Reports of Cases

JUDGMENT OF THE GENERAL COURT (Eighth Chamber)

14 May 2014*

(Approximation of laws — Directive 2009/48/EC — Toy safety — Limit values for nitrosamines, nitrosatable substances, lead, barium, arsenic, antimony and mercury in toys — Commission decision not to approve in full the maintenance of national provisions derogating therefrom — Time-limited approval — Proof of a higher level of protection for human health offered by the national provisions)

In Case T-198/12,

Federal Republic of Germany, represented by T. Henze and A. Wiedmann, acting as Agents,

applicant,

v

European Commission, represented by M. Patakia and G. Wilms, acting as Agents,

defendant,

APPLICATION for annulment in part of Commission Decision 2012/160/EU of 1 March 2012 concerning the national provisions notified by the German Federal Government maintaining the limit values for lead, barium, arsenic, antimony, mercury and nitrosamines and nitrosatable substances in toys beyond the date of entry into force of Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys (OJ 2012 L 80, p. 19).

THE GENERAL COURT (Eighth Chamber),

composed of M.E. Martins Ribeiro (Rapporteur), acting as President, A. Popescu and G. Berardis, Judges,

Registrar: K. Andová, Administrator,

having regard to the written procedure and further to the hearing on 19 September 2013,

gives the following

* Language of the case: German.

Judgment

Legal context

European Union law

1 Article 114 TFEU provides as follows:

‘1. Save where otherwise provided in the Treaties, the following provisions shall apply for the achievement of the objectives set out in Article 26. The European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

2. Paragraph 1 shall not apply to fiscal provisions, to those relating to the free movement of persons nor to those relating to the rights and interests of employed persons.

3. The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective.

4. If, after the adoption of a harmonisation measure by the European Parliament and the Council, by the Council or by the Commission, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 36, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them.

5. Moreover, without prejudice to paragraph 4, if, after the adoption of a harmonisation measure by the European Parliament and the Council, by the Council or by the Commission, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them.

6. The Commission shall, within six months of the notifications as referred to in paragraphs 4 and 5, approve or reject the national provisions involved after having verified whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market.

In the absence of a decision by the Commission within this period the national provisions referred to in paragraphs 4 and 5 shall be deemed to have been approved.

When justified by the complexity of the matter and in the absence of danger for human health, the Commission may notify the Member State concerned that the period referred to in this paragraph may be extended for a further period of up to six months.

7. When, pursuant to paragraph 6, a Member State is authorised to maintain or introduce national provisions derogating from a harmonisation measure, the Commission shall immediately examine whether to propose an adaptation to that measure.

8. When a Member State raises a specific problem on public health in a field which has been the subject of prior harmonisation measures, it shall bring it to the attention of the Commission which shall immediately examine whether to propose appropriate measures to the Council.

9. By way of derogation from the procedure laid down in Articles 258 and 259, the Commission and any Member State may bring the matter directly before the Court of Justice of the European Union if it considers that another Member State is making improper use of the powers provided for in this Article.

10. The harmonisation measures referred to above shall, in appropriate cases, include a safeguard clause authorising the Member States to take, for one or more of the non-economic reasons referred to in Article 36, provisional measures subject to a Union control procedure.'

2 On 3 May 1988, the Council of the European Communities adopted Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys (OJ 1988 L 187, p. 1).

3 Annex II to Directive 88/378, entitled 'Essential safety requirements for toys', provides:

'II. Particular risks

…

3. Chemical properties

1. Toys must be so designed and constructed that, when used as specified in Article 2(1) of the Directive, they do not present health hazards or risks of physical injury by ingestion, inhalation or contact with the skin, mucous tissues or eyes.

They must in all cases comply with the relevant Community legislation relating to certain categories of products or to the prohibition, restriction of use or labelling of certain dangerous substances and preparations.

2. In particular, for the protection of children's health, bioavailability resulting from the use of toys must not, as an objective, exceed the following levels per day:

0,2 µg for antimony,

0,1 µg for arsenic,

25,0 µg for barium,

…

0,7 µg for lead,

0,5 µg for mercury,

…

or such other values as may be laid down for these or other substances in Community legislation based on scientific evidence.

