ECLI:EU:T:2020:322

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

8 July 2020 (*)

(Public health — Specific rules for the organisation of official controls on products of animal origin intended for human consumption — Amendment of the lists of third country establishments from which imports of specified products of animal origin are permitted, regarding certain establishments from Brazil — Article 12(4)(c) of Regulation (EC) No 854/2004 — Comitology — Obligation to state reasons — Rights of defence — Powers of the Commission — Equal treatment — Proportionality)

In Case T-429/18,

BRF SA, established in Itajaí (Brazil),

SHB Comércio e Indústria de Alimentos SA, established in Itajaí,

represented by D. Arts and G. van Thuyne, lawyers,

applicants,

v

European Commission, represented by A. Lewis, B. Eggers and B. Hofstötter, acting as Agents,

defendant,

APPLICATION under Article 263 TFEU for the annulment of Commission Implementing Regulation (EU) 2018/700 of 8 May 2018 amending the lists of third country establishments from which imports of specified products of animal origin are permitted, regarding certain establishments from Brazil (OJ 2018 L 118, p. 1),

THE GENERAL COURT (Fifth Chamber, Extended Composition),

composed of D. Gratsias (Rapporteur), President, S. Frimodt Nielsen, J. Schwarcz, V. Valančius and R. Frendo, Judges,

Registrar: S. Spyropoulos, Administrator,

having regard to the written part of the procedure and further to the hearing on 21 January 2020,

gives the following

Judgment

Background to the dispute

1 The applicants, BRF SA and SHB Comércio e Indústria de Alimentos SA, belong to the BRF capital group, which is vertically integrated and active in the production and distribution of meat, including poultry meat, in more than 150 countries. In 2017, that group exported, through the applicants, 152 107 tonnes of poultry meat from Brazil to the EU market, representing approximately 38% of all Brazilian imports for that year.

2 Ten establishments belonging to the first applicant and two establishments belonging to the second applicant were, as undertakings exporting meat and meat products, including poultry meat, to the EU market, among those to appear on the lists drawn up under Article 12 of Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ 2004 L 139, p. 206). The lists in question name the establishments whose products of animal origin may be imported into the European Union.

3 On 21 February 2018, the Commission submitted to the Standing Committee on Plants, Animals, Food and Feed ('the Standing Committee') for its opinion, pursuant to Article 12(4)(c) of Regulation 854/2004, a draft of an implementing regulation on the delisting of certain third country establishments from which products of animal origin may be imported into the European Union. All the establishments concerned were located in Brazil.

4 On 10 April 2018, the Commission submitted to the Standing Committee a first amended version of the draft implementing regulation referred to in paragraph 3 above. On 19 April 2018, the Commission submitted a second amended version of the draft. The Standing Committee discussed it at its meeting of 19 April 2018 and gave a favourable opinion on the same day.

5 On 8 May 2018, the Commission adopted Implementing Regulation (EU) 2018/700 amending the lists of third-country establishments from which imports of specified products of animal origin are permitted, regarding certain establishments from Brazil (OJ 2018 L 118, p. 1; 'the contested implementing regulation').

6 Pursuant to the contested implementing regulation, a number of Brazilian establishments, including the 12 establishments belonging to the applicants referred to in paragraph 2 above, were removed from the lists in question.

7 It is apparent from recitals 4 to 6 of the contested implementing regulation that the decision to delist the said establishments was based on the notification, through the rapid alert system ('RASFF notification'), of a 'significant number of serious and repeated cases' of non-compliance with EU requirements due to the presence of *salmonella* in poultry meat and poultry meat preparations from those establishments. What is more, the Brazilian authorities had failed to take the requisite corrective actions to address the shortcomings identified, meaning that they could no longer be regarded as providing sufficient guarantees that imports of the products in question complied with public health rules.

8 In addition, it is also apparent from the information supplied by the Brazilian authorities that cases of fraud had been detected in March 2018 in Brazil concerning laboratory certification for meat and meat products exported to the European Union. Investigations into those cases indicated that there had been no sufficient guarantees of compliance with EU requirements in relation to the establishments belonging to the applicants.

Procedure and forms of order sought

9 By application lodged at the Court Registry on 13 July 2018, the applicants brought the present action. The defence, reply and rejoinder were lodged on 28 September 2018, 22 November 2018 and 7 January 2019, respectively.

10 By separate document lodged at the Court Registry on 13 July 2018 and registered as Case T-429/18 R, the applicants applied for suspension of the operation of the decision.

11 By letter of 9 January 2019, the parties were informed that the written part of the procedure had been closed and that they could request that a hearing be held under the conditions set out in Article 106 of the Rules of Procedure of the General Court. By letter of 30 January 2019, the applicants requested that a hearing be held.

12 By order of 13 February 2019, *BRF and SHB Comércio e Indústria de Alimentos* v *Commission* (T-429/18 R, not published, EU:T:2019:98), the President of the General Court dismissed the application to suspend the operation of the decision and costs were reserved.

13 As two members of the Fifth Chamber were unable to sit in the case, two other judges were designated to complete the Chamber.

14 On a proposal from the Fifth Chamber, the Court decided, pursuant to Article 28 of the Rules of Procedure, to assign the case to a Chamber sitting in extended composition.

15 By way of measures of organisation of procedure, adopted on 29 January, 12 September and 21 November 2019, the Court requested the parties to reply to a series of questions and to produce certain documents. The parties complied with those requests within the periods prescribed.

16 The hearing was held on 21 January 2020.

17 The applicants claim that the Court should:

– annul the contested implementing regulation in its entirety or, in the alternative, to the extent that it concerns the establishments belonging to them;

– order the Commission to pay the costs.

18 The Commission contends that the Court should:

– dismiss the action;

– order the applicants to pay the costs.

Law

19 In support of their action, the applicants put forward six pleas in law, alleging, respectively:

– infringement of the obligation to state reasons;

– infringement of their rights of defence;

– infringement of Article 12(2) and (4)(c) of Regulation No 854/2004;

– infringement of the principle of non-discrimination;

– infringement of the principle of proportionality;

– infringement of Article 291(3) TFEU and of Articles 3, 10 and 11 of Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ 2011 L 55, p. 13).

20 In addition to the fact that the Commission disputes the merits of all those pleas, it submits that the applicants are not entitled to seek the annulment of the contested implementing regulation in its entirety, on the ground that, apart from the 12 establishments belonging to the applicants, that regulation purports to remove from the lists drawn up in accordance with Article 12 of Regulation No 854/2004 eight other establishments which are not linked to the applicants.

21 It is therefore necessary to determine the extent to which the applicants have standing to bring an action for annulment of the contested implementing regulation.

Applicants' standing to bring proceedings

22 In order to rule on the applicants' standing to bring proceedings, it is necessary to assess, as a preliminary step, the nature of the contested implementing regulation. That assessment requires setting out the context in which an implementing regulation of that type was adopted.

23 In that regard, it should be noted that, according to Article 1(1) thereof, Regulation No 854/2004 lays down specific rules for the organisation of official controls on products of animal origin. Thus, Chapter II of that regulation, containing Articles 3 to 8, is dedicated to the official controls relating to establishments situated within the European Union, whereas Chapter III thereof, comprising Articles 10 to 15, deals with the procedures concerning imports.

24 As regards the procedures concerning imports, Article 11(1) of Regulation No 854/2004 provides that products of animal origin are to be imported only from a third country or a part of a third country that appears on a list drawn up and updated by the Commission pursuant to an implementing act adopted in accordance with the procedure referred to in Article 19(2) of that regulation.

