Reviewing science-based decisions: *CWS Powder Coatings GmbH v European Commission*

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In *CWS Powder Coatings GmbH v European Commission* the EU General Court annulled a delegated regulation of the European Commission which demanded harmonised classification and labelling of titanium dioxide as a carcinogen, on the basis that this could be the case where the substance is inhaled in certain powder forms. The ruling raises significant questions regarding the extent of the role of the court in reviewing science-based decisions and we consider these below.

The classification, labelling and packaging of hazardous substances

The Classification, Labelling and Packaging (CLP) Regulation of the European Union[1] seeks to ensure the protection of human health and the environment to a 'high level of protection', while allowing chemical (and other) substances to circulate freely in the single market. It does so by mandating that manufacturers, importers or downstream users of substances correctly classify and appropriately label and package hazardous chemicals. As such it applies across all industrial products, many of which will be more specifically regulated, for example as a pesticide or a biocide, but this initial regulatory task to classify, label, and safely package underpins more specific safeguards. CLP is based upon the Globally Harmonised System (GHS) promulgated by the United Nations. The consistency and relevance the GHS brings through harmonisation is crucial to a comprehensive framework to warrant the safe use, transportation, and disposal of chemical substances, which is grounded in information concerning the hazards and toxicology of the substances placed on the market. This concept of hazard is crucial to the operation of the CLP, which seeks to determine whether a substance manifests properties that could be considered hazardous to health or environment. The classification, according to the hazard presented, drives communication of those hazards through the supply chain to the point of end use, via labels and safety data sheets, which may inform risk management, including that adopted by further regulatory measures.

As part of the responsibility placed on manufacturers, importers, or downstream users, they must classify substances or mixtures when placed on the market. In addition, they must notify the European Chemicals Agency (ECHA) of any substances registered under the EU Chemicals Regulation (REACH)[2] or notified (as hazardous) substances, whether or not they are placed on the market, and they can propose classification in line with the harmonised framework. Where a substance has no harmonised classification in Annex VI to the CLP it must be self-classified if it exhibits hazardous properties. The ECHA, established under the REACH Regulation, will maintain a classification and labelling inventory, based upon these notifications. However, while maintaining the inventory, the ECHA does not, as such, accredit or even review the information submitted. The CLP demands that data informing classification accords with accepted test methods, although it does also promote alternative test methods without resort to testing on animals. Member State authorities are charged with oversight and enforcement of the CLP.[3] The competent authorities within Member States, of their own volition, can propose revisions to classification and, as explained in the following section, this is what happened in the instant case. Classification is based on physical, health, and environmental hazards; for present purposes, one health hazard is carcinogenicity, by which is meant that

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1 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the 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 L 353, 31 December 2008, pp 1–1355.

2 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 L 396, 30 December 2006, pp 1–850.

3 See, for example, CLP Articles 4 and 46.

the substance may induce or increase the risk of cancer under exposure.[4]

Classification of titanium dioxide

A recent case in the General Court of the European Union has reviewed elements of this process of classification of substances in a judgment in which the court annulled a European Commission Regulation classifying, as a suspected carcinogen, powder forms of titanium dioxide (TiO_2).[5] The applicants in the case were manufacturers or other industrial partners or suppliers of titanium dioxide, a chemical often employed as a white pigment to coat or colour a wide variety of products including paints, varnishes, cosmetics and toys. They petitioned the court to annul Delegated Regulation of the European Commission (EU) 2020/217 of 4 October 2019 which amended Table 3 of Part 3 of Annex VI of the CLP.

