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 and placing under control of certain substances and preparations containing hydroxyanthracene derivatives – First, second and third entries in Article 1(1), and Article 1(2), of Regulation (EU) 2021/468 – Concepts of 'substance', 'ingredient' and 'preparations' – Error of law)

In Case T-302/21,

Aboa SpA Soc. agr., established in Sansepolcro (Italy),

Coswell SpA, established in Funo di Argelato (Italy),

Associação portuguesa de suplementos alimentares (Apard), established in Lisbon (Portugal),

represented by B. Kelly, Solicitor, K. Ewert, lawyer, D. Scannell and C. Thomas, Barristers-at-Law,

applicants,

v

European Commission, represented by I. Galindo Martín, K. Mifsud-Bonnici and B. Rous Demiri, 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 7 July 2023,

gives the following

* Language of the case: English.

Judgment

1 By their action under Article 263 TFEU, the applicants, Aboca SpA Soc. agr., Coswell SpA and Associação portuguesa de suplementos alimentares (Apard), seek 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 containing hydroxyanthracene derivatives (OJ 2021 L 96, p. 6; 'the contested regulation'), in so far as, by the first, second and third entries in Article 1(1) of that regulation and by Article 1(2) thereof, the European Commission included certain hydroxyanthracene derivatives ('HADs') and certain preparations in Parts A and C 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 Aboca and Coswell are Italian companies specialising in the manufacture and marketing of food supplements and products containing HADs, including products containing juice from certain species of *Aloe*.

3 In view of the adoption of the contested regulation and the prohibition on adding to food, or using in the manufacture of food, preparations from the leaf of *Aloe* species containing HADs, Aboca and Coswell changed the formulation of their products. Following that reformulation, Aboca's products contained extracts from senna (*Cassia angustifolia* Vahl) and rhubarb (*Rheum palmatum* L), and Coswell's products contained extracts from senna (*Cassia angustifolia* Vahl), cascara (*Rhamnus purshiana* DC) and Frangula, commonly known as buckthorn (*Rhamnus frangula* L).

4 Apard is a Portuguese trade association representing the interests of the food supplements industry, whose member companies manufacture and market food supplement products containing *Aloe*, in the form of both whole plants and natural plant extracts, containing HADs.

5 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.

6 On 29 June 2016, the Commission asked the European Food Safety Authority (EFSA) to evaluate the available information on the safety in 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.

7 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).

8 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.'

9 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 including, on the basis of Article 8(1) and (2) of Regulation No 1925/2006, first, '*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, and, second, 'Rheum root, rhizome and its preparations originating from *Rheum palmatum* L., *Rheum officinale Baillon* and their hybrids used in food supplements intended for laxative purpose', 'Cassia leaf, fruit and its preparations originating from *Cassia senna L.* [and] *Cassia angustifolia Vahl* used in food supplements intended for laxative purpose' and 'Rhamnus bark and its preparations originating from *Rhamnus frangula L., Rhamnus purshianus D.C.* used in food supplements intended for laxative purpose' in the list, in Part C of Annex III to that regulation, of substances whose use in foods is subject to EU scrutiny.

10 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, first, prohibiting the addition to foods or the use in the manufacture of foods of, inter alia, 'aloe-emodin and all extracts in which this substance is present', 'emodin and all extracts in which this substance is present' and 'extracts from the leaf of *Aloe* species containing [HADs]', as well as, second, placing under EU scrutiny 'extracts from the root, rhizome of *Rheum palmatum L., Rheum officinale Baillon* and their hybrids containing [HADs]', 'extracts from the leaf, fruit of *Cassia senna L.* containing [HADs]' and 'extracts from the bark of *Rhamnus frangula L., Rhamnus purshiana DC.* containing [HADs]'.

11 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').

12 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.