The bioavailability of these substances means the soluble extract having toxicological significance.

…’

4 The bioavailability limit values laid down in Directive 88/378 define the maximum permissible quantity of a chemical substance which may, as a result of the use of the toys, be absorbed and be available for biological processes in the human body. Those limit values are expressed in micrograms of each harmful substance per day (μg/d) and make no distinction according to the consistency of the material of which the toy is made.

5 Upon instructions from the European Commission, the European Committee for Standardisation (CEN) drew up, and subsequently adopted on 13 December 1994, European harmonised standard EN 71-3 entitled ‘safety of toys’ (‘standard EN 71-3’), in order to make it easier — particularly for toy manufacturers — to prove conformity with the requirements of Directive 88/378.

6 Standard EN 71-3 infers from the limit values of bioavailability established in Directive 88/378 limit values for migration through ingestion in respect of toy materials and describes a procedure enabling those values to be determined. Compliance with the values of standard EN 71-3 entails a presumption of conformity with the essential requirements of Directive 88/378 and, therefore, with the limit values of bioavailability defined in that directive, as is apparent from the third recital in the preamble to, and Article 5(1) of, Directive 88/378.

7 The migration limit values state the maximum permissible quantity of a chemical substance which may migrate, that is to say, pass from a product to the exterior, for example to the skin or the gastric juices. They enable measurements to be performed on the toy itself and are expressed in milligrams of each harmful substance per kilogram of toy material (mg/kg).

8 Standard EN 71-3 uses the following migration limit values:

Element	Migration limit value
Antimony	60 mg/kg
Arsenic	25 mg/kg
Barium	1 000 mg/kg
Lead	90 mg/kg
Mercury	60 mg/kg

9 In 2003, a process to review Directive 88/378 was commenced. That process was completed on 18 June 2009 with the adoption of Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ 2009 L 170, p. 1), which the Federal Republic of Germany voted against.

10 Recital 22 in the preamble to Directive 2009/48 states:

‘The specific limit values laid down in Directive 88/378/EEC for certain substances should also be updated to take account of the development of scientific knowledge. Limit values for arsenic, cadmium, chromium VI, lead, mercury and organic tin, which are particularly toxic, and which should therefore not be intentionally used in those parts of toys that are accessible to children, should be set at levels that are half of those considered safe according to the criteria of the relevant Scientific Committee, in order to ensure that only traces that are compatible with good manufacturing practice will be present.’

11 Recital 47 in the preamble to Directive 2009/48 is worded as follows:

‘In order to allow toy manufacturers and other economic operators sufficient time to adapt to the requirements laid down by this Directive, it is necessary to provide for a transitional period of two years after the entry into force of this Directive during which toys which comply with Directive 88/378/EEC may be placed on the market. In the case of chemical requirements, this period should be set at four years so as to allow the development of the harmonised standards which are necessary for compliance with those requirements.’

12 Directive 2009/48 establishes specific migration limit values for several substances, including lead, arsenic, mercury, barium and antimony, based on recommendations made by the Rijksinstituut voor Volksgezondheid en Milieu (RIVM, Dutch National Institute for Public Health and the Environment) in its 2008 report entitled ‘Chemicals in toys. A general methodology for assessment of chemical safety of toys with a focus on elements’ (‘the RIVM report’). Three different migration limit values are defined by reference to the type of material present in the toy, namely dry, brittle, powder-like or pliable material, liquid or sticky material, and scraped-off material.

13 Annex II to Directive 2009/48, entitled ‘Particular safety requirements’, provides:

‘III. Chemical properties

…

13. Without prejudice to points 3, 4 and 5, the following migration limits, from toys or components of toys, shall not be exceeded:

Element	mg/kg in dry, brittle, powder-like or pliable toy material	mg/kg in liquid or sticky toy material	mg/kg in scraped-off toy material
…	…	…	…
Antimony	45	11,3	560
Arsenic	3,8	0,9	47
Barium	4 500	1 125	56 000
…	…	…	…
Lead	13,5	3,4	160
…	…	…	…
Mercury	7,5	1,9	94
…	…	…	…

…’

14 Article 53 of Directive 2009/48 provides:

‘1. Member States shall not impede the making available on the market of toys which are in accordance with Directive 88/378/EEC and which were placed on the market before 20 July 2011.