The origin of this amendment was as follows. The French National Agency for Food, Environment and Occupational Health and Safety,[6] in May 2016, submitted a dossier to ECHA proposing the harmonised classification and labelling of titanium dioxide as a category 1B carcinogen. As is ordinarily the case, the dossier submitted was published and opened to comment from interested parties. Thereafter, the Committee for Risk Assessment (RAC) of ECHA adopted an Opinion which reached the decision that titanium dioxide should be classified as a Category 2 carcinogen, with a hazard code of H351 drawing attention to inhalation. It was on this basis that the European Commission produced a draft of the Delegated Regulation, which went out for consultation in January 2019, before being adopted in February 2020. The amendment to the CLP contained in the Regulation added to the harmonised classification and labelling list an entry for 'titanium dioxide (in powder form containing 1% or more of particles with aerodynamic diameter ≤ 10μm)'. Notes were added to Annex VI, which read:

> It has been observed that the carcinogenic hazard of this substance arises when respirable dust is inhaled in quantities leading to significant impairment of particle clearance mechanisms in the lung.

Together with this it was said:

> The classification as a carcinogen by inhalation applies only to mixtures in powder form containing 1% or more of titanium dioxide which is in the form of or incorporated in particles with aerodynamic diameter ≤ 10μm.

In terms of labelling, Part 2 of Annex II to the CLP was amended to include statements on packaging labels for both liquid and solid mixtures containing titanium dioxide. For liquid and solid mixtures with 1 per cent or more of titanium dioxide particles of the requisite composition, the relevant warnings read respectively:

> EUH211: 'Warning! Hazardous respirable droplets may be formed when sprayed. Do not breathe spray or mist… '
> EUH212: 'Warning! Hazardous respirable dust may be formed when used. Do not breathe dust.'

The court joined several challenges relating to these measures, all of which sought an order that the contested Commission Regulations should be annulled in terms of the classification and labelling amendments to the CLP which they introduced. As such, the object of review is the amending regulation promulgated by the Commission (as defendant), and not the determination of the carcinogenic potential of the titanium dioxide either on the part of the French regulator or the RAC of ECHA, though the latter agency supported, as intervener, the European Commission in the court. Note also that according to Title V of the CLP, the purpose of the harmonised classification and consequent labelling of titanium dioxide is to highlight its 'intrinsic properties', which determine their classification as hazardous products, and which allows its hazards to be identified and notified.

Precautionary principle

Before considering the ruling of the General Court, it is helpful to say a little about the task with which it is charged, highlighting two factors, namely the application of the precautionary principle and the wider role of the courts in reviewing scientific decision-making in regulatory contexts. Beginning with the precautionary principle, this represents an important ground for judicial review in the EU. It falls within a wider group of grounds for review recognised by the Treaty for the Functioning of the European Union (TFEU) as 'infringement of the Treaties or of any rule of law relating to their application'.[7] The principle has extensive purchase in environmental law, food safety, public health, and other areas where a high level of environmental and human health protection comes to the fore. It was

4 See the CLP Regulation Annex1 Part 3.

5 Cases T–279/20 and T–288/20 *CWS Powder Coatings GmbH v European Commission* ECLI:EU:T:2022:725.

6 Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES).

7 TFEU Article 263(2).

introduced by the Maastricht Treaty and over time gained prominence such that it may be considered as a 'general principle of EU law'.[8]

As the principle is not defined in the Treaty, there was a need to further interpret the principle over time. There is a general understanding that this principle will apply in situations where there is a risk to human health and environment, although there is no conclusive or precise scientific evidence of the existence or the extent of the risk.[9] One of the early cases where this principle was tested and offers a good illustration is the *Mad Cow Disease* case, when in its statement in 1996, the Spongiform Encephalopathy Advisory Committee ('SEAC'), an independent scientific body which advises the UK Government, recognised the absence of direct causal evidence but stated that in the 'absence of any credible alternative the most likely explanation at present is that these cases are linked to exposure to BSE before the introduction of the [specified bovine offal] ban in 1989'.[10] However, the court ruled that the lack of this conclusive evidence did not represent a barrier to action by Member States, which can 'take protective measures without having to wait until the reality and seriousness of those risks are fully demonstrated'.[11]