13 On 18 March 2021, the Commission adopted the contested regulation, by which, by the first, second and fourth entries in Article 1(1), it added aloe-emodin, emodin, danthron and all preparations in which those substances are present, as well as, by the third entry, preparations from the leaf of *Aloe* species containing HADs, to Part A of Annex III to Regulation No 1925/2006. By the first, second and third entries in Article 1(2) of the contested regulation, it also added preparations from the root or rhizome of *Rheum palmatum* L., *Rheum officinale* Baillon and their hybrids containing HADs, preparations from the leaf or fruit of *Cassia senna* L. containing HADs and preparations from the bark of *Rhamnus frangula* L. or *Rhamnus purshiana* DC. containing HADs to Part C of Annex III to Regulation No 1925/2006.

14 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.'

15 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.'

16 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' and that '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.'

17 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.'

18 Lastly, in recital 11 of the contested regulation, the Commission noted that as there was a possibility of harmful effects on health associated with the use of *Rheum*, *Cassia* and *Rhamnus* and their preparations in food, but scientific uncertainty persisted regarding whether such preparations contained the substances listed in Part A of Annex III to Regulation No 1925/2006, such substances had to be placed under EU scrutiny and, therefore, they had to be included in Part C of Annex III to Regulation No 1925/2006.

Forms of order sought

19 The applicants claim that the Court should:

– annul the contested regulation;

– order the Commission to pay the costs.

20 The Commission contends that the Court should:

– dismiss the action;

– order the applicants to pay the costs.

Law

Delimitation of the subject matter of the action

21 In the present proceedings, it is common ground between the parties that none of Aboca, Coswell or the member companies of Apard produce products containing danthron.

22 Consequently, the applicants must be regarded as seeking the annulment of the first, second and third entries in Article 1(1), and Article 1(2), of the contested regulation.

Substance

23 In support of their action, the applicants rely on three pleas in law, the last two of which are put forward in the alternative.

24 The first plea alleges lack of competence, an error of law and/or infringement of essential procedural requirements, in that the Commission could not rely on Article 8 of Regulation No 1925/2006 in order to adopt the contested regulation and to include in Parts A and C of Annex III to that regulation 'preparations' in which certain substances are present.

25 The second plea is divided into two parts. The first part alleges that the contested regulation fails to observe the general principle of legal certainty, in that the scope and effects of its provisions are uncertain. The second part alleges failure to observe the principle of non-discrimination, in that the marketing of the substances in question is treated differently from the marketing of certain plants sold in their natural form or as an ingredient added to a food product for flavouring purposes.

26 The third plea alleges an error of law and infringement of the principle of proportionality or of essential procedural requirements, in that the adoption of the contested regulation concerning the inclusion of certain substances and preparations in Parts A and C of Annex III to Regulation No 1925/2006 is not justified in the light of EFSA's conclusions and does not comply with the conditions of Article 8(2) of Regulation No 1925/2006, since the 2017 scientific opinion did not identify any harmful effect or the possibility of any harmful effect of the substances and preparations in question and did not establish a safe level for the consumption of HADs.

27 The Court considers it appropriate to examine, in the first place, the arguments put forward by the applicants in the context of the first plea and the first part of the second plea, alleging that Article 8 of Regulation No 1925/2006 does not allow 'preparations' to be included in the lists in Parts A and C of Annex III to that regulation. In the second place, the Court will examine the applicants' arguments, put forward in the context of the third plea, alleging that a risk threshold has not been established for prohibiting the addition to foods or the use in the manufacture of foods of the substances and preparations in question, in accordance with Article 8(1) and (2)(a)(i) of that regulation.

The plea in law and the arguments alleging that Article 8 of Regulation No 1925/2006 does not allow 'preparations' to be included in the lists in Parts A and C of Annex III to that regulation

28 In the context of the first plea and the first part of the second plea, the applicants submit that, under Article 8 of Regulation No 1925/2006, only substances other than vitamins or minerals, or ingredients containing those substances, which are or could be added to a food or used in the manufacture of a food, where that results in the ingestion of amounts of those substances which greatly exceed those reasonably expected to be ingested under normal conditions or which represent a potential risk to consumers, are liable to be prohibited on the basis of that provision. By contrast, that regulation does not make it possible to prohibit a foodstuff, the food itself or whole plants.

