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 scrutiny of certain substances and preparations containing hydroxyanthracene derivatives – First and second entries in Article 1(1), and first and second entries in Article 1(2), of Regulation (EU) 2021/468 – Definition of 'substance', 'ingredient' and 'preparations' – Error of law)

In Case T-271/21,

Ortis, established in Bütgenbach (Belgium), represented by A. de Brosses, lawyer,

applicant,

v

European Commission, represented by F. Clotuche-Duvieusart, I. Galindo Martín 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: L. Ramette, Administrator,

having regard to the written part of the procedure,

further to the hearing on 27 June 2023,

gives the following

Judgment

1 By its action under Article 263 TFEU, the applicant, Ortis, 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: French.

containing hydroxyanthracene derivatives (OJ 2021 L 96, p. 6; 'the contested regulation'), in so far as, by the first and second entries in Article 1(1) of that regulation and the first and second entries in 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 The applicant is a company which manufactures and markets food supplements made of senna (*Cassia angustifolia* Vahl) and rhubarb (*Rheum palmatum* L. or *Rheum officinale* Baillon), which contain HADs, including emodin and aloe-emodin.

3 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.

4 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 sub-groups of the population.

5 To do 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).

6 On 22 November 2017, EFSA adopted a scientific opinion entitled 'Safety of hydroxyanthracene derivatives 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.'

7 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. [and] *Rhamnus purshianus* DC. 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.

8 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]'.

9 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').

10 On 5 October 2020, the Commission presented a revised draft regulation to the PAFF Committee.

11 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.

12 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 and 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.

13 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'.

14 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.'

15 In recital 9 of the contested regulation, the Commission also stated that, '[c]onsidering 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 No 1925/2006]'.

16 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'.

17 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

18 The applicant claims that the Court should:

– annul the contested regulation;

– order the Commission to pay the costs.

19 The Commission contends that the Court should:

– dismiss the action;

– order the applicant to pay the costs.

Law

Delimitation of the subject matter of the action

20 In the present proceedings, it is common ground between the parties that the applicant does not produce products containing danthron, 'preparations from the leaf of *Aloe* species containing HADs' or 'preparations from the bark of *Rhamnus frangula* L. or *Rhamnus purshiana* DC. containing HADs'.

21 Consequently, in accordance with its pleadings, the applicant must be regarded as seeking the annulment of the first and second entries in Article 1(1) of the contested regulation and the first and second entries in Article 1(2) thereof.

Admissibility of a new argument in the course of proceedings

22 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.

23 Thus, according to the Commission, the applicant relied, for the first time in the reply, on the argument that knowledge of exposure is a requirement under Article 8(1) of Regulation No 1925/2006, since it must be established that the amounts of a substance which may be ingested under normal conditions of consumption have been greatly exceeded. In addition, it did so in the context of the first part of the first plea in law. However, in the Commission's view, while, in the application, the applicant did mention the fact that the calculation of the exposure to HADs did not include any quantitative or qualitative assessment of the likelihood of exposure to HADs, that is a different argument which comes under the second part of the first plea in law.

24 In the context of an adversarial procedure, 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 therewith, must be declared admissible. Moreover, arguments which in substance have a close connection with a plea raised in the application initiating proceedings cannot be considered new pleas under 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).

25 In the present case, all the arguments raised by the applicant in the context of the first plea of the application are based, inter alia, on infringement of Article 8 of Regulation No 1925/2006. The argument relied on by the applicant in the reply must be understood to be seeking to substantiate the challenge to the legality of the contested regulation, in that the Commission failed to comply with its obligation to carry out a risk analysis and to assess the likelihood of exposure to HADs and to certain preparations, on the basis both of Article 6 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ 2002 L 31, p. 1) and of Article 8(1) and (2) of Regulation No 1925/2006, and reversed the burden of proof.

26 Furthermore, the General Court observes that the question of the risk assessment and the failure to consider a threshold also form the subject of arguments raised by the applicant in the application in the context of the second plea, alleging a misuse of powers, the third plea, alleging manifest errors of assessment, and the fifth plea, alleging breach of the principle of proportionality.

