Reports of Cases

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

13 November 2024*

(Consumer protection – Substances prohibited, restricted or under EU scrutiny – Article 8(1) and (2) of, and Annex III to, Regulation (EC) No 1925/2006 – Prohibition of preparations from the leaf of *Aloe* species containing hydroxyanthracene derivatives – Third entry in Article 1(1) of Regulation (EU) 2021/468)

In Case T-189/21,

Aloe Vera of Europe BV, established in Amsterdam (Netherlands), represented by B. Van Vooren and P. Bogaert, lawyers,

applicant,

v

European Commission, represented by B. Rous Demiri, I. Galindo Martín and K. Mifsud-Bonnici, acting as Agents,

defendant,

THE GENERAL COURT (Sixth Chamber, Extended Composition),

composed of M.J. Costeira, President, M. Kancheva, U. Öberg (Rapporteur), P. Zilgalvis and E. Tichy-Fisslberger, Judges,

Registrar: M. Zwozdziak-Carbonne, Administrator,

having regard to the written part of the procedure,

further to the hearing on 26 June 2023,

gives the following

Judgment

1 By its action under Article 263 TFEU, the applicant, Aloe Vera of Europe BV, seeks annulment of Commission Regulation (EU) 2021/468 of 18 March 2021 amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards botanical species

* Language of the case: English.

containing hydroxyanthracene derivatives (OJ 2021 L 96, p. 6; 'the contested regulation'), in so far as, by the third entry in Article 1(1) of that regulation, the European Commission included 'preparations from the leaf of *Aloe* species containing hydroxyanthracene derivatives' in Part A of Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ 2006 L 404, p. 26).

Background to the dispute

2 The applicant is a company incorporated under Netherlands law which is one of the European subsidiaries of the international group Aloe vera of America, Inc. This group specialises in products based on *Aloe vera*. The applicant sells gel from that plant in the form of beverages made from the inner jelly of *Aloe vera* leaves ('the applicant's products').

3 *Aloe vera* is a species of *Aloe* the leaf of which is formed of three layers: the first is a thick outer green peel that protects the plant against harsh weather; the second is a middle layer of yellow rind containing hydroxyanthracene derivatives ('HADs'); and the third is a moist and transparent inner layer of gelatinous liquid that contains the plant's nutrients ('*Aloe vera* inner leaf gel').

4 HADs are a class of chemical substances with different and heterogeneous structures. They are naturally occurring in different botanical species, such as certain species of *Aloe* as well as certain fruits and vegetables. They are widely used in food supplements and herbal medicinal products for their laxative effect.

5 On 29 June 2016, the Commission asked the European Food Safety Authority (EFSA) to evaluate the available information on the safety of the use of HADs from all food sources. It also asked EFSA to recommend a daily intake of HADs that does not give rise to concerns about possible harmful effects on health for the general population and, as appropriate, for vulnerable subgroups of the population.

6 In doing so, the Commission relied in particular on Article 8(1) and (2) of Regulation No 1925/2006 and on Commission Implementing Regulation (EU) No 307/2012 of 11 April 2012 establishing implementing rules for the application of Article 8 of Regulation No 1925/2006 (OJ 2012 L 102, p. 2).

7 On 22 November 2017, EFSA adopted a scientific opinion entitled 'Safety of hydroxyanthracene derivates for use in food' ('the 2017 scientific opinion'), in which it concluded as follows:

'… the hydroxyanthracenes, emodin, aloe-emodin and the structurally related substance danthron, have been shown to be genotoxic *in vitro*.

Aloe extracts have also been shown to be genotoxic *in vitro* and the Panel concluded this was most likely due – at least in part – to [HADs] present in the extract. However, the Panel further noted that *Aloe* extracts depleted of hydroxyanthracenes, contained an additional genotoxic component(s).

Furthermore, aloe-emodin was shown to be genotoxic in mice, the whole leaf aloe extract was carcinogenic to rats and there was evidence of carcinogenicity of the structural analogue danthron in both rodent species. Given that aloe-emodin and emodin may be present in the

extracts, the Panel concluded that [HADs] should be regarded as genotoxic and carcinogenic unless there are specific data to the contrary, such as for rhein, and that there is a safety concern for extracts containing [HADs] although uncertainty persists.

The Panel was unable to provide advice on a daily intake of [HADs] that does not give rise to concerns about harmful effects to health, for the general population, and as appropriate, for vulnerable subgroups of the population.'

