Reports of Cases

JUDGMENT OF THE GENERAL COURT (Fifth Chamber)

20 September 2019*

(REACH — Substances subject to authorisation — Inclusion of 1-bromoproprane (nPB) in Annex XIV to Regulation No 1907/2006 — Volumes — Registration dossier — Data — Substance grouping — Principle of sound administration — Right to conduct business and pursue a trade freely — Obligation to state reasons — Legitimate expectations — Proportionality — Equal treatment)

In Case T-610/17,

ICL-IP Terneuzen, BV, established in Terneuzen (Netherlands),

ICL Europe Coöperatief UA, established in Amsterdam (Netherlands),

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

applicants,

v

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

defendant,

supported by

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

intervener,

APPLICATION under Article 263 TFEU for annulment in part of Commission Regulation (EU) 2017/999 of 13 June 2017 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ 2017 L 150, p. 7), in so far as it includes 1-bromopropane (nPB) in that annex.

THE GENERAL COURT (Fifth Chamber),

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

Registrar: S. Bukšek Tomac, Administrator,

* Language of the case: English.

having regard to the written part of the procedure and further to the hearing on 14 February 2019,

gives the following

Judgment

I. Background to the dispute and the contested regulation

1 1-bromopropane (n-propylbromide; 'nPB') is a liquid brominated substance. It is used as a solvent in vapour degreasing. It is also used as an intermediate in the manufacture of other substances. It has been classified as a toxic substance for reproduction (category 1B) in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ 2008 L 353, p. 1).

2 One of the applicants, ICL-TP Terneuzen, BV, is the lead registrant of nPB. It manufactures and uses nPB within the meaning of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ 2006 L 396, p. 1).

3 The other applicant, ICL Europe Coöperatief UA, places nPB on the market for use as a solvent in vapour degreasing and surface cleaning applications and uses it within the meaning of Regulation No 1907/2006.

4 On 11 October 2002, ICL-IP Terneuzen submitted a registration dossier for nPB, for a tonnage band of 1 000 to 10 000 tonnes per annum. It subsequently invited all the members of the substance information exchange forum to become members of a joint submission for the substance.

5 On 3 September 2012, the European Chemicals Agency (ECHA) published on its website a dossier proposing the identification of nPB as a substance of very high concern on the basis of Article 57(c) of Regulation No 1907/2006.

6 On 18 October 2012, the applicants submitted comments on the proposed identification of nPB as a substance of very high concern. In their comments, the applicants emphasised in particular that nPB was mainly used as an intermediate, and therefore excluded from authorisation, and that its non-intermediate uses were either strictly controlled or subject to strict occupational exposure levels.

7 By Decision ED/169/2012 of the Executive Director of ECHA of 18 December 2012, nPB was included on the candidate list, in application of Article 59(8) of Regulation No 1907/2006.

8 On 1 September 2014, in the context of the sixth prioritisation exercise, ECHA published on its website a draft recommendation for the inclusion of substances, including nPB, in Annex XIV to Regulation No 1907/2006 ('Annex XIV') and invited interested parties to submit their comments by 1 December 2014. The 22 substances covered by that draft recommendation, including nPB, were selected on the basis of the provisional results of that prioritisation exercise, which were published on ECHA's website on the same date.

9 On 1 December 2014, the applicants submitted comments on that draft recommendation on behalf of the other registrants. In their comments, the applicants emphasised in particular that around 70% of nPB was used for intermediate purposes and was thus exempt from the application of Title VII of Regulation No 1907/2006.

10 On 1 July 2015, ECHA adopted a recommendation for the inclusion of substances in Annex XIV, in which it recommended the inclusion of nPB in Annex XIV without any exempted uses or categories of uses ('the ECHA recommendation'). On the same date, ECHA published its updated, final results and documents in support of its conclusions, including a reference document relating to nPB. It is apparent from that document that nPB received a total prioritisation score of 20/45 for the criteria set out in Article 58(3)(a) to (c) of Regulation No 1907/2006. That score is made up of the score of 1/15, awarded for inherent properties, 12/15 for volumes, and 7/15 for wide dispersive use. In its final conclusion on nPB, ECHA stated that although other substances on the candidate list assessed in that recommendation round were awarded a higher priority score on the basis of the criteria set out in Article 58(3)(a) to (c) of Regulation No 1907/2006, the inclusion of nPB in Annex XIV was recommended because of considerations connected with the grouping of that substance and trichloroethylene, a substance already included in that annex.

11 On 10 August 2015, the applicants sent a first letter to the European Commission. In that letter, they claimed that the ECHA recommendation was procedurally and legally flawed.

12 On 18 September 2015, the Commission replied to the applicants.

13 On 4 February 2016, the applicants sent a second letter to the Commission. In that letter, they put forward additional elements to demonstrate that the inclusion of nPB in Annex XIV on the basis of the ECHA recommendation would be legally flawed and requested a meeting with representatives of the Commission.

14 On 3 October 2016, the applicants sent a third letter to the Commission. In that letter, they informed the Commission that the volumes of nPB used in vapour degreasing and surface cleaning applications had declined further owing to the fact that the only other registrant of that non-intermediate use had suspended its registration, leaving ICL-IP Terneuzen as the only supplier of the non-intermediate use of nPB within the scope of the authorisation and that new data had been gathered on the substance in question and had allowed safe levels for nPB use to be established. The applicants asked the Commission to examine that additional information as a matter of urgency and requested that a meeting be held in any event before the forthcoming meeting of the regulation committee.

15 On 15 November 2016, the Commission informed the applicants by letter that, owing to an oversight, their letter of 4 February 2016 had not been answered. It added that it had asked ECHA to analyse the data sent by the applicants and agreed to their request for a meeting, inviting them to contact its secretariat in order to find a suitable date for a meeting in November.

16 On 7 and 8 December 2016, during the regulation committee meeting, the draft Commission Regulation amending Annex XIV to include the recommended substances, including nPB, was discussed.

17 On 7 December 2016, the applicants contacted the Commission by email to arrange the meeting referred to in paragraph 15. In their communication, they asked whether the regulation committee meeting on 7 and 8 December 2016 concerning the inclusion of nPB in Annex XIV would still take place.

18 On 8 December 2016, the regulation committee gave a favourable opinion on the ECHA recommendation.

19 On 23 December 2016, the Commission replied to the applicants' email of 7 December 2016. In its reply, it stated in particular that that email had arrived too late for a meeting with the applicants to be arranged, as the regulation committee meeting had taken place on the same date.

20 On 13 June 2017, on the basis of the favourable opinion of the regulation committee and the ECHA recommendation, the Commission adopted Regulation (EU) 2017/999 of 13 June 2017 amending Annex XIV (OJ 2017 L 150, p. 7; 'the contested regulation'). The contested regulation included nPB in Annex XIV in entry 32, without providing for any exemption for certain uses or categories of uses, and fixed the expiry date concerning that substance as 4 July 2020. As is apparent from recital 1 of that regulation, the Commission considered that nPB met the criteria for classification as toxic for reproduction (category 1B) in accordance with Regulation No 1272/2008 and therefore met the criteria for inclusion in Annex XIV set out in Article 57(c) of Regulation No 1907/2006. In recital 13 of the contested regulation, it stated that nPB had been identified and included in the list of candidate substances under Article 59 of Regulation No 1907/2006, which had been prioritised for inclusion in Annex XIV by ECHA in its recommendation and that, notwithstanding the information provided by the interested parties, it was appropriate to include nPB in that annex.

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

21 By application lodged at the Court Registry on 6 September 2017, the applicants brought the present action.

22 On 23 November 2017, the Commission lodged its defence.

23 On 15 January 2018, the applicants lodged their reply.

24 On 5 March 2018, the Commission lodged its rejoinder.

25 By document lodged at the Court Registry on 4 December 2017, ECHA sought leave to intervene in these proceedings in support of the form of order sought by the Commission. By order of 1 March 2018, *ICL-IP Terneuzen and ICL Europe Coöperatief* v *Commission* (T-610/17, not published, EU:T:2018:139), ECHA was granted leave to intervene in support of the form of order sought by the Commission. On 17 April 2018, ECHA lodged its statement in intervention. On 15 and 30 May 2018 the Commission and the applicants submitted their observations on that statement in intervention.

26 On a proposal from the Judge-Rapporteur, the General Court (Fifth Chamber) decided to open the oral part of the procedure and, by way of measures of organisation of procedure pursuant to Article 89 of its Rules of Procedure, to put a question in writing to the Commission and ECHA. The parties replied to that question within the prescribed period.

27 The applicants submitted written observations on the report for the hearing which were placed on the file by decision of the President of the Fifth Chamber.

28 At the hearing on 14 February 2019, the Commission and ECHA presented oral argument and answered the questions put by the Court. The Commission made oral submissions on the report for the hearing. In their oral argument, the applicants argued that, in Commission Decision C(2018) 5057 final of 10 August 2018 on the authorisation of trichloroethylene for certain uses, it is explicitly mentioned that, as regards the use of that substance for the industrial cleaning of parts by vapour degreasing, there are no suitable alternative substances or technologies from the point of view of their technical and economic feasibility. For their part, the Commission and ECHA commented on the admissibility and relevance of that argument.

29 The applicants claim that the Court should:

– annul the contested regulation in so far as it includes nPB in Annex XIV;

– order the Commission to pay the costs;

– 'take such other or further measure as justice may require'.

30 The Commission contends that the Court should:

– dismiss the application;

– order the applicants to pay the costs.

31 ECHA contends that the Court should:

– dismiss the application;

– order the applicants to pay the costs.

III. Law

32 In support of the action, the applicants put forward six pleas in law. The first plea alleges inadequate reasoning of the contested regulation, a manifest error of assessment and an infringement of the principle of sound administration. The second plea alleges infringement of Article 55 of Regulation No 1907/2006, infringement of the objective of competitiveness pursued by that regulation and infringement of the applicants' right to conduct business and pursue a trade freely. The third plea alleges, inter alia, infringement of the obligation to state reasons. The fourth plea in law alleges infringement of the principle of protection of legitimate expectations. That plea has three parts. The first part refers to the nPB volume criterion. The second part refers to the grouping of nPB and trichloroethylene. The third part alleges that, in view of the prioritisation score assigned to nPB, the applicants could have expected that that substance would not be included in Annex XIV. The fifth plea alleges breach of the principle of proportionality. Finally, the sixth plea in law alleges infringement of the principle of equal treatment and non-discrimination.