2. In addition to the requirement of paragraph 1, Member States shall not impede the making available on the market of toys which are in accordance with the requirements of this Directive, except those set out in [point] III of Annex II, provided that such toys meet the requirements set out in [point II.3] of Annex II to Directive 88/378/EEC and were placed on the market before 20 July 2013.'

15 Article 54 of Directive 2009/48, entitled 'Transposition', provides:

'Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 20 January 2011. They shall forthwith inform the Commission thereof.

They shall apply those measures with effect from 20 July 2011.

When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

Member States shall communicate to the Commission the provisions of national law which they adopt in the field covered by this Directive.'

16 Article 55 of Directive 2009/48, entitled 'Repeal', provides:

'Directive 88/378/EEC, except Article 2(1) and [point II.]3 of Annex II, is repealed with effect from 20 July 2011. Article 2(1) thereof and [point II.]3 of Annex II thereto are repealed with effect from 20 July 2013.

References to the repealed Directive shall be construed as references to this Directive.'

National law

17 The Federal Republic of Germany transposed Directive 88/378 into national law by means of the Verordnung über die Sicherheit von Spielzeug (Regulation on toy safety) of 21 December 1989 (BGBl. 1989 I, p. 2541), last amended by Article 6(2) of the Verordnung zur Umsetzung der EG-Richtlinien 2002/44/EG und 2003/10/EG zum Schutz der Beschäftigten vor Gefährdungen durch Lärm und Vibrationen (Regulation on the transposition of Directives 2002/44/EC and 2003/10/EC concerning the protection of workers from risks related to noise and vibrations) of 6 March 2007 (BGBl. 2007 I, p. 261). The limit values for lead, arsenic, mercury, barium and antimony set out in Article 2 of the abovementioned national regulation were those established in Directive 88/378.

18 20 July 2011 saw the entry into force of the Zweite Verordnung zum Geräte- und Produktsicherheitsgesetz (Verordnung über die Sicherheit von Spielzeug) (2. GPSGV) (Second Regulation on equipment and product safety (Regulation on toy safety), BGBl. 2011 I, p. 1350 et seq. and p. 1470, 'the second GPSGV 2011'), Article 10(3) of which, relating to essential safety requirements, reproduces the bioavailability limit values of Annex II to Directive 88/378 for lead, antimony, arsenic, barium and mercury.

Background to the dispute

19 By letter of 18 January 2011, the Federal Republic of Germany applied to the Commission, pursuant to Article 114(4) TFEU, for permission to maintain the provisions of German law regarding five elements, namely lead, arsenic, mercury, barium and antimony, as well as nitrosamines and nitrosatable substances released from certain toys, beyond 20 July 2013, being the date of entry into force of point III of Annex II to Directive 2009/48.

20 By letter of 2 March 2011, the Federal Republic of Germany sent a detailed statement of reasons for that application accompanied by annexes containing health assessments from the Bundesinstitut für Risikobewertung (Federal Institute for Risk Assessment, 'BfR'): one assessment for antimony, arsenic, lead, barium and mercury and another for nitrosamines and nitrosatable substances.

21 By Decision of 4 August 2011, the Commission informed the Federal Republic of Germany, pursuant to the third subparagraph of Article 114(6) TFEU, that the period of six months referred to in the first subparagraph of that article for approval or rejection of the national provisions concerning the five elements in question — in this case lead, arsenic, mercury, barium and antimony — as well as nitrosamines and nitrosatable substances, notified on 2 March 2011, had been extended until 5 March 2012.

22 The Commission gave the following ruling in Decision 2012/160/EU of 1 March 2012 concerning the national provisions notified by the German Federal Government maintaining the limit values for lead, barium, arsenic, antimony, mercury and nitrosamines and nitrosatable substances in toys beyond the entry into application of Directive 2009/48 (OJ 2012 L 80, p. 19, 'the contested decision'), a decision which was notified on 2 March 2012:

'Article 1

The German measures related to antimony, arsenic and mercury notified pursuant to Article 114(4) … TFEU are not approved.