The existence of a risk imposes, therefore, an obligation to assess this risk in order to be able to provide more information about possible adverse effects. Several cases provide further explanation regarding the assessment of risk. In the *Pfizer* case, the Court of Justice of the European Union (CJEU) relied on an already internationally accepted definition of *scientific risk assessment* as a *'scientific process consisting in the identification and characterisation of a hazard, the assessment of exposure to the hazard and the characterisation of the risk'*.[12] This was further elaborated by the CJEU in the *Gowan* case, whereby correct application of the precautionary principle consists of two phases: the first which allows for the identification of the potentially negative consequences for health; and the second 'a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research'.[13] It is an expectation that this assessment will be undertaken by expert scientific institutions following well recognised methods of assessment and validation, which helps in reaching an objective decision based on evidence. This is not to say that bias is simply removed by having an expert institution undertaking risk assessment; it is possible that institutional or other biases could affect the risk assessment.

As the precautionary principle relates to cases of scientific uncertainty, there is a wider question as to when this principle can be triggered. There is a general agreement that purely hypothetical risks which have not been scientifically confirmed cannot be accepted,[14] though in certain instances the 'likelihood of real harm' can trigger the application of the principle.[15] Once the risk assessment is completed, the ultimate decision lies with the competent authority which, guided by a high level of protection, exercises its margin of appreciation in selecting the appropriate measure. This margin of appreciation is often a contested issue in judicial review cases, since the court has to determine whether the authority in question demonstrated manifest error of appraisal, exceeded the limits of its discretion, or misused its powers. Finally, the application of this principle is highly dependent on scientific and technological advances, which may become a significant contextual factor for a public authority in determining whether to apply this principle.

Intensity of review

Turning now to the task of review with which the court is charged, as is commonly the case when judges review the exercise of discretion in discharging a regulatory power, the court is concerned not with the merits of the decision but with its legality. This stems from Article 263(1) of the TFEU, which states that:

8 Case T–74/00, T–76/00, T–83/00 to T–85/00, T–132/00, T–137/00 and T–141/00 *Artegodan GmbH and Others v Commission of the European Communities* ECLI:EU:T:2002:283: 'It follows that the precautionary principle can be defined as a general principle of Community law requiring the competent authorities to take appropriate measures to prevent specific potential risks to public health, safety and the environment, by giving precedence to the requirements related to the protection of those interests over economic interests' (para 184).

9 Communication on the Precautionary Principle (COM(2000)1 final), at 9 to 10. See Wybe Th. Douma, 'The Precautionary Principle in the European Union', RECIEL 9(2) 2000, 132–144.

10 Case C–180/96 *United Kingdom v European Commission* ECLI:EU:C:1998:192 at para 9.

11 ibid at para 99 and Case C–446/08 *Solgar Vitamin's France and Others v Ministre de l'Économie, des Finances et de l'Emploi and Others* ECLI:EU:C:2010:233 at para 67.

12 Case T–13/99 *Pfizer Animal Health SA v Council of the European Union* ECLI:EU:T:2002:209 at para 156; see also Case T–70/99 *Alpharma Inc. v Council of the European Union* ECLI:EU:T:1999:131.

13 Case C–77/09 *Gowan Comércio Internacional e Serviços Lda v Ministero della Salute* ECLI:EU:C:2010:803 at para 75.

14 Case T–392/02 *Solvay Pharmaceuticals BV v Council of the European Union* ECLI:EU:T:2003:277. See also *Pfizer* case (n 12 above).

15 Case C–269/13 P *Acino AG v European Commission* ECLI:EU:C:2014:255 at para 58.

> The Court of Justice of the European Union shall review the legality of legislative acts, of … the Commission … intended to produce legal effects vis-à-vis third parties. It shall also review the legality of acts of bodies, offices or agencies of the Union intended to produce legal effects vis-à-vis third parties.

Article 263(2) sets out the grounds for the exercise of this jurisdiction as follows:

> lack of competence, infringement of an essential procedural requirement, infringement of the Treaties or of any rule of law relating to their application, or misuse of powers.