33 As a preliminary remark, it should be recalled that, by its decision of 3 September 2012, ECHA identified nPB as a candidate substance within the meaning of Article 57(c) of Regulation No 1907/2006. As is apparent from Article 58 of that regulation, among the candidate substances, those to be included as a priority in Annex XIV should be identified. To that end, in accordance with Article 58(3) of that Regulation, on 1 July 2015, ECHA recommended the inclusion of the candidate substances it considered to be priorities. As regards nPB, it stated that, in view of the assessment of that substance in the light of the criteria expressly mentioned in Article 58(3)(a) to (c) of Regulation No 1907/2006, namely because of the intrinsic properties of that substance, its dispersive use and its volumes, as well as considerations of grouping that substance and trichloroethylene, it should be considered as a priority substance to be included in Annex XIV (see paragraph 10 above). Subsequently, on the basis of Article 58(1) of Regulation No 1907/2006, in accordance with the procedure referred to in Article 133(4) of that regulation, the Commission adopted the contested regulation, by which nPB was included in Annex XIV.

34 This action does not seek to call into question the identification of nPB as a candidate substance within the meaning of Article 57(c) of Regulation No 1907/2006, which may be included in Annex XIV. In the context of the action, the applicants merely claim that the inclusion of nPB in that annex is premature.

35 Moreover, it should be noted that the purpose of the present action is, clearly, the annulment of the contested regulation and that it is therefore not directly aimed at the ECHA recommendation. However, in that regulation, the Commission decided to follow the ECHA recommendation and to rely on ECHA's assessment of nPB in the light of the criteria provided for in Article 58(3)(a) to (c) of Regulation No 1907/2006, namely the intrinsic properties of that substance, its dispersive use and its volumes, and taking into account the criterion of grouping nPB and trichloroethylene. In those circumstances, it must be noted that the applicants' pleas in law concerning ECHA's assessment seek to call into question the validity of the considerations on which the contested regulation is based.

36 First, it is necessary to examine the applicants' arguments seeking to challenge the Commission's considerations based on the volume of nPB, which are developed in the first plea and the first part of the fourth plea.

37 Secondly, the applicants' arguments that seek to challenge the Commission's considerations based on the grouping of nPB and trichloroethylene, namely the arguments put forward in the third plea in law and the second part of the fourth plea in law, will be analysed.

38 Thirdly, the sixth plea in law, alleging infringement of the principle of equal treatment and non-discrimination, will be examined.

39 Fourthly, the third part of the fourth plea in law, alleging that, in view of the total prioritisation score assigned to nPB, the applicants could not have expected that that substance would be included in Annex XIV by the contested regulation, will be examined.

40 Fifthly, the second plea in law, alleging infringement of Article 55 of Regulation No 1907/2006, infringement of the objective of competitiveness pursued by that regulation and infringement of the applicants' right to conduct business and pursue a trade freely, and the fifth plea in law, alleging infringement of the principle of proportionality, will be analysed .

A. The Commission's considerations based on nPB volume

41 In the first plea and in the first part of the fourth plea, the applicants put forward arguments aimed at challenging the Commission's considerations which were based on the nPB volume.

1. The first plea in law, alleging that the contested regulation is insufficiently reasoned, that the principle of sound administration has been infringed and that there have been manifest errors of assessment

42 The first plea in law is composed of two parts. In the first part, the applicants claim that the statement of reasons for the contested regulation is insufficient. The Commission did not sufficiently explain how the volumes of nPB used to assess that substance were calculated. The second part alleges that the Commission infringed the principle of sound administration and committed manifest errors of assessment, relying exclusively on the data concerning the volumes contained in the registration file and not on the data submitted in the context of the public consultation and, subsequently, during the procedure leading to the adoption of the contested regulation.

(a) The first plea in law, alleging that the contested regulation is insufficiently reasoned

43 The applicants submit that the Commission's considerations based on nPB quantity were not sufficiently developed. More specifically, they argue that the way in which Commission calculated the nPB quantities taken into account was not sufficiently explained. They also claim that they were unable to defend their interests effectively.

44 The Commission, supported by ECHA, disputes the applicants' arguments.

45 First, it should also be noted that, pursuant to Article 296 TFEU, legal acts are to state the reasons on which they are based. The purpose of the obligation to state the reasons on which an act adversely affecting an individual is based, which is a corollary of the principle of respect for the rights of the defence, is (i) to provide the person concerned with sufficient information to make it possible to ascertain whether the act is well founded or whether it is vitiated by a defect which may permit its legality to be contested before the Courts of the European Union and (ii) to enable the latter to review the legality of that act (judgment of 15 April 2011, *Czech Republic* v *Commission*, T-465/08, EU:C:2011:186, paragraph 162).

46 The statement of reasons must, however, be appropriate to the act at issue and the context in which it was adopted. The requirements to be satisfied by the statement of reasons depend on the circumstances of each case, in particular the content of the measure in question, the nature of the reasons given and the interest which the addressees of the measure, or other parties to whom it is of direct and individual concern, may have in obtaining explanations. It is not necessary for the reasoning to go into all the relevant facts and points of law, since the question whether the statement of reasons is sufficient 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. In particular, the reasons given for a measure adversely affecting a person are sufficient if it was adopted in circumstances known to that person which enable him to understand the scope of the measure concerning him (judgment of 18 September 2015, *Petro Suisse Intertrade* v *Council*, T-156/13 and T-373/14, not published, EU:T:2015:646, paragraph 67).

47 It should also be recalled that the obligation to state reasons is an essential procedural requirement which must be distinguished from the question whether the reasons given are correct, the latter being a matter going to the substantive legality of the contested measure (judgment of 22 March 2001, *France* v *Commission*, C-17/99, EU:C:2001:178, paragraph 35).

48 Secondly, as regards the statement of reasons in the contested regulation, in the first place, it should be noted that it is apparent from recitals 1, 13 and 20 of the contested regulation that the Commission found that nPB was a candidate substance, that ECHA had recommended the priority inclusion of that substance in Annex XIV and that, despite the observations of interested parties, the Commission considered that that substance should be included in that annex by the contested regulation.

49 In the second place, in view of the fact that, in the contested regulation, the Commission referred to the ECHA recommendation and decided to follow it, it is necessary to take into account the content of that recommendation as well as the content of the documents to which that recommendation refers.

50 As is apparent from Annex I of the ECHA recommendation and the nPB reference document of 1 July 2015 to which that annex refers, the reasons why ECHA had recommended the priority inclusion of nPB in Annex XIV were the prioritisation score of 20/45 it had assigned to that substance for the criteria expressly set out in Article 58(3)(a) to (c) of Regulation No 1907/2006 (see paragraph 10 above) and considerations relating to the grouping of nPB and trichloroethylene, a substance which was already included in that annex. In that annex, ECHA also referred to other public documents on which it had relied in preparing its recommendation, including:

– the prioritisation guide of 10 February 2014;

– the provisional results of the sixth prioritisation exercise of 1 September 2014;

– the document of 1 July 2015 containing comments from interested parties and references to the responses to the draft sixth recommendation for the inclusion of nPB in Annex XIV;

– the document of 1 July 2015 containing ECHA's responses to those comments.

51 It is apparent from page 2 of the nPB reference document of 1 July 2015 that ECHA took account of the information in the registration dossier for that substance relating to the quantities corresponding to its various uses, namely the quantities indicated in paragraph 3.5 of the registration dossier for that substance. It is also apparent that, according to that data, the quantity of nPB coming within the scope of the authorisation was to be regarded as corresponding to the range from 1 000 to less than 10 000 tonnes provided for in section 5.2 of the prioritisation guide of 10 February 2014 and that, for that range, a score of 12/15 points had to be assigned.

52 In the document of 1 July 2015 containing ECHA's responses to the comments of the interested parties, ECHA set out the approach it had followed. In that context, it stated, inter alia, that the estimate of quantities took into account data from paragraphs 3.2 and 3.5 of the registration dossiers, data in chemical safety reports and information arising from the procedure which led to the identification of nPB as a substance of very high concern, namely the reports drawn up in that context and information submitted during the public consultation. According to the information provided by ECHA, when the information on uses falling within the scope of the derogations from the authorisation and on the corresponding tonnage was available, that was also evaluated in order to estimate the relevant quantity for prioritisation. In that context, ECHA stated that the estimate of quantities falling within the scope of the authorisation was based primarily on data from the registration dossiers and chemical safety reports. Other information, in particular on tonnages by use, based on reports on the identification of substances of very high concern and public consultations, could, according to that agency, be taken into consideration if the representativeness and reliability of the information could be evaluated. ECHA also stated that, in general, in the context of the prioritisation exercise, a prudent approach was followed in cases where it is not possible, on the basis of the available facts, to draw a clear conclusion on the intermediate status of the use of a substance or the application of other exemptions.

53 More specifically, with regard to nPB, ECHA explained that, on the basis of the data in the registration dossiers, it considered that the quantity of that substance falling within the scope of the authorisation was within the range from 1 000 to less than 10 000 tonnes, as provided for in section 5.2 of the prioritisation guide of 10 February 2014, which, according to ECHA, justified the granting of a quantity score of 12/15. This estimate would not be changed, even if the estimate of 30% of the total quantity of the European Union mentioned in the public consultation was taken into account. In that context, ECHA observed that, as regards the quantities of nPB falling within the scope of the authorisation, there were differences between the information in the registration dossiers and the information submitted in that public consultation. ECHA adds that, according to the statements of the industry in the context of public consultation, that quantity was less than 1 000 tonnes. In ECHA's opinion, the information provided in the comments was not sufficient to disregard the registration data and it was for the registrants to ensure that the exact quantities were indicated in the registration dossiers.

54 Account must also be taken of the information contained in the prioritisation guide of 10 February 2014, to which the ECHA recommendation referred. First of all, as is apparent from section 3 of that guide, the information necessary for the prioritisation exercise must in principle be found in the registration dossiers. In footnote 2 in relation to that section, it is recalled that registration of dossiers is a legal obligation, that registrants are required to provide correct information and to update it in good time if necessary and that the registrant is therefore responsible for the accuracy of the recording data. It is also stated that the information supplied following the registration requirement is used for the purposes of other processes under Regulation No 1907/2006. Next, as is apparent from the first paragraph of section 4 of the guide at issue, the data in the registration dossier constitutes the main source of information for the prioritisation exercise and it is recommended for the industry to indicate all the relevant data directly in the registration dossier. Furthermore, the third paragraph of that section states that, where the data required for the prioritisation exercise are available (in sufficient

quality) in the registration dossiers, the assessment of a substance is based on that data. In addition, it is stated in that paragraph that, in the event that such data are lacking, contradictory or of poor quality, the worst case assumptions are used. Finally, the fourth paragraph of that section draws attention to the fact that the quality of the data used will always affect the results of the prioritisation exercise.

