JUDGMENT OF THE GENERAL COURT (Sixth Chamber)

21 January 2026 (*)

(Environment and protection of human health – Regulation (EC) No 1272/2008 – Classification, labelling and packaging of certain substances and certain mixtures – Delegated Regulation (EU) 2024/197 – Classification and labelling of 1,4-Benzenediamine, N,N'-mixed Ph and tolyl derivs. – Criteria for classification of a substance in the hazard class reproductive toxicity category 1B – Multi-constituent substance – Relevance of adverse effects in humans – Read-across – Manifest errors of assessment – Equal treatment – Proportionality – Rights of the defence)

In Case T-174/24,

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

The Goodyear Tire & Rubber Company, established in Akron, Ohio (United States),

represented by C. Mereu and N. Konings, lawyers,

applicants,

v

European Commission, represented by B. Cullen and J. Jokubauskaitė, acting as Agents,

defendant,

supported by

Federal Republic of Germany, represented by J. Möller, acting as Agent,

by

Kingdom of the Netherlands, represented by M.K. Bulterman and J. Langer, acting as Agents,

and by

European Chemicals Agency (ECHA), represented by W. Broere and J.-P. Trnka, acting as Agents,

interveners,

THE GENERAL COURT (Sixth Chamber),

composed, at the time of the deliberations, of M.J. Costeira (Rapporteur), President, M. Kancheva and P. Zilgalvis, Judges,

Registrar: S. Spyropoulos, Administrator,

having regard to the order of 31 July 2024, *Djchem Chemicals Poland* v *Commission* (T-174/24 R, not published, EU:T:2024:513),

having regard to the written part of the procedure,

further to the hearing on 24 September 2025,

gives the following

Judgment

1 By their action under Article 263 TFEU, the applicants, Djchem Chemicals Poland S.A. and The Goodyear Tire & Rubber Company, seek the annulment of Commission Delegated Regulation (EU) 2024/197 of 19 October 2023 amending Regulation (EC) No 1272/2008 as regards the harmonised classification and labelling of certain substances (OJ L, 2024/197; 'the contested regulation'), in so far as it introduces the harmonised classification and labelling of 1,4-Benzenediamine, N,N'-mixed Ph and tolyl derivs. ('DAPD') in the hazard class reproductive toxicity category 1B.

Background to the dispute

2 Djchem Chemicals Poland is a company incorporated under Polish law and The Goodyear Tire & Rubber is a company incorporated under United States law. They market and use, in particular in the European Union, DAPD and products containing that substance.

3 DAPD, also known by the acronym Benpat, is a multi-constituent substance composed of three constituents, namely (i) N,N'-diphenylbenzene-1,4-diamine; (ii) N,N'-bis(2-methylphenyl)benzene-1,4-diamine; and (iii) N-(2-methylphenyl)-N'-phenylbenzene-1,4-diamine. That substance is used as an antioxidant in synthetic materials such as polymers or industrial rubber products.

4 The Goodyear Tire & Rubber appointed Labcorp Early Development Services GmbH as its exclusive representative in the European Union, under Article 8 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).

5 Djchem Chemicals Poland and Labcorp Early Development Services are 'registrants' of DAPD, within the meaning of point 7 of Article 3 of Regulation No 1907/2006 and of point 13 of Article 2 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 No 1907/2006 (OJ 2008 L 353, p. 1).

6 The applicants adopted self-classification decisions for DAPD as toxic for reproduction, category 2.

7 In February 2021, the Bundesstelle für Chemikalien (Federal Office for Chemicals, Germany) of the Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (Federal Institute for Occupational Safety and Health, Germany) ('the submitter of the classification proposal') submitted to the European Chemicals Agency (ECHA), pursuant to Article 37(1) of Regulation No 1272/2008, a proposal for harmonised classification and labelling of DAPD for, inter alia, the hazard class reproductive toxicity, category 1B, with the hazard statement code 'H360FD' (May damage fertility. May damage the unborn child) ('the classification proposal').

8 Between March and May 2021, a public consultation on the classification proposal was organised. Several Member States and interested parties, including the applicants through the DAPD consortium of which they are members, submitted comments.

9 On 26 November 2021, on the basis of Article 37(4) of Regulation No 1272/2008, the ECHA Committee for Risk Assessment ('RAC') adopted, by consensus, an opinion proposing the classification of DAPD in, inter alia, the hazard class reproductive toxicity, category 1B, with the hazard statement code 'H360FD' ('the RAC opinion').

10 On 19 October 2023, on the basis of the RAC opinion, the European Commission adopted the contested regulation. By Article 1 of that regulation, DAPD was added to Table 3 of Part 3 of Annex VI to Regulation No 1272/2008, with a harmonised classification and labelling in the hazard class reproductive toxicity, category 1B, with the hazard statement code 'H360FD' (May damage fertility. May damage the unborn child) ('the contested classification'). Furthermore, the contested regulation introduced the harmonised classification and labelling of that substance in the hazard class skin sensitisation, category 1, with the hazard statement code 'H317' (May cause an allergic skin reaction).

11 Pursuant to the second paragraph of Article 2 of the contested regulation, the amendments to Annex VI to Regulation No 1272/2008, in so far as the contested classification is concerned, apply from 1 September 2025 onwards.

Forms of order sought

12 The applicants claim that the Court should:

– annul the contested regulation as regards the contested classification;

– order the Commission to pay the costs.

13 The Commission, supported by the Federal Republic of Germany, the Kingdom of the Netherlands and ECHA, contends that the Court should:

– dismiss the action;

– order the applicants to pay the costs.

Law

14 In support of their action, the applicants put forward three pleas in law, alleging:

– first, infringement of Article 36(1)(d) and Article 37(5) of Regulation No 1272/2008 and of Sections 1.1.1.3., 1.1.1.5., 3.7.2.1.1. and 3.7.2.3.1. and Table 3.7.1(a) of Annex I to that regulation;

– second, manifest errors of assessment;

– third, breach of the principle of proportionality, of the rights of the defence and of the principle of good administration.

Preliminary considerations on the harmonised classification and labelling of substances in the hazard class reproductive toxicity

15 As a preliminary point, it should be noted that, in accordance with recital 1 and Article 1(1) of Regulation No 1272/2008, the purpose of that regulation is to ensure a high level of protection of human health and the environment as well as the free movement of chemical substances, mixtures and certain specific articles within the EU market. As is apparent, in particular, from recitals 5 to 8, 10 and 27 of that regulation, the latter's objective is to determine the intrinsic properties of substances which should lead to their classification as hazardous products, so that the hazards posed by those substances (and by mixtures containing such substances) can be correctly identified and communicated. To that end, in accordance with Article 1(1)(a),

that regulation aims, inter alia, to '[harmonise] the criteria for classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures'.

