Reports of Cases

JUDGMENT OF THE GENERAL COURT (Eighth Chamber, Extended Composition)

16 December 2020 *

(Non-contractual liability – Environment – Classification, labelling and packaging of certain substances and mixtures – Classification of pitch, coal tar, high-temp as an Aquatic Acute 1 (H400) toxic substance and as an Aquatic Chronic 1 (H410) toxic substance – Sufficiently serious breach of a rule of law intended to confer rights on individuals)

In Case T-635/18,

Industrial Química del Nalón, SA, established in Oviedo (Spain), represented by K. Van Maldegem, M. Grunchard, S. Saez Moreno and P. Sellar, lawyers,

applicant,

v

European Commission, represented by M. Wilderspin, R. Lindenthal and K. Talabér-Ritz, acting as Agents,

defendant,

supported by

Kingdom of Spain, represented by L. Aguilera Ruiz, acting as Agent,

and by

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

interveners,

ACTION under Article 268 TFEU seeking compensation for the damage which the applicant claims to have suffered as a result of the adoption of Commission Regulation (EU) No 944/2013 of 2 October 2013 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ 2013 L 261, p. 5), in so far as that regulation classified pitch, coal tar, high-temp ('CTPHT') as an Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) substance,

THE GENERAL COURT (Eighth Chamber, Extended Composition),

composed of J. Svenningsen, President, R. Barents, C. Mac Eochaidh, T. Pynnä and J. Laitenberger (Rapporteur), Judges,

* Language of the case: English.

Registrar: E. Coulon,

gives the following

Judgment

Legal context

1 The purpose of 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), as amended by Commission Regulation (EU) No 286/2011 of 10 March 2011 (OJ 2011 L 83, p. 1), is, according to Article 1 thereof, 'to ensure a high level of protection of human health and the environment as well as the free movement of substances [and] mixtures … by: (a) harmonising the criteria for classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures'.

2 Recitals 5 to 8 of Regulation No 1272/2008 are worded as follows:

'(5) With a view to facilitating worldwide trade while protecting human health and the environment, harmonised criteria for classification and labelling have been carefully developed over a period of 12 years within the United Nations (UN) structure, resulting in the Globally Harmonised System of Classification and Labelling of Chemicals (hereinafter referred to as "the GHS").

(6) This Regulation follows various declarations whereby the Community confirmed its intention to contribute to the global harmonisation of criteria for classification and labelling, not only at UN level, but also through the incorporation of the internationally agreed GHS criteria into Community law.

(7) The benefits for enterprises will increase as more countries in the world adopt the GHS criteria in their legislation. The Community should be at the forefront of this process to encourage other countries to follow and with the aim of providing a competitive advantage to industry in the Community.

(8) Therefore it is essential to harmonise the provisions and criteria for the classification and labelling of substances, mixtures and certain specific articles within the Community, taking into account the classification criteria and labelling rules of the GHS, but also by building on the 40 years of experience obtained through implementation of existing Community chemicals legislation and maintaining the level of protection achieved through the system of harmonisation of classification and labelling, through Community hazard classes not yet part of the GHS as well as through current labelling and packaging rules.'

3 The first paragraph of Article 3 of Regulation No 1272/2008 provides:

'A substance or a mixture fulfilling the criteria relating to physical hazards, health hazards or environmental hazards, laid down in Parts 2 to 5 of Annex I is hazardous and shall be classified in relation to the respective hazard classes provided for in that Annex.'

4 Annex I to Regulation No 1272/2008 sets out the criteria for classification of substances and mixtures in hazard classes.

5 Point 4.1.1.1 defines 'aquatic toxicity':

'"Acute aquatic toxicity" means the intrinsic property of a substance to be injurious to an aquatic organism in a short-term aquatic exposure to that substance.

…

"Chronic aquatic toxicity" means the intrinsic property of a substance to cause adverse effects to aquatic organisms during aquatic exposures which are determined in relation to the life-cycle of the organism.

…'

6 Regarding, more specifically, the classification criteria for mixtures, point 4.1.3 provides:

'4.1.3.1. The classification system for mixtures covers all classification categories which are used for substances, i.e. categories Acute 1 and Chronic 1 to 4. In order to make use of all available data for purposes of classifying the aquatic environmental hazards of the mixture, the following is applied where appropriate:

The "relevant components" of a mixture are those which are classified "Acute 1" or "Chronic 1" and present in a concentration of 0.1% (w/w) or greater, and those which are classified "Chronic 2", "Chronic 3" or "Chronic 4" and present in a concentration of 1 % (w/w) or greater, unless there is a presumption (such as in the case of highly toxic components (see section 4.1.3.5.5.5)) that a component present in a lower concentration can still be relevant for classifying the mixture for aquatic environmental hazards. Generally, for substances classified as "Acute 1" or "Chronic 1" the concentration to be taken into account is (0.1/M)% (for [an] explanation [of the] M-factor see Section 4[.]1.3.5.5.5.).

4.1.3.2. The approach for classification of aquatic environmental hazards is tiered, and is dependent upon the type of information available for the mixture itself and for its components. Figure 4.1.2 outlines the process to be followed.

Elements of the tiered approach include:

– classification based on tested mixtures;

– classification based on bridging principles;

– the use of "summation of classified components" and/or an "additivity formula".'

7 Point 4.1.3.5.5 of Annex I to Regulation No 1272/2008, entitled 'Summation method', provides:

'4.1.3.5.5.1.1. In case of the substance classification categories Chronic 1 to Chronic 3, the underlying toxicity criteria differ by a factor of 10 in moving from one category to another. Substances with a classification in a high toxicity band therefore contribute to the classification of a mixture in a lower band. The calculation of these classification categories therefore needs to consider the contribution of any substance classified as Chronic 1, 2 or 3.

4.1.3.5.5.1.2. When a mixture contains components classified as Acute 1 or Chronic 1, attention must be paid to the fact that such components, when their acute toxicity is below 1 mg/l and/or chronic toxicity is below 0.1 mg/l (if non-rapidly degradable) and 0.01 mg/l (if rapidly degradable) contribute to the toxicity of the mixture even at a low concentration. Active ingredients in pesticides often possess such high aquatic toxicity but also some other substances like organometallic compounds.

Under these circumstances the application of the normal generic concentration limits leads to an "under-classification" of the mixture. Therefore, multiplying factors shall be applied to account for highly toxic components, as described in Section 4.1.3.5.5.5.'

8 As regards the classification as Acute Category 1, point 4.1.3.5.5.3.1 of Annex I to Regulation No 1272/2008 provides:

'First all components classified as Acute 1 are considered. If the sum of the concentrations (in %) of these components multiplied by their corresponding M-factors is greater than 25 % the whole mixture is classified as Acute 1.'

9 As regards the classification as Chronic Categories 1, 2, 3 and 4, point 4.1.3.5.5.4.1 of Annex I to Regulation No 1272/2008 provides:

'First all components classified as Chronic 1 are considered. If the sum of the concentrations (in %) of these components multiplied by their corresponding M-factors is equal to or greater than 25 %, the mixture is classified as Chronic 1. If the result of the calculation is a classification of the mixture as Chronic 1, the classification procedure is completed.'

10 Regarding mixtures with highly toxic components, point 4.1.3.5.5.5 of that annex provides:

'4.1.3.5.5.5.1. Acute 1 and Chronic 1 components with toxicities below 1 mg/l and/or chronic toxicities below 0.1 mg/l (if non-rapidly degradable) and 0.01 mg/l (if rapidly degradable) contribute to the toxicity of the mixture even at a low concentration and shall normally be given increased weight in applying the summation of classification approach. When a mixture contains components classified as Acute or Chronic 1, one of the following shall be applied:

– The tiered approach described in [points] 4.1.3.5.5.3 and 4.1.3.5.5.4 using a weighted sum by multiplying the concentrations of Acute 1 and Chronic 1 components by a factor, instead of merely adding up the percentages. This means that the concentration of "Acute 1" in the left column of Table 4.1.1 and the concentration of "Chronic 1" in the left column of Table 4.1.2 are multiplied by the appropriate multiplying factor. The multiplying factors to be applied to these components are defined using the toxicity value, as summarised in Table 4.1.3. Therefore, in order to classify a mixture containing Acute/Chronic 1 components, the classifier needs to be informed of the value of the M-factor in order to apply the summation method;

…'

11 Table 4.1.3 of the annex defines the multiplying factors for highly toxic components of mixtures.

12 Regarding the administrative procedure, Article 37(1) of Regulation No 1272/2008, which empowers Member States to submit a proposal for the harmonised classification of a substance, provides:

'A competent authority may submit to the Agency a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits or M-factors, or a proposal for a revision thereof.'

13 According to Article 37(4) of that regulation, the Risk Assessment Committee of the European Chemicals Agency (ECHA) ('the RAC') set up pursuant to Article 76(1)(c) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ 2006 L 396, p. 1, and

corrigendum OJ 2007 L 136, p. 3) is to adopt an opinion on any proposal 'submitted pursuant to paragraphs 1 or 2 within 18 months of receipt of the proposal, giving the parties concerned the opportunity to comment' and the ECHA 'shall forward this opinion and any comments to the Commission'.