55 In the third place, in the light of the case-law referred to in paragraph 46 above, according to which the known context of the person concerned must also be taken into account, it is necessary to take into account the correspondence between the Commission and the applicants during the administrative procedure. In its letter of 18 September 2015, the Commission stated, inter alia, that the data in the registration dossier and that provided in the context of the public consultation were not consistent and that, in the light of the obligation for registrants to update the data in the registration dossier, the information provided in the registration dossier was the main source of information for the prioritisation exercise.

56 Thirdly, in the light of the above considerations, it must be held that the statement of reasons for the contested regulation must be regarded as sufficient. In the first place, it is apparent from the nPB reference document of 1 July 2015 that ECHA took account of the information in the registration dossier for that substance relating to the quantities corresponding to its various uses, namely the quantities indicated in section 3.5 of the registration file for that substance. In the second place, the reasons for which ECHA used those data are also apparent from that information. On the one hand, it is sufficiently clear that, in the event of inconsistency between the data in the registration dossiers and the information submitted in the context of public consultation or subsequently, preference is given, in principle, to the data in the registration dossiers. On the other hand, it is sufficiently clear that, when data are contradictory, the worst case assumption is taken into account. The considerations on which that approach was based are also sufficiently clear from the abovementioned documents.

57 Therefore, the arguments put forward alleging an inadequate statement of reasons in the contested regulation concerning the calculation of the nPB volumes which the Commission took into account must be rejected.

58 Lastly, the applicants submit that they did not have sufficient information to be able to exercise their participation rights under Regulation No 1907/2006 in the course of the procedure leading to the adoption of the contested regulation and to effectively assert their interests. In that regard, it is sufficient to point out that the information in the prioritisation guide of 10 February 2014, in the replies of ECHA and the Commission to the applicants' comments and in the other documents referred to in paragraphs 49 to 55 above, enabled the applicants to exercise their rights effectively during that procedure.

(b) Second part, alleging a breach of the principle of sound administration and the existence of manifest errors of assessment

59 The applicants claim that the Commission infringed the principle of sound administration and committed a manifest error in the exercise of its discretionary power. The Commission did not, it is alleged, carry out its own assessments. Moreover, it used data covering all the uses of nPB, including those as an intermediate product, when those uses did not fall within the scope of the authorisation and should not therefore have been taken into account. In addition, according to the applicants, the Commission should have taken into account the information which they submitted during the public consultation and in the context of their letters of 10 August 2015, 4 February and 3 October 2016. An approach according to which only the information in the registration dossier was taken into account rendered the public consultation provided for in Article 58(4) of Regulation No 1907/2006 devoid of purpose. There is, it is alleged, no obligation for registrants to indicate the volumes or volume ranges

of a substance for the various uses. In any event, an immediate updating of the registration dossiers is not required, but only an update without undue delay. According to the applicants, the approach followed by the Commission could also have the consequence that substances which are not genuinely 'priority' are included in Annex XIV.

60 The Commission, supported by ECHA, disputes the applicants' arguments.

61 At the outset, it should be pointed out that, under Article 41 of the Charter of Fundamental Rights of the European Union, every person has the right to have his or her affairs handled impartially, fairly and within a reasonable time by the institutions and bodies of the Union. The case-law has made clear that, in accordance with that principle, it was for the administration to examine all the relevant elements of a case carefully and impartially and gather all the factual and legal material necessary to exercise its discretion, and to ensure the proper conduct and effectiveness of the procedures that it implements (judgment of 30 January 2018, *Przedsiębiorstwo Energetyki Cieplnej* v *ECHA*, T-625/16, not published, EU:T:2018:44, paragraph 89).

62 First, it is necessary to examine the applicants' argument that the Commission used data concerning the overall quantity of nPB. Secondly, the Court will analyse the arguments that the Commission did not take sufficient account of the information submitted during the public consultation and in the context of their letters of 10 August 2015, 4 February and 3 October 2016.

(1) The argument that the Commission used data concerning the total quantity of nPB

63 The applicants claim that the Commission relied on the data in paragraph 3.2 of the registration dossier, whereas the quantities indicated in that paragraph also concerned intermediate uses of nPB, which, according to the applicants, should not have been taken into account.

64 In that regard, clearly, it must be borne in mind that, under Article 10(a)(iii) of Regulation No 1907/2006, any registrant is required to indicate the information on the manufacture and use(s) of the substance as specified in section 3 of Annex VI to Regulation No 1907/2006. Section 3.1 of that annex provides that the registrant must indicate in particular the overall manufacture, quantities used for production of an article that is subject to registration, and/or total imports in tonnes per registrant per year. That information is relevant for the application of the quantity ranges referred to in Article 7(4)(f) of Regulation No 1907/2006, which determine the information requirements (see Annexes VI to XI to Regulation No 1907/2006). It is this data that is set out in paragraph 3.2 of the registration dossier.

65 By contrast, where, in the context of the adoption of a regulation including a substance in Annex XIV, the quantity of that substance is taken into account, it may be inferred from Article 2(8) of Regulation No 1907/2006 that only the proportion of the quantity falling within the scope of the authorisation must be used. In that context, it is therefore not appropriate to take account of the proportion of the quantity relating to intermediate uses.

66 However, contrary to what the applicants claim, as is apparent from paragraph 51 above, in the present case the Commission did not rely on the overall nPB quantity indicated in paragraph 3.2 of the registration dossier to calculate the proportion of the quantity falling within the scope of the authorisation, but used the data indicated in paragraph 3.5 of the registration dossier concerning the various uses of nPB.

67 The argument that the Commission relied on data concerning the overall quantity of nPB indicated in paragraph 3.2 of the registration dossier must therefore be rejected.

(2) The arguments that the Commission did not take sufficient account of the information submitted during the public consultation and in the context of subsequent bilateral exchanges

68 The applicants also claim that the Commission did not take sufficient account of the information which they had submitted in the context of the public consultation and in their letters of 10 August 2015, 4 February and 3 October 2016.

(i) The data submitted during the public consultation

69 The applicants argue that, during the public consultation, they submitted additional information concerning the nPB quantity covered by the scope of the authorisation. First, they stated that 70% of the nPB quantity was used as an intermediate and therefore did not fall within the scope of the authorisation and that only 30% of that quantity therefore fell within that scope. Secondly, they stated an estimate of the market volume for use of nPB as a solvent.

70 In that regard, it should be noted, in the first place, that it is apparent from the document of 1 July 2015 containing ECHA's responses to the comments of the parties concerned that ECHA took into account the information which the applicants had submitted during the public consultation.

71 In that document, first, ECHA replied to the applicants' observation that, in that consultation, they had stated that 70% of the nPB quantity concerned the uses of that substance as an intermediate and therefore did not fall within the scope of the authorisation and that, consequently, only 30% of the nPB quantity fell within that scope. In that respect, ECHA stated that, as such, that information was not likely to change its assessment. According to the information in that document, even if the information submitted by the applicants was correct and only 30% of the nPB quantity fell within the scope of the authorisation, on the basis of the data in the assessment file, that would not have called into question the score assigned to the nPB quantity falling within the scope of the authorisation.

72 Secondly, in that document of 1 July 2015 containing ECHA's responses to the comments of the interested parties, the estimate of the market volume was also responded to. It is apparent from that document that these data were not taken into account, because they were not likely to call into question the data contained in paragraph 3.5 of the registration dossier.

73 In the second place, contrary to the applicants' submissions, the fact that the Commission decided to follow the ECHA recommendation, which referred, in particular, to the document of 1 July 2015 containing ECHA's replies to the comments of the interested parties (see paragraph 50 above), is not, in itself, capable of proving that the Commission did not make its own assessments. On the contrary, Regulation No 1907/2006 expressly provides that ECHA is to make a recommendation on the substances it considers to be priority for inclusion in Annex XIV and that the Commission is to make its decision taking that recommendation into account. In those circumstances, the mere fact that the Commission decided to follow the ECHA recommendation and that it referred to it in the contested regulation cannot be regarded as sufficient grounds for doubt as to whether the Commission made its own assessments.

74 In the third place, contrary to what the applicants suggest, it cannot be inferred from the fact that the Commission did not share their view and followed the ECHA recommendation that the Commission ignored the information they had submitted during public consultation.

75 In the fourth place, in so far as the applicants submit that the Commission committed errors of assessment by failing to use the information which they had submitted in the context of the public consultation, it must be borne in mind that the choice of candidate substances to be included in Annex XIV involves assessments of highly complex scientific and technical facts in respect of which the Commission has a broad discretion. That broad discretion also extends to the choice of data used.

In that regard, review by the General Court is limited (see, to that effect, order of 27 March 2014, *Polyelectrolyte Producers Group and Others* v *Commission*, C-199/13 P, not published, EU:C:2014:205, paragraph 28). Therefore, it is necessary to examine whether the applicants' arguments are capable of proving that, by not calculating the nPB quantity falling within the scope of the authorisation on the basis of the information which they submitted during the public consultation, the Commission committed a manifest error of assessment.

76 In that respect, in the first place, it should be noted that one of the objectives of the system for the registration, evaluation, authorisation and restriction of chemicals, which was introduced by Regulation No 1907/2006, is that that regulation should produce information on substances and their uses and that that information should be included in the registration dossiers.

77 In that context, first, it should be noted that it is apparent from recital 14 of Regulation No 1907/2006 that that regulation is intended to produce information on the substances and their uses. It is also apparent from that recital that that information should be used by the stakeholders concerned for the application and implementation of relevant legislation. As is apparent from recital 17 of Regulation No 1907/2006, all available and relevant information on the substances should be collected to assist in identifying hazardous properties.

78 Secondly, as is apparent from recital 19 of Regulation No 1907/2006, the objective of the provisions of that regulation, which form part of Title II, entitled 'Registration of substances', is to require manufacturers and importers to produce data on the substances they manufacture or import, to use those data to assess the risks associated with those substances and to develop and recommend appropriate risk management measures. To ensure that they actually meet these obligations, as well as for transparency reasons, operators who are seeking registration are required to submit to ECHA a dossier containing all the abovementioned information.