27 The mere fact that the applicant has still not put forward that line of argument in the context of the same part of the first plea is not decisive. According to case-law, an application must be interpreted with a view to giving it practical effect, by assessing it in its entirety (see, to that effect, order of 28 June 2011, *Verein Deutsche Sprache* v *Council*, C-93/11 P, not published, EU:C:2011:429, paragraphs 20 and 21).

28 The line of argument advanced by the applicant in the reply is therefore not new compared with the pleas put forward in the application.

29 Therefore, the doubts expressed by the Commission as to the admissibility of that argument must be dismissed as unfounded.

Substance

30 In support of its action, the applicant relies on five pleas in law.

31 The first plea is divided into three parts. The first part 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 allowing certain substances and preparations to be included in Part A of Annex III to that regulation and, second, a risk threshold in that regard was not established. The second part alleges infringement of the same provision, in that that provision does not allow 'preparations' to be included in Part C of Annex III to the Regulation. The third part also alleges infringement of the same provision as well as of Article 6 of Regulation No 178/2002, because the rules on risk assessment to which EFSA is subject and those on risk management to which the Commission is subject were not observed.

32 The second plea alleges a misuse of powers, in that the public health ground relied upon to justify the adoption of the contested regulation does not reflect the reality and that that regulation should have been applied only to food supplements at doses higher than those present in ordinary foods.

33 The third plea alleges manifest errors of assessment, in that the 2017 scientific opinion and the contested regulation were adopted in disregard of the risk assessment methods that should have been followed and without any consideration of thresholds for the purpose of prohibiting the substances and preparations at issue.

34 The fourth plea alleges that the contested regulation breaches the general principle of legal certainty, in that the term 'preparations' is not defined and imprecise and that the relationship between point 1 and point 2 of Article 1 of that regulation is vitiated by legal uncertainty.

35 The fifth plea alleges breach of the principle of proportionality, in that the inclusion of the substances at issue in Part A of Annex III to Regulation No 1925/2006, without a threshold having been set, is not necessary in order to achieve the objective of protecting public health.

36 In the first place, the Court considers it appropriate to examine the line of argument put forward by the applicant in the second part of the first plea, alleging that Article 8(2)(b) of Regulation No 1925/2006 does not allow 'preparations' to be included in the list in Part C of Annex III to that regulation. In the second place, the Court will examine the arguments raised by the applicant in the context of the first part of the first plea and the second, third and fifth pleas, alleging that a risk threshold was not established for prohibiting the addition to foods or the use in the manufacture of foods of some of the substances and preparations at issue, in accordance with Article 8(1) and (2)(a)(i) of that regulation.

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

37 In the context of the second part of the first plea, the applicant submits that, under Article 8(2)(b) of Regulation No 1925/2006, only 'substances' other than vitamins or minerals are liable to be placed under EU scrutiny on the basis of that provision. In addition, Article 1(2) of the contested regulation refers not to 'substances' but to 'preparations', which differ from one another semantically.

38 Therefore, the Commission could not rely on Article 8(2) of Regulation No 1925/2006 in order to adopt the first and second entries in Article 1(2) of the contested regulation.

39 The Commission contends that the term '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)'. It adds that the term 'substance' comes from the Latin 'substantia' meaning 'food' or 'foods', and that that ordinary meaning is consistent with the context and the objectives of Article 8 of Regulation No 1925/2006, namely the protection of consumers' health.

40 Moreover, the Commission states that, while the word 'ingredient' contained in Article 8(2)(a)(i) of Regulation No 1925/2006 is not reproduced in Article 8(2)(b) thereof, that is not the result of a conscious choice by the legislature, which could not have intended to prohibit it from including ingredients, or preparations, in Part C of Annex III to that regulation.

41 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 or would otherwise represent a potential risk to consumers.

42 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 effect on health is identified but scientific uncertainty persists, the substance shall be placed in Annex III, Part C.'

43 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.

44 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.

45 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.