8 On 22 June 2018, on the basis of the conclusions of the 2017 scientific opinion, the Commission presented, for discussion with a group of experts on food supplements and fortified foods, an initial proposal for a regulation. It proposed therein, inter alia, to include, on the basis of Article 8(1) and (2) of Regulation No 1925/2006, '*Aloe* leaf and its preparations originating from *Aloe* species used in food supplements intended for laxative purpose' in the list, in Part A of Annex III to Regulation No 1925/2006, of substances whose addition to foods or use in foods is prohibited.

9 On 4 March 2020, a draft regulation was submitted for public consultation in order to give all interested parties the opportunity to express their views. It contemplated, inter alia, prohibiting the addition to foods or the use in the manufacture of foods of 'extracts from the leaf of *Aloe* species containing [HADs]'.

10 On 10 June 2020, the Commission drew up a summary report on the meeting held with the General Food Law Section of the Standing Committee on the Food Chain and Animal Health ('the PAFF Committee').

11 On 5 October 2020, the Commission presented its revised draft regulation to the PAFF Committee.

12 It is apparent from the summary report of the meeting of 5 October 2020 that the PAFF Committee referred, in the form of a statement, to a limit of quantification for HADs according to which a level higher than or equal to 1 ppm of aloe-emodin, emodin or aloin A plus aloin B in certain products provided clear evidence of the presence of those substances in those products.

13 On 5 November 2020, the PAFF Committee was consulted by written procedure in order to deliver an opinion on the Commission's draft regulation. Following the favourable opinion delivered by the PAFF Committee on 12 November 2020, this draft regulation was examined by the European Parliament and by the Council of the European Union.

14 On 18 March 2021, the Commission adopted the contested regulation, by which, by the third entry in Article 1(1) of that regulation, it included 'preparations from the leaf of *Aloe* species containing [HADs]' in Part A of Annex III to Regulation No 1925/2006.

15 In that regard, in recital 7 of the contested regulation, the Commission stated that '[EFSA had] found that the [HADs] aloe-emodin and emodin and structurally related substance danthron [had] been shown to be genotoxic *in vitro*', that '*Aloe* extracts [had] also been shown to be genotoxic *in vitro* most likely due to [HADs] present in the extract', that 'furthermore, aloe-emodin [had been] shown to be genotoxic *in vivo*' and that 'the whole leaf aloe extract and structural analogue danthron [had been] shown to be carcinogenic.'

16 Recital 8 of the contested regulation is worded as follows:

'Given that aloe-emodin and emodin may be present in the extracts, [EFSA] concluded that [HADs] should be regarded as genotoxic and carcinogenic unless there are specific data to the contrary and that there is a safety concern for extracts containing [HADs] although uncertainty persists. [EFSA] was unable to provide advice on a daily intake of [HADs] that does not give rise to concerns for human health.'

17 In recital 9 of the contested regulation, the Commission also stated that, 'considering the severe harmful effects on health associated with the use of aloe-emodin, emodin, danthron and *aloe* extracts containing [HADs] in food, and that no daily intake of [HADs] that does not give rise to concerns for human health could be set, such substances should be prohibited. Therefore, aloe-emodin, emodin, danthron and *aloe* preparations containing [HADs] [had to] be included in Annex III, Part A of Regulation (EC) No 1925/2006.'

18 Lastly, in recital 10 of the contested regulation, the Commission added that 'during manufacture, [HADs could] be removed from the botanical preparations through a series of filtering processes resulting in products that contain those substances only at trace levels as impurities.'

Forms of order sought

19 The applicant claims that the Court should:

– annul the contested regulation in so far as it refers, in the third entry in Article 1(1), to 'preparations from the leaf of *Aloe* species containing [HADs]';

– order the Commission to pay the costs.

20 The Commission contends that the Court should:

– dismiss the action;

– order the applicant to pay the costs.

Law

Admissibility of a new argument in the course of the proceedings

21 In the rejoinder, the Commission expressed doubts as to the admissibility, within the meaning of Article 84 of the Rules of Procedure of the General Court, of a 'new plea in law' put forward by the applicant in the reply.

22 Thus, according to the Commission, the applicant stated in the application that the 2017 scientific opinion did not demonstrate any safety concerns as regards *Aloe vera* inner leaf gel and based its plea on the amount of HADs contained in its product. However, in its reply, the applicant put forward new arguments relating to the lack of specific evidence, in that opinion, of the harmful effects of certain HADs present in *Aloe vera* leaves, namely aloin A and aloin B.