29 The contested regulation does not refer only to HADs as substances but also, through the use of the words 'preparations in which [the] substance [in question] is present', to whole plants, plant extracts or substances present in those plants in their natural state, and thus to foodstuffs per se. Thus, it prohibits the addition of the plant species themselves to foods or their use in the manufacture of foods. The same is true of the preparations placed under EU scrutiny.

30 Therefore, the Commission could not rely on Article 8 of Regulation No 1925/2006 in order to adopt the contested regulation.

31 The Commission submits that the applicants' products are processed food products. The fact that they are made only of natural ingredients cannot exclude them from the scope of Regulation No 1925/2006. Thus, a product comprising a food obtained from whole plants satisfies the criterion 'added to foods or used in the manufacture of foods', within the meaning of Article 8 of that regulation. It also states that, although it does not have the general power to ban a foodstuff in the abstract, in accordance with Article 8 of that regulation it may regulate the consumption of substances in amounts greater than those that could be consumed through eating an adequate and varied diet, which prove to be dangerous to human health, which it did by adopting the contested regulation.

32 The Commission adds that the concept of 'preparations' was defined in EFSA's 'Guidance on Safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements' of 10 September 2009 ('the 2009 EFSA Guidance'), according to which 'this terminology includes all preparations obtained from botanicals by various processes (e.g. pressing, squeezing, extraction, fractionation, distillation, concentration, drying up and fermentation).' That concept thus encompasses processed products, but it does not, however, cover final products.

33 The Court recalls that 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.

34 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.’

35 Thus, under Article 8(2)(a)(i) of Regulation No 1925/2006, the purpose of the inclusion in Part A of Annex III to that regulation is to prohibit the addition of a ‘substance’ or an ‘ingredient containing [that] substance’ to foods, or its use in the manufacture of foods, where a harmful effect on health has been identified.

36 Inclusion in Part C of Annex III to Regulation No 1925/2006, the purpose of which is to place a substance under EU scrutiny, is reserved for ‘substances’ where the possibility of harmful effects on health has been identified but scientific uncertainty persists, in accordance with Article 8(2)(b) of that regulation.

37 The procedure referred to in Article 8 of Regulation No 1925/2006 is thus applied if 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.

38 As a preliminary point, the Court notes that the contested regulation refers in particular to, on the one hand, the specific HADs, namely aloe-emodin and emodin, and, on the other hand, preparations in which those substances are present, preparations from the leaf of *Aloe* species containing HADs, and, in essence, preparations from parts of certain species of *Rheum*, *Cassia* and *Rhamnus*, which contain HADs.

39 It is apparent from the documents before the Court that the HADs aloe-emodin and emodin must be regarded as 'substances' within the meaning of Article 8(1) and (2)(a)(i) of Regulation No 1925/2006. Those two HADs are also classified as such in the first and second entries in Article 1(1) of the contested regulation by the use of the expression 'all preparations in which this substance is present'.

40 In the light of the wording of Article 8 of Regulation No 1925/2006, the Commission did not therefore err in law in relying on that provision in order to include aloe-emodin and emodin in the list of substances whose addition to foods or use in the manufacture of foods is prohibited.

41 It remains to be examined whether Article 8 of Regulation No 1925/2006 permitted the adoption of the provisions of the contested regulation in so far as they refer to various 'preparations' containing HADs.

42 In the first place, the Court will examine whether the concept of 'preparations' in the first, second and third entries in Article 1(1) of the contested regulation may correspond to the concept of 'substance' other than vitamins or minerals or to the concept of 'ingredient containing a substance' other than vitamins or minerals within the meaning of Article 8(1) and (2)(a)(i) of Regulation No 1925/2006.

43 The Court finds that the concepts of 'substance' and 'ingredient containing a substance' in Article 8(1) of Regulation No 1925/2006, the concepts of 'substance and/or … ingredient containing the substance' in Article 8(2)(a)(i) of that regulation and the concept of 'preparations' in the contested regulation are not expressly defined in those regulations.