14 Last, the procedure for the adoption of the proposed classifications is laid down in Article 37(5) of Regulation No 1272/2008 as follows:

'Where the Commission finds that the harmonisation of the classification and labelling of the substance concerned is appropriate, it shall, without undue delay, submit a draft decision concerning the inclusion of that substance together with the relevant classification and labelling elements in Table 3.1 of Part 3 of Annex VI and, where appropriate, the specific concentration limits or M-factors.

…'

Background to the dispute

15 The applicant, Industrial Química del Nalón, SA, manufactures pitch, coal tar, high temp ('CTPHT'). Its activity focuses on the carbochemical sector and is based on the distillation of high-temperature coal tar which is obtained as a by-product in coke manufacture used in blast furnaces to produce pig iron. The applicant carries out its carbochemical activity at its Trubia site (Spain) in a set of autonomous plants which operate as a fully integrated unit.

16 CTPHT is, according to its description in Tables 3.1 and 3.2 of Annex VI to Regulation No 1272/2008, the residue from the distillation of high-temperature coal tar, a black solid with an approximate softening point from 30 °C to 180 °C, composed primarily of a complex mixture of three or more membered condensed ring aromatic hydrocarbons. This substance is among the substances of unknown or variable composition, complex reaction products or biological materials, because it cannot be fully identified by its chemical composition. CTPHT is used mainly to produce electrode binders for the aluminium and steel industry.

17 In September 2010, the Kingdom of the Netherlands submitted a dossier to the ECHA, pursuant to Article 37 of Regulation No 1272/2008, proposing that CTPHT should be classified as Carcinogenic 1A (H350), Mutagenic 1B (H340), Toxic for reproduction 1B (H360FD), Aquatic Acute 1 (H400), and Aquatic Chronic 1 (H410).

18 After having received observations on the dossier in question during a public consultation, the ECHA referred that dossier to the RAC.

19 On 21 November 2011, the RAC adopted its opinion on CTPHT, confirming by consensus the proposal submitted by the Kingdom of the Netherlands. That opinion was accompanied by a background document containing the RAC's detailed analysis ('the background document') and a document containing the answers of the Kingdom of the Netherlands to the observations made on the dossier drawn up by that Member State.

20 With regard to the classification of CTPHT as a substance having aquatic toxicity, the RAC considered in its opinion, as the Kingdom of the Netherlands had proposed in its dossier submitted to the ECHA, that this could not be based on data obtained in studies using the Water-Accommodated Fraction approach. The reasons stated by the RAC for that finding were, first, that those data had been obtained in the absence of ultraviolet (UV) irradiation, even though certain polycyclic aromatic hydrocarbon ('PAH') constituents of CTPHT are phototoxic and, secondly, that the studies concerned had been carried out with only a single loading. The RAC therefore took the view, as the Kingdom of the Netherlands had proposed in its dossier submitted to the ECHA, that the classification of that

substance was to be based on an alternative approach, namely to regard CTPHT as a mixture. According to that approach, the 16 PAH constituents of CTPHT, which have been defined as priority substances by the United States Environmental Protection Agency (EPA), and for which sufficient effect and exposure data were available, were analysed separately in accordance with their aquatic toxicity effects. By applying the method referred to in point 4.1.3.5.5 of Annex I to Regulation No 1272/2008, consisting in finding the sum of the results obtained by the attribution of multiplication factors ('M-factors') to the different PAHs in order to attach more weight to the highly toxic constituents of CTPHT ('the summation method'), that analysis showed, according to the RAC's opinion, that CTPHT had to be classified as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410).

21 On 2 October 2013, on the basis of the RAC's opinion, the European Commission adopted Regulation (EU) No 944/2013 amending, for the purposes of its adaptation to technical and scientific progress, Regulation No 1272/2008 (OJ 2013 L 261, p. 5). In accordance with Article 1(2)(a)(i) and (b)(i) of Regulation No 944/2013, read together with Annexes II and IV thereto, CTPHT was classified as Carcinogenic 1A (H350), Mutagenic 1B (H340), Toxic for reproduction 1B (H360FD), Aquatic Acute 1 (H400), and Aquatic Chronic 1 (H410). Pursuant to Article 3(3) of Regulation No 944/2013, that classification was applicable from 1 April 2016. According to recital 5 of Regulation No 944/2013, a longer transition time before the harmonised classification had to be applied was foreseen as regards CTPHT, in order to allow operators to comply with the obligations resulting from the new harmonised classification for substances classified as very toxic to aquatic organisms which may cause long-term effects in the aquatic environment, in particular with those set out in Article 3 of Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (OJ 2008 L 260, p. 13) and Annex III thereto.

22 By application lodged at the Court Registry on 20 December 2013 and registered as Case T-689/13, the applicant brought an action for the partial annulment of Regulation No 944/2013 in so far as it classified CTPHT as an Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) substance.

23 By judgment of 7 October 2015, *Bilbaína de Alquitranes and Others* v *Commission* (T-689/13, not published, EU:T:2015:767), the Court annulled Regulation No 944/2013 in so far as it classified CTPHT as an Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) substance.

24 More specifically, the Court, in paragraphs 30 to 34 of the judgment of 7 October 2015, *Bilbaína de Alquitranes and Others* v *Commission* (T-689/13, not published, EU:T:2015:767), held, inter alia, as follows:

> '30 In the present case, it must be held that the Commission committed a manifest error of assessment in that, by classifying CTPHT as an Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) substance on the basis of its constituents, it failed to comply with its obligation to take into consideration all the relevant factors and circumstances so as to take due account of the proportion in which the 16 PAH constituents are present in CTPHT and their chemical effects.
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> 31 According to point 7.6 of the background document, for the purpose of the classification of CTPHT on the basis of its constituents, it was assumed that all of the PAHs present in CTPHT dissolved in the water phase and were thus available to aquatic organisms. It is also mentioned that this assumption would likely give an overestimation of the toxicity of CTPHT and that, since the composition of the WAF was uncertain, that toxicity estimate could be regarded as the worst case scenario.
>
> 32 However, neither the Commission nor [the] ECHA was able to establish before the Court that, in basing the classification of CTPHT as an Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) substance on the assumption that all of the PAHs present in that substance dissolved in the water phase and were thus available to aquatic organisms, the Commission took into consideration the

fact that, according to point 1.3 of the background document, entitled "Physiochemical properties", the constituents of CTPHT were released from CTPHT only to a limited extent and that that substance was very stable.

33 First, neither the RAC's opinion on CTPHT nor the background document contains any reasoning which demonstrates that, in assuming that all of the PAHs present in that substance dissolve in the water phase and are available to aquatic organisms, account was taken of the low water solubility of CTPHT …

34 Secondly, it must be noted that, according to point 1.3 of the background document, the highest rate of water solubility of CTPHT in relation to a loading was 0.0014% at maximum. Given the low water solubility of CTPHT, the Commission has in no way demonstrated that it could base the classification in question of that substance on the assumption that all of the PAHs present in CTPHT dissolved in the water phase and were available to aquatic organisms. It is apparent from Table 7.6.2 in the background document that the 16 PAH constituents of CTPHT constitute 9.2% of that substance. By assuming that all of those PAHs dissolve in water, the Commission therefore, in essence, based the classification in question on the assumption that 9.2% of CTPHT could dissolve in water. However, as can be seen from point 1.3 of the background document, such a value is not realistic, given that the maximum rate is 0.0014%.'

25 By document lodged at the Registry of the Court of Justice on 17 December 2015, the Commission appealed against the judgment of 7 October 2015, *Bilbaína de Alquitranes and Others* v *Commission* (T-689/13, not published, EU:T:2015:767). The Kingdom of Denmark, the Federal Republic of Germany and the Kingdom of the Netherlands were granted leave to intervene by the President of the Court of Justice in support of the form of order sought by the Commission.

26 On 24 March 2016, the applicant made an application under Articles 278 and 279 TFEU for an order for the suspension of the operation and the effects of Regulation No 944/2013 pending the outcome of the appeal lodged by the Commission.

27 By order of 7 July 2016, *Commission* v *Bilbaína de Alquitranes and Others* (C-691/15 P-R, not published, EU:C:2016:597), the application for suspension of operation and interim measures was dismissed for lack of sufficient urgency of the requested measures.

28 By judgment of 22 November 2017, *Commission* v *Bilbaína de Alquitranes and Others* (C-691/15 P, EU:C:2017:882), following in that respect the Opinion of Advocate General Bobek in *Commission* v *Bilbaína de Alquitranes and Others* (C-691/15 P, EU:C:2017:646), the Court of Justice dismissed the Commission's appeal.

29 More specifically, the Court of Justice, in paragraphs 39, 41 to 47 and 51 to 55, held, inter alia, as follows:

'39 It is true that point 4.1.3.5.5 of Annex I to Regulation No 1272/2008 does not provide for the use of criteria other than those expressly referred to in that provision. However, it should be noted that no provision expressly prohibits other factors liable to be relevant to the classification of a … substance [which is among the substances of unknown or variable composition, complex reaction products or biological materials] from being taken into consideration.

…

41 … the use of the expressions "where appropriate" and "all available data" tends to undermine the interpretation that taking into account information other than that expressly used in the course of the summation method should, in all circumstances, be excluded.