25 The conditions which a third country must meet in order to appear on such a list are laid down in Article 11(2) to (4) of Regulation No 854/2004, as amended pursuant to Article 60 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ 2004 L 165, p. 1), which refer to Articles 46 and 48 of the latter regulation.

26 Those conditions relate essentially to the provision, by the competent authorities of the third country, of appropriate guarantees as regards compliance or equivalence with EU feed and food law and animal health rules. In that context, account is also taken of the legislation of the third country on, inter alia, products of animal origin, the use of veterinary medicinal products, the preparation and use of feedingstuffs and hygiene conditions. To that end, the Commission may carry out official controls in third countries. Those controls involve, inter alia, the legislation of the third country, the organisation, powers and independence of the competent authorities, the training of their staff, their resources, the effectiveness of their operation and, last, the assurances which the third country can give regarding compliance with, or equivalence to, EU law requirements.

27 In that regard, it should also be noted that Brazil appears, first, in Annex I to Commission Regulation (EC) No 798/2008 of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements (OJ 2008 L 226, p. 1), and, second, in Annex II to Commission Regulation (EU) No 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements (OJ 2010 L 73, p. 1). Those regulations were adopted on the basis, inter alia, of Article 11(1) of Regulation No 854/2004.

28 However, that inclusion of Brazil is not sufficient for the purposes of importing products of animal origin into the territory of the European Union from that country. Article 12(1) of Regulation No 854/2004 provides that, except in specific cases provided for in the same provision, products of animal origin may be imported into the Union only if they have been dispatched from, and obtained or prepared in, establishments that appear on lists drawn up and updated to that effect by the authorities of the third country concerned.

29 The conditions for including an establishment on one of the lists referred to in paragraph 28 above are set out in Article 12(2) of Regulation No 854/2004. In particular, according to that provision, an establishment may be placed on such a list only if the competent authority of the third country of origin guarantees that:

– that establishment, together with any establishments handling raw material of animal origin used in the manufacture of the products of animal origin concerned, complies with relevant EU requirements or with requirements that were determined to be equivalent to such requirements when deciding to add that third country to the relevant list in accordance with Article 11;

– an official inspection service in that third country supervises the establishments and makes available to the Commission, where necessary, all relevant information on establishments furnishing raw materials; and

– it has real powers to stop the establishments from exporting to the Union in the event that the establishments fail to meet the requirements referred to under the first subparagraph above.

30 In addition, according to Article 12(3) of Regulation No 854/2004, the competent authorities of third countries appearing on lists drawn up and updated by the Commission in accordance with Article 11 are to guarantee that lists of the establishments referred to in Article 12(1) thereof are drawn up, kept up-to-date and communicated to the Commission. According to Article 12(5) of that regulation, the Commission is to take the necessary measures to ensure that up-to-date versions of all lists drawn up or updated in accordance with the same article are available to the public.

31 It follows that, under Regulation No 854/2004, the import of products of animal origin into the territory of the European Union requires two cumulative conditions to be satisfied.

32 First, the third country of origin of those products must appear on a list of countries which the Commission considers appropriate for providing certain guarantees relating to their regulatory system concerning products of animal origin. That list is to be drawn up and updated pursuant to an implementing act which the Commission adopts in accordance with the procedure referred to in Article 19(2) of Regulation No 854/2004.

33 Second, the goods in question must originate from establishments which appear on a list drawn up by the competent authority of the third country in respect of which that authority provides the specific guarantees described in paragraphs 29 and 30 above.

34 Thus, unlike the lists of countries from which imports of certain products of animal origin are authorised, the lists of exporting establishments are drawn up and updated by the competent authorities of third countries, which communicate them to the Commission, that institution being responsible only for making those lists available to the public.

35 That division of tasks between the Commission and the competent authorities of third countries, such as is established by Regulation No 854/2004, required that provision be made for a safeguard measure for the protection of public health in the European Union. Therefore, according to Article 12(4)(c) of that regulation, whenever the Commission considers it necessary to modify a list of establishments drawn up by the authorities of a third country, in the light of relevant information such as European Union inspection reports or RASFF notifications put in place to that end pursuant to Article 50 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), it is to inform all Member States and include the point on the agenda of the next meeting of the relevant section of the Standing Committee for decision, where appropriate, in accordance with the procedure referred to in Article 19(2) of Regulation No 854/2004. That procedure leads to the adoption of an implementing act, such as the contested implementing regulation, modifying the list of third-country establishments whose products of animal origin may be imported into the European Union.

36 Article 12(4)(c) of Regulation No 854/2004 therefore empowers the Commission to adopt an implementing act pursuant to which the lists drawn up by the competent authorities of third countries are modified. It is apparent from paragraph 29 above that the modification of such a list may prove necessary where the competent authority of the third country of origin can no longer be regarded as providing the guarantees described in Article 12(2) of that regulation in respect of certain establishments. In that regard, as the applicants moreover argue under the third plea (see paragraph 97 below), Article 12(4) of that regulation does not provide for an evaluation by the Commission of the individual conduct of the establishments as such, but only an assessment of the reliability of the guarantees provided in respect of them by the competent authorities. That reliability may be cast into doubt on account of the shortcomings observed in the organisation and operation of those authorities, but also in the light of the action taken by them when they have to deal with cases of non-compliance, on the part of individual establishments, with the requirements laid down in Article 12(2)(a) of the same regulation. It is only to the extent that information relating to the prevailing situation within one or more establishments is relevant to assessing the reliability of the guarantees by the authorities of the third country that the Commission is required, as the case may be, to take it into account.

37 It must also be emphasised that, contrary to what the applicants claim (see paragraph 92 below), the establishments which appear on the list of third-country establishments whose products of animal origin may be imported into the European Union are not the beneficiaries of an individual right conferred on them pursuant to an act of EU law the object of which is the export of their products to the EU market. First, EU law provides that the export of products of animal origin to the EU market is conditional upon the third country in question being included on the list provided for in Article 11 of Regulation No 854/2004. Second, the inclusion of establishments belonging to the applicants on the lists provided for in Article 12 of that regulation is made not by an EU institution, body or agency, but solely by the authorities of the third country concerned, exclusively for the purposes of the operation of the system of guarantees set out in paragraphs 23 to 34 above with regard, in particular, to its second aspect described in paragraphs 28 to 30, 33 and 34 above.

38 Thus, an implementing act, such as the contested implementing regulation, pursuant to which the Commission removes certain establishments from the lists drawn up by the competent authorities of a third country does not constitute a bundle of individual acts the object of which is the revocation of a right supposedly conferred on those establishments. The implementing act in question in fact alters the second of the two conditions which must be satisfied, as has been set out in paragraph 33 above, by each consignment of products of animal origin exported to the EU market, namely the condition relating to the guarantees provided by the authorities of the third country of origin concerning the effective implementation of the relevant legislation of that country. That being the object, the contested implementing regulation establishes the rule that the import into the EU market of products of animal origin from establishments covered by that regulation is no longer permitted. That rule applies to all economic operators that might have an interest in importing such products from those establishments, but also to the customs authorities of the Member States of the European Union, such that the contested implementing regulation is of general application (see, by analogy, judgment of 30 September 2003, *Eurocoton and Others* v *Council*, C-76/01 P, EU:C:2003:511, paragraph 73).

39 In that context, it is necessary to establish, in accordance with the fourth paragraph of Article 263 TFEU, whether, and to what extent, the applicants are directly and, depending on the case, individually concerned by the contested implementing regulation.