In a setting such as the toxicological judgments underpinning decisions to classify and label substances as hazardous, procedural requirements are relatively easy to police when compared with the question of correct use and application of powers. Judges are not toxicologists, so it is not their task to substitute their judgment for that made in expert determination. Nonetheless, it is the task of the court to ensure that rules governing the exercise of discretion are met, so that the powers exercised are *intra vires,* within the scope of the powers delegated to the decision-maker. In undertaking such review, the court should have regard to the purpose of the regulation, and the CLP lists competing interests, namely:

> 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 on the EU market.[16]

As regards what may be termed the intensity of the review, it is accepted that a wide degree of discretion should be allowed to the expert decision-maker, in view of the complexity of the scientific and technical decisions at issue. From an earlier case relating to the withdrawal of certain plant protection products, the judgment of the situation was described as follows:

> If the Commission is to be able to pursue effectively the objective assigned to it, account being taken of the complex technical assessments which it must undertake, it must be recognised as enjoying a broad discretion. However, the exercise of that discretion is not excluded from review by the Court. The Court has consistently held that in the context of such a review the Community 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 powers.[17]

The applicants in the *CWS Powder Coatings* case did claim that the assessment made in relation to titanium dioxide was subject to a manifest error. In such a case, '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'.[18] The General Court in *CWS Powder Coatings* pointed out that sound administration encompasses a duty to act diligently, which the courts would review in all actions of the EU administrative structure.

Ground 1: methodology and reliability

In arguing as the first ground of appeal that there were manifest errors in the assessment, the crux of the argument by the applicants revolved around two main scientific issues: the reliability and acceptability of the study used to generate data, together with the methodology in calculating the degree of lung overload. With regards to the former, the applicants challenged the reliability and acceptability of data obtained from the *Heinrich* study,[19] which they argued formed the basis of the RAC Opinion. It is a requirement of the CLP Regulation that classification decisions are based on 'reliable and acceptable studies'.[20] Similarly, with regards to the latter argument about the calculation of the degree of lung overload, the parties were in disagreement as to what correct methodology should be applied, and in particular how the particle density value should have been established. The RAC deployed the *Morrow* overload calculation[21] as the correct methodology, which according to the applicants led to an assessment error regarding the density of the particles.

These opposing arguments reveal two main challenges that are worth noting. The first refers to the limits of the judicial review, and the justiciability of these issues in accordance with the powers of review exercisable by the court. The second refers to the knowledge and expertise of the court to examine different scientific findings as presented by both sides. The European Commission's case strongly implied such doubts by suggesting that the issues do not demonstrate a failure to take into account relevant actors, but entail a situation whereby the court is faced

16 CLP Regulation (n 1 above) Preamble (1).

17 Case C–326/05 P *Industrias Químicas del Vallés SA v Commission of the European Communities* ECR 1–06557 at paras 75 and 76.

18 C–691/15P *Commission v Bilbaína de Alquitranes and Others* EU:C:2017 882 at para 35.

19 U Heinrich *et al.*, 'Chronic inhalation exposure of Wistar rats and two different strains of mice to diesel exhaust, carbon black and titanium dioxide' (1995) 7 *Inhalation Toxicology* 533–556.

20 CLP Regulation (n 1 above) Annex 1 section 3.6.2.2.1.

21 Methodologies proposed by PE Morrow in: 'Possible mechanisms to explain dust overloading of the lungs' (1988) 10(3) *Fundamental Applied Toxicology* 369–84, and 'Dust overloading of the lungs: update and appraisal' (1992) 113 *Toxicology and Applied Pharmacology* 1 – 12.

with different scientific conclusions reached by opposing parties.[22] This line of argument was dismissed by the court which emphasised that examination of the manifest error of assessment requires careful consideration of whether an institution has fully and impartially considered all the facts, and has fulfilled its duty to rely on accurate and reliable evidence in a precise and objective manner.[23]