44 According to the settled case-law of the Court of Justice, the meaning and scope of terms for which EU law provides no definition must be determined by reference to their usual meaning in everyday language, while account is also taken of the context in which they occur and the purposes of the rules of which they form part (judgments of 9 November 2016, *Davitas*, C-448/14, EU:C:2016:839, paragraph 26, and of 26 October 2017, *The English Bridge Union*, C-90/16, EU:C:2017:814, paragraph 18).

45 In that regard, the General Court notes that the concept of 'substance other than vitamins or minerals', used in Article 8 of Regulation No 1925/2006, constitutes the concrete expression of the concept of 'other substance' defined in Article 2(2) of that regulation as 'a substance other than a vitamin or a mineral that has a nutritional or physiological effect'. The concept of 'other substance' is therefore defined in a residual manner by the exclusion of vitamins or minerals, which are the subject of specific provisions in the same regulation, and by the sole indication that they have a nutritional or physiological effect.

46 The concept of 'ingredient' in Regulation No 1925/2006 is, for its part, immediately presented by reference to the 'substance' which it contains. Thus, only ingredients containing the substance in question are referred to in Article 8(1) and (2)(a)(i) of that regulation. In other words, it is the harmful effect of the substance as such which results in the unsafe nature of the ingredient containing it and, therefore, the possible prohibition of its addition to foods or its use in the manufacture of foods, in accordance with Article 8(2)(a)(i) of that regulation.

47 Recital 1 of Regulation No 1925/2006 also states that 'there is a wide range of nutrients and other ingredients that might be used in food manufacturing, including, but not limited to, vitamins, minerals including trace elements, amino acids, essential fatty acids, fibre, various plants and

herbal extracts.' It follows from this that vitamins, minerals including trace elements, amino acids, essential fatty acids, fibre, various plants and herbal extracts are examples of what may constitute a nutrient or an ingredient within the meaning of that regulation.

48 As regards the concept of 'preparations', as the Commission rightly stated, it was defined in a footnote to the 2009 EFSA Guidance as including 'all preparations obtained from botanicals by various processes (e.g. pressing, squeezing, extraction, fractionation, distillation, concentration, drying up and fermentation)'.

49 However, as expressly stated in the 2009 EFSA Guidance, those guidelines are intended only to define a general framework for the scientific assessment of the safety of botanicals and botanical preparations intended for use in food supplements. Although guidance documents of EU authorities may indeed serve as a basis for interpreting an act of EU law, such documents are not legally binding for that purpose (see, to that effect, judgment of 5 May 2022, *Association France Nature Environnement (Temporary impacts on surface water)*, C-525/20, EU:C:2022:350, paragraph 31). Therefore, a definition of the concept of 'preparations' drawn from the 2009 EFSA Guidance is not binding on the Courts of the European Union, since they alone have jurisdiction to provide a binding interpretation of EU law.

50 The Court also notes that the definition of 'preparations' contained in the 2009 EFSA Guidance is circular and merely sets out a list of various processes enabling a preparation of a given plant to be obtained, citing in a non-exhaustive manner examples of those processes, such as pressing, squeezing, extraction, fractionation, distillation, concentration, drying up and fermentation. It does not, by contrast, allow for a precise interpretation of what is meant by 'preparations'.

51 In any event, first, in the light of the wording of the provisions of the contested regulation and, in particular, of the first and second entries listed in Article 1(1) of that regulation, which refers to certain HADs as substances as well as preparations in which those substances are present, it must be held that the meaning to be given to the term 'preparation' is broader than that of 'substance'. The Commission itself acknowledged that, by using the term 'preparations', those provisions sought to prohibit the addition to foods or the use in the manufacture of foods not only of substances as such but also of preparations containing those substances obtained from botanicals by various processes, such as pressing, squeezing, extraction, fractionation, distillation, concentration, drying up and fermentation.

52 It follows that a preparation containing a substance is a broader concept than that of 'substance', within the meaning of Regulation No 1925/2006, and cannot therefore be substituted for it.