40 According to settled case-law, the condition that a natural or legal person must be directly concerned by the decision against which the action is brought, laid down in the fourth paragraph of Article 263 TFEU, requires two cumulative criteria to be met, namely, first, the contested measure must directly affect the legal situation of the individual and, second, it must leave no discretion to its addressees who are entrusted with the task of implementing it, such implementation being purely automatic and resulting from the EU rules alone without the application of other intermediate rules (see judgment of 6 November 2018, *Scuola Elementare Maria Montessori* v *Commission*, *Commission* v *Scuola Elementare Maria Montessori* and *Commission* v *Ferracci*, C-622/16 P to C-624/16 P, EU:C:2018:873, paragraph 42 and the case-law cited).

41 In that regard, it must be pointed out that, by virtue of the contested implementing regulation alone, products originating from the establishments listed in the annex thereto no longer fulfil the second condition that must be satisfied in order for them to be exported to the EU market (see paragraphs 28 to 30, 33 and 34 above). Thus, that implementing regulation directly affects the applicants' legal situation in that it excludes *ipso iure* all imports of products of animal origin from the establishments listed in its annex belonging to the applicants. Moreover, it leaves no discretion to the customs authorities of the Member States to which it is addressed entrusted with the task of implementing it, that implementation being purely automatic and resulting from the EU rules alone without the application of other intermediate rules.

42 However, it is clear that the legal situation of the applicants is affected only in so far as the object of the contested implementing regulation is to remove from the lists drawn up in accordance with Article 12 of Regulation No 854/2004 establishments belonging to them. Consequently, it is only with regard to those latter establishments that the applicants are directly affected by that implementing regulation.

43 Furthermore, as a non-legislative act of general application, the contested implementing regulation constitutes a regulatory act within the meaning of the fourth paragraph of Article 263 TFEU (see, to that effect, judgment of 6 November 2018, *Scuola Elementare Maria Montessori* v *Commission*, *Commission* v *Scuola Elementare Maria Montessori* and *Commission* v *Ferracci*, C-622/16 P to C-624/16 P, EU:C:2018:873, paragraphs 23 to 28 and the case-law cited).

44 Consequently, the question of whether, in order to be recognised as having standing to bring an action for annulment of the implementing regulation at issue, it is necessary for the applicants to be individually concerned by that implementing regulation depends on whether it entails implementing measures within the meaning of the fourth paragraph of Article 263 TFEU.

45 In that regard, it should be noted that, as has been set out in paragraph 41 above, the contested implementing regulation excludes *ipso iure* any imports of products of animal origin from the establishments listed in its annex, 12 of which belong to the applicants. It follows that no implementing measure on the part of the EU authorities or of the Member States is necessary in order for that implementing regulation to produce its effects. In that context, only an act adopted by the customs authorities of a Member State refusing to release for free circulation on the EU market products of animal origin from the establishments belonging to the applicants and listed in the annex to the implementing regulation in question can be regarded as a measure implementing that regulation, within the meaning of the fourth paragraph of Article 263 TFEU.

46 The adoption of such an act is not, however, part of the regular operation of the system established by the applicable rules. Indeed, it is apparent from Article 12(2)(c) of Regulation No 854/2004 that, from the time a third country is added to the list provided for in Article 11 of the same regulation, the competent authorities of that third country must block, already at customs of the country of origin, each consignment intended for export to that market from an establishment which does not appear on the list of establishments authorised to export products of animal origin to the EU market.

47 Consequently, a hypothetical scenario whereby, despite the adoption of the contested implementing regulation, a consignment originating from an establishment belonging to the applicants which had been removed from the lists at issue would arrive at the EU border is based on the premiss that the applicants will seek, with the assistance of the Brazilian authorities, to infringe the contested implementing regulation by engaging in circumventing practices. Such a premiss cannot, however, be taken into account in the assessment of the existence of measures implementing a regulatory act within the meaning of the fourth paragraph of Article 263 TFEU, as amended by the Treaty of Lisbon. That provision is intended, inter alia, to enable a natural or legal person to bring an action against a regulatory act which is of direct concern to them and which does not entail implementing measures, thereby avoiding cases in which such a person would have to break the law in order to have access to justice (judgment of 6 June 2013, *T & L Sugars and Sidul Açúcares* v *Commission*, T-279/11, EU:T:2013:299, paragraph 58; see also, to that effect, order of 4 June 2012, *Eurofer* v *Commission*, T-381/11, EU:T:2012:273, paragraph 60).

48 If, in spite of that analysis, the contested implementing regulation had to be regarded as entailing implementing measures, it would have to be held that, in any event, that regulation is of

individual concern to the applicants in that it refers to each of them by name, in its annex, in their capacity as owners of certain of the establishments mentioned therein. To that extent, that implementing regulation affects the applicants by reason of an attribute which is peculiar to them and which differentiates them from all other persons, by reason of the fact that they are the owners of certain establishments listed in the annex to that regulation, and, by virtue of those factors, distinguishes them individually in the same way as the addressee, within the meaning of the judgment of 15 July 1963, *Plaumann* v *Commission* (25/62, EU:C:1963:17, p. 223).

49 It follows that, as the Commission contends, the action is admissible only to the extent that it concerns the establishments belonging to the applicants. The admissible part of the action thus coincides with the claim for annulment made in the alternative, such that it is necessary to examine its merits.

Substance

50 It is appropriate to start by examining the sixth plea in law.

Sixth plea: infringement of Article 291(3) TFEU and of Articles 3, 10 and 11 of Regulation No 182/2011

51 The applicants claim that the draft of the contested implementing regulation was scheduled to be subject to the opinion of the Standing Committee on its agenda of 19 April 2018. However, the draft in question was submitted to that committee that same day, in breach of Article 3(3) of Regulation No 182/2011, which provides for a period of at least 14 days between submission of the draft implementing act and the committee meeting. That period constitutes an essential procedural requirement, breach of which renders that contested implementing regulation void. Such a breach also deprives the European Parliament and the Council of the European Union of their right of scrutiny under Articles 10(4) and 11 of the same regulation.

52 It should be recalled that, under Article 12(4)(c) of Regulation No 854/2004, where the Commission brings a matter before the Standing Committee concerning the modification of the list of establishments whose products of animal origin may be imported into the European Union, that committee is to decide ‘in accordance with the procedure referred to in Article 19(2)’ of that same regulation.

53 According to Article 19(2) of Regulation No 854/2004, where reference is made to that paragraph, Articles 5 and 7 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ 1999 L 184, p. 23) are to apply.

54 Decision 1999/468 had been adopted on the basis of Article 202 EC (now, after amendment, Article 291 TFEU).

55 According to Article 291(2) and (3) TFEU:

‘2. Where uniform conditions for implementing legally binding Union acts are needed, those acts shall confer implementing powers on the Commission, or, in duly justified specific cases and in the cases provided for in Articles 24 and 26 of the Treaty on European Union, on the Council.

3. For the purposes of paragraph 2, the European Parliament and the Council, acting by means of regulations in accordance with the ordinary legislative procedure, shall lay down in advance the

rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.'

56 Pursuant to Article 291(3) TFEU, the Parliament and the Council adopted Regulation No 182/2011, which repealed Decision 1999/468.

57 Article 13(1) of Regulation No 182/2011 provides as follows:

'Where basic acts adopted before the entry into force of this Regulation provide for the exercise of implementing powers by the Commission in accordance with Decision [1999/468], the following rules shall apply:

' …

(c) where the basic act makes reference to Article 5 of Decision [1999/468], the advisory procedure referred to in Article 5 of this Regulation shall apply …'

58 Moreover, according to Article 13(2) of Regulation No 182/2011, 'Articles 3 and 9 of this Regulation shall apply to all existing committees for the purposes of paragraph 1'.

59 It is apparent from Article 13(1)(c) of Regulation No 182/2011, read in conjunction with the provisions of Regulation No 854/2004 referred to in paragraphs 52 and 53 above, that the Standing Committee is to intervene in the case in accordance with the examination procedure referred to in Article 5 of that same regulation.