42 Furthermore, it is apparent from recitals 4 to 8 of Regulation No 1272/2008 that the EU legislature intended "to contribute to the global harmonisation of criteria for classification and labelling, not only at UN level, but also through the incorporation of the internationally agreed [GHS] into Community law". To that effect, Annex I to that regulation reproduces verbatim almost all of the [provisions of the GHS].

43 … it is apparent from the very wording of the [GSH], in particular Annex 9, entitled "Guidance on hazards to the aquatic environment", that the indicated methodological approach for determining the classification of substances' hazards to the aquatic environment is difficult due, inter alia, to the fact that "the term substances covers a wide range of chemicals, many of which pose difficult challenges to a classification system based on rigid criteria". That document therefore highlights "a complex interpretational problem, even for experts" presented by classification, in particular of so-called "complex or multi-component" substances for which "biodegradation, bioaccumulation, partitioning behaviour and water solubility all present problems of interpretation, where each component of the mixture may behave differently".

44 The authors of that document thus sought to draw attention to the limits inherent in the methodological criteria laid down in the [GHS] for classification of hazards to the aquatic environment, in respect of certain substances characterised by, inter alia, their complexity, stability or low water solubility.

45 The EU legislature integrated the provisions of the [GHS] in Annex I to Regulation No 1272/2008, without demonstrating any intention to deviate from that approach. In those circumstances, it cannot be held that, by thus integrating the [GHS] in Regulation No 1272/2008, the EU legislature disregarded its methodological limitations.

46 The strict and automatic application of the summation method in all circumstances is liable to result in an undervaluing of the aquatic toxicity of a … substance [which is among the substances of unknown or variable composition, complex reaction products or biological materials] with few known constituents. Such a result cannot be regarded as consistent with the goal of protection of the environment and human health pursued by Regulation No 1272/2008.

47 … when it applies the summation method in order to determine whether a … substance [which is among the substances of unknown or variable composition, complex reaction products or biological materials] comes within the categories of acute or chronic aquatic toxicity, the Commission is not required to limit its assessment solely to the factors expressly referred to in point 4.1.3.5.5 of Annex I to Regulation No 1272/2008, to the exclusion of any other factor. In accordance with its duty to act diligently, the Commission is required to examine carefully and impartially other factors which, although not expressly referred to by those provisions, are nevertheless relevant.

…

51 The classification method referred to in point 4.1.3.5.5 of Annex I to Regulation No 1272/2008 is based on the assumption that the constituents taken into consideration are 100% soluble. On the basis of that assumption, that summation method implies that there is a concentration level of constituents below which the threshold of 25% cannot be reached and, thus, consists of calculating the sum of the concentrations of the constituents coming within the categories of acute or chronic toxicity, each weighted by factor M corresponding to their toxicity profile.

52 It is, however, inherent in that method that it loses reliability in situations where the weighted sum of the constituents exceeds the level of concentration corresponding to the threshold of 25% in a proportion less than the ratio between the observed solubility rate at the level of the substance in question as a whole and the hypothetical solubility rate of 100%. In such situations, it thus

becomes possible that the summation method may lead, in specific cases, to a result greater than or less than the level corresponding to the regulatory threshold of 25%, according to whether the hypothetical solubility rate of the constituents is taken into consideration or that of the substance as a whole.

53 It is common ground that Table 7.6.2 of Annex I to the report attached to the RAC's opinion shows that, first, the summation method leads to the result of 14 521% and that, secondly, that result is 581 times greater than the minimum level required for the threshold of 25%, after weighting by factor M, to be reached. Nor is it disputed that it is, moreover, apparent from point 1.3 of that document, entitled "Physiochemical properties", that the maximum rate of water solubility of CTPHT was 0.0014%, a rate approximately 71 000 times lower than the hypothetical solubility rate of 100% used for the constituents taken into consideration.

54 The General Court therefore did not distort or err in the legal classification of the facts in holding, in paragraph 34 of the [judgment of 7 October 2015, *Bilbaína de Alquitranes and Others* v *Commission* (T-689/13, not published, EU:T:2015:767)], that, "by assuming that all of those [constituents] dissolve in water, the Commission therefore, in essence, based the classification in question on the assumption that 9.2% of CTPHT could dissolve in water. However, as can be seen from point 1.3 of the background document [annexed to the RAC's opinion], such a value is not realistic, given that the maximum rate is 0.0014%".

55 Since it found, in paragraph 32 of [the judgment of 7 October 2015, *Bilbaína de Alquitranes and Others* v *Commission* (T-689/13, not published, EU:T:2015:767)], that "neither the Commission nor [the] ECHA [had been] able to establish that the Commission [had taken] into consideration the fact that, according to point 1.3 of the background document [annexed to the RAC's opinion], entitled 'Physiochemical properties', the constituents of CTPHT were released from CTPHT only to a limited extent and that that substance was very stable", the General Court held, without erring in law, in paragraph 30 of the judgment that "the Commission [had] committed a manifest error of assessment in that, by classifying CTPHT as an Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) substance on the basis of its constituents, it [had] failed to comply with its obligation to take into consideration all the relevant factors and circumstances so as to take due account of the proportion in which the 16 constituents … are present in CTPHT and their chemical effects".'

30 On 9 July 2018, the Commission published a notice in the *Official Journal of the European Union* (OJ 2018 C 239, p. 3) stating that the partial annulment of Regulation No 944/2013 by the General Court was maintained following the dismissal of the appeal and that CTPHT was '[no longer] classified as Aquatic Acute 1 and Aquatic Chronic 1'.

Procedure and forms of order sought

31 By application lodged at the Registry of the General Court on 23 October 2018, the applicant brought the present action for damages under Article 268 TFEU.

32 By documents lodged at the Court Registry on 11 February and 7 March 2019, respectively, the Kingdom of Spain and the ECHA applied for leave to intervene in support of the form of order sought by the Commission.

33 By separate documents, lodged at the Court Registry on 13 March, 5 April, 29 May, 31 May and 21 August 2019, the applicant requested, under Article 144(2) of the Rules of Procedure of the General Court, confidential treatment with regard to the Kingdom of Spain and the ECHA of certain information contained in the annexes to the application, in the defence, in the reply and the annexes thereto and in the rejoinder.

34 The defence was lodged at the Court Registry on 14 March 2019.

35 The reply was lodged on 17 May 2019.

36 By orders of the President of the Fifth Chamber of the General Court of 20 June 2019, the Kingdom of Spain and the ECHA were granted leave to intervene in support of the form of order sought by the Commission.

37 By documents lodged at the Court Registry on 8 July and 30 August 2019, the Kingdom of Spain objected to the requests for confidential treatment. By documents lodged on 9 July and 5 September 2019, the ECHA confirmed that it had no objections regarding the requests for confidential treatment.

38 The rejoinder was lodged on 24 July 2019.

39 On 6 September 2019, the Kingdom of Spain and the ECHA lodged their respective statements in intervention.

40 Following a change in the composition of the Chambers of the Court, the case was assigned to a new Judge-Rapporteur sitting in the Eighth Chamber.

41 By order of the President of the Eighth Chamber of the General Court of 25 November 2019, the requests for confidential treatment were rejected with regard to the Kingdom of Spain.

42 On 8 January 2020, the applicant requested under Article 69(c) of the Rules of Procedure that the proceedings be stayed until a hearing relating primarily to the issue of liability of the European Union had taken place in Case T-638/18 and a judgment had been delivered by the General Court on that issue. The Commission indicated its agreement to a stay of the present proceedings by letter of 28 January 2020.

43 On 2 April 2020, the Eighth Chamber decided not to stay the proceedings.

44 On 20 April 2020, on a proposal from the Eighth Chamber, the Court decided, pursuant to Article 28 of its Rules of Procedure, to refer the case to a chamber sitting in extended composition.

45 By measure of organisation of procedure of 22 April 2020, the Court put written questions to the parties, to which the parties replied within the prescribed period.

46 By measure of organisation of procedure of 15 June 2020, the Court invited each party to submit its observations on the replies to the Court's written questions of 22 April 2020. The parties submitted their observations within the prescribed period.

47 On a proposal from the Judge-Rapporteur, the Court (Eighth Chamber, Extended Composition) decided to open the oral part of the procedure. However, by letter of 8 June 2020, the main parties stated, in essence, that their representatives could not participate in person in the hearing due to be held at the Court in Luxembourg (Luxembourg) and that, should it not be possible for them to participate in that hearing by videoconference, they would forgo a hearing. In those circumstances, considering, moreover, that it had sufficient information available to it from the case file and, in particular, from the parties' replies to its questions and their respective observations on those replies, the Court (Eighth Chamber, Extended Composition) decided, pursuant to Article 108(2) of the Rules of Procedure, to close the oral part of the procedure.