79 Thirdly, according to recital 21 of Regulation No 1907/2006, the information supplied on substances may be used to initiate authorisation procedures and, therefore, it is appropriate to ensure that that information is available to the competent authorities and that it may be used by those authorities for the purposes of those procedures.

80 Fourthly, it is apparent from recital 27 of Regulation No 1907/2006 that, for the purposes of implementing and evaluating, and for reasons of transparency, the information relating to substances, and related information relating, inter alia, to risk management measures, should normally be submitted to the authorities.

81 Fifthly, as is apparent from recital 46 of Regulation No 1907/2006, in order to ensure that the information collected through registration is kept up to date, it is provided that registrants are obliged to inform ECHA of certain changes to the information given in the dossiers.

82 In the light of those factors, the Commission cannot be criticised for having relied primarily on data from the registration dossiers.

83 In the second place, the Commission cannot be criticised for having relied on the data concerning the quantities for each use of nPB indicated in paragraph 3.5 of the registration dossier, in spite of the fact that there was an inconsistency between that data and the data concerning the total quantity of nPB indicated in paragraph 3.2 of the registration dossier. In the light of the precautionary principle referred to in the second sentence of Article 1(3) of Regulation No 1907/2006, in the case of incoherent data concerning the quantity of the candidate substance in question, the Commission cannot be criticised for using the data in paragraph 3.5 of the registration dossier, which concerned the various uses of nPB and indicated a higher quantity of that substance falling within the scope of the authorisation.

84 In the third place, it is necessary to examine whether, in the presence of the information submitted by the applicants in the context of the public consultation, the Commission made a manifest error of assessment in calculating the nPB quantity falling within the scope of the authorisation on the basis of the data set out in paragraph 3.5 of the registration dossier.

85 First, it must be stated that the arguments put forward by the applicants are not capable of proving the manifestly erroneous nature of the Commission's finding that, even if 70% of the overall nPB quantity indicated in paragraph 3.2 of the registration file did not fall within the scope of the authorisation and, therefore, only 30% of the nPB quantity fell within that scope, on the basis of the data in the assessment file, this was not such as to call in question the score given to the nPB quantity coming within the scope of the authorisation.

86 Secondly, it must be examined whether the Commission committed a manifest error of assessment in taking the view that the applicants' estimate of the market volume for the use of nPB as a solvent was not capable of calling into question the data in paragraph 3.5 of the registration dossier.

87 In that regard, it must be borne in mind that, as stated in paragraphs 76 to 82 above, Regulation No 1907/2006 confers an important role on the data indicated in the registration dossiers of a substance.

88 Moreover, it is clear from the scheme of Regulation No 1907/2006 that the registrants are responsible for the data which they indicate in their registration dossier.

89 It is true that, as regards the information concerning the quantities of a substance, Article 22(1)(c) of Regulation No 1907/2006 does no more than indicate that registrants must update their registration without excessive delay by adding relevant new information and submit it to ECHA where the annual or total quantities manufactured or imported by the registrant or the quantities of substances present in the articles which it imports or produces are modified and that results in a change of the tonnage band. That provision therefore refers to the overall quantity ranges provided for in Regulation No 1907/2006 and which must be indicated when registering a substance (see paragraph 64 above), and not the part of the quantity that falls within the scope of the authorisation (see paragraph 65 above).

90 However, where a registrant indicates in the registration dossier data concerning the quantities of a substance, even if they are not data such as those referred to in Article 22(1)(c) of Regulation No 1907/2006, but are quantities relating to the various uses of a substance, having regard to the importance which Regulation No 1907/2006 gives to the data in that dossier and the liability of the registrant regarding those data, it is incumbent upon that registrant to update the data indicated in due time, at least in the case of data which are relevant for the purposes of the procedures provided for in Regulation No 1907/2006.

91 As regards the data indicating the nPB quantities for the various uses, it should be borne in mind that, as is apparent from the first paragraph of section 4 of the prioritisation guide of 10 February 2014, the data in the registration dossier constitute the main source of information for the prioritisation exercise carried out by ECHA and that that guide advises industry to indicate all relevant data directly in the registration dossier.

92 In the light of the foregoing considerations, it must be concluded that it was for the applicants to update the data in paragraph 3.5 of the registration dossier in good time if, in accordance with the bands provided for in section 5.2 of the prioritisation guide of 10 February 2014, an amendment to the quantity stated was likely to have an impact on the prioritisation score assigned for the volume criterion within the meaning of Article 58(3)(c) of Regulation No 1907/2006.

93 In that context, it should also be noted that the data in paragraph 3.5 of the registration dossier were not amended before the adoption of the contested regulation and that the applicants do not put forward any argument to show that such an amendment would not have been possible.

94 Furthermore, it must be stated that, in the context of the public consultation, the applicants have not put forward any evidence to explain the inconsistency between the data submitted in the course of that consultation and the data set out in paragraph 3.5 of the registration dossier. On the contrary, according to the information provided by ECHA, which have not been called into question in detail by the applicants, the data submitted by the applicants were inconsistent with the data set out in the chemical safety report annexed to the observations submitted by the applicants, which showed much higher quantities.

95 In those circumstances, the Commission cannot be criticised for taking the view that the applicants' estimate of the market volume for the use of nPB as a solvent submitted by the applicants during public consultation was not capable of calling into question the data set out in paragraph 3.5 of the registration dossier.

96 That conclusion is not called into question by the applicants' argument that it is necessary to preserve the practical effect of the public consultation provided for in Article 58(4) of Regulation No 1907/2006.

97 That provision stipulates that ECHA is to invite all interested parties to submit, within 3 months of the date of publication of its recommendation, comments concerning, in particular, the uses which should be exempt from the authorisation requirement.

98 It is true that the public consultation provided for in Article 58(4) of Regulation No 1907/2006 enables all interested parties to provide relevant data. It therefore enables the registrants to produce additional information concerning the uses to be exempted from the authorisation requirement. However, that provision is not intended to enable registrants to revisit the data in their registration dossiers during the public consultation, without explaining why they were unable to update them in due time or why there are differences between those data and the information submitted during the public consultation.

99 In the present case, the applicants failed not only to substantiate the reasons for which they had not been in a position to update the data in the registration dossier in good time, but also to explain the inconsistencies, first, between the data submitted in the context of the public consultation and those set out in paragraph 3.5 of the registration dossier and, secondly, between the estimate in their observations and the data set out in the chemical safety report annexed thereto (see paragraph 94 above).

100 In that context, it is necessary to reject the applicants' argument that, as the data in the registration dossier were inconsistent, the Commission was required to attach more importance to the information they had submitted during the public consultation. Such an approach would have the effect of favouring registrants who do not correct contradictory data in their registration dossiers in due time.

101 In view of the above considerations, the applicants' arguments based on the information they submitted during the public consultation must be rejected.

(ii) The information contained in the letter of 10 August 2015

102 The applicants claim that the Commission did not take sufficient account of the information they submitted in their letter of 10 August 2015. In that letter, it is alleged, they reiterated the arguments they had already put forward during the public consultation. They also claimed that ECHA had used the data set out in paragraph 3.5 of the registration dossier, although it had doubts as to their reliability.

103 In that regard, first, it should be noted that it is apparent from the Commission's letter of 18 September 2015 that it explained why it considered it inappropriate to use the data submitted by the applicants in their letter of 10 August 2015. In that context, the Commission stated, inter alia, that the registration dossier was the main source for the prioritisation exercise, that there were inconsistencies between the data in the registration dossier, on the one hand, and the data submitted in the context of the public consultation, on the other, and that it was for the registrants to update the registration dossier. In those circumstances, it cannot be considered that the Commission did not take into account the information contained in the letter of 10 August 2015.

104 Secondly, contrary to what the applicants suggest, it cannot be inferred from the fact that, after receiving the applicants' letter of 10 August 2015, the Commission consulted ECHA with regard to the information contained in that letter and decided to follow the opinion of that agency that the Commission did not carry out its own assessments. That is all the more true as such an approach is in line with Regulation No 1907/2006, which provides in recital 78 that ECHA is to provide advice on the prioritisation of substances to be made subject to the authorisation procedure, to ensure that decisions reflect the needs of society as well as scientific knowledge and developments. There is nothing to prevent the Commission, where it decides to follow an ECHA opinion, from reiterating its content in its response to interested parties. Consequently, contrary to what the applicants suggest, the fact that there is such reiteration is not in itself such as to raise doubts as to whether the Commission has made its own assessments.

105 Thirdly, it cannot be inferred from the fact that the Commission did not share the applicants' position, and followed ECHA's opinion, that the Commission ignored the information submitted in the letter of 10 August 2015.

106 Fourthly, having regard to the considerations set out in paragraphs 75 to 101 above, it must be held that the Commission did not commit a manifest error of assessment by considering that it was appropriate to use the data in paragraph 3.5 of the registration dossier.

107 Therefore, the arguments based on the letter of 10 August 2015 must be rejected.

(iii) The information contained in the letter of 4 February 2016

108 The applicants claim that the Commission did not take sufficient account of the information they had submitted in their letter of 4 February 2016. In that letter, they stated that they had obtained data on the nPB quantity falling within the scope of the authorisation which established that the quantity was less than 1 000 tonnes and they had proposed to present the results of their survey on a confidential basis.

109 In that regard, first, it should be noted that, although it is regrettable that the Commission failed to reply to the applicants' letter of 4 February 2016, it cannot be inferred from this that it did not take account of the information contained in that letter. As is apparent from the documents produced by the Commission, after receiving that letter, it consulted ECHA concerning the information which it contained.

110 Secondly, for the reasons set out in paragraphs 104 and 105 above, it cannot be inferred from the fact that the Commission consulted ECHA and that it decided to follow the Agency's opinion that it did not undertake its own assessments, nor can it be inferred from the fact that the Commission did not share the applicants' view, but followed the opinion of ECHA, that it ignored the information submitted in the letter of 4 February 2016.

111 Thirdly, it is necessary to examine whether the Commission committed a manifest error of assessment in using the data referred to in paragraph 3.5 of the registration dossier, in spite of the information submitted in the letter of 4 February 2016.

112 In the first place, referring to the considerations set out in paragraphs 75 to 100 above, it must be borne in mind that it is for a registrant to update the data in the registration dossier in good time.