60 Last, according to Article 3 of Regulation No 182/2011, entitled 'Common provisions':

'1. The common provisions set out in this Article shall apply to all the procedures referred to in Articles 4 to 8.

…

3. The chair shall submit to the committee the draft implementing act to be adopted by the Commission.

Except in duly justified cases, the chair shall convene a meeting not less than 14 days from submission of the draft implementing act and of the draft agenda to the committee. The committee shall deliver its opinion on the draft implementing act within a time limit which the chair may lay down according to the urgency of the matter. Time limits shall be proportionate and shall afford committee members early and effective opportunities to examine the draft implementing act and express their views.

4. Until the committee delivers an opinion, any committee member may suggest amendments and the chair may present amended versions of the draft implementing act.'

61 It should be noted that the requirements set by Article 3(3) of Regulation No 182/2011 constitute essential procedural rules imposed by the FEU Treaty, which are essential procedural requirements governing the proper conduct of proceedings, breach of which renders the act concerned void (judgment of 20 September 2017, *Tilly-Sabco* v *Commission*, C-183/16 P, EU:C:2017:704, paragraph 114).

62 Since Article 291(3) TFEU expressly provides for control by Member States of the Commission's exercise of implementing powers conferred on it by paragraph 2 of that article, it must be held that the 14-day time limit, liable to be shortened in justified cases, aims to guarantee that the governments of the Member States are informed through their Management Committee members about the Commission's proposals, so that those governments may, by means of internal and external consultations, define a position in order to protect the specific interests of each of them within the Management Committee (see, to that effect, judgment of 20 September 2017, *Tilly-Sabco* v *Commission*, C-183/16 P, EU:C:2017:704, paragraph 103).

63 In the case at hand, it is apparent from paragraphs 212 to 214 of the application that the applicants base their line of argument on the fact that the Commission submitted the draft that led to the adoption of the contested implementing regulation at the Standing Committee on 19 April 2018, that is to say, the very day of the meeting at which that committee examined it, without complying with the 14-day time limit provided for in the second subparagraph of Article 3(3) of Regulation No 182/2011 (see paragraph 60 above).

64 In that regard, it is apparent from the extracts from the register of the Standing Committee produced by the Commission that it had submitted to that committee a draft of the contested implementing regulation on 21 February 2018 and that a first amended version of that draft had been submitted on 10 April 2018. The Commission adds that the second amended version of that draft, submitted to that committee on 19 April 2018, concerned only a purely formal additional amendment, moving the date of entry into force of the proposed measures to the second day following publication of that implementing regulation in the *Official Journal of the European Union*, instead of the 15th day previously provided for. That version of the facts is corroborated by the documents produced by the Commission on 30 January and 13 December 2019 by way of measures of organisation of procedure.

65 It should be recalled that, under Article 3(4) of Regulation No 182/2011, until the committee delivers an opinion, the chair may present amended versions of the draft implementing act (see paragraph 60 above).

66 It follows that, contrary to what the applicants claim, no infringement of Article 3(3) of Regulation No 182/2011 can be found in the present case.

67 Last, to the extent that the applicants base the alleged infringement of the other provisions on which they rely, namely Article 291(3) TFEU and Articles 10 and 11 of Regulation No 182/2011, exclusively on the failure to comply with the four-day period laid down by Article 3(3) of that regulation alone, no infringement of those other provisions relied on can be found in the present case, either.

68 It follows that the sixth plea must be rejected.

First plea: breach of the obligation to state reasons

69 The applicants submit that, as part of its obligation to state the reasons for the contested implementing regulation, the Commission ought to have set out the specific reasons for considering that each of the establishments concerned ought to be removed from the lists referred to in Article 12 of Regulation No 854/2004. First, according to recital 4 thereof, that implementing regulation is based on notifications to the presence of *salmonella* in poultry meat and poultry meat preparations, originating from several establishments in Brazil, though the establishments concerned are not identified. In addition, it is apparent from the annex to that implementing

regulation that the Commission removed certain establishments belonging to the first applicant from the list of establishments authorised to import meat of domestic ungulates and meat products, although recital 4 of the same implementing regulation does not concern that type of product.

70 Second, according to recital 5 of the contested implementing regulation, the Brazilian authorities were unable to address the shortcomings identified, meaning that there were no sufficient guarantees that the establishments to which recital 4 refers complied with EU requirements. According to the applicants, the lack of any precision regarding the factual and legal basis of that assessment and the identity of the establishments concerned amounts to a failure to state sufficient reasons.

71 Third, recital 6 of the contested implementing regulation reveals a contradiction in referring, in respect of the same facts, to cases of proven fraud and to the existence of ongoing investigations and does not explain why the investigations in question cause a loss of confidence rather than strengthening it. Moreover, the implementing regulation in question contains no reference to the facts relevant to each of the establishments concerned.

72 It should be recalled that the statement of reasons required by Article 296 TFEU must be appropriate to the measure in question and must disclose in a clear and unequivocal fashion the reasoning followed by the institution which adopted that measure, in such a way as to enable the persons concerned to ascertain the reasons for the measure and to enable the competent court to carry out its review. The requirements to be satisfied by the statement of reasons depend on the circumstances of each case, in particular the content of the measure in question, the nature of the reasons given and the interest which the addressees of the measure, or other parties to whom it is of direct and individual concern, may have in obtaining explanations. It is not necessary for the reasoning to go into all the relevant facts and points of law, since the question whether the statement of reasons meets the requirements of Article 296 TFEU must be assessed with regard not only to its wording but also to its context and to all the legal rules governing the matter in question (judgment of 11 September 2003, *Austria* v *Council*, C-445/00, EU:C:2003:445, paragraph 49).

73 Regarding in particular measures of general application, such as the contested implementing regulation (see paragraph 38 above), the statement of reasons may be confined to indicating the general situation which led to its adoption, on the one hand, and the general objectives which it is intended to achieve, on the other (judgment of 9 September 2003, *Kik* v *OHIM*, C-361/01 P, EU:C:2003:434, paragraph 102).

74 It must also be recalled that, contrary to what the applicants suggest at numerous points in their submissions (see paragraph 92 below), EU law does not confer on them any individual right purporting to permit them to export their products to the EU market (see paragraph 37 above). As has been set out in paragraphs 23 to 34 above, an act such as the contested implementing regulation is not intended to revoke any individual right granted under other provisions of EU law, which would require initiating an investigation into the conduct of the person in question giving rise to the adoption of an individual act accompanied by a statement of reasons detailing the conduct complained of.

75 That reality is further highlighted by comparing the legal framework in which exporting undertakings established in third countries operate (see paragraphs 23 to 34 above) and that in which EU undertakings operate.

76 In particular, first, EU institutions are subject to an approval requirement under Article 3 of Regulation No 854/2004. The approval procedure is initiated at the request of the operator, approval

itself being granted by the competent authorities of the Member States under the conditions and according to the detailed rules provided for in Article 31(2) of Regulation No 882/2004. To that end, the operator must demonstrate that it complied with the relevant requirements of EU feed or food law. Approval confers on the operators of EU establishments an individual right to place on the EU market products of animal origin. In addition, Article 54(2) of the latter regulation provides for a series of other enforcement measures which the competent authorities of the Member States are required to take against establishments failing to fulfil their obligations under the applicable legislation. It follows that the individual right enjoyed by operators of EU establishments, which has its origin in EU law, can be affected only under the conditions set out in Article 31(2)(e) of that regulation, concerning the withdrawal of approval on account of serious deficiencies or repeated instances of production being stopped, and in Article 54(1) to (3) of the same regulation, laying down a series of other enforcement measures due to non-compliance. Those provisions enable a procedure to be instituted against the operator of the establishment in question, leading to the adoption of an individual measure together with a statement of reasons explaining that operator's failings.