16 In addition, 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 the level of the United Nations Organisation, but also through the incorporation of the internationally agreed Globally Harmonized System of Classification and Labelling of Chemicals criteria into EU law. To that effect, Annex I to that regulation reproduces verbatim almost all of the provisions of that system (judgment of 22 November 2017, *Commission* v *Bilbaína de Alquitranes and Others*, C-691/15 P, EU:C:2017:882, paragraph 42).

17 As regards the classification of hazardous substances and mixtures, it should be noted that, according to Article 3 of Regulation No 1272/2008, a substance or a mixture fulfilling the criteria relating to physical hazards, health hazards or environmental hazards, as laid down in Annex I to that regulation, is hazardous and is to be classified in relation to the respective hazard classes provided for in that annex.

18 In that regard, Regulation No 1272/2008 provides, in Title V, for a procedure for harmonisation, throughout the European Union, of classification and labelling of substances, which concerns substances fulfilling the criteria set out in Annex I for the hazards listed in Article 36(1)(a) to (d) of that regulation, including for the hazard of reproductive toxicity. That regulation also lays down, in particular in Articles 5, 9 and 13 thereof, a self-classification obligation imposed on manufacturers, importers and downstream users, which relates to substances and mixtures.

19 The procedure for harmonisation of classification and labelling of substances is triggered by the competent authority of a Member State or by manufacturers, importers or downstream users of a substance, and by the submission, to ECHA, of a proposal for harmonised classification and labelling of that substance, in accordance with Article 37(1) and (2) of Regulation No 1272/2008. Next, RAC is to 'adopt an opinion on any proposal submitted … giving the parties concerned the opportunity to comment', and ECHA is to 'forward this opinion and any comments to the Commission', in accordance with Article 4(4) of that regulation. Lastly, where the Commission finds that the harmonisation of classification and labelling of the substance concerned is appropriate, it is to adopt a delegated act, in accordance with Article 37(5) and Article 53a of that regulation, in order to amend Annex VI to that regulation by including, in Table 3 of Part 3 of that annex, the substance in question together with the relevant classification and labelling elements.

20 As regards the hazard of reproductive toxicity, Article 36(1)(d) of Regulation No 1272/2008 provides that, if a substance fulfils the criteria set out in Annex I to that regulation for the hazard of reproductive toxicity, it will normally be subject to harmonised classification and labelling. Those criteria are laid down in Section 3.7. of Annex I to the regulation.

21 In particular, in the first paragraph and in points (a) and (b) of the second paragraph of Section 3.7.1.1. of Annex I to Regulation No 1272/2008, it is provided that reproductive toxicity is subdivided into two 'headings' of adverse effects, the first relating to adverse effects on sexual function and fertility in adult males and females, and the second to adverse effects on development of their offspring.

22 As regards hazard categories, it follows from Section 3.7.2.1.1. and from Table 3.7.1(a) of Annex I to Regulation No 1272/2008 that classification for reproductive toxicity is divided into two categories, namely category 1, which is subdivided into categories 1A and 1B, and category 2. In particular, category 1B corresponds to presumed human reproductive toxicants and category 2 corresponds to suspected human reproductive toxicants.

23 Furthermore, it should be noted that Regulation No 1272/2008 concerns the assessment of hazards of substances and that that assessment must be distinguished from the risk assessment provided for in Regulation No 1907/2006. The assessment of hazards constitutes

the first stage of the process of risk assessment, which is a more specific concept. Thus, an assessment of the hazards linked to the substances' intrinsic properties must not be limited in light of specific circumstances of use, as in the case of a risk assessment, and may be properly carried out regardless of the place where the substance is used (in a laboratory or elsewhere), or the possible levels of exposure to the substance (see, to that effect, judgment of 21 July 2011, *Nickel Institute*, C-14/10, EU:C:2011:503, paragraphs 81 and 82).

Preliminary observations on the intensity of the Court's review

24 As regards the intensity of the Court's review, it should be borne in mind that, according to settled case-law, if the Commission is to be able to classify a substance pursuant to Regulation No 1272/2008, account being taken of the complex scientific and technical assessments which it must undertake, it must be recognised as enjoying a broad discretion (see judgment of 22 November 2017, *Commission* v *Bilbaína de Alquitranes and Others*, C-691/15 P, EU:C:2017:882, paragraph 34 and the case-law cited).

25 However, the exercise of that discretion is not excluded from review by the Court. The latter has consistently held that, in the context of such a review, the EU judicature must verify whether the relevant procedural rules have been complied with, whether the facts admitted by the Commission have been accurately stated and whether there has been a manifest error of appraisal or a misuse of power (see judgment of 18 July 2007, *Industrias Químicas del Vallés* v *Commission*, C-326/05 P, EU:C:2007:443, paragraph 76 and the case-law cited).

26 In particular, where a party claims that the institution competent in the matter has committed a manifest error of assessment, the EU judicature must verify whether that institution has examined, carefully and impartially, all the relevant facts of the individual case on which that assessment was based. That duty to act diligently is inherent in the principle of sound administration and applies generally to the actions of the EU administration (see judgment of 22 November 2017, *Commission* v *Bilbaína de Alquitranes and Others*, C-691/15 P, EU:C:2017:882, paragraph 35 and the case-law cited).

27 Furthermore, the limits on the review by the EU judicature do not affect the latter's duty to establish whether the evidence relied on is factually accurate, reliable and consistent and to review whether that evidence contains all the information which must be taken into account in order to assess a complex situation and whether it is capable of substantiating the conclusions drawn from it (see, to that effect, judgment of 6 November 2008, *Netherlands* v *Commission*, C-405/07 P, EU:C:2008:613, paragraph 55 and the case-law cited).

28 It must be added that, in order to establish that the administration made a manifest error in assessing complex facts such as to justify the annulment of the contested measure, the evidence adduced by the applicant must be sufficient to make the factual assessments used in that measure implausible. Without prejudice to that examination of plausibility, it is not for the General Court to substitute its assessment of complex facts for that of the institution which adopted the measure (see judgment of 17 May 2018, *BASF Agro and Others* v *Commission*, T-584/13, EU:T:2018:279, paragraph 94 and the case-law cited; see also, to that effect and by analogy, judgment of 14 June 2018, *Lubrizol France* v *Council*, C-223/17 P, not published, EU:C:2018:442, paragraph 39).

29 Furthermore, as regards the evaluation of scientific studies, the Court has already held that the Commission must be allowed a broad discretion with regard to that assessment, as well as the choice of studies which must take precedence over others, irrespective of their chronology. Thus, it is not sufficient for the applicant to rely on the age of a scientific study to call into question its reliability, but it is also necessary for the applicant to provide sufficiently precise and objective evidence to argue that any recent scientific developments would call into question the soundness of the conclusions of such a study (see, to that effect, judgment of 24 October 2018, *Deza* v *Commission*, T-400/17, not published, EU:T:2018:712, paragraph 95).