The German measures related to lead and notified pursuant to Article 114(4) … TFEU are approved until the date of entry into force of [European Union] provisions setting new limits for lead in toys or 21 July 2013, whichever comes first.

The German measures related to barium and notified pursuant to Article 114(4) … TFEU are approved until the date of entry into force of [European Union] provisions setting new limits for barium in toys or 21 July 2013, whichever comes first.

The German measures related to nitrosamines and nitrosatable substances notified pursuant to Article 114(4) … TFEU are approved.'

Procedure and forms of order sought by the parties

23 By application lodged at the Registry of the General Court on 14 May 2012, the Federal Republic of Germany brought the present action.

24 The Federal Republic of Germany contends that the Court should:

— declare the contested decision null and void in so far as, first, it did not approve the national provisions laying down limit values for antimony, arsenic and mercury, which were notified with a view to being maintained, and, second, only approved until 21 July 2013 the national provisions laying down limit values for lead and barium, which were also notified with a view to being maintained;

— order the Commission to pay the costs.

25 The Commission contends that the Court should:

— dismiss the action;

— order the Federal Republic of Germany to pay the costs of the action.

26 By document lodged at the Registry of the General Court on 27 August 2012, the Kingdom of Denmark sought leave to intervene in this case in support of the form of order sought by the applicant. By order of 27 September 2012, the President of the Eighth Chamber allowed that intervention.

27 By letter lodged at the Registry of the General Court on 13 November 2012, the Kingdom of Denmark informed the Court that it was withdrawing its intervention. By order of the President of the Eighth Chamber of 14 December 2012, the Kingdom of Denmark was removed from the case as intervener.

28 By document of 13 February 2013, the Federal Republic of Germany lodged an application for interim measures, seeking:

— provisional approval of the notified national provisions maintaining limit values for lead, barium, arsenic, antimony and mercury, pending the Court's decision in the main proceedings;

— in the alternative, an order requiring the Commission to approve provisionally the notified national provisions maintaining limit values for lead, barium, arsenic, antimony and mercury, pending the Court's decision in the main proceedings.

29 By order of 15 May 2013, the President of the General Court, ruling in interim proceedings, ordered the Commission to authorise the maintenance of the national provisions notified by the Federal Republic of Germany concerning limit values for antimony, arsenic, barium, lead and mercury in toys pending the Court's decision in the main proceedings.

30 On hearing the report of the Judge-Rapporteur, the General Court (Eighth Chamber) decided to open the oral procedure in this case and, by way of measures of organisation of procedure provided for in Article 64 of its Rules of Procedure, put questions in writing to the parties, to which they replied within the prescribed period.

31 The parties presented oral arguments and replied to the oral questions put to them by the Court at the hearing on 19 September 2013.

Law

Application for a declaration that there is no need to adjudicate on part of the action made by the Federal Republic of Germany during the hearing

32 During the hearing, the Federal Republic of Germany stated that after the present action had been raised, the Commission adopted Regulation (EU) No 681/2013 of 17 July 2013 amending point III of Annex II to Directive 2009/48 (OJ 2013 L 195, p. 16), which altered the migration limits for barium set out in that annex, and asked the Court to declare that there is no need to adjudicate on the action in so far as it seeks to annul the contested decision, as regards barium, and to order the Commission to pay the costs.

33 The adoption of Regulation No 681/2013 rendered the action devoid of purpose to the extent that it seeks to annul the contested decision in so far as it concerns barium.

34 In those circumstances, the examination of the head of claim relating to the application for annulment of the time-limited approval for lead and barium until 21 July 2013, on account of its alleged unlawfulness, shall only cover the approval for lead, so that it is no longer necessary to adjudicate on the application for annulment of the contested decision in so far as it concerns barium.

The head of claim seeking annulment of the contested decision

35 The action raised by the Federal Republic of Germany seeks the partial annulment of the contested decision in so far as, first, the national measures establishing limit values for lead, which were notified with a view to being maintained, were only approved until 21 July 2013 and, second, the national measures establishing limit values for antimony, arsenic and mercury, which were also notified with a view to being maintained, were not approved.