77 Second, under Articles 4 to 8 of Regulation No 854/2004, the competent authorities of the Member States are to carry out a series of official controls in respect of all products of animal origin falling within the scope of that regulation.

78 It follows that operators of EU establishments may initiate a procedure leading to the grant of approval, which occurs if the applicant satisfies certain objective criteria. Establishments holding such approval thus enjoy an individual right to place on the EU market products of animal origin, a right which can be withdrawn only in the circumstances described in paragraph 76 above. In return, the Member States assume, pursuant to EU law, the obligations referred to in paragraph 76 above, the Commission having in respect of them, moreover, the enforcement powers provided for by the Treaty.

79 In contrast to that situation, it is apparent from Articles 11 and 12 of Regulation No 854/2004 that the possibility for third country establishments to export products of animal origin to the EU market requires, first, the country in question and, second, the establishment concerned to be included on the lists provided for in those provisions. First, the EU legislature did not reserve to the operators of interested third country establishments any role in initiating the procedures relating to them nor did it grant them the possibility of raising a matter before the Commission in the event that the competent authority of the third country refused to include them on the lists at issue. Second, the procedures in question do not lead to the adoption of an EU act granting an individual right that could be withdrawn only following a procedure initiated against each of the establishments concerned. As has been set out, the two-tier system established by that regulation is intended to enable the Commission to assess whether the competent authorities of the third country provide the guarantees required by Articles 11 and 12 of that regulation (see paragraphs 24 to 38 above). First, the removal of an establishment from the lists at issue does not equate to revocation of an individual right conferred by EU law (see paragraph 38 above) and, second, neither the Commission nor the Member States have enforcement powers in respect of establishments outside the European Union or countries not directly subject to obligations imposed by EU law.

80 In view of those differences, the Commission is free, in return, to establish the reliability threshold of the guarantees provided by the competent authorities of a third country at a particularly high level and may thus go so far as to require, by reference to essential parameters, practically irreproachable performance on the part of the competent authorities of third countries.

81 In that context, the requirements to state reasons set out in paragraphs 72 and 73 above mean that the Commission must set out the reasons that led it to consider that the Brazilian authorities no longer provided, in respect of the establishments concerned, the guarantees provided for in Article 12(2) of Regulation No 854/2004.

82 If the reasons in question involve matters relating to certain establishments, the statement of those reasons must describe the matters in question as relevant information within the meaning of Article 12(4)(c) of Regulation No 854/2004, only in so far as it is necessary to explain, in combination with the conduct or statements of the authorities of the third country concerned, the reasons why the Commission considers that those authorities no longer provide the guarantees required by Article 12(2) of that regulation.

83 In the case at hand, it is apparent from the annex to the contested implementing regulation that the establishments belonging to the applicants covered by it appear on four different tables. The first table concerns the meat of domestic ungulates (section I of the sectoral nomenclature) and shows a single establishment belonging to the first applicant. The second table concerns the meat from poultry and lagomorphs (section II of the sectoral nomenclature) and shows eight establishments belonging to the first applicant and two establishments belonging to the second applicant. The third table concerns minced meat, meat preparations and mechanically separated meat (section V of the sectoral nomenclature) and shows, inter alia, eight establishments belonging to the first applicant and one establishment belonging to the second applicant. The fourth table concerns meat products (section VI of the sectoral nomenclature) and shows six establishments belonging to the first applicant.

84 The Commission stated, in recitals 4 and 5 of the contested implementing regulation, that the Brazilian authorities had been requested to take the necessary corrective actions to remedy the serious and repeated cases of non-compliance with EU requirements due to the presence of *salmonella* in poultry meat and poultry meat preparations. It is apparent from the information provided by those authorities and from the results of the official controls carried out at the borders of the European Union, however, that the necessary actions had not been taken, so the placing on the market of the products from the establishments concerned constituted a risk for public health. Those reasons relate to the 10 establishments belonging to the applicants and set out in the second table of the annex to that implementing regulation.

85 Moreover, according to recital 6 of the contested implementing regulation, investigations into cases of fraud detected in Brazil in March 2018 indicate that there had been no sufficient guarantees that the establishments belonging to the applicants and removed from the lists at issue complied with the relevant EU requirements. Those reasons concern all the establishments of the applicants which appear on the four tables of the annex to the contested implementing regulation. In that regard, it must be stated that the very nature of the fraud in question, concerning laboratory certification for meat, including poultry meat, and meat products exported to the European Union, is such as to call into question the reliability of the guarantees which the Brazilian authorities are supposed to provide under Article 12(2) of Regulation No 854/2004, a circumstance which, according to that same recital, makes the products from those establishments liable to constitute a risk for human health.

86 That motivation contains all the elements enabling an understanding, in the light of the applicable legal framework, of the reasons underpinning the adoption of the contested implementing regulation in the field of meat and meat products, including poultry meat.

87 The elements cited in the contested implementing regulation refer to shortcomings of the competent Brazilian authorities as regards the guarantees which they are supposed to provide within the meaning of Article 12(2) of Regulation No 854/2004, a circumstance which bears an obvious connection with the protection of public health, the safeguarding of which is that regulation's objective. That motivation also enables the applicants, as persons with standing to bring proceedings for the annulment of the contested implementing regulation, to bring an action contesting the accuracy of the findings underlying the Commission's action.

88 In that regard, contrary to what the applicants claim, the Commission is not obliged to set out, in the contested implementing regulation, which specific notifications, issued by the authorities of the Member States following each control at the borders of the European Union, concerned each of the establishments listed in the annex to that regulation or which specific facts underpin the accusation of certifications fraud with regard to each of the establishments concerned.

89 First, given that the Commission states, in recital 5 of the contested implementing regulation, that only the establishments concerned were removed from the relevant list, the applicants are in a position to verify whether products dispatched from an establishment listed in that annex have been the subject of notifications and whether the number of those notifications, if any, can be deemed large. Second, the reason set out in recital 6 of that implementing regulation, according to which the applicable certification system has deficiencies illustrated in documents relating to the investigations carried out by the police and the Brazilian judiciary in relation to meat and meat products, is sufficient, in the light of the stated objective of protecting human health, to support the operative part of an act such as that implementing regulation. Moreover, the fact that the Brazilian authorities themselves discovered the fraud and the fact that they conduct investigations which are still ongoing does not reveal any contradictory reasoning. Indeed, in view of the stated objective of Regulation No 854/2004 of protecting human health, the Commission is entitled to respond to concrete suspicions of fraud relating to the certification of products where those suspicions cast serious doubt on the systemic capacity of the authorities of the third country to provide the guarantees stipulated in Article 12(2) of that regulation without awaiting the final outcome of those investigations.

90 Last, contrary to what the applicants claim, the ungulate meat sector and the meat products sector fall within the ambit of recital 6 of the contested implementing regulation, which refers to 'meat' in general. That circumstance explains why certain establishments belonging to the applicants appear on the first and fourth tables in the annex to that implementing regulation, which are dedicated to the products in question.

91 It follows that the first plea must be rejected.

Second plea: infringement of the applicants' rights of defence

92 The applicants submit that the circumstances surrounding the adoption of the contested implementing regulation amount to an infringement of their rights of defence, which are protected by Article 41(2)(a) of the Charter of Fundamental Rights of the European Union. They claim that the Commission failed to inform them of the evidence adduced against them and invite them to make their views known in that regard prior to the adoption of that implementing regulation They assert that that institution did not even respond to their requests to be heard on the matter. The procedure laid down in Article 12 of Regulation No 854/2004 led, pursuant to an act of the Commission, to their losing their right to export the products in question to the EU market due to facts relating to their individual conduct. The applicants infer that the ability to discuss the matter

with the Brazilian authorities cannot replace the requirement for their rights of defence to be respected by the institution responsible for the act adversely affecting them.