30 It is in the light of those considerations that the applicants' pleas in law must be examined.

The first plea in law, alleging infringement of Article 36(1)(d) and Article 37(5) of Regulation No 1272/2008 and of Sections 1.1.1.3., 1.1.1.5., 3.7.2.1.1. and 3.7.2.3.1. and Table 3.7.1(a) of Annex I to that regulation

31 The present plea alleges infringement of Article 36(1)(d) and Article 37(5) of Regulation No 1272/2008 and of Sections 1.1.1.3., 1.1.1.5., 3.7.2.1.1. and 3.7.2.3.1. and of Table 3.7.1(a) of Annex I to that regulation. It is divided into five complaints relating to:

– first, the lack of clear evidence demonstrating the relevance of adverse effects of DAPD in humans;

– second and third, failure to take into account all the relevant information;

– fourth, failure to use the read-across approach;

– fifth, infringement of Article 36(1)(d) and Article 37(5) of Regulation No 1272/2008.

32 The Commission, supported by the Federal Republic of Germany, the Kingdom of the Netherlands and ECHA, disputes the applicants' arguments.

The first complaint, relating to the lack of clear evidence demonstrating the relevance of adverse effects of DAPD in humans

33 The applicants submit that the Commission infringed Section 3.7.2.1.1. and Table 3.7.1(a) of Annex I to Regulation No 1272/2008 on account of the lack of clear evidence demonstrating the relevance of adverse effects of DAPD in humans, as required for the classification of a substance as toxic for reproduction, category 1B. However, there are, in their view, doubts as to the reasons for adverse effects on sexual function and fertility observed in rats, in particular as regards the mechanism of the effects and dystocia. Thus, they argue, the Commission should not have assumed that those effects are relevant in humans, since that would amount to a 'suspicion' that the effects are relevant for humans, and not a 'presumption' of relevance, as is required for the classification of a substance in category 1B. Both the submitter of the classification proposal and RAC accepted that those doubts existed. The applicants claim that the Commission reversed the burden of proof, expecting the applicants to prove that there were no effects in order to cast doubt on the alleged appropriateness of a classification in category 1B.

34 In the reply, the applicants add that the Malik (2020) study demonstrates major differences between rats and humans as regards the anatomy and physiology of the uterus. Furthermore, they argue that it is apparent from Table 3.7.1(a) of Annex I to Regulation No 1272/2008 that, where doubts arise, classification in category 2 is more appropriate.

35 As stated in paragraph 21 above, the first paragraph and points (a) and (b) of the second paragraph of Section 3.7.1.1. of Annex I to Regulation No 1272/2008 provide that 'reproductive toxicity' is subdivided into two 'headings' of adverse effects, the first relating to adverse effects on sexual function and fertility in adult males and females, and the second to adverse effects on the development of their offspring.

36 In addition, as stated in paragraph 22 above, it follows from Section 3.7.2.1.1. and from Table 3.7.1(a) of Annex I to Regulation No 1272/2008 that classification for reproductive toxicity is divided into two categories, namely category 1, which is subdivided into categories 1A and 1B, and category 2. Category 1B corresponds to presumed human reproductive toxicants and category 2 corresponds to suspected human reproductive toxicants.

37 Furthermore, Table 3.7.1(a) of Annex I to Regulation No 1272/2008 provides, inter alia, that substances are classified in category 1 when 'there is evidence from animal studies, possibly supplemented with other information, to provide a strong presumption that the substance has the capacity to interfere with reproduction in humans'. In particular, a substance is classified in category 1B when such data from animal studies 'provide clear evidence of an adverse effect

on sexual function and fertility or on development in the absence of other toxic effects, or if occurring together with other toxic effects the adverse effect on reproduction is considered not to be a secondary non-specific consequence of other toxic effects'. As regards the latter category, it is also stated in that table that, 'however, when there is mechanistic information that raises doubt about the relevance of the effect for humans, classification in category 2 may be more appropriate.'

38 In the present case, as follows from the opinion of RAC, the latter found that DAPD had adverse effects on both sexual function and fertility and on development, relying on data from animal studies. As regards adverse effects on sexual function and fertility, RAC stated that it agreed with the classification proposal, taking the view that the classification of that substance in category 1B was justified, on the basis of adverse effects on female fertility, namely abnormal cycles, increased gestation duration, dystocia and offspring mortality. In its view, those effects had been observed in the absence of marked maternal toxicity and were considered relevant for humans. As regards adverse developmental effects, it concluded that there was clear evidence of adverse effects on foetal development (including post-implantation loss) in animals, that those effects were not considered secondary to marked general toxicity and that they were relevant for humans.

39 The applicants submit that there was no 'clear evidence' demonstrating the relevance of the observed adverse effects for humans.

40 However, contrary to what appears to follow from the applicants' line of argument, the criteria for classification of a substance as toxic for reproduction category 1B, set out in Table 3.7.1(a) of Annex I to Regulation No 1272/2008, do not require clear evidence of the relevance, for humans, of the adverse effects observed in animals. However, as follows from paragraph 37 above, those provisions require, in essence, first, the existence of data, in particular from animal studies, clearly demonstrating an adverse effect on sexual function and fertility or on development in animals, and the absence of other toxic effects, or demonstrating, if other toxic effects are observed, that the toxic effect on reproduction is considered not to be a secondary non-specific consequence of those other toxic effects and, second, that there is no information casting doubt on the relevance of those adverse effects for humans and making classification in category 2 possibly more appropriate.

41 In the present case, it does not follow from the RAC opinion that there was information calling into question the relevance, for humans, of the adverse effects of DAPD observed in rats. On the contrary, RAC concluded, on the basis of animal studies which it identified, that the adverse effects on female fertility, namely abnormal cycles, increased gestation duration, dystocia and offspring mortality, which had been observed in those studies, were considered relevant for humans (see paragraph 38 above). In that regard, it stated that there were no available human data on adverse effects on sexual function or fertility in the event of exposure to that substance and that there was no evidence that the adverse effects observed in animal studies were not relevant for humans. Moreover, according to RAC, there was no 'mechanistic information' indicating that the effects observed were not relevant for humans. Consequently, it considered that the adverse effects on sexual function and fertility reported in rats were relevant for humans.

42 The applicants' general assertion that there are uncertainties or doubts concerning the mechanism of the effects and studies which demonstrate 'major differences between rats and humans regarding anatomy and physiology of the uterus' is not sufficient, in the absence of other details, to call into question the plausibility of RAC's assessment referred to in paragraph 41 above.

43 Consequently, the applicants are wrong to maintain that the Commission reversed the burden of proof by expecting the applicants to prove that there are no effects in order to cast doubt on the alleged appropriateness of a classification in category 1B.

44 In addition, as regards the applicants' arguments relating to dystocia, they will be examined below, in the context of the second complaint of the present plea.

45 The first complaint must therefore be rejected as unfounded, without it being necessary to rule on the admissibility of the arguments raised, for the first time, in the reply.