23 The Court notes that, as the Commission states, EFSA was asked to examine the possible link between the intake of HADs, as a group of substances, and harmful effects on health. By contrast, it was not asked to specify the particular composition of HADs for each plant species studied.

24 Nevertheless, in Section 2.2 of the 2017 scientific opinion, EFSA stated that 'the leaves of *Aloe vera* (L) contain aloin A and aloin B', which are two specific HADs.

25 The applicant's products contain *Aloe vera* inner leaf gel. In that regard, it claimed, in the application, that the prohibition on the addition to foods or the use in the manufacture of foods of its products based on *Aloe vera* inner leaf gel was not based on any scientific basis and that the only HADs present in its products were aloin A and aloin B. Its argument, raised in the reply, concerning the lack of evidence as regards the harmful effects of those two specific HADs in the 2017 scientific opinion, therefore constitutes a corroboration and more specific expression of its statements in the application.

26 In the context of adversarial proceedings, an argument which may be regarded as amplifying a plea made previously, whether directly or by implication, in the original application, and which is closely connected thereto, cannot be declared inadmissible. Moreover, arguments which in substance have a close connection with a plea raised in the application initiating the proceedings cannot be considered new pleas on the basis of Article 84(1) of the Rules of Procedure and they may be raised at the stage of the reply or the hearing (judgment of 8 November 2018, "*Pro NGO*!" v *Commission*, T-454/17, EU:T:2018:755, paragraph 70).

27 The arguments put forward by the applicant in the reply are therefore not new in relation to the plea put forward in the application.

28 Accordingly, the doubts expressed by the Commission as to the admissibility of those arguments must be rejected as unfounded.

Substance

29 In the application, the applicant relied on a single plea in law, alleging infringement of the precautionary principle. At the hearing, the applicant stated that that plea had to be understood as alleging, inter alia, infringement of Article 8 of Regulation No 1925/2006, with the result that there was no need for the Court to rule on the infringement of the precautionary principle as such. It also stated that that plea could be understood as consisting of four pleas in law.

30 Thus, the first plea, as reformulated, alleges infringement of Article 8(1) and (2)(a)(i) of Regulation No 1925/2006 and a manifest error of assessment, in that, first, there is no scientific certainty as to the existence of a harmful effect on preparations from the leaf of *Aloe* species, including preparations based on *Aloe vera* inner leaf gel, and, second, a risk threshold in that regard has not been established.

31 The second plea, as reformulated, alleges that, in adopting the contested regulation, the Commission wrongly relied on the written procedure provided for in Article 3(5) of Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ 2011 L 55, p. 13).

32 The third plea and the fourth plea, as reformulated, allege, respectively, that the third entry in Article 1(1) of the contested regulation entails an arbitrary total prohibition on *Aloe vera* preparations, which includes *Aloe vera* inner leaf gel, and failure to observe the principles of proportionality and non-discrimination.

33 The Court considers it appropriate to examine, first of all, the applicant's argument that no risk threshold was identified for preparations from the leaf of *Aloe* species, including preparations based on *Aloe vera* inner leaf gel, in accordance with Article 8(2)(a)(i) of Regulation No 1925/2006.

34 In that regard, the applicant submits that, under Article 8(2)(a)(i) and (b) of Regulation No 1925/2006, the Commission may decide to include certain substances or ingredients containing them in a list which prohibits their addition to foods or their use in the manufacture of foods, or in a list which places them under EU scrutiny.

35 The applicant submits, in particular, that the Commission confuses two distinct concepts, namely the level of HADs that may be intentionally added to foods without raising concerns for health and the level of HADs that may remain behind in foods as residues without raising concerns for health.

36 Regarding the first concept, EFSA was unable to advise on an acceptable daily intake because the mechanism behind the genotoxicity of certain HADs was unclear. As regards the second concept, it was not possible to recommend an acceptable daily intake on account of a lack of relevant data. In that regard, EFSA expressly stated that there was an absence of information relating to *Aloe vera* gel. Accordingly, the lack of advice on a safe daily intake was not due to concerns about genotoxicity, but due to the lack of data.

37 Therefore, by including 'preparations from the leaf of *Aloe* species containing [HADs]', which includes preparations based on *Aloe vera* inner leaf gel, in Part A of Annex III to Regulation No 1925/2006, without establishing a risk threshold, the Commission failed to comply with Article 8(2)(a)(i) of Regulation No 1925/2006.