113 In the second place, it should be noted that Regulation No 1907/2006 does not expressly provide for the possibility for a registrant to submit data after the public consultation provided for in Article 58(4) of Regulation No 1907/2006. It is therefore only in exceptional circumstances that it may be envisaged that, following the submission of information subsequent to the public consultation, the Commission is obliged to depart from the data indicated by a registrant in the registration dossier.

114 In the third place, it must be pointed out that the applicants have not put forward any argument to prove that they were not able to update the data set out in the registration dossier in good time.

115 In the fourth place, it must be stated that the information provided by the applicants in their letter of 4 February 2016 was somewhat abstract and did not contain anything to explain the inconsistency between the data set out in paragraph 3.5 of the registration dossier and those given in that letter.

116 In those circumstances, the Commission cannot be criticised for relying on the data set out in paragraph 3.5 of the registration dossier and not on those provided by the applicants in their letter of 4 February 2016.

117 Therefore, the arguments based on the letter of 4 February 2016 must be rejected.

(iv) The information contained in the letter of 3 October 2016

118 The applicants claim that the Commission did not take sufficient account of the information they had submitted in their letter of 3 October 2016. In that letter, they stated that the only other co-registrant for non-intermediate uses had deactivated its registration, that the particulars given by the other co-registrants were solely intended for intermediate uses, that they remained the only registrants to provide information on nPB quantities that were relevant for the assessment of the volume criterion falling within the scope of the authorisation and that they therefore had information enabling it to establish that the quantity of nPB falling within the scope of the authorisation was less than 1 000 tonnes per annum.

119 In that regard, it should be noted that, although it is apparent from the evidence submitted by the Commission that, after receiving the applicants' letter of 3 October 2016, it consulted ECHA in that regard, its statements suggest that, before receiving ECHA's response, it did not undertake a thorough examination of whether the information contained in that letter was capable of calling into question ECHA's assessment of the quantity of nPB falling within the scope of the authorisation. The Commission received that response on 22 December 2016 and therefore after the opinion of the regulation committee (see paragraphs 16, 18 and 19 above).

120 However, in that context, in the first place, it should also be recalled that Regulation No 1907/2006 does not explicitly provide for the possibility, for a registrant, to submit data after the public consultation provided for in Article 58(4) of Regulation No 1907/2006 (see paragraph 113 above), that it is the responsibility of a registrant to update the data in the registration dossier in a timely manner (see paragraphs 75 to 100 above) and that the applicants do not put forward any arguments to prove that they were not able to update the data in the registration dossier in a timely manner.

121 In the second place, it must be noted that the information provided by the applicants in their letter of 4 February 2016 was somewhat abstract and did not contain, in particular, evidence capable of explaining the inconsistency between the data set out in paragraph 3.5 of the registration dossier and those indicated in that letter.

122 In the third place, it should be noted that, by letter of 15 November 2016, the Commission invited the applicants to contact it in order to fix a meeting during November in order to discuss in greater detail the data collected by the applicants. However, it is not apparent from the information in the dossier that the applicants contacted the Commission in order to set a date for a meeting during the month of November. It was only on 7 December 2016, that is to say, on the day on which the regulation committee met, that the applicants contacted the Commission in that regard.

123 In those circumstances, the Commission cannot be criticised for relying on the data indicated in paragraph 3.5 of the registration dossier to assess the amount of nPB falling within the scope of the authorisation.

124 Therefore, even if the facts found in paragraph 119 above were to be classified as a breach by the Commission of the principle of sound administration, such an infringement has no effect on the legality of the contested regulation.

125 It follows that the arguments based on the letter of 3 October 2016 and, therefore, all the applicants' arguments alleging that the Commission did not take sufficient account of the information which they submitted during the public consultation and in the context of their letters of 10 August 2015, 4 February and 3 October 2016, must be rejected.

126 In view of the foregoing considerations, the first plea in law should be rejected.

2. The first part of the fourth plea in law, alleging a breach of the principle of the protection of legitimate expectations

127 In the first part of the fourth plea, the applicants claim, in essence, that the Commission infringed the principle of the protection of legitimate expectations by failing to take into account ECHA's administrative guidance for determining the score for the volume criterion within the meaning of Article 58(3)(c) of Regulation No 1907/2006.

128 The Commission, supported by ECHA, disputes the applicants' arguments.

129 In the first place, the arguments put forward in support of a breach of the principle of the protection of legitimate expectations must be rejected. In that regard, it is sufficient to point out that the Commission is not bound by the guidelines drawn up by ECHA with a view to the recommendation which it is required to make pursuant to Article 58(3) of Regulation No 1907/2006. That recommendation was purely advisory in nature and did not bind the Commission. Therefore, the Commission was entitled to depart from ECHA's administrative guidance with regard to that recommendation without infringing the principle of the protection of legitimate expectations.

130 In the second place, in so far as the applicants claim that the Commission itself referred to ECHA's administrative guidance, it should be noted, first, that when the Commission decides to follow an ECHA recommendation and where, in that recommendation, that agency relied on the methodology which emerges from its administrative guidance, any argument alleging that the Commission's considerations are not in line with ECHA's administrative guidance must be regarded as seeking to demonstrate the existence of an error vitiating the Commission's reasoning.

131 Secondly, it must be noted that it cannot be inferred from the contested regulation that the Commission did not comply with the rule laid down in section 5.2 of the prioritisation guide of 10 February 2014, according to which the quantities concerning intermediate uses of nPB should be taken into account.

132 Thirdly, in so far as the applicants' arguments relate to the Commission's choice as to the data which it has used, it should be noted that it is stated in the first paragraph of section 4 of the prioritisation guide of 10 February 2014 that the data set out in the registration dossier constitute the main source of information for the prioritisation exercise. Moreover, as is apparent from footnote 2 in section 3 of that guide, the registrants are responsible for the accuracy of the registration data.

133 Therefore, even though it is stated in the first paragraph of section 4 of that guide that information other than the data in the registration dossiers may also be used as additional data sources, this did not preclude the Commission from using, in the circumstances described in paragraphs 59 to 125 above, the data concerning the different uses of nPB indicated in paragraph 3.5 of the registration dossier to assess the quantity of that substance coming within the scope of authorisation.

134 In the light of those factors, it cannot be considered that the Commission's approach was contrary to the information in the prioritisation guide of 10 February 2014.

135 In the light of the foregoing, the first part of the fourth plea in law must be rejected.

B. On the Commission's considerations based on the grouping of nPB and trichloroethylene

136 The applicants also submit arguments calling into question the Commission's considerations concerning the grouping of nPB and trichloroethylene, a substance which was already included in Annex XIV. First, in the third plea, they claim in particular that, in that regard, the Commission infringed the obligation to state reasons and their rights of defence. Secondly, in the second part of the fourth plea, they claim, inter alia, that the Commission's considerations relating to the grouping do not comply with the principle of the protection of legitimate expectations, since the Commission did not follow the indications contained in ECHA's administrative guidelines.

1. The third plea in law, alleging, inter alia, infringement of the obligation to state reasons

137 In the first place, the applicants claim that the Commission failed to fulfil its obligation to state reasons. In its prioritisation guide of 10 February 2014, it is claimed, ECHA stated that when factors such as substance grouping, which is not among the criteria expressly mentioned in Article 58(3)(a) to (c) of Regulation No 1907/2006, are taken into account, the reasons why the candidate substance in question should be considered as a priority should be clearly set out. The Commission's finding concerning the grouping of nPB and trichloroethylene was not, it is claimed, sufficiently reasoned. It does not enable them to understand the reasons why nPB could be used to replace trichloroethylene. The Commission has not provided any assessment of the actual interchangeability potential of nPB and trichloroethylene.

138 The Commission, supported by ECHA, disputes the applicants' arguments.

139 As regards the statement of reasons for the contested regulation, as set out in paragraphs 45 to 55 above, it is necessary not only to take account of the reasons set out in the contested regulation, but also those in the ECHA recommendation, on which the Commission relied, and in the documents to which that recommendation refers, and also the reasons developed in connection with the correspondence between the Commission and the applicants.

140 In that context, first, recitals 1, 13 and 20 of the contested regulation (see paragraph 48 above) and the ECHA recommendation, its annex and the ECHA public documents to which that annex refers (see paragraphs 49 to 51 above) should therefore be taken into account.

141 Secondly, with regard more specifically to the nPB reference document of 1 July 2015, it should be borne in mind that it is apparent from that document that ECHA had taken the view that, even if other substances on the candidate list had obtained higher priority scores than nPB with regard to the criteria mentioned in Article 58(3)(a) to (c) of Regulation No 1907/2006, that candidate substance was a priority because of the overall score of 20/45 and due to grouping considerations. As regards the grouping criterion, ECHA stated that, in view of the information provided by the industry during, on the one hand, the public consultation in the procedure which led to the inclusion of nPB on the list of candidate substances and, on the other hand, the public consultation within the meaning of Article 58(4) of Regulation No 1907/2006 carried out in the context of the sixth prioritisation exercise, nPB could be used to replace trichloroethylene.

142 Thirdly, in the document of 1 July 2015 containing comments of the interested parties and references to the responses to the draft sixth recommendation for the inclusion of nPB in Annex XIV, to which Annex I to the ECHA recommendation and the reference document of 1 July 2015 refer, comments from interested parties are mentioned, indicating that producers and distributors had positioned nPB on the market as an alternative to trichloroethylene.

143 Fourthly, in its final results (see paragraph 10 above), which it had updated taking into account the comments received on the draft recommendation, ECHA had explained that, according to information provided by the industry, nPB could be used as an alternative to trichloroethylene for vapour degreasing and surface cleaning and that trichloroethylene was already included in Annex XIV.

144 Fifthly, in its letter to the applicants of 18 September 2015, the Commission not only referred to the fact that nPB could be used to replace trichloroethylene for vapour degreasing and cleaning of surfaces, but also indicated that applications for authorisation of trichloroethylene had already been submitted for uses which were similar to those for which nPB could be used. In that letter, the Commission also stated that grouping considerations could justify considering a substance as a priority, even when the overall score it had achieved with regard to the criteria explicitly mentioned in Article 58(3)(a) to (c) of Regulation No 1907/2006 was very low. In the annex to that letter, the Commission stated in particular that, 'even if the overall priority score for [nPB] would have been considerably lower, ECHA could have recommended the substance based on grouping considerations'.

