it to refuse an authorisation which could be granted on the basis of Article 60(4) of Regulation No 1907/2006.

296 In the second place, regarding the applicant's complaint based on the proposition according to which, in view of the properties of DEHP as an endocrine disruptor of very high concern, the Commission should have requested the authorisation applicants to update the application for authorisation in accordance with the precautionary principle (see paragraph 275 above), it must be noted that, by that argument, the applicant appears to take the view that the Commission could have asked the authorisation applicants to provide it with additional information before taking its decision. Such an

argument, however, was not raised by the applicant as such in the request for internal review. Indeed, the applicant did not allege in any part of the application for internal review that, by virtue of the precautionary principle, the Commission was obliged to request the authorisation applicants to provide it with additional information and thus to update the application for authorisation. However, in the request for internal review, the applicant claimed breach of that principle on account of the fact that the Commission failed to take into account the properties of DEHP as an endocrine disruptor of very high concern.

297 For the same reasons as those set out in paragraph 55 above, that argument must be rejected as inadmissible.

298 What is more, for the sake of completeness, regarding the substance, the applicant's complaint, relating to the need for the authorisation applicants to update the application for authorisation, in view of the properties of DEHP as an endocrine disruptor of very high concern, is unfounded. Indeed, given that, at the time of the authorisation decision, the properties of DEHP as an endocrine disruptor of very high concern were not included in Annex XIV to Regulation No 1907/2006, the Commission was under no obligation to take them into account. Those properties are not among the totality of the relevant elements that the Commission must imperatively take into account, such as the relevant information mentioned in paragraph 216 above.

299 Given those circumstances, the argument of the applicant set out in paragraph 275 above must be rejected.

300 In the third place, in the light of the foregoing, the applicant's complaint that, in essence, had the Commission taken into account the properties of DEHP as an endocrine disrupter of very high concern before the grant of the authorisation decision, the authorisation applicants would not have been in a position to entertain the legitimate expectation that the Commission would not request them to update the data to take account of those properties is ineffective.

301 The same applies, in the fourth place, to the applicant's argument, set out in paragraph 270 above, aimed at demonstrating that the Commission cannot rely on the principle of legal certainty in order to remedy the fact that, at the time the application for authorisation was made, the authorisation applicants were not aware of the properties of DEHP as an endocrine disruptor of serious concern.

302 Last, in the fifth place, the applicant's argument, set out in paragraph 277 above, that the Commission did not provide any explanation as to how it applied the precautionary principle in the present case must be rejected.

303 In so far as that argument is to be interpreted as a complaint seeking to demonstrate the existence of a failure in the reasoning of the decision on the request for internal review, the following elements should be recalled.

304 According to settled case-law, the statement of reasons required by the second paragraph of Article 296 TFEU must be appropriate to the act at issue and disclose in a clear and unequivocal fashion the reasoning followed by the institution which adopted the measure in question, in such a way as to enable the persons concerned to ascertain the reasons for the measure and to enable the competent court to exercise its power of review. The requirements to be satisfied by the statement of reasons depend on all 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 (see judgment of 1 February 2018, *Schenker* v *Commission*, C-263/16 P, not published, EU:C:2018:58, paragraph 51 and the case-law cited).

305 However, 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 for a measure meets the requirements of the second paragraph 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 1 February 2018, *Schenker* v *Commission*, C-263/16 P, not published, EU:C:2018:58, paragraph 51 and the case-law cited).

306 In the present case, in point 7 of the decision on the request for internal review, the Commission declared that '[i]f, based on the precautionary principle, all uses of a substance listed in Annex XIV [to Regulation No 1907/2006] had to be prohibited because that substance has been identified as an endocrine disruptor, the whole purpose and effectiveness of the authorisation requirement would be nullified'. It follows that, contrary to what the applicant claims, the Commission did explain how it intended to apply the precautionary principle in the present case.

307 Given those circumstances, as all the arguments raised in support of the fourth plea have been rejected, the fourth plea must be rejected in its entirety.

308 In the light of the foregoing, the four pleas in law raised in support of the third head of claim having been rejected, as well as the second head of claim, the action must be dismissed in its entirety, including the fifth head of claim, which moreover has not been supported by any arguments, requesting that any other measure deemed appropriate be ordered.

Costs

309 Under Article 134(1) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. As the applicant has been unsuccessful, it must be ordered to bear its own costs and to pay those incurred by the Commission.

310 In accordance with Article 138(1) of the Rules of Procedure, the institutions which have intervened in the proceedings are to bear their own costs. Under Article 1(2)(f) of the Rules of Procedure, the term 'institutions' means the institutions of the European Union referred to in Article 13(1) TEU and the bodies, offices or agencies established by the Treaties, or by an act adopted in implementation thereof, which may be parties before the General Court. According to Article 100 of Regulation 1907/2006, ECHA is a European Union body. It follows that ECHA must bear its own costs.

On those grounds,

THE GENERAL COURT (Fifth Chamber),

hereby:

1. **Dismisses the action;**

2. **Orders ClientEarth to bear its own costs and to pay the costs incurred by the European Commission;**

3. **Orders the European Chemicals Agency (ECHA) to bear its own costs.**

Gratsias Dittrich Ulloa Rubio

Delivered in open court in Luxembourg on 4 April 2019.

E. Coulon
Registrar

D. Gratsias
President

Table of contents