38 According to the Commission, first, the Panel was unable to provide advice on a daily intake of HADs that does not give rise to concerns about harmful effects to health because of the specific concern for their genotoxicity. With regard to genotoxicity, no safety threshold is set, as the system provides that genotoxic substances cannot be intentionally added to the food chain.

39 Second, the Commission contends that the applicant's products are used for adding to food, which may result in higher intakes of the substance in question than if it were consumed in its natural state. Moreover, EFSA makes no distinction according to whether HADs were intentionally added to or naturally present in food. Even if EFSA were to have distinguished between the intentional and unintentional addition of HADs, that would not have prevented it from reaching its conclusion on HADs as a class of substances.

40 Therefore, no harmless amount of the substances in question could be established. The Commission thus acted within the limits of the conditions laid down by Regulation No 1925/2006.

41 The Court recalls that, in accordance with the case-law, where the Commission is called upon to undertake complex technical or scientific assessments, it has a broad discretion. In such a situation, judicial review is confined to determining whether the relevant procedural rules have been complied with, whether the facts established by the Commission are correct and whether there has been a manifest error of appraisal of those facts or a misuse of powers. However, as

regards the Commission's conclusions which do not involve complex technical or scientific assessments, the Court has full jurisdiction to review them. Similarly, as regards questions of law, the Court can only carry out full judicial review (judgment of 23 September 2020, *Medac Gesellschaft für klinische Spezialpräparate* v *Commission*, T-549/19, EU:T:2020:444, paragraph 47 (not published) and the case-law cited).

42 In order to establish that an institution committed a manifest error in assessing complex facts so as to justify the annulment of an act, the evidence adduced by the applicant must be sufficient to make the factual assessments used in that act implausible. Subject to that review of plausibility, it is not the Court's role to substitute its assessment of complex facts for that made by the institution which adopted the decision. The limits to the review by the Courts of the European Union do not, however, affect their duty to establish whether the evidence relied on is factually accurate, reliable and consistent, 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 judgment of 11 February 2015, *Spain* v *Commission*, T-204/11, EU:T:2015:91, paragraphs 32 and 33 and the case-law cited).

43 In addition, the discretion of the EU authorities, which implies limited judicial review of its exercise, does not concern only the nature and scope of the measures to be taken but also, to some extent, the finding of the basic facts. However, even though such judicial review is of limited scope, it requires that the EU authorities which have adopted the act in question must be able to show before the EU judicature that in adopting the act they actually exercised their discretion, which presupposes that they took into consideration all the relevant factors and circumstances of the situation the act was intended to regulate (see judgment of 8 July 2010, *Afton Chemical*, C-343/09, EU:C:2010:419, paragraphs 33 and 34 and the case-law cited; judgments of 30 April 2015, *Polynt and Sitre* v *ECHA*, T-134/13, not published, EU:T:2015:254, paragraph 53, and of 11 May 2017, *Deza* v *ECHA*, T-115/15, EU:T:2017:329, paragraph 164).

44 The questions of law in respect of which the Court is to carry out a comprehensive review include the interpretation to be given to legal provisions on the basis of objective factors and whether or not the conditions for the application of such a provision are satisfied (see, to that effect and by analogy, judgments of 11 July 1985, *Remia and Others* v *Commission*, 42/84, EU:C:1985:327, paragraph 34, and of 9 November 2022, *Cambodia and CRF* v *Commission*, T-246/19, EU:T:2022:694, paragraph 45).

45 Article 8 of Regulation No 1925/2006 sets out the procedure for including a substance other than vitamins or minerals, or an ingredient containing a substance other than vitamins or minerals, in Annex III to that regulation, which contains lists of those substances whose addition to foods or use in the manufacture of foods is prohibited or subject to conditions or in respect of which there is scientific uncertainty.

46 In that regard, Article 8(1) of Regulation No 1925/2006 provides that the procedure for prohibition, restriction or placement under EU scrutiny is to be followed where a substance other than vitamins or minerals, or an ingredient containing a substance other than vitamins or minerals, is added to foods or used in the manufacture of foods under conditions that would result in the ingestion of amounts of that substance greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or would otherwise represent a potential risk to consumers.