48 The applicant claims that the Court should:

– declare the application admissible and well founded;

– order that it must be compensated for the damage caused to it by the Commission;

– order the Commission to pay it compensation for the damage it suffered as a direct consequence of the unlawful classification, evaluated at a total amount of EUR 652 733, or any other amount as established by it in the course of the proceedings or assessed by the Court;

– in the alternative, rule on interlocutory judgment that the Commission must make reparation for the damage suffered and order the parties to produce to the Court within a reasonable period from the date of the judgment, figures as to the amount of the compensation agreed between the parties or, failing agreement, order the parties to produce to the Court, within the same period, their submissions with detailed figures in support;

– order the Commission to pay it compensatory interest at the default rate from the date of the losses suffered (that is, either from the date of entry into force of the unlawful classification or from the date when the damage materialised);

– order the Commission to pay default interest of 8%, or any other appropriate rate to be determined by the Court, calculated on the amount payable as from the date of the Court's judgment until actual payment; and

– order the Commission to pay all the costs of the proceedings.

49 The Commission contends that the Court should:

– dismiss the action for damages;

– order the applicant to pay the costs of the present proceedings;

– in the alternative, should the General Court find in favour of the applicant on the issue of liability, grant the parties a six-month period to agree on the quantum of damages.

50 The Kingdom of Spain claims that the Court should:

– dismiss the action for damages;

– order the applicant to pay the costs.

51 The ECHA claims that the Court should:

– dismiss the action for damages;

– order the applicant to pay the costs of the present proceedings.

Law

52 In support of its action for damages, the applicant submits, in essence, that the unlawful classification of CTPHT as an Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) substance by way of Regulation No 944/2013 caused it material damage which it assesses at EUR 652 733. First, that damage corresponds to the costs incurred on account of the adaptation of the packaging and the conditions for transportation as set out in the UN Model Regulations for Transport of Dangerous Goods, that is to say, inter alia, the European Agreement concerning the International Carriage of Dangerous Goods by Road, the Regulations concerning the International Transport of Dangerous Goods by Rail and the International Maritime Dangerous Goods Code. Second, the applicant also

invokes damage caused by the additional costs incurred, as a result of the classification laid down in Regulation No 944/2013, in order to update safety data sheets in accordance with Regulation No 1907/2006.

53 The Commission, supported by the Kingdom of Spain and the ECHA, contends that, first, it has not committed a sufficiently serious breach of a rule of law intended to confer rights on individuals, second, the applicant has not proved that actual and certain damage has occurred and, third, the applicant has not established a causal link between the unlawful act and the damage allegedly suffered.

54 It must be stated that it is settled case-law that the European Union may incur non-contractual liability only if a number of conditions are fulfilled, namely the existence of a sufficiently serious breach of a rule of law intended to confer rights on individuals, the fact of damage and the existence of a causal link between the breach of the obligation resting on the author of the act and the damage sustained by the injured parties (see judgment of 10 September 2019, *HTTS* v *Council*, C-123/18 P, EU:C:2019:694, paragraph 32 and the case-law cited).

55 According to equally settled case-law, if one of those three conditions is not satisfied, the action must be rejected in its entirety and it is unnecessary to consider the other conditions (see judgment of 15 September 1994, *KYDEP* v *Council and Commission*, C-146/91, EU:C:1994:329, paragraph 81 and the case-law cited).

56 Regarding the first of those conditions, the applicant submits that the unlawful classification of CTPHT as an Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) substance, as held by the Court of Justice in its judgment of 22 November 2017, *Commission* v *Bilbaína de Alquitranes and Others* (C-691/15 P, EU:C:2017:882), constitutes a sufficiently serious breach of a rule of law intended to confer rights on individuals.

57 In order to assess whether the unlawful act committed by the Commission is capable of resulting in the European Union incurring non-contractual liability, it must be ascertained first whether the applicant has established the existence of a breach, in the present case, of a rule of law intended to confer rights on individuals within the meaning of the case-law, then whether the breach of that rule of law was sufficiently serious within the meaning of the case-law.

The nature of the rule breached by the Commission in adopting Regulation No 944/2013

58 It is settled case-law that a rule of law is intended to confer rights on individuals where the infringement concerns a provision which gives rise to rights for individuals which the national courts must protect, so that it has direct effect, which creates an advantage that could be defined as a vested right, which is intended to protect the interests of individuals or which entails the grant of rights to individuals and the content of those rights are sufficiently identifiable (see judgment of 16 October 2014, *Evropaïki Dynamiki* v *Commission*, T-297/12, not published, EU:T:2014:888, paragraph 76 and the case-law cited).

59 The applicant submits that the rules that the Commission breached are found in point 4.1.3.5.5 of Annex I to Regulation No 1272/2008, namely, the summation method, and in the duty to act diligently which is inherent in the principle of sound administration. It argues that the combination of those rules confers a right on individuals which makes it possible for them to protect the interests of their individual undertaking, in so far as the Commission has a duty to act diligently when classifying a substance.

60 In answer to a question asked by the Court, the applicant specified that, in its submission, the provisions of Regulation No 1272/2008 are capable of protecting the interests of individuals in so far as they impose or strengthen the obligations with which operators such as the applicant must comply in order to be able to enjoy their right to place classified chemical substances and mixtures on the market. In that regard, the applicant refers, inter alia, to Article 4(10) of that regulation, which provides that 'substances and mixtures shall not be placed on the market unless they comply with this Regulation'. Thus, an inaccurate classification would infringe the applicant's right to place on the market substances and mixtures which comply *in fine* with that regulation.

61 The Commission, supported by the Kingdom of Spain and the ECHA, contends, conversely, that the provisions of Annex I to Regulation No 1272/2008, the summation method laid down in point 4.1.3.5.5 thereof in particular, do not confer rights on individuals. Those provisions – which, according to the Commission, are purely methodological and stem from the GHS – consist of technical and scientific criteria for the classification of substances and mixtures on the basis of the intrinsic properties of those substances. The rules on the summation method in Annex I to that regulation are simply designed to determine the aquatic toxicity hazard of substances or mixtures on the basis of scientific data and do not entail any balancing of interests of individuals. Moreover, they do not lay down any procedural rules intended to protect the interests of individuals. Thus, neither the body submitting the initial proposal for classification, nor the RAC, nor the Commission, has a duty to balance the interests of individuals.

62 In that regard, it must be noted that, according to the judgments of 22 November 2017, *Commission* v *Bilbaína de Alquitranes and Others* (C-691/15 P, EU:C:2017:882), and of 7 October 2015, *Bilbaína de Alquitranes and Others* v *Commission* (T-689/13, not published, EU:T:2015:767), the Commission committed a manifest error of assessment when applying the summation method set out in point 4.1.3.5.5 of Annex I to Regulation No 1272/2008. Thus, it is apparent from paragraph 47 of the judgment of 22 November 2017, *Commission* v *Bilbaína de Alquitranes and Others* (C-691/15 P, EU:C:2017:882), that 'when it applies the summation method in order to determine whether a … substance [which is among the substances of unknown or variable composition, complex reaction products or biological materials] comes within the categories of acute or chronic aquatic toxicity, the Commission is not required to limit its assessment solely to the factors expressly referred to in point 4.1.3.5.5 of Annex I to Regulation No 1272/2008, to the exclusion of any other factor'. However, according to paragraph 32 of the judgment of 7 October 2015, *Bilbaína de Alquitranes and Others* v *Commission* (T-689/13, not published, EU:T:2015:767), neither the Commission nor the ECHA was able to establish before the Court that the Commission had taken into account the low water solubility of CTPHT. Therefore, it must be held that the infringed rule, as the General Court and subsequently the Court of Justice held in their respective judgments, is in point 4.1.3.5.5 of Annex I to that regulation, namely the summation method.

63 The summation method contained in point 4.1.3.5.5 of Annex I to Regulation No 1272/2008 is a method for the classification of aquatic environmental hazards. As such, that method does not confer a right *stricto sensu* on individuals. However, as the applicant essentially argues, the classification of a mixture as a substance having aquatic toxicity pursuant to those provisions is capable of creating or strengthening obligations with which operators such as the applicant must, as the case may be, comply in order to be able to place such a mixture on the market.

64 In the present case, it is relevant to note that the purpose of Article 1(1) of Regulation No 1272/2008 is to ensure not only a high level of protection of human health and the environment, but also the free movement of substances.

65 Accordingly, since the harmonised classification of substances and mixtures gives rise to certain obligations with which manufacturers and suppliers of chemical substances must comply in order to participate in the free circulation of chemical substances and mixtures, it inevitably affects the economic interests of those operators. That is apparent, inter alia, from recitals 4 and 5 of Regulation

No 944/2013, which state that a certain period of time is necessary to allow operators to adapt the labelling and packaging of substances and mixtures to the new classifications and to sell existing stocks.

66 However, as regards the specific rule infringed in this case, namely the summation method contained in point 4.1.3.5.5 of Annex I to Regulation No 1272/2008, it should be noted that it is intended only to make it possible, on the basis of technical and scientific criteria, to determine the aquatic toxicity hazard of a mixture taking into account, inter alia, the aquatic toxicity of its components for the purpose of classifying that mixture. That assessment of toxicity hazard excludes any consideration unconnected to the intrinsic properties of the substance. In particular, no balancing of the interests of individuals is provided for in the application of that method.

67 Thus, the summation method appears to be a methodological rule, comparable to a procedural rule, the sole purpose of which is to provide guidance on the assessment of the hazards posed by chemical mixtures on the basis of their intrinsic properties, not to protect the interests of individuals (see, to that effect and by analogy, judgments of 13 September 2007, *Common Market Fertilizers* v *Commission*, C-443/05 P, EU:C:2007:511, paragraphs 143 to 145, and of 29 April 2020, *Tilly-Sabco* v *Commission*, T-437/18, not published, EU:T:2020:159, paragraph 52).