The second and third complaints, relating to a failure to take into account all the relevant information

46 By the second and third complaints, the applicants claim that the Commission infringed Sections 1.1.1.3. and 1.1.1.5. of Annex I to Regulation No 1272/2008 by failing to weigh up all the evidence produced by the applicants. They argue that they had, however, submitted evidence demonstrating that there were insufficient available data to presume that the effects observed in rats were likely to occur in humans.

47 In that regard, in the first place, the applicants submit that the Sugitomo et al. (2015) and Mitchell et al. (2009) studies and the document justifying the self-classification of DAPD demonstrated that the adverse effect observed in rats, namely dystocia, is caused by a mechanism of prostaglandin inhibition, which, in the applicants' view, gives rise to doubts as to the relevance of that effect in humans, given that prostaglandin plays a more important role in the process of parturition in rats than in the process of parturition in humans. They submit that RAC's assertion that prostaglandin PGF2alpha plays a significant role during childbirth in humans is not substantiated in any way and does not address the doubts which the applicants had raised. They accept that prostaglandin plays a role in parturition in humans, but claim that that role is not decisive.

48 In the second place, the applicants submit that account should be taken of the fact that humans will not be exposed to DAPD, which, they argue, gives rise to serious doubts as to the relevance, for humans, in real life, of animal studies in which that substance is administered directly to animals at high doses.

49 In the third place, the applicants submit that the Commission failed to take into account the comments which they had submitted on the classification proposal, which, they argue, demonstrate that the adverse effects on kidneys were direct toxicity effects rather than developmental effects. In that regard, they refer to the arguments which they put forward in the context of the second plea.

50 As a preliminary point, it should be noted that, according to Section 1.1.1.3. of Annex I to Regulation No 1272/2008:

'A weight of evidence determination means that all available information bearing on the determination of hazard is considered together, such as the results of suitable *in vitro* tests, relevant animal data, information from the application of the category approach (grouping, read-across), (Q)SAR [(quantitative) structure–activity relationship)] results, human experience such as occupational data and data from accident databases, epidemiological and clinical studies and well-documented case reports and observations. The quality and consistency of the data shall be given appropriate weight. Information on substances or mixtures related to the substance or mixture being classified shall be considered as appropriate, as well as site of action and mechanism or mode of action study results. Both positive and negative results shall be assembled together in a single weight of evidence determination.'

51 Furthermore, Section 1.1.1.5. of Annex I to Regulation No 1272/2008 provides that 'for the purpose of classification for health hazards … route of exposure, mechanistic information and metabolism studies are pertinent to determining the relevance of an effect in humans', that 'when such information, as far as there is reassurance about the robustness and quality of the data, raises doubt about relevance in humans, a lower classification may be warranted' and that, 'when there is scientific evidence that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified.'

52 As regards the weight of evidence in the hazard class reproductive toxicity, Section 3.7.2.3.1. of Annex I to Regulation No 1272/2008 provides, inter alia, that 'classification as a

reproductive toxicant is made on the basis of an assessment of the total weight of evidence', that 'the weight given to the available evidence will be influenced by factors such as the quality of the studies, consistency of results, nature and severity of effects, the presence of maternal toxicity in experimental animal studies, level of statistical significance for inter-group differences, number of endpoints affected, relevance of route of administration to humans and freedom from bias' and that 'both positive and negative results are assembled together into a weight of evidence determination.'

53 In the first place, the applicants submit that the Commission failed to take into account all the relevant evidence submitted by the applicants, namely the Sugitomo et al. (2015) and Mitchell et al. (2009) studies and the document justifying the self-classification of DAPD. Those documents demonstrated that there were insufficient data available to presume that the adverse effect of DAPD observed in rats, namely dystocia caused by prostaglandin inhibition, was likely to occur in humans.

54 However, it appears that, in the present case, the Commission took into account the Sugitomo et al. (2015) and Mitchell et al. (2009) studies as well as the document justifying the self-classification of DAPD for the purposes of the contested classification.

55 As regards the document justifying the self-classification of DAPD, it should be noted, as the Commission has submitted, that that document was compulsorily part of the dossier for the classification proposal, in accordance with Article 37(1) of Regulation No 1272/2008, read in conjunction with Parts 1 and 2 of Annex VI to that regulation. The Commission cannot therefore be criticised for not having taken that document into account.

56 As regards the Sugitomo et al. (2015) and Mitchell et al. (2009) studies, it should be noted that the latter study is expressly referred to, in particular, in the classification proposal and in the RAC opinion. What is apparent from the file is that the applicants and the Commission have different views as to the relevance of those studies. The applicants consider that those studies showed that prostaglandin inhibition does not cause dystocia in humans. By contrast, the Commission takes the view that those studies do not dispute the adverse effects of prostaglandin inhibition on the process of parturition in humans and are not such as to constitute 'mechanistic information that raises doubt about the relevance of the effect for humans' within the meaning of the provisions of Table 3.7.1(a) of Annex I to Regulation No 1272/2008.

57 In that regard, it is apparent from the RAC opinion that the submitter of the classification proposal acknowledged that the process of parturition differed between humans and rats, but also noted that prostaglandin PGF2alpha played a significant role in childbirth in humans. In addition, RAC observed that studies showed that one of the three constituents of DAPD, namely N,N'-diphenylbenzene-1,4-diamine ('the constituent DPPD'), acted as a prostaglandin inhibitor and that, in humans, prostaglandins play an important role in various physiological mechanisms, such as pregnancy and childbirth.

58 RAC also stated that there was no 'mechanistic information' indicating that the observed adverse effects were not relevant for humans and stated that, therefore, the adverse effects on sexual function and fertility reported in rats were considered relevant for the classification of DAPD (see paragraph 41 above).

59 It follows from the foregoing that RAC took into account the fact that the process of parturition differed between humans and rats, but that it also found that prostaglandin PGF2alpha played an important role in childbirth in humans.

60 It follows that the Commission did in fact take into consideration the Sugitomo et al. (2015) and Mitchell et al. (2009) studies submitted by the applicants, but that it does not share the applicants' view as to the relevance of those studies, in particular as regards the assessment of a complex scientific element, namely the role of prostaglandin in humans.

61 It should also be noted that, contrary to what the applicants claim, the criteria for classification of a substance as toxic for reproduction category 1B, set out in Table 3.7.1(a) of Annex I to Regulation No 1272/2008, do not require 'clear evidence' of the relevance, for humans, of the adverse effects observed in animals. As follows from paragraph 37 above, those criteria merely require, in essence, first, the existence of data, in particular from animal studies, clearly demonstrating an adverse effect on sexual function and fertility or on development in animals, and the absence of other toxic effects, or demonstrating, if other toxic effects are observed, that the toxic effect on reproduction is considered not to be a secondary non-specific consequence of those other toxic effects and, second, that there is no information casting doubt on the relevance of those adverse effects for humans and making classification in category 2 possibly more appropriate.

62 In the present case, RAC concluded, without the plausibility of that conclusion being called into question by the applicants' arguments, that, first, the animal studies identified in its opinion clearly demonstrated an adverse effect of DAPD on sexual function and fertility, namely dystocia caused by prostaglandin inhibition, and that, second, there was no information calling into question the relevance of those effects for humans.