145 Contrary to the applicants' submission, the elements mentioned in paragraphs 139 to 144 above were sufficient to enable the applicants to challenge the inclusion of nPB in Annex XIV before the Courts of the European Union if they considered that it was vitiated by a defect. In particular, if the applicants considered that nPB could not be regarded as an alternative to trichloroethylene for vapour degreasing and surface cleaning, the reasons set out in those points were sufficient to enable them to call them into question.

146 Accordingly, the arguments alleging an infringement of the obligation to state reasons must be rejected.

147 In the second place, the applicants claim that they were not sufficiently informed to be able to exercise their participation rights under Regulation No 1907/2006 during the procedure leading to the adoption of the contested regulation and to be able to assert their interests effectively.

148 The Commission, supported by ECHA, disputes the applicants' argument.

149 In that regard, it should be noted that it is apparent from the seventh paragraph of section 2, and from section 6 of the prioritisation guide of 10 February 2014 that the potential interchangeability between the substance in question and other substances already included in Annex XIV or already recommended for such inclusion was another aspect to be taken into account. That indication and those contained in the documents referred to in paragraphs 141 to 144 above enabled the applicants to exercise their rights effectively.

150 Consequently, that argument must also be rejected.

151 In the third place, the applicants claim that the Commission was not entitled to rely on considerations relating to the grouping of nPB and trichloroethylene. The Commission's findings as to the alternative nature of those substances are purely speculative and hypothetical. It would not appear that that aspect had been examined or verified by the Commission. Moreover, according to the applicants, if nPB had actually been considered to be a viable alternative for trichloroethylene, sales of that product should have started to increase in 2016, when trichloroethylene was made subject to the authorisation requirement. In fact, demand for nPB fell. Furthermore, in their oral argument, the applicants also argued that, in Commission Decision C(2018) 5057 final of 10 August 2018 on the authorisation of trichloroethylene for certain uses, it is explicitly mentioned that, as regards the use of that substance for the industrial cleaning of parts by vapour degreasing, there are no suitable alternative substances or technologies from the point of view of their technical and economic feasibility.

152 The Commission, supported by ECHA, disputes the applicants' arguments.

153 At the outset, it should be noted that those arguments of the applicants are not put forward in support of a breach of the duty to state reasons, which is an essential procedural requirement (see paragraph 47 above), but concern whether the Commission's considerations are well founded.

154 First, the applicants claim that the Commission's considerations concerning the possibility of substituting nPB for trichloroethylene were speculative and hypothetical.

155 That argument must be rejected.

156 In that context, it should be noted that, as is apparent from recital 77 of the Regulation No 1907/2006, the number of substances that are included at the same time in Annex XIV is limited in view of workability and practicality considerations, both as regards natural and legal persons, who have to prepare application files and take appropriate risk management measures, and as regards the authorities, who have to process authorisation applications.

157 Therefore, at the stage where the Commission decides that a candidate substance must be included in Annex XIV for reasons of grouping with a substance already included in it, it is not required to establish to the requisite legal standard that such substitution has already taken place or will necessarily take place. It is sufficient for it to establish the existence of a potential risk of substitution.

158 Secondly, as regards the question whether the Commission was entitled to consider that such a potential substitution risk existed, it should be noted that that question involves assessments of highly complex scientific and technical facts, in respect of which the Commission has a broad discretion. According to the case-law in that regard, the General Court's review is limited. It must therefore be examined whether the applicants' arguments are capable of demonstrating that the Commission has

committed a manifest error of assessment, a misuse of powers or whether it has manifestly exceeded the limits of its discretion (see, to that effect, judgment of 21 July 2011, *Etimine*, C-15/10, EU:C:2011:504, paragraph 60 and the case-law cited).

159 As is apparent from the nPB reference document of 1 July 2015, the considerations relating to the grouping of that substance and trichloroethylene were based on information provided by the industry, according to which nPB could be used as an alternative to trichloroethylene for vapour degreasing and surface cleaning. In that context, it should be recalled that, on the one hand, it is apparent from the document of 1 July 2015 containing comments from interested parties and references to the responses to the draft sixth recommendation for the inclusion of nPB in Annex XIV that the use of nPB as an alternative to trichloroethylene was envisaged by some market stakeholders. On the other hand, it is apparent from the document of 19 November 2011 containing comments on the proposal to identify nPB as a substance of very high concern and responses to those comments that, according to some market stakeholders, nPB had been used for years as a direct replacement for trichloroethylene for vapour degreasing and surface cleaning.

160 In the light of those elements, it cannot be held that the Commission's conclusion that there was a risk of substitution of trichlorethylene by nPB for vapour degreasing and surface cleaning was devoid of plausibility.

161 That conclusion is not affected by the applicants' other arguments.

162 First, the mere fact that nPB sales did not increase as from the time trichloroethylene was subject to the authorisation scheme, namely from 21 April 2016, is not capable of demonstrating a manifest error of assessment by Commission with regard to the grouping criterion. In particular, it cannot be ruled out that that lack of increase is the consequence of the fact that, by ECHA's decision of 19 December 2012, nPB was identified as a candidate substance, which was liable to be included in Annex XIV.

163 On the other hand, contrary to what the applicants claim, the fact that, in the Commission Decision of 10 August 2018 on the authorisation of trichloroethylene for certain uses, it is mentioned that, as regards the use of that substance for the industrial cleaning of parts by vapour degreasing, there are no suitable alternative substances or technologies from the point of view of their technical and economic feasibility (see paragraph 28 above), is not capable of demonstrating the existence of a manifest error of assessment affecting the Commission's considerations on which the contested regulation is based.

164 In so far as the applicants merely assert the existence of the Commission Decision of 10 August 2018 on the authorisation of trichloroethylene for certain uses, it suffices to recall that the contested regulation was adopted before that decision and that the legality of a Commission act must be assessed on the basis of the information available to it at the time it adopted it (see, to that effect, judgment of 10 July 1986, *Belgium* v *Commission*, 234/84, EU:C:1986:302, paragraph 16).

165 In any event, in so far as the applicants' arguments are based on the existence of an inconsistency between the considerations on which the contested regulation is based, on the one hand, and the considerations on which the Commission Decision of 10 August 2018 on the authorisation of trichloroethylene for certain uses is based, on the other hand, it must be noted that that decision was adopted on the basis of Article 60(4) of Regulation No 1907/2006. One of the requirements laid down in that provision is that there are no 'appropriate' alternative substances or technologies. Therefore, it cannot be inferred from that decision that, if nPB had not been included in Annex XIV, technically or economically, there would not have been a potential risk of replacing trichloroethylene with nPB. The reason why the Commission did not identify nPB as a suitable alternative substance for

trichloroethylene may also reside in the fact that it considered that it was not an appropriate alternative, since it was a substance which, at the time of the adoption of the decision in question, was included in Annex XIV.

166 In addition, it should be noted that the Commission Decision on the authorisation of trichloroethylene for certain uses was adopted more than 1 year after the adoption of the contested regulation, following an authorisation procedure such as that provided for in Title VII, Chapter 2, of Regulation No 1907/2006. As stated in Article 62(4)(e) of that regulation, an application for authorisation must contain in particular an analysis of the alternatives considering their risks and the technical and economic feasibility of substitution and including, if appropriate, information about any relevant research and development activities of the applicant. Moreover, where an authorisation is granted under Article 60(4) of Regulation No 1907/2006, the Commission must examine in particular whether there are no suitable alternative substances or technologies. As is apparent from Article 60(5) of that regulation, when examining that question, all relevant aspects are to be taken into account by the Commission.

167 However, while, in a procedure leading to the adoption of an authorisation decision based on Article 60(4) of Regulation No 1907/2006, it is required that the Commission carry out an assessment of the availability of appropriate alternative substances or technologies, taking into account all relevant aspects, this is not required in the context of a procedure leading to the inclusion of a substance in Annex XIV (see paragraphs 156 and 157 above). Moreover, in the context of an authorisation procedure, the Commission has specific information in that regard, in particular information submitted by the applicant for authorisation, which is not necessarily the case in a procedure leading to the inclusion of a substance in that annex.

168 In the light of those considerations, the mere fact that, in the Commission Decision of 10 August 2018, it is mentioned that, as regards the use of that substance for the purposes of industrial cleaning of spare parts by vapour degreasing, there are no suitable alternative substances or technologies from the point of view of their technical and economic feasibility, is not capable of demonstrating the existence of a manifest error of assessment affecting the Commission's considerations on which the contested regulation is based.

169 In the light of those considerations, it is also necessary to reject the arguments seeking to call into question the merits of the Commission's considerations relating to the grouping of nPB and trichloroethylene and, therefore, all the arguments put forward in the context of the third plea must also be rejected.

170 In the light of those considerations the third plea in law must be rejected.

2. The second part of the fourth plea in law, alleging that the Commission's considerations relating to the grouping do not comply with the principle of the protection of legitimate expectations

171 In the context of the second part of the fourth plea, the applicants claim that the Commission infringed the principle of the protection of legitimate expectations by departing from ECHA's administrative guidance concerning the prioritisation of the candidate substances. The Commission is obliged to take these guidelines into account when analysing ECHA's recommendations. They were, it is alleged, given precise assurances that, as part of its recommendation, ECHA would apply the substance grouping considerations described in the General Approach Guidance of 28 May 2010. According to that guide, the considerations linked with the grouping of substances that would be taken into account in order to define the overall priority of a substance referred to a different form of the substance at issue. First of all, it was not possible to identify nPB as a different form of trichloroethylene. These, it is claimed, are very different substances which are not chemically similar.

Secondly, neither ECHA nor the Commission carried out a general analysis of interchangeability. Lastly, the volumes of nPB did not significantly increase after the inclusion of trichloroethylene in Annex XIV.

172 The Commission, supported by ECHA, disputes the applicants' arguments.

173 In the first place, it should be recalled that the arguments put forward in support of a breach of the principle of the protection of legitimate expectations are unfounded, as the Commission is not bound by guidance drafted by ECHA (see paragraph 129 above).