68 That interpretation is supported by the fact that neither the Court of Justice nor the General Court, in their judgments of 22 November 2017, *Commission* v *Bilbaína de Alquitranes and Others* (C-691/15 P, EU:C:2017:882), and of 7 October 2015, *Bilbaína de Alquitranes and Others* v *Commission* (T-689/13, not published, EU:T:2015:767), held that the manifest error of assessment stemmed from a failure on the part of the Commission to have regard to the interests of the manufacturers and suppliers of CTPHT. Rather, those judgments held that there was a manifest error of assessment in that the Commission, when applying the summation method, failed to taken into account the low solubility of the mixture itself, that is to say, a factor that can affect the aquatic hazard of the mixture. In other words, the infringement of the rule in question established in those judgments is restricted to a failure to have regard to its technical and scientific scope.

69 As the summation method rule is not, by its very nature, intended to protect the interests of individuals, the applicant cannot therefore rely *stricto sensu* on a failure to have regard to that rule in support of its action for damages.

70 However, the Court considers that the case-law cited in paragraph 58 above does not necessarily exclude the possibility that the European Union may incur non-contractual liability as a result of the infringement of a rule of law which is not intended *stricto sensu* to confer rights on individuals, but rather is likely to lead to the imposition or strengthening of obligations on individuals pursuant to other rules of EU law. In a similar manner to the approach adopted by the Court of Justice regarding the circumstances in which the rules of customary international law may be relied on (judgment of 21 December 2011, *Air Transport Association of America and Others*, C-366/10, EU:C:2011:864, paragraph 107), it could be considered that the unlawful conduct of an EU institution affecting the legal situation of a natural or legal person – made up of its rights and, inversely, its obligations – can, in certain cases, justify the European Union's incurring non-contractual liability, whether as a result of the infringement of rights or the addition or strengthening of unlawful obligations. In that regard, in the light of the adverse effect on that legal situation, the question whether the administration's allegedly unlawful conduct consisted in the infringement of rights or led to the addition or strengthening of obligations under EU law might be irrelevant, depending on the circumstances of the case. Nevertheless, in the present case, although the summation method rule does not, in itself, confer rights on individuals, the question remains whether the obligations triggered by an incorrect application of the summation method are capable of affecting the applicant's legal situation such that the latter can be considered to have, *in fine*, a personal right to the correct application of the summation method or whether, conversely, those obligations are merely a purely indirect consequence of the application of that rule affecting only the applicant's economic situation.

71 In any event, the answer to the question whether, in the present case, the infringement of the summation method rule on which the unlawful classification of CTPHT is based can be relied on in support of the present action for damages, from the perspective of the addition or strengthening of obligations affecting the applicant's legal situation, would be decisive for the solution of the present dispute only if that infringement were sufficiently serious within the meaning of the case-law cited above, which will be examined below.

72 Regarding the breach of the duty of diligence inherent in the principle of sound administration, as alleged by the applicant in its reply, it must be pointed out that, formally, in the application, the applicant did not specifically and independently allege the breach of that duty of diligence in support of its action for damages. It is also not apparent that that allegation can be regarded as amplifying an argument previously put forward in the application. In those circumstances, as the Commission submitted in its observations on the replies to a written question put to the applicant in that regard, the action for damages must be declared inadmissible in so far as it is based on a breach of the duty of diligence.

The seriousness of the alleged breach of the summation method rule

73 As regards the condition that the breach of the legal rule must be sufficiently serious in order for the European Union to incur non-contractual liability, the applicant submits that the judgments of 22 November 2017, *Commission* v *Bilbaína de Alquitranes and Others* (C-691/15 P, EU:C:2017:882), and of 7 October 2015, *Bilbaína de Alquitranes and Others* v *Commission* (T-689/13, not published, EU:T:2015:767) do not leave any room for doubt as to whether the Commission's manifest error of assessment, that is to say, its failure to have regard to the actual scope of its discretion when adopting the unlawful classification of CTPHT, constitutes such a breach.

74 The applicant submits that, in the context of an action for damages, it is the conduct and actions of the EU institution concerned up to the point that the damage was caused that must be subject to scrutiny. The Commission's conduct and actions indicate clearly that it considered that it had no discretion in applying the summation method. Therefore, according to the applicant, in the context of an action for damages, it must be considered that the infringed rule left no scope for discretion, with the result that, in accordance with the judgment of 4 July 2000, *Bergaderm and Goupil* v *Commission* (C-352/98 P, EU:C:2000:361), the mere infringement of law is sufficient to establish the existence of a sufficiently serious breach.

75 Relying on the judgment of 14 July 1967, *Kampffmeyer and Others* v *Commission* (5/66, 7/66, 13/66 to 16/66 and 18/66 to 24/66, not published, EU:C:1967:31), the applicant argues that, since the Commission refused to exercise its discretion and continued to do so until its appeal before the Court of Justice was dismissed, it 'improperly applie[d] the relevant substantive … rules', which is the applicable criterion in the context of the present action.

76 The applicant also submits that the legislation in question was clear and the Commission cannot therefore rely on a lack of clarity of the law or 'place blame for its error onto the European Parliament and Council'. According to the applicant, the law has always been perfectly clear on whether the Commission had any discretion when examining the classification of CTPHT. The applicant refers in that regard to, inter alia, the order of 22 May 2014, *Bilbaína de Alquitranes and Others* v *ECHA* (C-287/13 P, not published, EU:C:2014:599) and the judgment of 7 March 2013, *Bilbaína de Alquitranes and Others* v *ECHA* (T-93/10, EU:T:2013:106), which confirm, albeit in the context of Regulation No 1907/2006, that the Commission can derogate from prescribed rules by exercising its discretion in order to avoid unreasonable conclusions that would result from a strict application of those rules.

77 The applicant emphasises, inter alia, the allegedly unrealistic nature of the results of the Commission's calculation using the summation method, which the Court of Justice also pointed out in paragraph 53 of the judgment of 22 November 2017, *Commission* v *Bilbaína de Alquitranes and Others* (C-691/15 P, EU:C:2017:882). The applicants in that case pointed out the irrational nature of those results to the Commission on several occasions before Regulation No 944/2013 was adopted and during the written part of the procedure in Case T-689/13. The Commission's choice resulted in the classification of CTPHT as a substance having aquatic toxicity, whereas, according to the applicant, it does not dissolve in water but rather solidifies and sinks in water. According to the applicant, that choice 'verged on the arbitrary' within the meaning of the judgment of 5 December 1979, *Amylum and Tunnel Refineries* v *Council and Commission* (116/77 and 124/77, EU:C:1979:273) and is one that no normal and prudent authority would have taken.

78 Last, the applicant argues that the Commission's decisions to appeal against the judgment of 7 October 2015, *Bilbaína de Alquitranes and Others* v *Commission* (T-689/13, not published, EU:T:2015:767) and to challenge the application for suspension of operation aggravated and continued its error.

79 The Commission, supported by the Kingdom of Spain and the ECHA, contests those arguments.

80 As a preliminary point, it should be borne in mind that, according to settled case-law, a finding of the unlawfulness of a legal measure is not enough, however regrettable that unlawfulness may be, for it to be held that the condition for the incurring of the European Union's non-contractual liability relating to the unlawfulness of the institutions' alleged conduct has been satisfied (see, to that effect, judgment of 23 November 2011, *Sison* v *Council*, T-341/07, EU:T:2011:687, paragraph 31 and the case-law cited). Indeed, according to the case-law, the action for damages was established as an autonomous form of action with a particular purpose to fulfil within the system of legal remedies and its exercise is subject to conditions dictated by its specific object (judgment of 17 December 1981, *Ludwigshafener Walzmühle Erling and Others* v *Council and Commission*, 197/80 to 200/80, 243/80, 245/80 and 247/80, EU:C:1981:311, paragraph 4). Thus, it is not intended to ensure compensation for damage caused by all unlawful conduct (judgment of 3 March 2010, *Artegodan* v *Commission*, T-429/05, EU:T:2010:60, paragraph 51).

81 In that connection, it should be noted that the requirement of a sufficiently serious breach seeks, whatever the nature of the unlawful measure in question, to avoid the situation where the risk of having to bear the losses alleged by the undertakings concerned hinders the ability of the institution concerned to fully exercise its competences in the general interest, both in the context of its activities that are regulatory or involve economic policy choices and in the sphere of its administrative competence, without thereby leaving third parties to bear the consequences of flagrant and inexcusable misconduct (see judgment of 3 March 2010, *Artegodan* v *Commission*, T-429/05, EU:T:2010:60, paragraph 55 and the case-law cited).

82 The fact that a measure of the Commission giving rise to the losses claimed by the applicant may have been annulled, even by a judgment of the General Court delivered before the action for damages had been brought, is not irrefutable evidence of a sufficiently serious breach on the part of that institution, giving rise *ipso jure* to liability on the part of the Union (see, to that effect, judgment of 8 May 2019, *Export Development Bank of Iran* v *Council*, T-553/15, not published, EU:T:2019:308, paragraph 55).