63 Accordingly, the applicants are wrong to claim that the Commission failed to take into account all the relevant data for the purposes of the contested classification.

64 In the second place, the applicants submit that account should be taken of the fact that humans are not exposed to DAPD in real life.

65 In that regard, it is sufficient to recall that, as follows from the case-law cited in paragraph 23 above, Regulation No 1272/2008 concerns the assessment of hazards of substances and that that assessment must be distinguished from the risk assessment provided for in Regulation No 1907/2006. An assessment of the hazards linked to the substances' intrinsic properties must not be limited in light of specific circumstances of use, as in the case of a risk assessment, and may be properly carried out regardless of the place where the substance is used or the possible levels of exposure to the substance.

66 It follows that, in the context of harmonised classification and labelling of DAPD on the basis of an assessment of the hazards linked to its intrinsic properties, in accordance with Regulation No 1272/2008, the Commission was not required to take into account the circumstances of exposure to that substance.

67 In the third place, as regards the applicants' argument relating to the adverse effects on kidneys, it is appropriate to examine it in the context of the second plea, to which, moreover, the applicants refer.

68 The second and third complaints must therefore be rejected as unfounded.

The fourth complaint, relating to the non-use of the read-across approach

69 The applicants claim that the Commission infringed Sections 1.1.1.5. and 3.7.2.3.1. of Annex I to Regulation No 1272/2008, in so far as it did not use the read-across approach in order to take into account the mechanistic study relating to the constituent DPPD as being representative for all constituents of DAPD. Such read-across data are one of the available pieces of evidence under Section 3.7.2.3.1. of that annex and, in the case of multi-constituent substances, as is the case with DAPD, the use of read-across is a well-established practice. In addition, the constituent DPPD and the other constituents of DAPD share the same mode of action and RAC itself took data relating to the constituent DPPD in order to support its conclusion on the classification of DAPD. By failing to take into account the read-across data, the Commission, in the applicants' submission, infringed the abovementioned provisions and misused its discretion, in breach of the principles of 'excellence, transparency and independence'.

70 As regards the read-across approach, it follows from Section 1.5. of Annex XI to Regulation No 1907/2006 that it is an approach which makes it possible to predict, by interpolation, the properties of a target substance by using data relating to one or more substances in the same group.

71 In the procedure for harmonisation of classification and labelling of substances, it follows from Article 9(3) of Regulation No 1272/2008 that, where the criteria for classification for each hazard class cannot be applied directly to available identified information, a weight of evidence approach must be used, in accordance with Section 1.1.1. of Annex I to that regulation. More specifically, it follows from Section 1.1.1.3. of that annex that the weight of evidence determination means that all available information bearing on the determination of hazard is considered together, including information from the application of the category approach, which includes read-across.

72 As regards weight of evidence in the context of the hazard class reproductive toxicity, Section 3.7.2.3.1. of Annex I to Regulation No 1272/2008 provides that all available information that bears on the determination of reproductive toxicity is to be considered together. Evaluation of substances chemically related to the substance under study may also be included for the classification, 'particularly when information on the substance is scarce'.

73 Section 1.5. of Annex XI to Regulation No 1907/2006 provides, inter alia, that 'substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or "category" of substances', that 'application of the group concept requires that physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach)' and that 'this avoids the need to test every substance for every endpoint.'

74 The provisions of Section 1.5. of Annex XI to Regulation No 1907/2006 are relevant to the procedure for harmonisation of classification and labelling at issue in the present case, in accordance with Article 5(1)(c), Article 6(1)(c) and Article 8(1) of Regulation No 1272/2008. They are also relevant as regards data relating not to other substances belonging to the same group, but to constituents of a multi-constituent substance such as that at issue in the present case (see paragraph 3 above).

75 It follows from paragraphs 70 to 74 above that it is true that any information arising from the application of the read-across approach constitutes one of the available pieces of evidence under Section 3.7.2.3.1. of Annex I to Regulation No 1272/2008. However, the use of that approach is subject to the conditions referred to in paragraph 72 above and is not, in any event, mandatory, as follows from the wording of Section 3.7.2.3.1. of that annex, according to which that method 'may' be taken into account.

76 In the present case, it is apparent from the RAC opinion that the contested classification is based on animal studies relating to DAPD itself, namely, primarily, the two-generation reproduction toxicity study (OECD TG 416) and, by way of support, the one-generation reproduction toxicity study (non-guideline study).

77 In addition, it should be noted that, even though RAC did not use the read-across approach on the basis of studies relating to the constituent DPPD, its opinion does not ignore those studies, namely the Fujimoto et al. (1984) and Marois (1998) studies. In that regard, RAC considered that dystocia and prolonged parturition induced by that constituent in animals were evidence supporting a possible mode of action. However, it considered that the effects observed for DAPD could not be attributed solely to that constituent, since that substance contained other components and impurities whose toxicity and mode of action were unknown.

78 In that context, even if it were accepted that the conditions for using the read-across approach, which are referred to in paragraph 72 above, were satisfied and that data could be

obtained from studies on one of the constituents of DADP, the fact remains that the Commission was not required to use that method.

79 It should be noted that, in the context of the weight of evidence, the Commission has a broad discretion in deciding to use the read-across approach, in accordance with Section 3.7.2.3.1. of Annex I to Regulation No 1272/2008, referred to in paragraph 72 above. In addition, in accordance with Section 3.7.2.3.1. of that annex, the evaluation of substances chemically related to the substance under study may be taken into account for classification 'particularly when information on the substance is scarce', which was not the case here since there were studies relating to DAPD itself.

80 Accordingly, the fact that the Commission did not use the read-across approach for the purposes of the contested classification does not constitute an infringement of Sections 1.1.1.5. and 3.7.2.3.1 of Annex I to Regulation No 1272/2008.

81 Consequently, the applicants' arguments alleging misuse of discretion and breach of the principles of 'excellence, transparency and independence' cannot succeed.

82 The fourth complaint must therefore be rejected as unfounded.

The fifth complaint, relating to infringement of Article 36(1)(d) and Article 37(5) of Regulation No 1272/2008

83 The applicants claim that, as a result of the errors made by the Commission, the latter infringed Article 36(1)(d) and Article 37(5) of Regulation No 1272/2008.

84 In that regard, it is sufficient to note that the applicants merely refer to the arguments which they put forward in the context of the first four complaints of the first plea; those complaints have been rejected (see paragraphs 45, 68 and 82 above).

85 Accordingly, the fifth complaint must be rejected as unfounded and, consequently, the first plea must be rejected in its entirety.

The second plea in law, alleging manifest errors of assessment

86 The applicants submit that the Commission made several manifest errors of assessment in classifying DAPD as a substance that is toxic for reproduction category 1B.