Unlawfulness of the time-limited approval relating to lead

– Admissibility

36 The Commission submits that the challenge to the time-limited approval for lead is inadmissible because the Federal Republic of Germany does not have legal interest in bringing proceedings.

37 However, it should be recalled that Article 263 TFEU draws a clear distinction between the right of EU institutions and Member States to bring an action for annulment and that of legal persons and individuals, in that the second paragraph of Article 263 TFEU gives all Member States the right to contest the legality of decisions of the Commission by means of an action for annulment without having to establish any legal interest in bringing proceedings (see, to that effect, Case 131/86 *United Kingdom* v *Council* [1988] ECR 905, paragraph 6; order in Case C-208/99 *Portugal* v *Commission* [2001] ECR I-9183, paragraphs 22 to 24; and Joined Cases T-415/05, T-416/05 and T-423/05 *Greece* v *Commission* [2010] ECR II-4749, paragraph 57).

38 The Federal Republic of Germany is therefore perfectly entitled to seek the annulment of the contested decision in so far as the national provisions establishing limit values for lead, which were notified with a view to being maintained, were only approved until 21 July 2013.

– Substance

39 The Federal Republic of Germany essentially relies on three pleas in law alleging, first, infringement of the obligation to state reasons, second, infringement of Article 114 TFEU and third, misuse of powers.

40 Its plea alleging infringement of the obligation to state reasons should be considered first.

41 The Federal Republic of Germany claims that the Commission did not provide sufficient reasons for the temporal limit imposed on approval of the national provisions on lead. It states that the Commission's 'manner of proceeding' reveals a logical inconsistency which should have led the Commission to provide particularly detailed reasons for that limit.

42 Recitals 53 to 55 in the preamble to the contested decision are worded as follows:

'The position of the German Federal Government

(53) The German authorities refer to the 2010 EFSA [European Food Safety Authority] study carrying out a comprehensive assessment on lead. In EFSA's opinion, there is no scientifically justified threshold dose for the adverse effects of lead on human health. Therefore Germany considers that the migration limits for lead, as established in the Directive, are no longer scientifically based and request maintaining national measures.

Evaluation of the position of the German Federal Government

(54) The Commission acknowledges that the migration limits for lead as established in the Directive no longer offer an appropriate level of protection for children. The tolerable daily intake used for calculating the limits was questioned by EFSA and JECFA [Food and Agriculture Organisation/World Health Organisation Expert Committee on Food Additives] in 2010, after the revision of the toy safety legislation. Taking this into account, the Commission already undertook the revision of the abovementioned limits.

(55) In the light of the above considerations, the Commission is of the opinion that the measures notified by Germany with regard to lead are considered as justified on grounds of major need of protection of human health.'

43 Recital 91 in the preamble to the contested decision, in the section entitled 'Absence of obstacles to the functioning of the internal market', states:

'With regard to lead …, the Commission notes that manufacturers, when applying the provisions of the Directive, will be able to market toys in all Member States, except for Germany. Manufacturers are not likely to develop two sets of different toys, but align on the derogating provisions in order to have toys which can be marketed in all Member States. The Commission further notes that the German limits for lead … are those that have been applicable in the EU since 1990 on the basis of Directive 88/378/EEC, and therefore can be technically met by manufacturers. Toy manufacturers have confirmed this assumption when expressing their position on the German measures. The Commission has therefore reasons to consider that the effect on the functioning of the internal market is proportionate in relation to the objective of protecting children's health.'

44 Recital 94 in the preamble to the contested decision, in the section entitled 'Conclusion', provides:

'With regard to the national measures notified by Germany in relation to lead …, the Commission concludes that these measures are considered as justified by the need to protect human health, and that they do not constitute either a means of arbitrary discrimination, a disguised restriction on trade between Member States, or a disproportionate obstacle to the functioning of the internal market. The Commission has therefore reasons to consider that the national measures notified can be approved, subject to a limitation in time.'

45 The obligation to state reasons laid down in the second paragraph of Article 296 TFEU is an essential procedural requirement which must be distinguished from the question whether the reasoning is well founded, which is concerned with the substantive legality of the measure at issue (see Case C-367/95 P *Commission* v *Sytraval and Brink's France* [1998] ECR I-1719, paragraph 67, and Case C-17/99 *France* v *Commission* [2001] ECR I-2481, paragraph 35).