174 In the second place, in so far as the applicants' arguments relate to the existence of an error in the Commission's reasoning, which decided to follow the ECHA recommendation (see paragraph 130 above), it should be noted that, in this context, the applicants merely argue that the Commission's considerations are not in line with ECHA's guidance resulting from the General Approach Guidance of 28 May 2010, whereas, in its letter of 18 September 2015, the Commission referred to that guidance. It should be noted that, in that letter, the Commission did not refer to the General Approach Guidance of 28 May 2010, but to the prioritisation guide of 10 February 2014. Furthermore, the applicants' argument alleging that, in footnote 3 of the annex to that letter and in the reference document on nPB of 1 July 2015, reference was made to the General Approach Guidance of 28 May 2010, should be rejected. In that regard, it is sufficient to note that the hyperlinks in those documents to which the applicants refer do not refer to the General Approach Guidance of 28 May 2010, but to the prioritisation guide of 10 February 2014, and that the applicants do not put forward any argument to demonstrate that the target of those hyperlinks has been changed. Therefore, the applicants' argument is based on the incorrect premiss that the Commission and ECHA relied on the General Approach Guidance of 28 May 2010. In that context, it should also be noted that, according to the prioritisation guide of 10 February 2014, grouping considerations are not limited to different forms of the same substance, but may also take potential interchangeability into account.

175 In view of those considerations, the arguments that the Commission did not comply with ECHA's administrative guidance should be rejected.

176 In the third place, in so far as the applicants' arguments summarised in paragraph 171 above are intended to demonstrate that the Commission breached its obligation to state reasons or that its considerations concerning the grouping of nPB and trichloroethylene were manifestly incorrect, they must be rejected by referring to the considerations set out in paragraphs 137 to 169 above.

177 In the fourth place, having regard to the information contained in the prioritisation guide of 10 February 2014, contrary to what the applicants claim, it cannot be held that the applicants were not sufficiently informed in order to be able to exercise their participation rights under Regulation No 1907/2006 during the procedure leading to the adoption of the contested regulation and to be able to assert their interests effectively.

178 In the light of those considerations the second part of the fourth plea must be rejected.

C. The sixth plea in law, alleging infringement of the principle of equal treatment and non-discrimination

179 The applicants claim that the Commission has infringed the principle of equal treatment and non-discrimination.

180 As a preliminary point, it should be noted that, according to the principle of equal treatment and non-discrimination, comparable situations must not be treated differently or different situations treated in the same way, unless such difference in treatment is objectively justified (judgment of 28 June 1990, *Hoche*, C-174/89, EU:C:1990:270, paragraph 25).

181 The elements which characterise different situations and their comparability must, in particular, be determined and assessed in the light of the subject matter and purpose of the European Union act which makes the distinction in question. In that context, the principles and objectives of the field to which the act relates must also be taken into account (judgment of 16 December 2008, *Arcelor Atlantique and Lorraine and Others*, C-127/07, EU:C:2008:728, paragraph 26).

182 A difference in treatment is justified if it is based on an objective and reasonable criterion, that is, if the difference relates to a legally permitted aim pursued by the legislation in question, and it is proportionate to the aim pursued by the treatment (judgment of 16 December 2008, *Arcelor Atlantique and Lorraine and Others*, C-127/07, EU:C:2008:728, paragraph 47).

183 In the first place, the applicants claim that, during the sixth prioritisation exercise, orange lead, lead monoxide, pentalead tetraoxide sulphate and tetralead trioxide sulphate received overall priority scores for the criteria set out in Article 58(3)(a) to (c) of Regulation No 1907/2006 that were higher than that received by nPB. However, unlike nPB, those substances have not been included in Annex XIV, which constitutes an infringement of the principle of equal treatment and non-discrimination.

184 The Commission, supported by ECHA, disputes the applicants' arguments.

185 In that regard, first, it must be recalled that, in the contested regulation, the Commission relied on the ECHA recommendation and therefore on ECHA's conclusions resulting from the sixth prioritisation exercise.

186 Secondly, it must be noted that, admittedly, it is apparent from the first subparagraph of Article 58(3) of Regulation No 1907/2006 that three criteria must be taken into account when ECHA determines the order of priority of candidate substances, namely (i) the persistent, bioaccumulative and toxic properties of the substances in question or their very persistent and very bioaccumulative properties (subparagraph (a)), (ii) wide dispersive use (subparagraph (b)), and (iii) high volumes (subparagraph (c)).

187 However, it is also apparent from Article 58(3) of Regulation No 1907/2006 that the criteria referred to in paragraph 186 above are not the only criteria that may be taken into account in that context. On the one hand, as is apparent from the use of the word 'normally' in the first subparagraph of that paragraph, the three expressly mentioned criteria do not constitute an exhaustive list of all the criteria which may be taken into account. On the other hand, as is apparent from the first sentence of the second subparagraph of that paragraph, in this context it is also appropriate to take account of ECHA's ability to process requests within the time limits laid down.

188 Thirdly, it should be recalled that the Commission has a wide margin of discretion as regards the criteria it takes into account when prioritising the various candidate substances (see paragraph 158 above). It cannot be held that the Commission committed a manifest error of assessment in taking into account the criterion of grouping nPB and trichloroethylene. On the contrary, it must be noted that that criterion, which takes account of the potential interchangeability of a candidate substance with other candidate substances or substances already included in Annex XIV, is intended to follow the principles and achieve the objectives pursued by Regulation No 1907/2006. It aims to prevent substances that are candidates for inclusion or already included in that annex from being replaced, at least temporarily, by other substances that are themselves identified as being of very high concern. It

therefore has one of the objectives pursued by the authorisation requirement, namely the objective of progressively replacing substances of very high concern by other suitable substances or technologies (Article 55 of Regulation No 1907/2006).

189 Therefore, as such, the applicants' argument that orange lead, lead monoxide, pentalead tetraoxide sulphate and tetralead trioxide sulphate received overall priority scores for the criteria set out in Article 58(3)(a) to (c) of Regulation No 1907/2006 that were higher than that received by nPB is not capable of proving that the Commission infringed the principle of equal treatment and non-discrimination.

190 Fourthly, since, in the sixth plea, the applicants put forward arguments calling into question the considerations on which the Commission based its conclusion that there was a potential risk that trichloroethylene might be replaced by nPB, these must be rejected by referring to the considerations set out in paragraphs 136 to 169 above.

191 Fifthly, it is necessary to examine the applicants' argument that the Commission gave disproportionate weight to the grouping criterion in relation to the criteria expressly mentioned in the Article 58(3)(a) to (c) of Regulation No 1907/2006.

192 As a preliminary point, it must be noted that, in its letter of 18 September 2015, the Commission indicated that the grouping criterion justified treating nPB as a priority candidate for inclusion in Annex XIV, even if the overall priority score for the criteria referred to in Article 58(3)(a) to (c) of that regulation was very low. That Commission consideration was not limited to the assumption of an overall score of 20/45, but also the case where the nPB achieved a priority score of only 17/45. On the one hand, it should be noted that, in that letter, the Commission first came to a decision on the applicants' arguments seeking to demonstrate that nPB should have obtained a score of 17/45 and not 20/45 and that it introduced its considerations concerning grouping with the adverbial expression 'furthermore', from which it can be inferred that this was a consideration that was valid regardless of whether nPB should have obtained a score of 17/45 or 20/45. On the other hand, it must be noted that the Commission's reference to a 'very low [score]' includes the score of 17/45 and even some scores below that. In that context, it should be noted that, in the sixth prioritisation exercise, candidate substances that achieved a score of only 1/45 were included in Annex XIV, due to grouping considerations, such as the phthalates mentioned in ECHA's final results (see paragraph 10 above).

193 As regards the applicants' arguments, it should be noted that the applicants merely argue that, for other substances such as orange lead, lead monoxide, pentalead tetraoxide sulphate and tetralead trioxide sulphate, there were also considerations of grouping.

194 On the one hand, it appears from ECHA's final results (see paragraph 10 above), which had been updated taking into account the observations received on the draft recommendation, that, as regards orange lead, lead monoxide, pentalead tetraoxide sulphate and tetralead trioxide sulphate, the existence of a potential risk that those substances may be used to replace other candidate substances or other substances already included in Annex XIV seemed less obvious.

195 On the other hand, as the Commission stated, without being challenged on this point by the applicants, the uses of nPB were limited and the foreseeable workload resulting from the estimated volume of applications for authorisation was therefore lower for nPB than for comparable substances not included in Annex XIV and which had more diverse uses.

196 Moreover, the Commission's approach cannot be considered to be inconsistent, since it included in Annex XIV candidate substances which had received overall priority scores for the criteria referred to in the first subparagraph of Article 58(3) of Regulation No 1907/2006 significantly lower than the score of 17/45.

197 In those circumstances, the Commission cannot be considered to have infringed the principle of equal treatment and non-discrimination by deciding to include nPB in Annex XIV and not orange lead, lead monoxide, pentalead tetraoxide sulphate and tetralead trioxide sulphate, which had received higher priority scores than nPB. This is the case regardless of whether nPB should have received the prioritisation score of 20/45 or 17/45 for the criteria set out in Article 58(3)(a) to (c) of Regulation No 1907/2006.

198 In the second place, the applicants claim that, if nPB had obtained the overall priority score of 17/45 for the criteria referred to in Article 58(3)(a) to (c) of Regulation No 1907/2006, it would have received the same overall score as antimony lead yellow. Accordingly, nPB, which was included in Annex XIV, and antimony lead yellow, which was not included in that annex, were treated differently, even though they were in a comparable situation.

199 The Commission, supported by ECHA, disputes the applicants' arguments.

200 In this respect, first, it should be noted that considerations concerning the grouping criterion are certainly included both in the reference document on nPB of 1 July 2015 and in the reference document on antimony lead yellow of 1 July 2015.

201 However, it must be noted that, as stated in paragraphs 153 to 160 above, as regards nPB, the Commission had information that that substance could be used to replace trichloroethylene for vapour degreasing and surface cleaning. Thus, in the nPB reference document of 1 July 2015, it is stated that, according to the observations submitted during the public consultation, that substance could be used to substitute trichloroethylene for some of its uses. On the other hand, in the reference document on antimony lead yellow of 1 July 2015, it was indicated that, on the basis of the available information, the interchangeability of antimony lead yellow and another candidate substance seemed unlikely due to differences in their physicochemical properties.

202 Moreover, in so far as, in the sixth plea, the applicants put forward arguments calling into question the considerations on which the Commission based its conclusion that there was a potential risk that trichloroethylene would be replaced by nPB, they should be rejected by referring to the considerations set out in paragraphs 136 to 178 above.