87 The Commission, supported by the Federal Republic of Germany, the Kingdom of the Netherlands and ECHA, disputes the applicants' arguments.

88 In the first place, the applicants claim that, if the Commission had not wrongly presumed the relevance, for humans, of the adverse effects of DAPD that were observed in rats, or had not ignored the doubts which the applicants had raised in that regard, and if it had taken a view on the possible need for further testing, that would have led it to classify DAPD in category 2.

89 In that regard, it should be noted that the applicants' arguments relating to the relevance, for humans, of the adverse effects of DAPD that were observed in rats are identical to the arguments put forward in the context of the first and second complaints of the first plea. Those arguments must therefore be rejected for the same reasons as those set out in paragraphs 35 to 45 and 50 to 68 above.

90 Furthermore, as regards the applicants' argument concerning the lack of additional tests, it is appropriate to examine it in the context of the third plea.

91 In the second place, the applicants submit that, by relying on the RAC opinion, the Commission disregarded the mechanistic studies which, in the applicants' view, give rise to doubts as to the mode of action of DAPD in humans. In particular, they argue that RAC should have considered that the absence of evidence supporting other explanations allowed,

at most, a suspicion, rather than a presumption, that prostaglandin inhibition might be relevant to humans. In addition, the applicants argue that the Commission wrongly rejected the importance of the data relating to the constituent DPPD showing that prostaglandin inhibition is the mechanism that is actually responsible for dystocia in rats.

92 In that regard, it is sufficient to note that the arguments referred to in paragraph 91 above, alleging, in essence, that the Commission ignored mechanistic studies that gave rise to doubts as to the mode of action of DAPD in humans, namely studies on the constituent DPPD, are identical to the arguments put forward in the fourth complaint of the first plea. Those arguments must therefore be rejected for the same reasons as those set out in paragraphs 70 to 82 above.

93 In the third place, the applicants submit that the Commission did not take into account the reversibility of the effects observed on kidneys (polycystic kidneys) following exposure to DAPD, when only the irreversible effects on reproduction justify a classification in category 1B. In addition, the post-implantation losses were not due to those effects on kidneys, which are developmental effects, but rather were due to dystocia, which is an effect on fertility.

94 As regards the reversibility of the effects observed on kidneys, it follows from the opinion of RAC that the latter considered that the fact that polycystic kidneys are also observed in adults indicates that the effect is not fully reversible and that, overall, it is not clearly established whether polycystic kidneys are the result of exposure to DAPD *in utero*, via lactation or via diet (or a combination thereof).

95 As regards post-implantation losses, it follows from the opinion of RAC that the latter considered that consistent and dose-related post-implantation losses were key to the classification of DAPD under the heading of developmental effects. In addition, it took the view that polycystic kidneys observed in offspring were a factor which supported that conclusion, given that the effects were regarded as permanent and serious, but that it was not certain that they were due solely to *in utero* exposure.

96 It follows that RAC, first, took into account the reversibility of polycystic kidneys and concluded that the effect was not entirely reversible and, second, considered that polycystic kidneys, the causes of which were unclear, were merely a factor in support of its conclusion that post-implantation losses were in themselves an irreversible and dose-related effect and therefore key to the classification of DAPD under the heading of developmental effects.

97 Accordingly, the applicants' arguments concerning polycystic kidneys and post-implantation losses are based on a misreading of the RAC opinion and cannot therefore succeed. In any event, those arguments are not sufficient to call into question the plausibility of the RAC's assessments and therefore to establish that the Commission made a manifest error of assessment.

98 In the fourth place, the applicants submit that the classification of DAPD in category 1B is arbitrary and unjustified, in so far as that substance is similar to salicylic acid and acetylsalicylic acid, which are classified as toxic for reproduction category 2. The applicants therefore rely on breach of the principle of equal treatment.

99 In that regard, it should be recalled that the principle of equal treatment requires that comparable situations must not be treated differently and different situations must not be treated in the same way unless such treatment is objectively justified (see judgment of 16 December 2008, *Arcelor Atlantique et Lorraine and Others*, C-127/07, EU:C:2008:728, paragraph 23 and the case-law cited).

100 In addition, it must be borne in mind that the procedure for harmonisation of classification and labelling of substances, pursuant to Title V of Regulation No 1272/2008, relates only to the substance which, first of all, is the subject of the classification proposal submitted to the Commission, the initiative for which belongs to those identified in Article 37 of that regulation, next, is the subject of the RAC opinion on the proposal that was submitted and, lastly, is the

subject of a delegated act of the Commission, where the latter considers that harmonisation is appropriate (see paragraph 19 above). In the present case, the procedure for harmonised classification and labelling at issue cannot therefore be based on a comparison between DAPD and other substances which have not been the subject of such a procedure.

101 The contested classification covers only DAPD, in accordance with the classification proposal and the procedure for harmonisation of classification and labelling which gave rise to it (see paragraphs 7 to 10 above). Thus, the fact that DAPD was classified as toxic for reproduction category 1B, whereas salicylic acid and acetylsalicylic acid were classified as toxic for reproduction category 2, cannot result in a breach of the principle of equal treatment, irrespective of any similarities between those acids and DAPD.

102 Consequently, the second plea must be rejected as being unfounded.

The third plea in law, alleging breach of the principle of proportionality, infringement of the rights of the defence and breach of the principle of good administration

103 In the first place, the applicants submit that the contested regulation is in breach of the principle of proportionality, laid down in Article 5(4) TEU, since the Commission should have pursued the objectives of Regulation No 1272/2008 by balancing that regulation's various objectives, namely, on the one hand, to ensure a high level of protection of human health and the environment and, on the other hand, to ensure the free movement of chemical substances, while enhancing competitiveness and innovation. They assert that DAPD has already been the subject of self-classification decisions as toxic for reproduction category 2, which entails obligations similar to those in category 1B, in particular as regards the safety and protection of workers, and does not cause disproportionate disadvantages to manufacturers and users of DAPD, of which they are part. In addition, they complain that the Commission did not carry out the economic cost-benefit analysis, advocated by Communication COM(2000) 1 final of 2 February 2000 on the precautionary principle.

104 In the second place, the applicants submit that, when adopting the contested regulation, the Commission infringed their rights of defence, in particular the right to be heard, provided for in Article 41(2)(a) of the Charter of Fundamental Rights of the European Union. First of all, they submit that RAC did not respond to the comments which they had submitted, in writing, during the public consultation, and orally, at the meetings. Next, they claim that additional information was added to the RAC opinion, without the applicants having had the opportunity to examine it. Lastly, they state that, although the Commission had a meeting with their representative and authorised it to attend several meetings of the 'Competent Authorities for REACH and CLP' expert group, the Commission did not respond to the comments which they had made. In addition, they claim that they were not able to defend their position, since they had not been authorised to carry out additional animal testing and had been placed in the impossible situation of having to demonstrate that DAPD had no adverse effects in humans. Furthermore, they complain that the Commission disregarded the Interinstitutional Agreement of 13 April 2016 between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making (OJ 2016 L 123, p. 1), which requires that a fair hearing be guaranteed and that all available information and evidence be examined before the adoption of a decision imposing constraints on the economic operators concerned.