46 According to settled case-law, the statement of reasons required under the second paragraph of 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 the reasons for a measure meets the requirements of the second paragraph 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 (see *Commission* v *Sytraval and Brink's France*, paragraph 45 above, paragraph 63 and the case-law cited, and Case T-304/02 *Hoek Loos* v *Commission* [2006] ECR II-1887, paragraph 58).

47 It should be noted that the statement of the reasons for a measure must be logical and contain no internal inconsistency that would prevent a proper understanding of the reasons underlying the measure (Case C-521/09 P *Elf Aquitaine* v *Commission* [2011] ECR I-8947, paragraph 151).

48 A contradiction in the statement of the reasons on which a decision is based constitutes a breach of the obligation laid down in the second paragraph of Article 296 TFEU such as to affect the validity of the measure in question if it is established that, as a result of that contradiction, the addressee of the measure is not in a position to ascertain, wholly or in part, the real reasons for the decision and, as a result, the operative part of the decision is, wholly or in part, devoid of any legal justification (Case T-5/93 *Tremblay and Others* v *Commission* [1995] ECR II-185, paragraph 42; Case T-65/96 *Kish Glass* v *Commission* [2000] ECR II-1885, paragraph 85; and Case T-347/09 *Germany* v *Commission* [2013] ECR, paragraph 101).

49 It is also apparent from the case-law that, although a decision of the Commission which fits into a well-established line of decisions may be reasoned in a summary manner, for example by a reference to those decisions, the Commission must, if a decision goes appreciably further than the previous decisions, give an account of its reasoning (Case 73/74 *Groupement des fabricants de papiers peints de Belgique and Others* v *Commission* [1975] ECR 1491, paragraph 31, and Case C-295/07 P *Commission* v *Département du Loiret* [2008] ECR I-9363, paragraph 44).

50 In addition, it should be noted that review of the observance of the guarantees conferred by the European Union legal order in administrative procedures, such as the Commission's obligation to give an adequate statement of reasons, is even more important in the procedure under Article 114(4) TFEU since the right to be heard does not apply to it (see, to that effect, Case C-3/00 *Denmark* v *Commission* [2003] ECR I-2643, paragraph 50, and Case C-405/07 P *Netherlands* v *Commission* [2008] ECR I-8301, paragraphs 56 and 57).

51 In the present case, it is noteworthy that the contested decision contains preliminary observations (recitals 19 to 24 in the preamble thereto) recalling, in particular, the circumstances in which the limit values for arsenic, lead, antimony, barium and mercury were set in Directives 88/378 and 2009/48. So far as concerns Directive 2009/48, the Commission notes that, on the basis of recommendations set out in the RIVM report, the exposure of children to chemicals in toys may not exceed a certain level, called the 'tolerable daily intake', and that, since tolerable daily intakes are established by scientific studies, and science may evolve, the legislature has provided for the possibility of amending these limits when new scientific evidence is made available.

52 The Commission examined the reasons put forward by the Federal Republic of Germany in support of its request for a derogation in respect of each substance concerned. At the end of its analysis, the Commission approved the Federal Republic of Germany's request for the maintenance of national provisions establishing limit values for lead, considering that they were 'justified on grounds of major need of protection of human health' (recitals 55 and 94 in the preamble to the contested decision).

53 According to the Commission, this conclusion is the result of specific problems linked to the tolerable daily intake used for calculating the migration limit values for lead, which was questioned by some scientific assessments (recital 54 in the preamble to the contested decision). The Commission thus stated that the tolerable daily intake used for calculating the limit value had been called in question by the European Food Safety Authority (EFSA) and the Food and Agriculture Organisation/World Health Organisation expert committee (JECFA) in 2010, after the revision of the toy safety legislation, and that, consequently, it had already undertaken the review of the abovementioned limits.

54 In the contested decision, the Commission also noted that the provisions notified by the Federal Republic of Germany relating to lead were not a means of arbitrary discrimination, a disguised restriction on trade between Member States, or a disproportionate obstacle to the functioning of the internal market (recitals 83, 86, 91 and 94 in the preamble thereto).