83 The decisive test for a finding that the requirement of not leaving those parties to bear the consequences of flagrant and inexcusable misconduct by the institution concerned has been satisfied is whether the institution concerned has manifestly and gravely disregarded the limits of its discretion (see, to that effect, judgments of 4 July 2000, *Bergaderm and Goupil* v *Commission*, C-352/98 P, EU:C:2000:361, paragraph 43, and of 30 May 2017, *Safa Nicu Sepahan* v *Council*, C-45/15 P, EU:C:2017:402, paragraph 30). The concept of 'manifest and grave disregard' is not the same as the concept of 'manifest error of assessment', but must be regarded as a distinct concept. If such a distinction were not made, any manifest error of assessment and, therefore, any error made by an

administrative authority of the European Union in circumstances where it has some discretion could result in its incurring non-contractual liability. However, as mentioned, it does not follow from the relevant case-law set out above that any unlawful act is, by itself, a basis for such liability. The determining factor in deciding whether there has been such an infringement is, therefore, the discretion available to the institution concerned. It is thus apparent from the criteria set out in the case-law that, if the institution in question has only considerably reduced or even no discretion, the mere infringement of EU law may be sufficient to establish the existence of a sufficiently serious breach (see judgment of 23 November 2011, *Sison* v *Council*, T-341/07, EU:T:2011:687, paragraph 35 and the case-law cited).

84 However, that case-law does not establish any automatic link between, on the one hand, the fact that the institution concerned has no discretion and, on the other, the classification of the infringement as a sufficiently serious breach of EU law (see judgment of 3 March 2010, *Artegodan* v *Commission*, T-429/05, EU:T:2010:60, paragraph 59).

85 The extent of the discretion enjoyed by the institution concerned, although determinative, is not the only yardstick. On the contrary, account must be taken of, in particular, the complexity of the situations to be regulated and the difficulties in applying or interpreting the texts (see judgment of 23 November 2011, *Sison* v *Council*, T-341/07, EU:T:2011:687, paragraphs 36 and 37 and the case-law cited) or, more generally, the field, circumstances and context in which the infringed rule was imposed on the EU institution or body concerned (see judgment of 4 April 2017, *Ombudsman* v *Staelen*, C-337/15 P, EU:C:2017:256, paragraph 40 and the case-law cited).

86 It follows that only the finding of an irregularity that an administrative authority, exercising ordinary care and diligence, would not have committed in similar circumstances, can render the European Union liable (see judgment of 3 March 2010, *Artegodan* v *Commission*, T-429/05, EU:T:2010:60, paragraph 62).

87 In that regard, the case-law further clarified that the failure to fulfil a legal obligation can be taken to constitute a breach which is sufficiently serious to give rise to the non-contractual liability of the European Union only where such conduct takes the form of action manifestly contrary to the rule of law and seriously detrimental to the interests of persons outside the institution and cannot be justified or accounted for by the particular constraints to which the staff of the institution, operating normally, are objectively subject (judgment of 9 September 2008, *MyTravel* v *Commission*, T-212/03, EU:T:2008:315, paragraph 43).

88 It is, consequently, for the EU judicature, once it has first determined whether the institution concerned enjoyed any discretion, next to take into consideration the complexity of the situations to be regulated, any difficulties in applying or interpreting the legislation, the clarity and precision of the rule infringed, and whether the error made was inexcusable or intentional (see judgment of 23 November 2011, *Sison* v *Council*, T-341/07, EU:T:2011:687, paragraph 40 and the case-law cited).

89 In the light of those criteria, it is appropriate to examine whether the infringement on the part of the Commission, as found in the judgments of 22 November 2017, *Commission* v *Bilbaína de Alquitranes and Others* (C-691/15 P, EU:C:2017:882), and of 7 October 2015, *Bilbaína de Alquitranes and Others* v *Commission* (T-689/13, not published, EU:T:2015:767), constitutes a sufficiently serious breach within the meaning of the case-law referred to above.

90 To that end, it is necessary to recall the considerations that led the General Court, and subsequently the Court of Justice, to hold that the Commission had committed a manifest error of assessment when classifying CTPHT on the basis of the summation method.

91 Regarding the judgment of 7 October 2015, *Bilbaína de Alquitranes and Others* v *Commission* (T-689/13, not published, EU:T:2015:767), it should be noted that it is apparent from paragraph 24 thereof that the General Court's starting point was that the Commission had 'a broad discretion' when classifying CTPHT. According to paragraph 30 of that judgment, 'the Commission committed a manifest error of assessment in that, by classifying CTPHT as an Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) substance on the basis of its constituents, it failed to comply with its obligation to take into consideration all the relevant factors and circumstances so as to take due account of the proportion in which the 16 PAH constituents are present in CTPHT and their chemical effects'. The General Court therefore considered that the Commission had been unable to establish that it had taken into consideration the fact that the constituents of CTPHT were released from CTPHT only to a limited extent and that that substance was very stable and its water solubility was therefore low. Moreover, the General Court pointed out that, assuming that all of the PAHs of CTPHT dissolve in water, the Commission based the classification of CTPHT on the assumption that 9.2% of CTPHT could dissolve in water, whereas it was apparent from the background document that such a value was not realistic, given that the highest rate of water solubility of CTPHT is 0.0014%. In addition, the General Court referred to the definition of acute aquatic toxicity in point 4.1.1.1 of Annex I to Regulation No 1272/2008 which, according to the General Court, concerned the properties of the substance, not only those of its constituents. Furthermore, the General Court relied on the Court of Justice's case-law as cited in paragraph 29 of its judgment of 7 October 2015, *Bilbaína de Alquitranes and Others* v *Commission* (T-689/13, not published, EU:T:2015:767), according to which it cannot be held that, merely because a constituent of a substance has a certain number of properties, the substance itself also has them.

92 In its judgment of 22 November 2017, *Commission* v *Bilbaína de Alquitranes and Others* (C-691/15 P, EU:C:2017:882), the Court of Justice did not call into question the General Court's finding that the Commission had a broad discretion in classifying a substance pursuant to Regulation No 1272/2008 and in carrying out the complex scientific and technical assessments which it had to undertake for that purpose. The Court of Justice also held that the General Court had not erred in law in holding that the Commission had committed a manifest error of assessment. The Court of Justice referred, inter alia, to the fact that Annex I to Regulation No 1272/2008 had integrated the criteria of the GHS into EU law, reproducing verbatim almost all of those provisions. That document highlights the complex interpretational problem, even for experts, presented by classification, in particular that of so-called 'complex or multi-component' substances for which '… water solubility [presents] problems of interpretation, where each component of the mixture may behave differently' (judgment of 22 November 2017, *Commission* v *Bilbaína de Alquitranes and Others*, C-691/15 P, EU:C:2017:882, paragraph 43).

93 Thus, according to the Court of Justice, the authors of the GHS sought to draw attention to the limits inherent in the methodological criteria for classification of hazards to the aquatic environment, in respect of certain substances characterised by their complexity, stability or low water solubility. Moreover, according to the Court of Justice, the EU legislature did not disregard those methodological limitations in integrating the GHS in Regulation No 1272/2008. The Court of Justice therefore took the view that the Commission was not required to limit its assessment solely to the factors expressly referred to in point 4.1.3.5.5 of Annex I to Regulation No 1272/2008, to the exclusion of any other factor.

94 In that regard, the Court of Justice also observed that, according to point 4.1.3.1, introducing the classification criteria for mixtures, the approach followed '[is applied where appropriate] in order to make use of all available data for [the] purposes of classifying the aquatic environmental hazards of the mixture', which, according to the Court of Justice, tended to undermine the interpretation that taking into account information other than that expressly used in the course of the summation method should, in all circumstances, be excluded. Moreover, the Court of Justice observed that it is inherent in the summation method applied by the Commission in this case that it loses reliability in certain situations, such as in the circumstances of this case, where the summation method led to the result of

14 521%, 581 times greater than the minimum level required for the threshold of 25%, after weighting by M-factor, to be reached and the maximum rate of water solubility of CTPHT was 0.0014%, a rate approximately 71 000 times lower than the hypothetical solubility rate of 100% used for the constituents taken into consideration.

95 Having regard to the finding of the General Court, confirmed by the Court of Justice, that the Commission infringed, in this case, a rule affording it some discretion, it is appropriate to reject the applicant's argument that the Commission considered that the summation method was a strict rule leaving it no scope for discretion. The damage that the applicant could potentially rely on stems from the Commission's manifest error of assessment in applying that method. However, that same method cannot, for the purposes of determining the non-contractual liability of the authority that applied it, be regarded as both leaving scope for discretion as regards the infringement criterion and leaving no scope for discretion as regards the sufficiently serious breach criterion.