93 According to Article 41(2)(a) of the Charter of Fundamental Rights, the right to good administration includes the right of every person to be heard before any individual measure which would affect him or her adversely is taken. Respect for the rights of the defence is, in all proceedings initiated against a person liable to culminate in a measure adversely affecting that person, a fundamental principle of EU law which must be guaranteed even in the absence of any rules governing the proceedings in question. That principle requires that the addressees of decisions which significantly affect their interests should be placed in a position in which they can effectively make known their views on the accusation made against them forming the basis of the contested measure (judgments of 21 September 2000, *Mediocurso* v *Commission*, C-462/98 P, EU:C:2000:480, paragraphs 36 and 43, and of 1 October 2009, *Foshan Shunde Yongjian Housewares and Hardware* v *Council*, C-141/08 P, EU:C:2009:598, paragraph 83).

94 As regards measures of general application, on the other hand, unless there is express provision to the contrary, neither the process of their drafting nor those measures themselves require, by virtue of general principles of EU law, such as the right to be heard, consulted or informed, the participation of the persons affected (orders of 30 September 1997, *Federolio* v *Commission*, T-122/96, EU:T:1997:142, paragraph 75; judgment of 11 September 2007, *Honig-Verband* v *Commission*, T-35/06, EU:T:2007:250, paragraph 45, and judgment of 15 September 2016, *TAO-AFI and SFIE-PE* v *Parliament and Council*, T-456/14, EU:T:2016:493, paragraph 69).

95 In the case at hand, as is apparent from paragraphs 23 to 38 above, the contested implementing regulation constitutes a measure of general application adopted on the basis of assessments relating to the unreliability of the guarantees provided by the Brazilian authorities regarding the effective implementation of their national legislation by certain establishments in that third country.

96 It follows that the procedure leading to the adoption of the contested implementing regulation was not initiated against the applicants nor did it amount to the adoption of an individual measure addressed to them. Regulation No 854/2004 does not moreover contain any provision establishing the right of persons such as the applicants to be heard. Consequently, the Commission was not obliged to invite the applicants to make known their views to it on the factors taken into account for the purposes of the adoption of the contested implementing regulation, with the result that the second plea must be rejected.

Third plea: infringement of Article 12(2) and (4)(c) of Regulation No 854/2004

97 According to the applicants, the removal of only certain establishments from the lists at issue shows that the Commission assessed the individual conduct of each of them, even though the legal basis for the contested implementing regulation, namely Article 12(4)(c) of Regulation No 854/2004, authorises only an evaluation of the performance of the competent Brazilian authorities.

98 Even assuming that the reasons underpinning the contested implementing regulation relate to the Commission's assessment of the performance of those authorities, that assessment is vitiated by manifest errors. In particular, according to the applicants, first, the request to the Brazilian authorities to take the necessary corrective actions following the detection of *salmonella* in poultry meat and poultry meat preparations relates to the recommendations made in the report of an audit conducted in May 2017. However, it is apparent from the report of a second audit carried out

between the end of January and the beginning of February 2018 that the Brazilian authorities had implemented the measures called for in those recommendations.

99 Second, for the period from 1 March 2017 to 19 April 2018, only 41 cases relating to the 12 delisted establishments belonging to the applicants were subject to an RASFF notification. During that same period, the establishments in question were the origin of 6 766 containers exported to the European Union under a reinforced checks regime involving systematic inspections of consignments arriving at customs. In addition, between 19 June 2017 (the date on which the Brazilian authorities began controlling all consignments intended for export) and 19 April 2018, nine establishments belonging to the applicants were subject to between zero and two RASFF notifications, and two other establishments were subject to between four and six RASFF notifications. Moreover, the suspension by the Brazilian authorities, in March 2018, of the approval of two establishments belonging to the applicants did not take effect until April of that year, so the minimal number of RASFF notifications during the first three months of 2018 cannot be attributed to that suspension. The Commission does not appear, however, to have drawn any conclusions from the 140 RASFF notifications that were issued between 1 March 2017 and 19 April 2018, which concerned establishments not belonging to the applicants and which were not removed from the lists at issue.

100 Third, it is apparent from the relevant statistics that the percentage of containers from establishments belonging to the applicants and removed from the lists at issue, in respect of which the presence of *salmonella* was found during reinforced checks, is close to one third of the corresponding percentage established in relation to products from European establishments, the latter being supposed, however, to comply with EU rules. For seven establishments belonging to the applicants, the percentage in question is between 0 and 3.1%. What is more, only one RASFF notification was issued between 1 January and 19 April 2018 in connection with establishments belonging to the applicants. It follows, in the applicants' view, that the number of RASFF notifications relating to establishments belonging to the applicants cannot be described as significant and the instances of non-compliance found cannot be taken as an indication of an overall business culture. That circumstance is reflected in the first draft of the implementing regulation, which was submitted on 21 February 2018 to the Standing Committee for its opinion (see paragraph 3 above) and which mentioned almost none of the establishments belonging to the applicants.

101 Fourth, the applicants submit that no case of *salmonella* was found in meat products other than poultry meat from the delisted establishments belonging to the applicants, so recitals 4 and 5 of the contested implementing regulation are vitiated by a manifest error of assessment in that respect.

102 Fifth, according to the applicants, the findings of the report drawn up by the Commission in 2018, after its second audit (see paragraph 98 above), confirm that the Brazilian authorities took all necessary measures not only to determine the facts relating to the case of fraud referred to in recital 6 of the contested implementing regulation, but also to ensure thereafter compliance of the products exported with the EU market. Those measures included a decision in March 2018 to suspend, as a precautionary measure, exports from certain establishments belonging to the applicants. In addition, the checks carried out by the Commission in three establishments belonging to the applicants did not reveal any obvious failings. Given that only a single establishment out of those belonging to the first applicant and authorised to export poultry meat to the European Union was questioned during that investigation and that the judicial investigations to which the Commission refers in the same recital relate to the period between 2012 and early 2017 at the latest, the circumstances relied upon by the Commission are not sufficient to cast doubt on the reliability

of the guarantees provided by the Brazilian authorities in relation to the delisted establishments belonging to the applicants.

103 It is apparent from paragraphs 96 to 102 above that the applicants' line of argument may be divided into two parts. The first part alleges an error of law consisting in the infringement of Article 12(4)(c) of Regulation No 854/2004 (see paragraph 97 above). The second alleges a manifest error vitiating the Commission's assessment of the reliability of the guarantees provided by the Brazilian authorities in respect of the establishments belonging to the applicants (see paragraphs 98 to 102 above).

104 It is appropriate to reject at the outset the first part of the present plea, according to which the Commission in reality assessed the individual conduct of each of the establishments covered by the contested implementing regulation in breach of Article 12(4)(c) of the contested implementing regulation (see paragraph 97 above). Indeed, as is apparent from paragraphs 82 to 87 above, the reference in the recitals of that implementing regulation to matters relating to the establishments belonging to the applicants and removed from the lists at issue is made only in so far as it is necessary to explain the reasons why, in combination with the conduct or statements of the authorities of the third country concerned, the Commission considers that those authorities no longer provide the guarantees required by Article 12(2) of Regulation No 854/2004. Moreover, that reference is also explained by the need for the Commission to act carefully and impartially, which means that it must carry out a full and detailed examination of the cause. Consequently, contrary to what the applicants claim, the fact that the Commission did not remove all Brazilian establishments from the lists at issue does not mean that, in reality, it based its decision solely on the conduct or performance of the establishments in question without considering the performance of the Brazilian authorities affecting the reliability of the guarantees which those authorities are supposed to provide.