46 In the light of the parties' arguments, the Court will examine whether the term 'preparations' in the first and second entries in Article 1(2) of the contested regulation corresponds to 'substance' other than vitamins or minerals, or to 'ingredient containing a substance' other than vitamins or minerals within the meaning of Article 8(1) and (2)(a)(i) and (b) of Regulation No 1925/2006.

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

48 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).

49 In that regard, the Court notes that the term 'substance other than vitamins or minerals', used in Article 8 of Regulation No 1925/2006, is the concrete expression of the term 'other substance' defined in Article 2(2) thereof as 'a substance other than a vitamin or a mineral that has a nutritional or physiological effect'. The term '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.

50 The term '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 potential 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.

51 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.

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

53 However, as expressly stated in the 2009 EFSA Guidance document, 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.

54 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. By contrast, it does not allow for a precise interpretation of what is meant by 'preparations'.

55 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) thereof, 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'. At the hearing, the Commission itself acknowledged that the term 'preparations' covered 'all forms of processing applied to a plant' or 'all forms of processing which [could] be applied to plants'.

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

57 Second, although the Commission contends that it can decide to place 'ingredients' within the meaning of Article 8 of Regulation No 1925/2006 under EU scrutiny, and that they overlap with the term 'preparations', the Court notes that, at the hearing, the Commission stated that the definition of 'ingredient' contained in Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers,

amending Regulations (EC) No 1924/2006 and No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ 2011 L 304, p. 18), could apply to Regulation No 1925/2006.

58 Under Article 2(2)(f) of Regulation No 1169/2011, an ingredient is defined as being 'any substance or product, including flavourings, food additives and food enzymes, and any constituent of a compound ingredient, used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form', whereas 'residues shall not be considered as "ingredients"'.

59 A preparation, which may contain an ingredient, must therefore be regarded as a broader term than that of 'ingredient', within the meaning of Regulation No 1925/2006, and cannot therefore be substituted for it.

60 Therefore, regardless of whether the legislature deliberately intended to draw a distinction between the placement under EU scrutiny of 'substances' and the prohibition of the addition to foods or the use in the manufacture of foods of 'substances and/or … ingredients containing the substance', and without it being necessary to establish a precise definition of those concepts contained in Article 8(1) and (2)(a)(i) and (b) of Regulation No 1925/2006, it follows from the foregoing that, in the present case, the term 'preparations' in the first and second entries in Article 1(2) of the contested regulation has a broader scope and meaning than that of 'substances' and, as the case may be, 'ingredients' and cannot be substituted for them, since the term 'preparations' can encompass all types of processed food products.

61 Since the terms 'substance', 'ingredient' and 'ingredient containing a substance' in Article 8 of Regulation No 1925/2006 thus evoke different notions from that conveyed by the concept of 'preparations' referred to in the first and second entries of Article 1(2) of the contested regulation, the scope of a placement under EU scrutiny of the 'preparations' at issue cannot be the same as that of substances or, as the case may be, ingredients.

62 As noted in paragraph 42 above, Article 8(2)(b) of Regulation No 1925/2006 permits the inclusion in Part C of Annex III to that regulation only of a 'substance'.

63 Therefore, the Commission could not rely on Article 8(2)(b) of Regulation No 1925/2006 in order to adopt the first and second entries in Article 1(2) of the contested regulation, which sought to place under EU scrutiny 'preparations from the root or rhizome of *Rheum palmatum* L., *Rheum officinale* Baillon and their hybrids containing [HADs]' and 'preparations from the leaf or fruit of *Cassia senna* L. containing [HADs]'.

64 This would also be the case even if it were to be held that the EU legislature allowed the placement under EU scrutiny of 'ingredients'.

65 The applicant's arguments alleging infringement of Article 8(2)(b) of Regulation No 1925/2006 must therefore be upheld and the first and second entries in Article 1(2) of the contested regulation must be annulled.