105 In the third place, the applicants submit that the Commission acted in breach of the principle of good administration, referred to in Article 6(1) TEU and in Article 41 of the Charter of Fundamental Rights, in so far as it did not respect their right to be heard or take account of all the relevant scientific studies, as follows from the second plea. In their view, the Commission relied on the RAC opinion which did not take into account all the relevant scientific studies, thus failing to apply the weight of evidence approach.

106 The Commission, supported by the Federal Republic of Germany, the Kingdom of the Netherlands and ECHA, disputes the applicants' arguments.

107 In the first place, as regards the applicants' complaint alleging breach of the principle of proportionality, it should be recalled that, according to settled case-law, the principle of proportionality, which is one of the general principles of EU law, requires that measures adopted by EU institutions do not exceed the limits of what is appropriate and necessary in order to attain the objectives legitimately pursued by the legislation in question; when there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued (see judgment of 21 July 2011, *Etimine*, C-15/10, EU:C:2011:504, paragraph 124 and the case-law cited).

108 With regard to judicial review of the conditions referred to in paragraph 107 above, in so far as adoption by the Commission of a directive or a regulation entails political, economic and social choices on its part, in which it is called upon to undertake complex assessments, it must be stated that the Commission has a broad discretion in that respect, so that judicial review of the legality of those acts is necessarily limited. The legality of a measure adopted in that sphere can be affected only if the measure is manifestly inappropriate having regard to the objective which the Commission is seeking to pursue (see judgment of 21 July 2011, *Etimine*, C-15/10, EU:C:2011:504, paragraph 125 and the case-law cited).

109 In the present case, it should be noted at the outset that, as follows from the case-law cited in paragraph 24 above, the contested classification was made in a context of complex scientific and technical assessments which the Commission had to carry out and in respect of which it must be recognised as enjoying a broad discretion.

110 First of all, as regards the applicants' argument alleging a failure to weigh up the objectives of Regulation No 1272/2008, it follows from paragraph 15 above that the purpose of that regulation is to ensure a high level of protection of human health and the environment as well as the free movement of chemical substances, mixtures and certain specific articles within the EU market. The objective of that regulation is to determine the intrinsic properties of the substances which are to lead to their classification as hazardous products, so that the hazards posed by those substances (and mixtures containing such substances) can be correctly identified and communicated.

111 In addition, it follows from Article 1(1)(a) of Regulation No 1272/2008 that the purpose of that regulation is to ensure a high level of protection of human health and the environment as well as the free movement of substances, mixtures and articles as referred to in Article 4(8) of that regulation, by harmonising the criteria for classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures.

112 In that regard, first, it follows from Article 3 of Regulation No 1272/2008 that a substance or a mixture fulfilling the criteria relating to physical hazards, health hazards or environmental hazards, as laid down in Parts 2 to 5 of Annex I to that regulation, is hazardous and is to be classified in one of the hazard classes provided for in Annex I to that regulation.

113 In addition, it follows from Article 36 of Regulation No 1272/2008 that a substance that fulfils the criteria set out in Annex I to that regulation for the hazards indicated in paragraph 1(a) to (d) of that article, including for the hazard of reproductive toxicity, is normally subject to harmonised classification and labelling in accordance with Article 37 of that regulation.

114 Second, according to the free movement clause laid down in Article 51 of Regulation No 1272/2008, Member States are not to prohibit, restrict or impede the placing on the market of substances or mixtures which comply with that regulation and, where appropriate, with EU acts adopted in implementation of that regulation, on grounds relating to the classification, labelling and packaging of substances and mixtures within the meaning of that regulation.

115 It follows that, in the context of Regulation No 1272/2008, the objective of the free movement of chemical substances, mixtures and certain specific articles within the EU market cannot be achieved without ensuring a high level of protection of human health and the environment, which is achieved by, inter alia, the harmonised classification and labelling of substances in

order to identify and communicate their hazards. Moreover, harmonised classification and labelling do not result in a prohibition on the placing on the market of substances which comply with the provisions of that regulation.

116 Thus, in the present case, the contested classification, in so far as it adopts a harmonised classification and labelling under Article 37 of Regulation No 1272/2008, in order to identify and communicate the reproductive toxicity hazard of DAPD, must be regarded as a means of enhancing protection of health which, however, does not prevent the free movement of the substance within the EU market.

117 It follows from the foregoing that the applicants' argument alleging that the objectives of Regulation No 1272/2008 were not weighed up cannot succeed.

118 Next, as regards the applicants' argument that the contested classification is not necessary given that DAPD had already been the subject of self-classification decisions as toxic for reproduction, category 2, suffice it to note that, first, the self-classification of DAPD cannot replace the procedure for harmonisation of classification and labelling of that substance (see paragraphs 15 to 19 above) and, second, categories 1B and 2 of the hazard reproductive toxicity do not identify or communicate the same hazard. Category 1B corresponds to presumed human reproductive toxicants whereas category 2 corresponds to suspected human reproductive toxicants (see paragraph 22 above).

119 Lastly, as regards the applicants' argument based on the absence of an economic cost-benefit analysis, it should be noted that, even though such an analysis is referred to in the Communication from the Commission of 2 February 2000 on the precautionary principle, it is not however provided for in the context of the procedure for harmonisation of classification and labelling of substances referred to in Title V of Regulation No 1272/2008.

120 In that regard, as noted in paragraph 23 above, Regulation No 1272/2008 concerns the assessment of the hazards of substances and that assessment must be distinguished from the risk assessment provided for in Regulation No 1907/2006. Thus, an assessment of the hazards linked to the intrinsic properties of substances must not be limited in view of specific circumstances of use, as in the case of a risk assessment.

121 In any event, an economic cost-benefit analysis cannot derogate from the criteria for classification of substances for the hazard of reproductive toxicity, set out in Section 3.7. of Annex I to Regulation No 1272/2008 (see paragraph 20 above). As follows from a reading of the first paragraph of Article 3 in conjunction with Article 36(1) of that regulation, harmonised classification and labelling are based on criteria relating to physical hazards, health hazards or environmental hazards, as laid down in Annex I to that regulation (see paragraph 111 above), and not on other factors not provided for in that regulation.

122 The applicants' complaint alleging breach of the principle of proportionality must therefore be rejected.

123 In the second place, as regards the applicants' complaint alleging infringement of their rights of defence and, in particular, of the right to be heard, it should be noted that, according to Article 41(2)(a) of the Charter of Fundamental Rights, the right to good administration includes the right of every person to be heard before any individual measure which would affect him or her adversely is taken. Respect for the right to be heard is, in all proceedings initiated against a person which are liable to culminate in a measure adversely affecting that person, a fundamental principle of EU law which must be guaranteed even in the absence of rules governing the proceedings in question. That principle requires that the addressees of decisions which significantly affect their interests should be placed in a position in which they can effectively make known their views on the accusation made against them forming the basis of the contested measure (see, to that effect, judgment of 19 December 2019, *Probelte* v *Commission*, T-67/18, EU:T:2019:873, paragraph 86 and the case-law cited).