96 It is apparent from the settled case-law cited above that it is also appropriate to reject the applicant's argument that a manifest error of assessment is, in all circumstances, a sufficiently serious breach of a rule leaving scope for discretion. As observed in paragraphs 80 to 83 above, as an action for damages is an independent form of action, the fact that a measure adopted by the Commission is unlawful is not, in itself, enough for the European Union to incur non-contractual liability. The characterisation of an error of assessment as manifest relates to the overstepping of the limits of discretion and is therefore intended to distinguish situations in which that overstepping constitutes a breach of law from situations in which there is a mere disagreement over the appropriate exercise of that discretion. Consequently, where the institution in question has broad discretion, a finding that a sufficiently serious breach has occurred can be made only after it has been found that a manifest error of assessment has been committed, with the purpose of identifying, based on the criteria referred to in paragraph 88 above, the most serious and inexcusable errors that amount to a manifest and serious failure to have regard to the limits imposed on the discretion of the institution concerned.

97 Regarding, in the first place, the criteria relating to the degree of clarity and precision of the rule infringed, namely point 4.1.3.5.5 of Annex I to Regulation No 1272/2008, it should be noted that, according to the wording of that provision, the summation method is set out as an almost mechanical calculation, by way of which the Commission verifies whether the sum of concentrations (as a percentage) of the highly toxic constituents of the mixture multiplied by their corresponding M-factors is equal to or greater than 25%. If that is the case, the mixture, CTPHT in the present case, 'is classified' as Acute or Chronic Category 1 (see points 4.1.3.5.5.3.1 and 4.1.3.5.5.4.2 of Annex I to Regulation No 1272/2008). As found by the Court of Justice in paragraph 39 of the judgment of 22 November 2017, *Commission* v *Bilbaína de Alquitranes and Others* (C-691/15 P, EU:C:2017:882), point 4.1.3.5.5 of Annex I to that regulation does not provide explicitly for the use of criteria other than those expressly referred to in that provision.

98 In that regard, it is appropriate to reject the applicant's argument that the judgment of 7 March 2013, *Bilbaína de Alquitranes and Others* v *ECHA* (T-93/10, EU:T:2013:106) can be regarded as a precedent which clarified the summation method approach. As observed correctly by the Commission, neither the General Court nor the Court of Justice referred to that judgment. Moreover, it is clear that that judgment did not relate to the classification of a mixture pursuant to Regulation No 1272/2008, such as that at issue in the present case, but to an entirely different issue, namely that of identifying CTPHT as a substance of very high concern under Article 57 of Regulation No 1907/2006. Thus, in so far as the General Court held in the judgment of 7 March 2013, *Bilbaína de Alquitranes and Others* v *ECHA* (T-93/10, EU:T:2013:106), that the ECHA did not commit a manifest error of assessment when it found that CTPHT had certain properties, namely 'persistent and bioaccumulative' properties in that case, because its constituents had those properties, the General Court did not establish a general rule that when a piece of legislation establishes criteria for taking a decision without a specific and express prohibition on taking into account other factors, an institution could or even must always take into account other factors. In any event, as also observed by the Commission,

even assuming that that judgment of the General Court had established a clear precedent regarding the issue raised – which it did not – it must be stated that that judgment became final only after the appeal was dismissed by the Court of Justice by order of 22 May 2014, *Bilbaína de Alquitranes and Others* v *ECHA* (C-287/13 P, not published, EU:C:2014:599), that is to say, after Regulation No 944/2013 was adopted, which means that it could not, on that basis alone, constitute a precedent that the Commission could have and should have taken into account when adopting Regulation No 944/2013.

99 Accordingly, point 4.1.3.5.5 of Annex I to Regulation No 1272/2008 cannot be regarded as having constituted, on the date of adoption of Regulation No 944/2013, a completely clear rule as regards the Commission's discretion when applying the summation method. Its wording does not suggest that such discretion exists and, above all, does not mention that the solubility of a mixture is a factor to be taken into account. In that regard, it must be noted that the General Court and, in particular, the Court of Justice acknowledged that the Commission does have a discretion, which should have led it to take into account factors other than those referred to expressly in point 4.1.3.5.5, based on considerations that do not stem directly or explicitly from the wording of that point. More specifically, the Court of Justice relied on considerations connected to the more general regulatory context, namely, in particular, the fact that the summation method does not disregard the methodological limitations identified by the GHS which Regulation No 1272/2008 aims to integrate in EU law, according to recital 6 of the regulation. As observed by the Court of Justice in paragraph 43 of the judgment of 22 November 2017, *Commission* v *Bilbaína de Alquitranes and Others* (C-691/15 P, EU:C:2017:882), that document highlights the problems of interpretation connected to the classification of complex or multi-component substances such as CTPHT. Those difficulties of interpretation, which complicate the application of the summation method and which were rendered apparent, moreover, by that judgment, preclude the Commission's conduct from being regarded as manifestly and seriously contrary to the rule of law infringed (see, to that effect, judgment of 9 September 2008, *MyTravel* v *Commission*, T-212/03, EU:T:2008:315, paragraph 43). Although, in accordance with the judgments of 22 November 2017, *Commission* v *Bilbaína de Alquitranes and Others* (C-691/15 P, EU:C:2017:882), and of 7 October 2015, *Bilbaína de Alquitranes and Others* v *Commission* (T-689/13, not published, EU:T:2015:767), that conduct is, admittedly, unlawful, it can at the very least be explained by the wording of point 4.1.3.5.5 and the difficulties of interpretation in respect of the classification of complex substances.

100 Regarding, in the second place, the question whether the error committed by the Commission, as established by the General Court and subsequently by the Court of Justice, is intentional or inexcusable, it is necessary to point out the following.

101 First of all, it must be noted that neither the General Court nor the Court of Justice called into question the use of the summation method. As observed in paragraph 26 of the judgment of 22 November 2017, *Commission* v *Bilbaína de Alquitranes and Others* (C-691/15 P, EU:C:2017:882), the Commission committed a manifest error of assessment 'when applying the summation method'.

102 Moreover, it must be pointed out that the Commission applied the summation method by following the wording of point 4.1.3.5.5 rigorously. It calculated the sum of the concentrations of the highly toxic constituents of CTPHT after applying the corresponding M-factors. The application of that method in accordance with the wording of point 4.1.3.5.5 shows that the Commission intended to act within its powers, which, as a general rule, can be regarded as a prudent approach in particularly complex scientific and technical situations. As observed by Advocate General Bobek in point 75 of his Opinion in *Commission* v *Bilbaína de Alquitranes and Others* (C-691/15 P, EU:C:2017:646), in principle 'such a vision can only be commended', even though it proved to be incorrect in the present case.

103 While it is true that that approach was held by the Court of Justice and the General Court to be vitiated by a manifest error of assessment, to categorise that approach – which follows the relatively prescriptive wording of a rule of law in a field that is highly complex, scientifically and technically, and which, moreover, forms part of a regulation the purpose of which, according to Article 1 of Regulation No 1272/2008, is 'to ensure a high level of protection of human health and the environment as well as the free movement of substances [and] mixtures … by … harmonising the criteria for classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures …' – as inexcusable would go beyond the criteria defining a sufficiently serious breach established by the case-law referred to above. In particular, such an approach does not constitute an act manifestly and seriously contrary to the rule of law, which cannot be justified or accounted for by the particular constraints imposed on the Commission objectively when exercising its powers relating to the classification of substances of unknown composition (see, to that effect, judgment of 9 September 2008, *MyTravel* v *Commission*, T-212/03, EU:T:2008:315, paragraph 43).

104 In addition, it should be borne in mind that, in the present case, the Commission followed the RAC's opinion which, in turn, is the result of a procedure laid down in Regulation No 1272/2008. That procedure was initiated by the classification proposal submitted by the Kingdom of the Netherlands pursuant to Article 37(1) of that regulation. That proposal was subsequently the subject of a public consultation, following which the RAC – which is itself composed of representatives of the Member States – adopted the opinion in question by consensus in accordance with Article 37(4) of that regulation.

105 The low solubility of CTPHT was raised by the Coal Chemicals Sector Group in a dossier drawn up in accordance with Annex VI to Regulation No 1272/2008 and submitted to the public consultation on 15 November 2010. In addition, that group specified, in a letter of 27 June 2011 to the secretariat of the RAC, referring to a scientific article, that the maximum water solubility of CTPHT was 0.0004%. Therefore, it must be noted that the RAC's opinion was given in full knowledge of the low solubility of CTPHT. Thus, the low solubility of CTPHT was addressed by the RAC in page 92 of the background document in so far as it specifies that, for the purpose of the application of the summation method, the assumption is that all PAHs dissolve in water and that assumption likely contributes to an overestimation of the toxicity of CTPHT. At the same time, the RAC explained, however, in its opinion that such toxicity could be regarded as the worst case scenario, since the composition of CTPHT was uncertain and it could not be ruled out that other constituents of CTPHT could contribute to the toxicity of CTPHT itself. The RAC's opinion therefore contains an explanation relating, at the very least, to the tension between the assumption that all PAHs dissolve in water and the low water solubility of CTPHT.

106 Having regard to all the foregoing considerations, it is not established in the present case that, in the light of the applicable complex legal framework, an administrative authority exercising ordinary care and diligence would have considered it necessary to doubt the plausibility of the RAC's opinion to the point of being required to depart from it in order to take into account a criterion not expressly laid down in Regulation No 1272/2008. In that regard, it is important to bear in mind that the fact that CTPHT is a substance of complex and unknown composition was a specific constraint on the Commission when adopting Regulation No 944/2013. With such uncertainty surrounding the exact composition of CTPHT, the fact that an administrative authority followed, in the interests of caution, the opinion of a group of experts such as the RAC which, moreover, had been adopted by consensus and was based on the identification of a risk of underestimating the toxicity of CTPHT, given that page 92 of that opinion states that that risk was a worst case scenario where the contribution to aquatic toxicity of the other constituents of CTPHT was unknown, cannot, at the very least, be regarded as an inexcusable error.