With regards to the first argument of deployment of an irrelevant and unreliable study, the applicants pointed out that the *Heinrich* study was initially dismissed by the French authority, who initiated the new classification and labelling, as unreliable, as it was conducted solely on female rats and it was based on the administration of a single excessive testing dose.[24] However, it is worth pointing out that although the French authorities rated this study with a Klimisch reliability of score 3 (unreliable), they still determined that 'carcinogenic effects observed during the *Heinrich* study should be regarded as relevant'.[25] The European Commission, on the other hand, insisted that it deployed other studies such as the *Lee* study,[26] which informed their findings. In deciding on this issue, the court's focus was solely on determining whether the *Heinrich* study was decisive in the RAC's decision on contested classification and labelling. This is rather problematic, as the Commission is perfectly free to follow or depart from a committee opinion as it constitutes scientific advice to the Commission, so that arguably greater attention should have been given to the Commission's determination.

Nonetheless, in reviewing the RAC opinion and the studies on which it was based, the court noted that the RAC failed to record two studies which did not report tumours (the *Muhle*[27] and *Thyssen*[28] studies). According to the court, the *Heinrich* study was key, therefore, in reaching the conclusion leading to the contested classification and labelling. It remains unclear from the court judgment, despite its reference to a single sex study with an excessive testing dose, why this study was thought to be so unreliable and unacceptable that it could not be considered alongside other studies on a weight of evidence basis.

Discussion about the second allegation of the manifest error in relation to the particle density value is particularly engaging. It demonstrated that whereas many courts might have shied away, the General Court boldly embarked on evaluating and deciding a very technical issue. This is somewhat at odds with the General Court observation in the judgment that it is not for the court to examine the precise density value for the purposes of the *Morrow* overload calculation (the methodology applied by the RAC).[29] However, the court went on to demonstrate how, by drawing upon the density value of un-agglomerated primary particles instead of agglomerated particles of titanium dioxide, the RAC failed to take into account all factors of significance to this case.[30] This raises an issue of the court's knowledge and expertise to make this judgment. The court accepts that it was not its job to determine the precise density value that had to be taken into account by the RAC for the purposes of the *Morrow* overload calculation. The Commission argued, without any real challenge to this view, that the *Heinrich* study did not provide any indication as to the density or the extent of the agglomeration and the packing of the titanium dioxide particles tested. Nonetheless, the court ruled that this meant that relevant factors were overlooked in terms of the characteristics of the particles tested in the *Heinrich* study, their nano size, and the fact that those particles tend to agglomerate and that the agglomerates of particles occupied more volume in the lungs. It is the task, of course, of a court to adjudicate between competing arguments of the parties, but here it is hard to escape the conclusion that the General Court allowed itself to be enticed into determining which scientific methods it found acceptable to the point of ruling that those which it did not prefer proved unreliable such that reliance on them constituted a manifest error.

Ground 2: intrinsic properties of a substance

Although the court upheld the first ground of review, which was a sufficient ground to annul the Regulation, it proceeded to examine the second ground and deliver a ruling in 'the interest of the sound administration of justice'.[31] With regards to the second claim, the applicant again argued manifest errors of assessment and infringement of the criteria set out by the CLP Regulation No 1272/2008, by classifying and labelling titanium dioxide as carcinogenic. As stated by the applicants, the contested classification and labelling of carcinogenicity is

22 At para 54.
23 See paras 41 to 44.
24 Para 50.
25 Para 73.
26 KP Lee *et al.*, 'Pulmonary response to impaired lung clearance in rats following excessive TiO2 dust deposition' (1986) 41(1) *Environmental Research*, 144-167.
27 H Muhle *et al.*, 'Lung response to test toner upon 2-year inhalation exposure in rats' (1989) 37 *Exposure Pathology* 239–242.
28 J Thyssen *et al.*, 'Inhalation studies with polyurethane foam dust in relation to respiratory tract carcinogenesis' (1978) 1 *Journal of Environmental Pathology and Toxicology* 501–508.
29 Cases T–279/20 and T–288/20 (n 5 above) at para 97.
30 ibid at para 100.
31 ibid at paras 122–123.

solely based on 'the form and the size of titanium dioxide particles'[32] resulting from accumulation of deposited particles in the lungs by inhalation, whereas it should have been based upon the 'intrinsic properties of substance to cause cancer' as required by the CLP Regulation.[33] As a result, the court undertook further analysis of the notion of 'intrinsic' and whether the particle toxicity of titanium dioxide constitutes an intrinsic property of the substance within the meaning of the CLP Regulation.