47 In addition, under Article 8(2) of Regulation No 1925/2006, the Commission may, on its own initiative or on the basis of information provided by Member States, take a decision, following in each case an assessment of available information by EFSA, to include, if necessary, the substance or ingredient in question in Annex III to that regulation. In particular, Article 8(2)(a) and (b) of Regulation No 1925/2006 states as follows:

'…

(a) if a harmful effect on health has been identified, the substance and/or the ingredient containing the substance shall:
   (i) be placed in Annex III, Part A, and its addition to foods or its use in the manufacture of foods shall be prohibited; or
   (ii) be placed in Annex III, Part B, and its addition to foods or its use in the manufacture of foods shall only be allowed under the conditions specified therein;

(b) if the possibility of harmful effects on health is identified but scientific uncertainty persists, the substance shall be placed in Annex III, Part C.'

48 It also follows from recital 2 of Regulation No 1925/2006 that that regulation aims to 'regulate the addition of vitamins and minerals to foods and the use of certain other substances or ingredients containing substances other than vitamins or minerals that are added to foods or used in the manufacture of foods under conditions that result in the ingestion of amounts greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or would otherwise represent a potential risk to consumers'.

49 The Court notes that the procedure established by Article 8 of Regulation No 1925/2006 is characterised by the essential role assigned to a scientific assessment by EFSA of the effect of the addition of a substance, or an ingredient containing that substance, to foods or of its use in the manufacture of foods. Since the Commission is not in a position to carry out scientific assessments regarding the identification of their potential harmful effects on health, the aim of the mandatory consultation of EFSA is to provide the Commission with the evidence of scientific assessment which is essential for it to be able to determine, in full knowledge of the facts, the appropriate measures to ensure a high level of public health protection.

50 Article 8(2) of Regulation No 1925/2006 must be read in conjunction with Article 8(1) of that regulation, with the result that the Commission may decide to prohibit or authorise under specified conditions the addition to foods or the use in the manufacture of foods of a substance other than vitamins or minerals, or of an ingredient containing that substance, or even to place a substance under EU scrutiny, subject to certain conditions, essentially where there is a risk, or as the case may be a potential risk, in particular in the event of ingestion of amounts of the substance in question greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced or varied diet or that would otherwise represent a potential risk to consumers.

51 Thus, more specifically, under Article 8(2)(a)(i) of Regulation No 1925/2006, read in the light of Article 8(1) of that regulation, there are two conditions that must be satisfied in order that the addition to foods or the use in the manufacture of foods of a substance or ingredient containing it may be prohibited: first, it results in the 'ingestion of amounts of [the substance in question]

greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or would otherwise represent a potential risk to consumers' and, second, a 'harmful effect on health has been identified'.

52 Such an interpretation is confirmed by reading recital 20 of Regulation No 1925/2006, in which a distinction is made between the ingestion of substances other than vitamins or minerals, or ingredients, under normal conditions, which should not be regulated, and the ingestion of such substances or ingredients containing them which are added to foods in the form of extracts or concentrates, and which may result in 'intakes that are significantly higher than those that could be ingested through eating an adequate and varied diet'.

53 In the present case, the Commission relied on the 2017 scientific opinion, the conclusions of which set out in paragraph 7 above are reproduced in recitals 7 and 8 of the contested regulation, in order to include, in Part A of Annex III to Regulation No 1925/2006, 'preparations from the leaf of *Aloe* species containing [HADs]', on the basis of Article 8(2)(a)(i) of Regulation No 1925/2006, with the result that their addition to foods or their use in the manufacture of foods is prohibited.

54 As regards the first condition for prohibiting the addition of a substance or ingredient containing it to foods or its use in the manufacture of foods, namely the ingestion of amounts greatly exceeding those reasonably expected to be ingested under normal conditions of consumption or that would otherwise represent a potential risk to consumers, the Court finds that, by the third entry in Article 1(1) of the contested regulation, all 'preparations from the leaf of *Aloe* species containing [HADs]' are prohibited, irrespective of the amount of HADs which they contain.

55 In that regard, the Commission stated, in recitals 8 and 9 of the contested regulation, that EFSA was unable to provide advice on a daily intake of HADs that does not give rise to concerns for human health, which is also apparent from the conclusion of the 2017 scientific opinion, as reproduced in paragraph 7 above. In Section 2.7.2 of the 2017 scientific opinion, entitled 'Exposure via normal diet', EFSA also stated that parts of plants containing HADs may be part of a normal diet, but that no data on the concentrations of HADs present in those parts of the plants consumed had been made available by interested parties following a call for data.

56 In addition, it is apparent from recital 10 of the contested regulation that, during manufacture, HADs can be removed from the botanical preparations through a series of filtering processes resulting in products that contain those substances only at trace levels as impurities.