105 So far as concerns the second part, it includes complaints calling into question both the reason relating to the number of RASFF notifications issued concerning the presence of *salmonella* in poultry meat (recitals 4 and 5 of the contested implementing regulation) and the reason relating to a case of fraud linked to the falsification of Brazilian laboratory certificates regarding the quality of meat in general, including poultry meat (recital 6 of that implementing regulation).

106 It is apparent from the detailed rules for the implementation of Article 12(1) and (2) of Regulation No 854/2004, as those rules appear from the online publication of the lists at issue, that the establishments included therein are broken down by country and by sector of activity. Correlatively, as has been set out in paragraph 83 above, the establishments belonging to the applicants were removed from four different lists relating, respectively, to the meat of domestic ungulates (section I of the sectoral nomenclature, Table 1 of the annex to the contested implementing regulation), the meat from poultry and lagomorphs (section II of the sectoral nomenclature, Table 2 of that annex), minced meat, meat preparations and mechanically separated meat (section V of the sectoral nomenclature, Table 3 of that annex) and meat products (section VI of the sectoral nomenclature, Table 4 of that annex). Each establishment included on the lists at issue bears an approval number issued by the competent Brazilian authority.

107 It should be recalled that the reasons set out in recitals 4 to 6 of the contested implementing regulation (see paragraph 105 above) underpin, in a cumulative manner, the removal from the lists at issue of the 10 establishments in Table 2 of the annex to that implementing regulation as establishments whose production of the meat of poultry and lagomorphs is authorised for import into the European Union (section II of the sectoral nomenclature). As regards the establishments in Tables 1, 3 and 4 of the annex to the contested implementing regulation (sections I, V and VI of the

sectoral nomenclature), however, solely the reason relating to the abovementioned case of fraud underpins their removal from those same lists as establishments whose production of meat of domestic ungulates, minced meat, meat preparations, meat products and mechanically separated meat is authorised for import into the European Union.

108 It follows that, as long as the Commission's assessments relating to the fraud case linked to the falsification of Brazilian laboratory certificates relating to the quality of meat in general, including poultry meat, are not unlawful, they are a sufficient base, to the requisite legal standard, for the contested implementing regulation. It is therefore necessary to examine, in the first place, the complaints raised by the applicants against the assessments in question.

109 In that regard, where the Commission sets out the reasons underlying a measure such as the contested implementing regulation, the review of legality carried out by the EU Courts is directed towards the accuracy of the facts set out therein and whether the facts in question may, by virtue of their nature, undermine the Commission's confidence in the reliability of the guarantees which the competent third country authorities are supposed to provide within the meaning of Article 12(2) of Regulation No 854/2004 (see paragraph 29 above). However, given the broad discretion which the Commission enjoys in establishing the threshold up to which it no longer considers the guarantees in question reliable (see paragraph 80 above), it is not for the EU Courts, in the review of legality entrusted to them under the first paragraph of Article 263 TFEU, to substitute their own assessment for that of the Commission with regard to the level of that threshold. Nevertheless, the EU Courts must be able to censure a manifest error of assessment where, in a particular case, the Commission has set the threshold in question at a level which blatantly affects the plausibility of its conclusions regarding the reliability of those guarantees.

110 In the case at hand, according to recital 6 of the contested implementing regulation, the information provided to the Commission by the competent Brazilian authorities notes instances of fraud detected in March 2018 in Brazil as regards laboratory certification for meat, including poultry meat, and meat products exported to the European Union. According to that recital, the ongoing investigations and recent actions of the judiciary in Brazil indicated that there were no sufficient guarantees that the applicants' establishments complied with the relevant EU requirements, with the result that the products from their establishments were liable to constitute a risk for human health.

111 The applicants claim, first, that those assessments are invalidated by the reports drawn up following two audits carried out by the Commission in Brazil.

112 It should be noted that, in May 2017, the Commission carried out an initial audit in Brazil, pursuant to Article 46 of Regulation No 882/2004. That audit had highlighted a number of shortcomings relating to the following aspects:

– checks and supervision by the competent authorities;

– conflicts of interest;

– eligibility of raw meat;

– presence of official veterinarians;

– re-export of goods rejected following RASFF notifications;

– updating of lists of establishments certified to export to the EU market;

– *salmonella* checks.

113 The Commission then carried out a second audit in Brazil between 22 January and 5 February 2018.

114 While it is true that the report relating to the second audit mentions a number of improvements in the performance of the competent authorities in the fields mentioned in paragraph 112 above, the conclusions of that report do not call into question the assessment set out in recital 6 of the contested implementing regulation.

115 Indeed, it is apparent both from the findings and from the conclusions of the report relating to the second audit that the latter describes the measures taken by the national authorities to remedy systemic deficiencies in the frequency of checks, conflicts of interest in relation to controllers, quality of raw materials, recruitment of an adequate number of official veterinarians appropriate for guaranteeing their effective presence in order to carry out their duties, the measures necessary for preventing consignments that have been subject to an RASFF notification from being re-exported to the EU market, in-time updating of the lists of establishments certified to export to that market and, last, sampling for the purposes of *salmonella* checks.

116 Even though the factual findings underpinning the conclusion of the report on the second audit relate to the actions of the competent authorities with regard to certain sampled establishments for the purposes of the audit, however, the conclusions indicating the improvements made by those authorities refer to their performance in general terms. Thus, the conclusions of that report note systemic deficiencies resulting from the dysfunction of the authorities in question, in terms of methods and staffing, requiring improvements such as speeding up the procedure for updating the lists of establishments. As the Commission contends, Article 46 of Regulation No 882/2004, which constitutes the legal basis empowering it to carry out those controls, provides that the purpose of the controls is to enable it to verify the compliance or equivalence of third country legislation and systems with EU feed and food law and EU animal health legislation. Owing to their nature, those controls are not therefore intended to detect individual conduct, such as that consisting in the extensive falsification of certificates involving the agents and executives of a particular undertaking. It should be added, in any event, that the circumstances mentioned in recital 6 of the contested implementing regulation were brought to the Commission's attention in March 2018, whereas the audit in question had already been closed on 5 February of the same year.

117 In that context, it must be held that the factors set out in paragraphs 97 to 104 of the defence support to the requisite legal standard the reasons set out in recital 6 of the contested implementing regulation.

118 In particular, it is apparent from those factors — and above all from the decision of the competent judge authorising on-the-spot investigations in respect of a series of natural persons, adopted on 4 March 2018 — that the investigations by the Brazilian Federal Police and the judicial authorities relate to extensive cases of fraud in the form of falsifications linked to the certification of products of animal origin with the participation of high-ranking staff and the knowledge of members of the applicants' board of directors. That decision refers to conduct within the group to which the applicants belong aimed at frustrating the public health control system by means of falsified certificates. In that context, the fact, assuming it were established, that, at the time when that document was drawn up, a single establishment appearing until that point on the lists at issue was directly concerned, namely the establishment bearing approval number 1001, does not affect

the Commission's assessment on the scale of the threat posed by such conduct and, consequently, on the reliability of the guarantees provided by the Brazilian authorities specifically against that type of threat. Moreover, as the Commission submits, the fully integrated nature of that group means that their products must move from one establishment to another in order to undergo the necessary processing operations. In addition, the possible involvement of members of the board of directors and of the applicants' senior staff does not permit a conclusion to be drawn with certainty, while the investigation is still ongoing, that the conduct complained of is confined to a single establishment.