107 In that regard, it must, again, be noted that the purpose of the classification of substances and mixtures such as CTPHT, according to Article 1(1) of Regulation No 1272/2008, is to ensure a high level of protection of human health and the environment. Moreover, although the precautionary principle is

not expressly mentioned in Regulation No 1272/2008, that principle, on which the provisions of, inter alia, Regulation No 1907/2006 are based, cannot be disregarded when classifying chemical substances and mixtures, which is a closely connected field to that covered by Regulation No 1907/2006. The precautionary principle, which is a general principle of EU law, authorises the competent authorities, where there is uncertainty, to take appropriate measures in order to prevent certain potential risks for public health, safety and the environment without having to wait until the reality and seriousness of those risks become fully apparent (see, to that effect, judgment of 10 April 2014, *Acino* v *Commission*, C-269/13 P, EU:C:2014:255, paragraph 57 and the case-law cited).

108 In that regulatory context, Regulation No 1272/2008 confers on the Commission the power to classify chemical substances. As illustrated by the present case, in exercising that power it may be necessary to come to conclusions on the toxicity of complex substances. The exercise of that power could be hindered, to the detriment of the objectives referred to above, if the adoption of a decision on the classification of complex substances could lead to the European Union incurring non-contractual liability without consideration being given to scientific complexity and the resulting uncertainties, as well as the complexity of the applicable regulatory framework, as factors that could render a potential error excusable.

109 In any event, the error committed by the Commission does not constitute conduct verging on the arbitrary within the meaning of the judgment of 5 December 1979, *Amylum and Tunnel Refineries* v *Council and Commission* (116/77 and 124/77, EU:C:1979:273). Contrary to the applicant's assertions, the high result of the application of the summation method in the present case cannot lead to the conclusion that the Commission's conduct verged on the arbitrary. It is true that the Court of Justice referred to the result of 14 521% as an illustration of a situation in which the summation methods loses reliability. However, that result of 14 521% – although initially striking, in particular when compared to the 25% threshold necessary for a classification of Acute or Chronic Category 1 – is the mathematically inevitable result of the application of the summation method, since the M-factor of certain components of CTPHT is very high. For example, it should be noted that an M-factor of 10 000 was applied to certain constituents of CTPHT, such as fluoranthene in the present case. Accordingly, there is no reason to assume that the high result of such calculation is, in itself, evidence of the inexcusable nature of the error committed by the Commission. Given that it was reasonable for the Commission to believe, when Regulation No 944/2013 was adopted, that it had no discretion in classifying CTPHT on the basis of the summation method and given the regulatory context of that classification, characterised by the objective of ensuring a high level of protection of the environment in full compliance with the precautionary principle, the fact that, given the presence of very high M-factors such as those in the present case, the result of 14 521% did not lead it to call into question its application of the summation method, appears to be, on the contrary, excusable.

110 The Commission's conduct is therefore closer to that which could be expected from an administrative authority exercising ordinary care and diligence rather than that of an administrative authority verging on the arbitrary. In an analogous situation and in the absence of an alternative method expressly laid down in Regulation No 1272/2008, it would not have been entirely surprising for an administrative authority to consider that it would run the risk of annulment if it were to take into account factors other than those expressly set out in Annex I to Regulation No 1272/2008, and in point 4.1.3.5.5 thereof in particular.

111 It must, moreover, be pointed out that neither the General Court nor the Court of Justice ruled on whether the classification of CTPHT as an Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) substance was materially correct or incorrect. As also noted by Advocate General Bobek in point 70 of his Opinion in *Commission* v *Bilbaína de Alquitranes and Others* (C-691/15 P, EU:C:2017:646), the dispute did not concern whether the classification of CTPHT was correct, but only the issue of what factors should have been taken into account when applying the summation method. In particular, it

cannot be ruled out that, even if the Commission had taken into account the low water solubility of CTPHT, it would nevertheless have come to the same conclusion regarding the classification of CTPHT as an Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) substance.

112 In that regard, it should also be noted that no new classification procedure has been opened following the judgment of 22 November 2017, *Commission* v *Bilbaína de Alquitranes and Others* (C-691/15 P, EU:C:2017:882). As explained by the Commission in response to a written question of the General Court in that regard, the fact that no new classification has been made can be explained by the fact that CTPHT may have been considered of lower priority given that, pursuant to Commission Regulation (EU) 2017/999 of 13 June 2017 amending Annex XIV to Regulation No 1907/2006 (OJ 2017 L 150, p. 7), CTPHT was included in Annex XIV to Regulation No 1907/2006 on the basis of its carcinogenic, persistent, bioaccumulative and toxic and very persistent and very bioaccumulative properties and its use must therefore be subject to an authorisation procedure from 4 October 2020. Moreover, the Commission stated that another possible reason is that the issue of the correct application of the summation method to a substance or mixture with low water solubility has remained open following that judgment of the Court of Justice.

113 Admittedly, the hypothetical nature of the reasons why no new classification has been made prevents a definitive assessment of their relevance in the present case. Nevertheless, it should be considered that the fact that the error committed by the Commission as held by the General Court and subsequently by the Court of Justice was not corrected by way of a new classification can serve as an illustration of the difficulties of applying the summation method correctly. The fact that it is difficult to correct the error committed by the Commission, as potentially highlighted by the present case, thus also runs counter to the characterisation of that error as inexcusable.

114 Last, contrary to what the applicant appears to allege, the fact that the Commission exercised its procedural rights by challenging the application for suspension of operation and by appealing against the judgment of 7 October 2015, *Bilbaína de Alquitranes and Others* v *Commission* (T-689/13, not published, EU:T:2015:767), cannot constitute a factor aggravating the error committed. In that regard, it can reasonably be expected that any administrative authority exercising ordinary care and diligence, in an analogous situation, would bring an appeal in order to obtain clarification from the Court of Justice regarding the scope of its obligations when classifying complex substances. It should also be noted that the judgment of 22 November 2017, *Commission* v *Bilbaína de Alquitranes and Others* (C-691/15 P, EU:C:2017:882), contains a certain amount of interpretative elements that at the very least supplement the analysis set out in the judgment of 7 October 2015, *Bilbaína de Alquitranes and Others* v *Commission* (T-689/13, not published, EU:T:2015:767).

115 In the light of the foregoing, the error committed by the Commission therefore appears to be excusable. Given the lack of clarity and the difficulties in interpreting the relevant provisions in Annex I to Regulation No 1272/2008 regarding the consideration that can be given to factors other than those expressly provided for when applying the summation method, the Commission's conduct is close to that which could reasonably be expected from an administrative authority exercising ordinary care and diligence in an analogous situation, that is to say, a situation characterised by scientific complexity connected to the classification of a substance of unknown composition such as CTPHT with the purpose of ensuring a high level of protection of human health and the environment. That conduct is not equivalent to a manifest and grave disregard of the limits on the Commission's discretion. Therefore, the error committed does not constitute a sufficiently serious breach of a rule of law, with the result that the European Union has not, in any event, incurred non-contractual liability in the present case. That finding applies equally to the infringement of the summation method and, for the sake of completeness and on the grounds set out above, to the alleged breach of the duty of diligence.

116 As the applicant has not shown that there has been a sufficiently serious breach of a rule of law such as to result in the European Union incurring non-contractual liability, its action for damages must be rejected as unfounded, without it being necessary to return to the question of infringement of a rule conferring rights on individuals or to examine the conditions for the existence of actual and certain damage and a causal link.

117 As a result, the first head of claim must be rejected as being, in any event, unfounded and, consequently, all of the other heads of claim and, ultimately, the action in its entirety, must be dismissed.

Costs

118 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. Since the applicant has been unsuccessful, it must be ordered to pay, in addition to its own costs, the costs incurred by the Commission, in accordance with the form of order sought by the Commission.

119 Article 138(1) of those rules provides that Member States and institutions which have intervened in the proceedings are to bear their own costs. Under Article 1(2)(f) of the Rules of Procedure, the term 'institutions' means the institutions of the European Union referred to in Article 13(1) TEU and the bodies, offices or agencies established by the Treaties, or by an act adopted in implementation thereof, which may be parties before the General Court. According to Article 100 of Regulation No 1907/2006, the ECHA is a European Union body. It follows that the Kingdom of Spain and the ECHA must bear their own costs.

On those grounds,

THE GENERAL COURT (Eighth Chamber, Extended Composition)

hereby:

1. **Dismisses the action;**

2. **Orders Industrial Química del Nalón, SA, to bear its own costs and to pay those incurred by the European Commission;**

3. **Orders the Kingdom of Spain and the European Chemicals Agency (ECHA) to bear their own costs.**

Svenningsen Barents Mac Eochaidh

Pynnä Laitenberger

Delivered in open court in Luxembourg on 16 December 2020.

E. Coulon
Registrar

M. van der Woude
President