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

66 In the context of the first part of the first plea and the second, third and fifth pleas, the applicant claims inter alia that, under Article 8(1) of Regulation No 1925/2006, the classification of a substance in Annex III of that regulation is allowed only if, as a result of the addition of that substance, amounts are ingested which greatly exceed those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet. The exceeding of those amounts must be established and the Commission must, to that end, rely on a complete assessment of the exposure, or of the possibility of exposure, to the substances concerned and a characterisation of their risks. However, in the present case, EFSA did not quantitatively or qualitatively assess the likelihood of exposure to the substances and preparations at issue.

67 The applicant adds that the contested regulation should apply only to food supplements containing HADs at doses greater than those of ordinary foods and that, if the HADs posed such a high risk that setting a threshold was not viable, the European Medicines Agency (EMA) would not have allowed them to be present in herbal medicinal products at doses significantly higher than the detection threshold set by the PAFF Committee at its meeting of 5 October 2020 on the draft of a regulation which culminated in the contested regulation.

68 Therefore, by regarding the addition or the use of HADs or the preparations at issue as being likely to lead to the quantities consumed under normal conditions being greatly exceeded, but without however setting a risk threshold in that regard, the Commission infringed Article 8 of Regulation No 1925/2006 and committed manifest errors of assessment.

69 The Commission contends that the standard of the scientific evidence meets the requirements of Article 8(2)(a)(i) of Regulation No 1925/2006 and that EFSA could not set a daily intake of HADs which does not give rise to concerns for human health. As for the fact that a substance posing risks may be prohibited in food but used in medicinal products, that results from the different legal framework of the relevant legislation.

70 The Commission adds that the applicant does not explain how the failure to evaluate exposure to the substances concerned establishes scientific uncertainty vis-à-vis HADs and that it distorted EFSA's finding that serious harmful effects on health are associated with the use of those HADs in foodstuffs and a daily intake that does not give rise to concerns for human health cannot be set.

71 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 (see, to that effect, 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).

72 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 EU Courts 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).

73 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).

74 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).

75 As observed in paragraphs 41 and 42 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 conditions, or in respect of which there is scientific uncertainty.

76 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 or would otherwise represent a potential risk to consumers'.

77 The Court observes 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.

78 Article 8(2) of Regulation No 1925/2006 must be read together with Article 8(1) thereof, 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 and varied diet or that would otherwise represent a potential risk to consumers.

79 Thus, more specifically, under Article 8(2)(a)(i) of Regulation No 1925/2006, read in the light of Article 8(1) thereof, 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'.

80 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'.

81 In the present case, the Commission relied on the 2017 scientific opinion, the conclusions of which set out in paragraph 6 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', 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.

82 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 provisions of the contested regulation, all the substances and preparations in question are prohibited, irrespective of the amount of HADs which they contain.

83 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 6 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.

84 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.

85 Despite those considerations, the first and second entries in Article 1(1) of the contested regulation refer to 'aloe-emodin' and 'emodin', as well as 'all preparations in which [those] substance[s] [are] present', irrespective of the amount of HADs present therein.

86 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 concerns 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.

87 That absence of a threshold is contrary to Article 8(2)(a)(i) of Regulation No 1925/2006, read together with Article 8(1) of that regulation, from which it is apparent, as stated in paragraph 78 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'.

88 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.

89 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.

90 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 and second 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.

91 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 that 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, a fact which the Commission moreover acknowledges in paragraph 83 of the defence and paragraph 41 of the rejoinder.

92 The Commission also acknowledged, in paragraph 33 of the defence, that the safety of foods was examined so as to ensure that they are safe when consumed regularly and by the population as a whole, and that 'EFSA calculate[d] for the different substances a "permissible daily intake", defined as the "estimated amount of a substance present in the food … which [could] be consumed daily throughout a person's life without presenting a significant risk to health"'.

93 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 the substance concerned 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.

94 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) thereof, 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.

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

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

Costs

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

98 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.

On those grounds,

THE GENERAL COURT (Sixth Chamber, Extended Composition)

hereby:

1. Annuls the first and second entries in Article 1(1), and the first and second entries in 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.

[Signatures]