124 By contrast, in the case of acts of general application, neither the process of drafting them nor those acts themselves require, in accordance with the general principles of EU law, such as the right to be heard, consulted or informed, the participation of the persons affected. That is not the case if an express provision of the legal context governing the adoption of that act confers a procedural right on a person affected (see, to that effect, judgment of 19 December 2019, *Probelte* v *Commission*, T-67/18, EU:T:2019:873, paragraph 87 and the case-law cited).

125 In the present case, the contested regulation lays down measures of general application, including the contested classification. As follows from paragraph 10 above, Article 1 of that regulation lays down a measure of general application concerning the inclusion of DAPD on the 'list of harmonised classification and labelling of hazardous substances', which is set out in Table 3 of Part 3 of Annex VI to Regulation No 1272/2008.

126 Against that background, the procedural rights which the applicants enjoy in the procedure for harmonisation of classification and labelling of substances are those expressly provided for in Regulation No 1272/2008 (see, to that effect, judgment of 5 July 2023, *TIB Chemicals* v *Commission*, T-639/20, not published, EU:T:2023:374, paragraph 180 and the case-law cited).

127 In that regard, Article 37(4) of Regulation No 1272/2008 provides that 'the [RAC] … shall adopt an opinion on any proposal submitted pursuant to paragraphs 1 or 2 [of that article] within 18 months of receipt of the proposal, giving the parties concerned the opportunity to comment' and that ECHA 'shall forward this opinion and any comments to the Commission.'

128 Article 37(4) of Regulation No 1272/2008 must be interpreted in the light of the procedure for harmonisation of classification and labelling of substances, referred to in that article. As stated in paragraph 19 above, that procedure takes place in several stages, namely, first of all, the submission of a classification proposal; next, the adoption of an opinion by RAC 'giving the parties concerned the opportunity to comment'; subsequently, the forwarding, by ECHA, of that opinion and all comments to the Commission; and, lastly, the adoption, by the Commission, of a delegated act, where it considers that harmonisation of classification and labelling of the substance concerned is appropriate.

129 It follows that the public consultation provided for in Article 37(4) of Regulation No 1272/2008 is intended to allow interested parties to comment on the classification proposal and thus possibly to contribute elements not mentioned in that proposal, so as to allow RAC to take into consideration, in its opinion, the comments and elements presented by the interested parties during that phase (see, to that effect and by analogy, judgment of 9 June 2021, *Exxonmobil Petroleum & Chemical* v *ECHA*, T-177/19, not published, EU:T:2021:336, paragraph 236 and the case-law cited).

130 Accordingly, it must be noted that, although Article 37(4) of Regulation No 1272/2008 provides for the possibility of submitting comments on the proposal for harmonised classification and labelling, that regulation does not, however, provide for the possibility for the parties concerned to submit observations on RAC's opinion (see, to that effect, judgment of 5 July 2023, *TIB Chemicals* v *Commission*, T-639/20, not published, EU:T:2023:374, paragraph 184).

131 Thus, in the present case, the applicants had the right to comment on the proposal for harmonised classification and labelling of DAPD and to be heard in that regard before RAC, which did happen. Between March and May 2021, a public consultation on the classification proposal was organised and several Member States and interested parties, including the applicants through the DAPD consortium of which they are members, submitted comments (see paragraph 8 above). Moreover, as follows from the content of the opinion of RAC, the latter took into consideration the comments submitted by several Member States and parties concerned; those comments were compiled as an annex to that opinion.

132 In those circumstances and in accordance with the case-law cited in paragraphs 123 and 124 above, it should be noted that, first, the applicants did not have a right to obtain a

response from RAC to the comments which they submitted. Second, they did not have a right to be consulted on any additional information added by RAC in its opinion.

133 Furthermore, it has not been demonstrated in the present case that the applicants were prevented from carrying out additional tests or that such tests were necessary for the adoption of the contested classification. As the Commission submits, the applicants could have submitted to ECHA a testing proposal under Articles 40 and 41 of Regulation No 1907/2006. In addition, it follows from recital 3 of the contested regulation that the Commission received additional information from stakeholders challenging the scientific assessment set out in the RAC opinion, and that the Commission examined that information but did not consider it sufficient to cast doubt on the scientific analysis set out in that opinion.

134 It follows that the applicants' argument alleging infringement of the Interinstitutional Agreement referred to in paragraph 104 above, in that the Commission did not follow a fair hearing and did not examine all the available information and evidence, cannot succeed.

135 Furthermore, the applicants' argument that they were placed in the impossible situation of having to demonstrate that DAPD had no adverse effects in humans must be rejected for the same reasons previously examined in the context of the first complaint of the first plea (see paragraphs 35 to 45 above).

136 The applicants' complaint alleging infringement of their rights of defence must therefore be rejected.

137 In the third place, as regards the applicants' complaint alleging breach of the principle of good administration, it should be noted that the applicants have not put forward any new argument in relation to those which have already been rejected in the context of the examination of the second plea and the present plea.

138 Furthermore, in the reply, the applicants raise an argument alleging that there was no weight of evidence approach, without, however, explaining how the absence of such an approach, which, moreover, has not been demonstrated, is linked to the principle of good administration.

139 The applicants' complaint alleging breach of the principle of good administration must therefore be rejected.

140 Accordingly, the third plea must be rejected as unfounded and, consequently, the action must be dismissed in its entirety.

Costs

141 Under Article 134(1) of the Rules of Procedure of the General Court, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings.

142 Since the applicants have been unsuccessful, they must be ordered to bear their own costs and to pay those incurred by the Commission, in accordance with the form of order sought by the Commission, including the costs relating to the proceedings for interim relief.

143 Under Article 138(1) of the Rules of Procedure, the Member States and institutions which have intervened in the proceedings are to bear their own costs. Under Article 1(2)(g) 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, ECHA is a body of the European Union. It follows that the Federal Republic of Germany, the Kingdom of the Netherlands and ECHA shall each bear their own costs.

On those grounds,

THE GENERAL COURT (Sixth Chamber)

hereby:

1. **Dismisses the action;**

2. **Orders Djchem Chemicals Poland S.A. and The Goodyear Tire & Rubber Company to bear their own costs and to pay those incurred by the European Commission, including the costs relating to the proceedings for interim relief registered under number T-174/24 R;**

3. **Orders the Federal Republic of Germany, the Kingdom of the Netherlands and the European Chemicals Agency (ECHA) each to bear their own costs.**

Costeira Kancheva Zilgalvis

Delivered in open court in Luxembourg on 21 January 2026.

V. Di Bucci M. van der Woude

Registrar President

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* Language of the case: English.