53 Second, the Court notes that, at the hearing, the Commission stated that the term 'preparations' 'refers to a manufacturing process so, if an ingredient is manufactured, then the ingredient and what comes out of manufacturing are not the same thing'. The Commission therefore accepted that the meaning to be given to the concept of 'preparations' differed from that of 'ingredient'.

54 Furthermore, contrary to what the Commission maintained in response to the questions put by the Court by way of measures of organisation of procedure and at the hearing, there is nothing to suggest that the term 'preparations' in the provisions of the contested regulation is not capable of covering, inter alia, final products resulting from a manufacturing process.

55 Therefore, without it being necessary to establish a precise definition of the concepts of 'substance', 'ingredient' and 'ingredient containing a substance' in Article 8(1) and (2)(a)(i) of Regulation No 1925/2006, it follows from the foregoing that, in the present case, the concept of 'preparations' in the first, second and third entries in Article 1(1) of the contested regulation, and in Article 1(2) thereof, has a broader scope and meaning than those of 'substances' and 'ingredients', within the meaning of Article 8 of Regulation No 1925/2006, and cannot be substituted for them.

56 Since the concepts of 'substance', 'ingredient' and 'ingredient containing a substance' in Article 8 of Regulation No 1925/2006 thus evoke notions different from that conveyed by the concept of 'preparations' referred to in the provisions of the contested regulation, the scope of a prohibition on the addition of 'preparations' to foods or on their use in the manufacture of foods cannot be the same as that of substances or ingredients containing substances.

57 As noted in paragraph 35 above, Article 8(2)(a)(i) of Regulation No 1925/2006 permits the inclusion in Part A of Annex III to that regulation only of a 'substance' or an 'ingredient containing [that] substance'.

58 Accordingly, the Commission could not rely on Article 8 of Regulation No 1925/2006 in order to adopt the first, second and third entries in Article 1(1) of the contested regulation, which sought to prohibit the addition to foods or the use in the manufacture of foods of 'all preparations in which [aloe-emodin] is present', 'all preparations in which [emodin] is present' and 'preparations from the leaf of *Aloe* species containing [HADs]'.

59 In the second place, that conclusion is all the more compelling as regards the inclusion of 'preparations from the root or rhizome of *Rheum palmatum* L., *Rheum officinale* Baillon and their hybrids containing [HADs]', 'preparations from the leaf or fruit of *Cassia senna* L. containing [HADs]' and 'preparations from the bark of *Rhamnus frangula* L., *Rhamnus purshiana* DC. containing [HADs]' in Part C of Annex III to Regulation No 1925/2006, on the basis of Article 8(2)(b) of that regulation, since that provision allows only 'substances' within the meaning of that regulation to be placed under EU scrutiny.

60 It follows from all of the foregoing that the provisions of Article 1(1) and (2) of the contested regulation were adopted in breach of Article 8(2)(a)(i) and (b) of Regulation No 1925/2006, since that provision does not permit the inclusion of 'preparations' on the lists in Part A or C of Annex III to the latter regulation. The applicants' arguments in that regard must, therefore, be upheld.

61 Accordingly, the first and second entries in Article 1(1) of the contested regulation in so far as they use the words 'and all preparations in which this substance is present', the third entry of Article 1(1) of that regulation in so far as it refers to 'preparations from the leaf of *Aloe* species containing [HADs]', and Article 1(2) of that regulation must be annulled.

The plea in law and arguments alleging that a risk threshold was not established for prohibiting the addition to foods or the use in the manufacture of foods of certain substances and preparations, in accordance with Article 8(1) and (2)(a)(i) of Regulation No 1925/2006

62 In the context of the third plea, the applicants submit, inter alia, that the conclusions of the 2017 scientific opinion do not identify any harmful effects on human health which would allow the substances and preparations in question, referred to in the first, second and third entries in Article 1(1) of the contested regulation, to be included in Part A of Annex III to Regulation No 1925/2006, and do not establish a specific level for safe use in that regard.