To that end, the court decided to resort to the literal rules of statutory interpretation. This is applied in cases when judges want to primarily examine specific concepts, notions and terms with the aim of understanding their ordinary meaning, which in this case, revolved around the meaning of the word 'intrinsic'. The Cambridge Dictionary offers a good starting point in discussing the notion of 'intrinsic', where it is understood as 'an extremely important or basic characteristic of a thing'.[34] It is worth noting here that there are 24 languages in the EU, and that all linguistic versions are regarded as equally authentic.[35] However, if we look closely at the translation of the term 'intrinsic' as used in the CLP Regulation for classifying and labelling substance as carcinogenic, the examination of different linguistic versions of this Regulation reveals that some languages, such as Slovenian and Bulgarian, use the term 'inherent' rather than 'intrinsic', which may be argued to have a slightly different meaning from the term 'intrinsic.' It may be considered that intrinsic should be understood as fundamental to the object and without that intrinsic quality the object would not exist, while inherent may be understood as a constituent part, a characteristic of that object. Depending on the term employed, the perception and understanding of intrinsic properties may vary.

In this case, the interpretation of the term 'intrinsic' exposed different understandings of its meaning. According to the applicants, particle toxicity does not constitute an 'intrinsic hazard' within the meaning of the CLP Regulation, and they emphasised that development of tumours in rat studies was a secondary effect of exposure to dust resulting from excessive lung overload and not 'from an alleged carcinogenic potential' of titanium dioxide.[36] Unlike the applicant, the Commission was of the view that the concept of 'intrinsic property' is not only referring to intrinsic hazard emanating from a substance but also included a certain form or physical state of the substance, which could include the particle toxicity of titanium dioxide.[37] This view is aligned with the interpretation provided by the RAC in its Opinion, which recognised that despite the lack of intrinsic property in the traditional sense of the term, the substance remains intrinsically toxic within the meaning of the harmonised classification and labelling as per the CLP Regulation.

As the term is not defined by the CLP, the court provided its own understanding of the term, drawing on the literal meaning whereby intrinsic is understood as 'referring to properties which a substance has in and of itself'.[38] Intrinsic hazard in this instance, according to the court, is 'linked solely to certain respirable titanium dioxide particles, when they are present in a certain form, physical state, size and quantity'.[39] As a result, the court concluded that the mode of action of carcinogenicity described in the RAC Opinion could not be regarded as indicating intrinsic toxicity in the substance, such that it was not a ground for classification as a carcinogen under the CLP. This raises wider issues regarding the interpretative techniques of the court, as it might be argued that a less literal and more purposive approach to interpretation might have produced a more precautionary stance. It is true that chemicals regulation in the EU is based on hazard assessment rather than a system of regulation that is exposure-based, but this does not completely eliminate the question of how that hazard arises. So, for example, powders of lead and nickel are classified under the CLP as carcinogens, and the General Court places emphasis on the designation of the substance in solid form as well as powder form as a point of distinction with titanium dioxide. The General Court takes the same line with asbestos. Yet nickel powder is classed additionally as 'hazardous to the aquatic environment', so that here the form of the substance is indicative of additional hazard. With asbestos, the fibre size and shape appear to be a significant factor in its carcinogenicity,[40] so that the distinction drawn here by the General Court seems a very fine one.

32 ibid at para 125.

33 CLP at 3.6.2.2.1. Classification as a carcinogen is made on the basis of evidence from reliable and acceptable studies and is intended to be used for substances which have an intrinsic property to cause cancer. The evaluations shall be based on all existing data, peer-reviewed published studies and additional acceptable data.