119 In that regard, it is important to note that, by letter of 5 March 2018, the Commission approached the Brazilian authorities in the course of contacts in relation to the fraud involving the certification of meat with regard to the *salmonella* bacterium. In that context, after recalling that it had repeatedly asked those authorities to extend their investigation to all establishments in all Brazilian federal states exporting meat products to the European Union, the Commission requested, first, detailed information concerning the first applicant and five laboratory analyses which appeared to be associated with the fraudulent activities according to the latest press reports and, second, the immediate suspension of all consignments originating from the first applicant or certified by the laboratories in question.

120 Following that request, the Brazilian Ministry of Agriculture informed the Commission, by letter of 15 March 2018, that it had just suspended certification for seven establishments belonging to the applicants and was maintaining the previous suspension of three other establishments belonging to the applicants.

121 However, by two orders of 17 April 2018, the Brazilian authorities lifted that suspension for all establishments except for that bearing approval number 466, without offering any tangible evidence justifying that measure in favour of the applicants even though the investigation was still at an early stage.

122 As the Commission contends, those circumstances are objectively such as to undermine its confidence in the guarantees provided by the Brazilian authorities regarding the establishments belonging to the applicants and do not reveal, in the light of the broad discretion it enjoys in establishing the threshold up to which those guarantees no longer must be deemed reliable (see paragraphs 79, 80 and 109 above), any manifest error of assessment.

123 In that regard, the circumstance that, at the time of the adoption of the contested implementing regulation, the investigations had not yet been closed, such that the statements of the police and judicial authorities concerning the findings made in the course of those investigations are without prejudice to the definitive findings, is irrelevant. Indeed, as has been stated in paragraphs 74 to 82 above, that implementing regulation is not intended to revoke any individual rights enjoyed by the applicants, which would require the prior initiation of an investigation leading to definitive findings. Its sole purpose is to establish the extent to which the Commission continues to have confidence in the guarantees provided by the Brazilian authorities in accordance with Article 12(2) of Regulation No 854/2004. The risks identified in the case at hand resulting from the deficient performance on the part of the Brazilian authorities (see paragraphs 117 to 122 above), however, are directly linked to the imperatives of human and animal health safeguarded by Articles 11 and 12 of that regulation. It follows that that implementing regulation may lawfully be based, as in the present case, on factors which are objectively capable of undermining that confidence.

124 Consequently, the Commission's assessments relating to the fraud case linked to the falsification of Brazilian laboratory certificates regarding the quality of meat in general, including

poultry meat, are sufficient to support the contested implementing regulation, with the result that the second part of the third plea must be rejected without it being necessary to examine the applicants' arguments concerning the number of RASFF notifications issued in regard to the presence of *salmonella* in poultry meat (see paragraphs 107 and 108 above).

125 Since the first part of the third plea has also been rejected (see paragraph 104 above), that plea must be rejected in its entirety.

Fourth plea: infringement of the principle of non-discrimination

126 According to the applicants, an analysis of relevant statistical data shows that there are other establishments which were subject, proportionally, to more RASFF notifications than those belonging to them yet were not removed from the lists at issue. Consequently, they consider the establishments belonging to them to be in a comparable situation, in the light of the criteria set out in recitals 4 and 5 of the contested implementing regulation, to that of those other establishments. It follows, in their view, that the assessments of risk for public health posed by those two categories of establishment are no different, since the Commission's references to the case of fraud mentioned in recital 6 of that implementing regulation relate only to allegations about a small number of establishments.

127 It must be recalled that the applicants are requesting the Court to annul the contested implementing regulation, by virtue of which 12 establishments belonging to them have been removed from the lists at issue. It is apparent from the analysis of the third plea, however, that that implementing regulation could validly be adopted in view of the reason relating to the case of fraud mentioned in recital 6 thereof, connected with the forgery of Brazilian laboratory certificates (see paragraphs 107, 108 and 124 above). By their fourth plea, the applicants claim that the Commission infringed the principle of non-discrimination in relying on the other reason invoked by the Commission to adopt the contested implementing regulation, namely that of the number of RASFF notifications issued concerning the presence of *salmonella* in poultry meat (recitals 4 and 5 of that implementing regulation). Thus, supposing that the Commission had to take the view that the guarantees provided by the Brazilian authorities in respect of other establishments in that third country were not reliable, either, that circumstance would in no way affect the legality of that implementing regulation as regards the establishments belonging to the applicants.

128 It follows that the adoption of the contested implementing regulation cannot be regarded as infringing the principle of non-discrimination, with the result that the fourth plea must be rejected.

Fifth plea: infringement of the principle of proportionality

129 The applicants submit, first, that the removal of the establishments belonging to them from the lists at issue was a clearly unnecessary measure since other less draconian measures, such as reinforced checks on export and at the EU border, would have sufficed to safeguard the objective pursued by the contested implementing regulation. Second, according to the applicants, the investigations into the case of fraud referred to in recital 6 of the contested implementing regulation concern only one establishment belonging to them, while the investigations into another case mentioned by the Commission in its defence concern only four establishments belonging to them, of which only one exported poultry meat and poultry meat preparations to the European Union, and only in small quantities.

130 It must be recalled that the contested implementing regulation is based on the Commission's finding that the guarantees provided by the Brazilian authorities in accordance with Article 12(2) of

Regulation No 854/2004 are no longer reliable in relation to the establishments belonging to the applicants. Given the fact that, as is apparent from the analysis of the third plea, the Commission's assessments relating to the unreliability of the guarantees in question due to the case of fraud linked to the falsification of Brazilian laboratory certificates relating to the quality of meat are not vitiated by illegality, the removal of the establishments belonging to the applicants from the lists at issue is the measure which the Commission is required to take, in accordance with Article 12(2) of Regulation No 854/2004, read in conjunction with 12(4)(c) thereof. Under the latter provision, an establishment may be placed on such a list only if the competent authority of the third country provides it with the guarantees described therein.

131 Thus, since the Commission, exercising its discretion in the matter (see paragraphs 80 and 109 above), found that the safeguards provided by the Brazilian authorities in accordance with Article 12(2) of Regulation No 854/2004 were no longer reliable with regard to the applicants and, consequently, are lacking, the removal of the establishments belonging to the applicants from the lists at issue constitutes, as follows from the latter provision, read in conjunction with Article 12(4)(c) of the same regulation, the appropriate and necessary measure to remedy that situation.

132 Consequently, even putting aside the fact that, before the adoption of the contested implementing regulation, the products from several establishments belonging to the applicants and removed from the lists at issue had already been subject to reinforced checks (see paragraphs 99 and 100 above), the principle of proportionality cannot force the Commission to lay down measures such as the reinforcement of checks at the EU borders for those products, when that institution no longer considers the guarantees provided by the Brazilian authorities in favour of the establishments in question to be reliable.

133 It follows that the fifth plea must be rejected and the action must be dismissed in its entirety.

Costs

134 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. Since the applicants have been unsuccessful, they must be ordered to pay the costs, including those relating to the interim proceedings, in accordance with the form of order sought by the Commission.

On those grounds,

THE GENERAL COURT (Fifth Chamber, Extended Composition)

hereby:

1. **Dismisses the action;**

2. **Orders BRF SA and SHB Comércio e Indústria de Alimentos SA to pay the costs of the Commission, including those pertaining to the interim proceedings.**

Frimodt Nielsen Gratsias Schwarcz
Valančius Frendo

Delivered in open court in Luxembourg on 8 July 2020.

E. Coulon
Registrar

S. Papasavvas
President

* Language of the case: English.