63 According to the applicants, the insufficiency of the data available to EFSA did not enable it to recommend a specific level for safe use. Yet the Commission considered that that insufficiency of data allowed it to assume that there was no level for safe use and, therefore, it simply prohibited the addition to foods and the use in the manufacture of foods of the substances and preparations in question. Such an approach reverses the burden of proof by requiring the applicants to prove the safety of their products, whereas it is the Commission which must satisfy the conditions contained in Article 8 of Regulation No 1925/2006. The scale of the prohibition is therefore inappropriate and unjustified in the light of the evidence adduced and the Commission's approach in that regard is disproportionate and does not fulfil the criterion of 'necessity' required by Regulation No 1925/2006.

64 Accordingly, in their view, the first, second and third entries in Article 1(1) of the contested regulation are vitiated by an error of law.

65 The Commission submits that, according to the 2017 scientific opinion, HADs, in particular aloe-emodin and emodin, as well as *Aloe* extracts, which are used as or in food, are of high concern for human health, and that it has been demonstrated that they are all genotoxic *in vitro*. Since EFSA had concerns about the genotoxicity potential of HADs, it was unable to identify a daily intake that did not give rise to concerns for human health. The Commission therefore had no alternative but to prohibit the addition to foods and the use in the manufacture of foods of the substances and preparations in question.

66 According to the Commission, the inclusion of the substances and preparations listed in the first, second and third entries in Article 1(1) of the contested regulation in Part A of Annex III to Regulation No 1925/2006 therefore complies with the standard and the requirement for scientific proof laid down in Article 8(2)(a)(i) of the latter regulation.

67 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).

68 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).

69 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).

70 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).

71 As noted in paragraphs 33 and 34 above, 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 EU scrutiny.

72 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'.

73 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.

74 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.

75 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'.

76 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'.

77 In the present case, the Commission relied on the 2017 scientific opinion, the conclusions of which set out in paragraph 8 above are reproduced in recitals 7 and 8 of the contested regulation, in order to include, inter alia, in Part A of Annex III to Regulation No 1925/2006, 'aloe-emodin' and 'emodin', and 'all preparations in which [those] substance[s] [are] present', as well as '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.

78 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 first, second and third entries in Article 1(1) of the contested regulation and Article 1(2) of that regulation, all the substances and preparations in question are prohibited, irrespective of the amount of HADs which they contain.

79 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 8 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.

80 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.

81 Despite those considerations, the provisions of the contested regulation refer to 'aloe-emodin' and 'emodin', as well as 'all preparations in which [those] substance[s] [are] present', and all preparations from the leaf of *Aloe* species containing HADs, irrespective of the amount of HADs present therein.

82 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.

83 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 75 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'.

84 Moreover, it is not apparent from the 2017 scientific opinion or from any material in the case file that the provisions of the contested regulation were adopted because the substances and preparations in question otherwise represented a potential risk to consumers.

85 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.

86 The general prohibition on the addition to foods or the use in the manufacture of foods of substances and preparations containing certain substances, such as those referred to in the first, second and third entries in Article 1(1) of the contested regulation, irrespective of the amount of those substances present, 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.

87 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, according 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.

88 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.

89 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.

90 Consequently, the first, second and third entries in Article 1(1) of the contested regulation infringe Article 8(2)(a)(i) of Regulation No 1925/2006, read in conjunction with Article 8(1) of that regulation, in so far as they prohibit the HADs, 'aloe-emodin' and 'emodin', and preparations in which those substances are present, as well as preparations from the leaf of *Aloe* species containing HADs, from being added to foods or used in the manufacture of foods, irrespective of the amount of HADs concerned. The applicants' arguments in that regard must, therefore, be upheld.

91 It follows from all of the foregoing that the first, second and third entries in Article 1(1) of the contested regulation, and Article 1(2) of that regulation, must be annulled, without it being necessary for the Court to rule on the applicants' other pleas and arguments.

Costs

92 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.

93 Since the Commission has been unsuccessful, it must be ordered to pay the costs, in accordance with the form of order sought by the applicants.

On those grounds,

THE GENERAL COURT (Sixth Chamber, Extended Composition)

hereby:

1. **Annuls the first, second and third entries in Article 1(1), and Article 1(2), 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;**

2. **Orders the European Commission to pay the costs.**

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