203 Therefore, even if nPB and antimony lead yellow ought to have obtained the same overall priority score for the criteria referred to in the first subparagraph of Article 58(3) of Regulation No 1907/2006, namely 17/45, the arguments put forward by the applicants are not capable of demonstrating that the Commission infringed the principle of equal treatment and non-discrimination by including nPB in Annex XIV, and not antimony lead yellow.

204 Secondly, and in any event, it must be recalled that, according to the ECHA recommendation, on which the Commission relied, an overall priority score of 20/45 for the criteria referred to in Article 58(3)(a) to (c) of Regulation No 1907/2006 must be assigned to nPB. As set out in paragraphs 41 to 135 above, the arguments put forward by the applicants are not capable of calling into question that conclusion. Accordingly, the difference in treatment of nPB and antimony lead yellow was also justified by their overall priority scores.

205 In view of the foregoing considerations, the sixth plea in law must be rejected.

D. The third part of the fourth plea in law, based on the fact that, in view of the priority score assigned to nPB, the applicants could not have expected that that substance would be considered a priority

206 In the third part of the fourth plea in law, the applicants claim that, in view of the overall priority score of 20/45 that nPB had obtained for the criteria referred to in Article 58(3)(a) to (c) of Regulation No 1907/2006, or the overall score of 17/45 that it ought to have obtained, in the light of ECHA's administrative guidelines, they could not have expected that nPB would be included in Annex XIV. Even the score of 20/45 is lower than those attributed to most of the substances examined in the course of the sixth prioritisation exercise. Substances that received scores of 23/45 or 28/45 were not recommended for inclusion on the ground that other substances had a higher priority. Furthermore, a substance which had received the score of 17/45, a score that, in the applicants' view, nPB should have received if the Commission had not erred in its assessment of the volume criterion, should not have been recommended by ECHA or included in that annex by the Commission.

207 The Commission, supported by ECHA, disputes the applicants' arguments.

208 In the first place, in so far as the applicants' arguments are put forward in support of a breach of the principle of the protection of legitimate expectations, it must be recalled that, referring to the considerations set out in paragraph 129 above, the Commission is not bound either by ECHA's administrative guidance or by its recommendations and that, for those reasons, any infringement of the principle of the protection of legitimate expectations must therefore be excluded in the present case.

209 In the second place, in so far as the applicants claim that the Commission itself referred to ECHA's administrative guidance, it should be recalled, first, that when the Commission decides to follow an ECHA recommendation and, in that recommendation, that agency relied on the methodology set out in its administrative guidance, arguments that the Commission's considerations do not comply with ECHA's administrative guidance must be regarded as seeking to demonstrate the existence of an error vitiating the Commission's reasoning (see paragraph 130 above).

210 Secondly, contrary to what the applicants suggest, it cannot be deduced from the prioritisation guide of 10 February 2014 that only the priority score for the criteria mentioned in Article 58(3)(a) to (c) of Regulation No 1907/2006 is decisive for the decision to include a candidate substance in Annex XIV or that other criteria such as the grouping criterion cannot be taken into account in that context. On the contrary, section 6 of that guidance clearly states that, in determining the order of priority of candidate substances, the criterion of grouping with other candidate substances or substances already included in Annex XIV may also be taken into account.

211 In view of the above considerations, the third part of the fourth plea in law and, therefore, the fourth plea in law in its entirety must also be rejected, regardless of whether nPB should have obtained the overall priority score of 20/45 in respect of the criteria referred to in Article 58(3)(a) to (c) of Regulation No 1907/2006, as found by the Commission, or 17/45, as alleged by the applicants.

E. The second plea, alleging infringement of Article 55 of Regulation No 1907/2006, infringement of the objective of competitiveness and infringement of the applicants' freedom to conduct business and their right to pursue a trade freely, and the fifth plea, alleging infringement of the principle of proportionality

212 In the second plea, the applicants claim that the contested regulation does not comply with Article 55 of Regulation No 1907/2006, that it runs counter to the objective of competitiveness pursued by that regulation and that it interferes with their right to trade freely. In their fifth plea, they claim that the contested regulation does not comply with the principle of proportionality.

213 First of all, the Court will examine the applicants' arguments alleging that the contested regulation complies neither with Article 55 of Regulation No 1907/2006 nor with that regulation's objective of competitiveness. Secondly, it will examine the applicants' arguments in support of their claim that there has been a breach of the applicants' right to trade freely and of the principle of proportionality.

1. Infringement of Article 55 of Regulation No 1907/2006 and failure to observe the objective of competitiveness pursued by that regulation

214 By the second plea, the applicants claim that the contested regulation is not consistent with Article 55 of Regulation No 1907/2006, because it does not ensure the good functioning of the internal market.

215 The Commission, supported by ECHA, disputes the applicants' arguments.

216 In that regard, in the first place, it should be recalled that, pursuant to Article 1(1) of Regulation No 1907/2006, the objective of that regulation is to ensure a high level of protection of human health and of the environment, including the promotion of alternatives for the assessment of hazards related to substances, as well as the free circulation of substances in the internal market while enhancing competitiveness and innovation.

217 Article 55 of Regulation No 1907/2006, entitled 'Aim of authorisation and considerations for substitution', provides:

'The aim of this Title is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.'

218 It cannot be inferred from those provisions that it would be contrary to the provisions of Regulation No 1907/2006 or the objectives pursued by it to include the candidate substances which must be considered as priorities in Annex XIV.

219 In the second place, it must be noted that, as the applicants expressly state in their written pleadings, the reason why they consider that the inclusion of nPB in Annex XIV was neither consistent with Article 55 of Regulation No 1907/2006 nor the objective of competitiveness pursued by that regulation is that, in their view, nPB should not have been considered as a priority candidate substance.

220 In that context, first, the applicants refer to their arguments concerning the Commission's findings concerning the grouping of nPB and trichloroethylene. Those arguments have already been examined and rejected in paragraphs 136 to 178 above.

221 Secondly, the applicants submit that nPB should not have obtained the overall priority score of 20/45 for the criteria set out in Article 58(3)(a) to (c) of Regulation No 1907/2006, but only that of 17/45. In that regard, on the one hand, it should be recalled that, as already explained in paragraphs 41 to 135 above, the arguments put forward by the applicants are not capable of calling into question the Commission's conclusion that, according to the methodology used by ECHA, the overall score for nPB should have been 20/45. On the other hand, and in any event, as set out in paragraphs 179 to 211 above, even if nPB should have obtained a score of only 17/45, the arguments put forward by the applicants are not capable of demonstrating that the considerations on which the Commission based its decision to include nPB in Annex XIV were manifestly incorrect.

222 In the light of those considerations, the Court must reject the arguments which the applicants put forward alleging an infringement of Article 55 of Regulation No 1907/2006 and of that regulation's objective of competitiveness.

2. Infringement of the applicants' right to trade freely and of the principle of proportionality

223 By the second plea, the applicants claim that, by including nPB in Annex XIV, even though it did not meet the criteria for prioritisation, the Commission encroached on their freedom to conduct business and their right to pursue a trade freely, enshrined in Article 16 of the Charter of Fundamental Rights of the European Union and recognised as a general principle of EU law. By the fifth plea in law, they claim that the Commission infringed the principle of proportionality. In the first place, the contested regulation exceeded the limits of what is appropriate and necessary in order to attain the objectives pursued by the determination of priority substances for inclusion in Annex XIV. The objective of prioritising candidate substances is to select the substances of very high concern which should be included on Annex XIV as priority substances. In the sixth prioritisation exercise, nPB had not presented a high priority. In the second place, the contested regulation is not the least onerous measure to which the Commission could have had recourse. According to the applicants, the Commission could, first, have requested ECHA to reconsider its recommendation in the light of the information provided by the applicants and, secondly, decided not to include nPB in Annex XIV, in spite of the ECHA recommendation and to postpone the inclusion of that substance in that annex.

224 The Commission, supported by ECHA, disputes the applicants' arguments.

225 In that regard, in the first place, it must be borne in mind that, under Article 16 of the Charter of Fundamental Rights, the freedom to conduct a business freely and to pursue a trade freely is recognised in accordance with European Union law and national laws and practices. That right, however, does not appear to be an absolute prerogative, but must be taken into consideration with regard to its function in society. As stated in Article 52(1) of the Charter of Fundamental Rights, limitations may be made to the exercise of that freedom, provided that they in fact meet the objectives of general interest recognised by the European Union or the need to protect the rights and freedoms of others and comply with the principle of proportionality (see, to that effect, judgment of 17 March 2016, *Zoofachhandel Züpke and Others* v *Commission*, T-817/14, EU:T:2016:157, paragraph 126).

226 In the second place, it must be noted that, by their arguments, the applicants do not call into question the possibility of including priority substances in Annex XIV, pursuant to Article 58 of Regulation No 1907/2006. They merely argue that, first, the inclusion of nPB in Annex XIV was premature on the ground that that substance was not a priority and, secondly, that its premature inclusion in the annex in question restricted their freedom to conduct business and their right to pursue a trade freely.

227 In the third place, as regards the applicants' arguments seeking to demonstrate that the inclusion of nPB in Annex XIV was premature, it is sufficient to note that those are arguments which have already examined and rejected in paragraphs 219 to 221 above.

228 In the light of the foregoing considerations, the Court must also reject the arguments which the applicants put forward alleging a breach of their freedom to conduct a business and to trade freely and infringement of the principle of proportionality and, consequently, the second and fifth pleas in their entirety.

229 None of the pleas in law put forward by the applicants is therefore well founded. In that context, it must be pointed out that, even if the overall score for nPB should only have been 17/45, the Commission's considerations based on the grouping of nPB and trichloroethylene were such as to justify the contested regulation.

230 In the light of all the foregoing considerations, the action must be dismissed.

Costs

231 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. Under Article 138(3) of the Rules of Procedure, the General Court may decide that an intervener other than those referred to in paragraphs 1 and 2 of that provision is to bear its own costs. Since the applicants have been unsuccessful, they must be ordered to pay the Commission's costs in accordance with the form of order sought by the Commission. ECHA must be ordered to bear its own costs.

On those grounds,

THE GENERAL COURT (Fifth Chamber),

hereby:

1. **Dismisses the action;**

2. **Orders ICL-IP Terneuzen, BV and ICL Europe Coöperatief UA to bear their own costs and to pay those incurred by the European Commission;**

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

Gratsias Labucka Dittrich

Delivered in open court in Luxembourg on 20 September 2019.

E. Coulon
Registrar

D. Gratsias
President