34 https://dictionary.cambridge.org/dictionary/english/intrinsic

35 TEU Article 55(1).

36 Cases T–279/20 and T–(n 5 above) at paras 126–127.

37 ibid at para 128.

38 ibid at para 138.

39 ibid at para 146.

40 Melisa Bunderson-Schelvan, Jean C Pfau, Robert Crouch and Andrij Holian Nonpulmonary, 'Outcomes of asbestos exposure' (2011) 14:1-4 *Journal of Toxicology and Environmental Health, Part B*, 122–52.

Conclusion

The European Commission has appealed against the judgment of the General Court.[41] The Commission raises three grounds of appeal:

1. that the General Court erred in law by distorting the evidence before it when concluding that the RAC and the Commission committed a manifest error of assessment as regards the reliability and acceptability of the 1995 *Heinrich* study;
2. that the General Court erred in law when it substituted its own assessment for that of the RAC and the Commission when concluding that the RAC failed to take into account all the relevant factors in order to calculate the lung overload in the *Heinrich* study;
3. that the General Court erred in law when concluding that the contested classification and labelling did not relate to a substance that has the intrinsic property to cause cancer.

At the heart of this appeal is the concept of a manifest error. Taken literally, the word manifest, which is derived from the Latin word '*manifestus*', meaning palpable, indicates that the error should be evident and obvious.[42] In English common law, one still finds this interpretation when reviewing an expert determination which is said to have fallen into manifest error. In a recent case, the High Court ruled that a manifest error is not merely arriving at a wrong answer but should exhibit '*oversights and blunders so obvious and obviously capable of affecting the [outcome] as to admit of no difference of opinion.*'[43] The House of Lords (now the Supreme Court) has gone so far as to state that to be manifest, an error should be apparent to the court even without the benefit of adversarial argument.[44]

This standard is clearly a long way from that applied by the General Court but then there is no reason why an English law precedent, or indeed any precedent at all, should bind the General Court. Moreover, it is clear, looking at jurisprudence in relation to the manifest error test, that the threshold is not as high as to require obvious blunders, but does allow, nonetheless, a wide degree of discretion to the Commission in scientific assessment.[45] This discretion must necessarily extend to the determination of relevant facts (see ground 1 of the appeal above) since these will be crucial to the application of scientific theory. This is not to say that decision-makers cannot fall into manifest error in determining evidence to be evaluated, but, where a decision is reached in a procedurally correct manner, challenge to the substance of a decision must concern itself with legality. This entails ensuring that an institution has acted dutifully and impartially within its powers. In ruling on this question, a degree of judicial self-restraint is called for, given the complexity of the assessment, the scientific competence of the decision-makers, and the wider political accountability of the Commission when compared with the court. It will be for the Court of Justice on appeal to determine whether the General Court did exercise such self-restraint, but the Commission clearly feels, and perhaps with good reason, that the intensity of review by the General Court overstepped the threshold.

41 Case C–82/23 P, 14 February 2023, see: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:62023CN0082.

42 See George Hardy, 'Forum juridicum: the manifest error rule' (1961) 21(4) *Louisiana Law Review* 749–754.

43 *Flowgroup plc (in liquidation) v Co-operative Energy Ltd* [2021] EWHC 344 Comm.

44 *Pioneer Shipping Ltd* v *BTP Tioxide Ltd* [1982] AC 724.

45 Case C–326/05 P *Industrias Químicas del Vallés* v *Commission* ECLI:EU:C:2007:443, para 75 (Commission enjoys broad discretion in decision-making); Case C–77/09 *Gowan Comércio Internacional e Serviços* ECLI:EU:C:2010:803, para 55 (with regard to complex scientific assessments, Commission allowed wide discretion); Case C–78/16 *Pesce and Others* ECLI:EU:C:2016:428, para 49 (validity of a measure adopted can be nullified only if the measure is manifestly inappropriate).