57 Despite those considerations, the contested regulation refers, by the third entry in Article 1(1) thereof, to all 'preparations from the leaf of *Aloe* species containing [HADs]', irrespective of the amount of HADs present.

58 The Commission therefore appears to have taken the view that the insufficiency of data relating to a daily intake that does not give rise to concern for health allowed it to assume that there was no level for safe use of HADs, with the result that it could prohibit them entirely.

59 That absence of a threshold is contrary to Article 8(2)(a)(i) of Regulation No 1925/2006, read in conjunction with Article 8(1) of that regulation, from which it is apparent, as stated in paragraph 33 above, that the prohibition procedure laid down therein presupposes that a harmful effect on health has been identified where substances other than vitamins or minerals, or

ingredients containing them, are added to foods or used in their manufacture, resulting in 'ingestion of amounts of [that] substance greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet'.

60 Moreover, it is not apparent from the 2017 scientific opinion or from any material in the case file that the third entry in Article 1(1) of the contested regulation was adopted because the preparations in question otherwise represented a potential risk to consumers.

61 Although Article 8(1) of Regulation No 1925/2006 confers on the Commission the power to include substances, other than vitamins or minerals, or ingredients containing such substances, in Annex III to that regulation, it must satisfy the conditions laid down in that provision.

62 The general prohibition on the addition to foods or the use in the manufacture of foods of preparations containing certain substances, such as that referred to in the third entry in Article 1(1) of the contested regulation, irrespective of the amount of those substances present in those preparations, does not comply with the conditions laid down in Article 8(2)(a)(i) of Regulation No 1925/2006, read in conjunction with Article 8(1) of that regulation.

63 It is true that it follows from recital 20 of Regulation No 1925/2006 that food business operators, responsible for the safety of the foods they place on the market, assume the burden of proof in relation to their safety. However, pursuant to the same recital, it is only in cases where the addition of that substance as extracts or concentrates may result in intakes which are significantly higher than those that could be ingested through eating an adequate and varied diet that the burden of proof lies with the food business operators.

64 That conclusion is confirmed by Article 3(3) of Implementing Regulation No 307/2012, according to which, for the purposes of that regulation, those conditions that would result in the ingestion of amounts of a substance greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet are to occur under actual circumstances and are to be assessed on a case-by-case basis in comparison with the average intake of the concerned substance by the general adult population or other specified population group for which health concerns have been raised.

65 In the absence of data on the amount of the substance that can 'be ingested through eating an adequate and varied diet', within the meaning of recital 20 of Regulation No 1925/2006, or on the amounts which are 'reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet', within the meaning of Article 8(1) of that regulation, a food business operator is not in a position to make an appropriate comparison between, on the one hand, the amounts of a substance under normal conditions of consumption and, on the other hand, the amounts of that same substance under the conditions of use and addition as concentrates.

66 Consequently, the third entry in Article 1(1) of the contested regulation infringes Article 8(2)(a)(i) of Regulation No 1925/2006, read in conjunction with Article 8(1) of that regulation, in so far as it prohibits all 'preparations from the leaf of *Aloe* species containing [HADs]', irrespective of the amount of HADs they contain, from being added to foods or used in the manufacture of foods.

67 It follows from the foregoing that the first plea in law, alleging infringement of Article 8(1) and (2) of Regulation No 1925/2006 and a manifest error of assessment, must be upheld and the third entry in Article 1(1) of the contested regulation must be annulled, without there being any need for the Court to rule on the applicant's other pleas in law and arguments.

Costs

68 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.

69 Since the Commission has been unsuccessful, it must be ordered to pay the costs, in accordance with the form of order sought by the applicant, including those relating to the interlocutory proceedings.

On those grounds,

THE GENERAL COURT (Sixth Chamber, Extended Composition)

hereby:

1. **Annuls the third entry in Article 1(1) of Commission Regulation (EU) 2021/468 of 18 March 2021 amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards botanical species containing hydroxyanthracene derivatives, by which 'preparations from the leaf of *Aloe* species containing hydroxyanthracene derivatives' were included in Part A of Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods;**

2. **Orders the European Commission to pay the costs, including those relating to the interlocutory proceedings.**

Costeira Kancheva Öberg

Zilgalvis Tichy-Fisslberger

Delivered in open court in Luxembourg on 13 November 2024.

V. Di Bucci M. van der Woude
Registrar President