55 Only at the end of the contested decision did the Commission state that it had reasons to consider that the national measures notified could be approved, 'subject to a limitation in time' (recital 94 in the preamble thereto), as defined in Article 1 of the operative part of the decision. The Commission therefore approved the maintenance of the provisions of German law on lead in toys 'until the date of entry into force of [European Union] provisions setting new limits for lead in toys or 21 July 2013, whichever comes first'.

56 As a preliminary point, it should be noted that the temporary approval of the national measures notified on lead is subject to a deadline which is the earliest of two alternative events: the first, uncertain, being the 'the date of entry into force of EU provisions setting new limits for lead in toys', and the second, certain, being 21 July 2013. Even though the Commission states in its pleadings that, when the contested decision was adopted, what prompted it to impose a temporal limitation on the derogation granted was the fact that measures had already been taken to adjust the values particularly for lead, as established in Directive 2009/48, in view of developments in scientific knowledge, it must be stated that that decision does not include any specific development in that respect.

57 As regards the limitation on the approval 'until the date of entry into force of EU provisions setting new limits for lead in toys', it was possible for the Federal Republic of Germany to ascertain the Commission's reasoning from reading the contested decision as a whole and linking its clear recitals on the review of the limit values for lead set out in Directive 2009/48 to the wording of Article 1 of the operative part of the decision limiting the approval until the entry into force of '[European Union] provisions setting new limits' for that substance.

58 By contrast, as regards the limitation until '21 July 2013', the Federal Republic of Germany points out, first of all, that the Commission acknowledged in recital 54 in the preamble to the contested decision that the migration limit for lead, as set out in Directive 2009/48, no longer offered an appropriate level of protection for children and that the national provisions notified were justified on grounds of major need to protect human health, with the result that the principle of a limitation in time reveals a logical inconsistency. Second, the limitation in time should be regarded as being at variance with the legislative requirement of Article 114(4) and (6) TFEU, by which the Commission is bound to approve the national provision notified if the conditions for the application of that provision are satisfied. Furthermore, the inconsistency is even more obvious in the light of the Commission's arguments relating to the national provisions on nitrosamines and nitrosatable substances, which were approved without any limitation in time. Lastly, the limitation in time until the night of 21 July 2013 is tantamount, as to its effect, to a refusal, having regard to the general scheme of Directive 2009/48.

59 It should be observed that the EU legislature provided, first, that although Directive 2009/48 had to be transposed no later than 20 January 2011, the Member States were only to apply their national implementing provisions from 20 July 2011 (Article 54 of Directive 2009/48) and, second, that Directive 88/378 was repealed with effect from 20 July 2011, except for Article 2(1) thereof and point II.3 of Annex II thereto, which were repealed with effect from 20 July 2013 (Article 55 of Directive 2009/48).

60 It was in the light of the exception referred to in the previous paragraph that the Federal Republic of Germany asked the Commission for permission to maintain the provisions set out in its national legislation for various substances, including lead in toys, 'beyond 20 July 2013, the date of entry into force of [point] III of Annex II to Directive 2009/48', in so far as the bioavailability limit values laid down in Directive 88/378 and reproduced in those provisions continued to apply until that date, irrespective of any Commission authorisation.

61 It is common ground that the Commission approved the maintenance of the national provisions on lead only until the entry into force of revised migration limit values for that substance and, in any event, until 21 July 2013 at the latest.

62 Accordingly, the expiry of the approval for maintaining the national provisions on lead was either (a) to coincide with the entry into force of new European Union provisions laying down revised migration limit values for that substance, which would only make sense if that entry into force occurred before 21 July 2013, or (b) to occur, due to the passage of time, on 21 July 2013, which was to coincide, with a difference of one day, with the expiry of the maintenance in force of point II.3 of Annex II to Directive 88/378, replaced by point III of Annex II to Directive 2009/48.

63 As regards this second scenario, the Commission explained, in reply to a written question from the Court:

'The limit values for the chemical substances set out in the directive apply from 00.00 on 20 July 2013. When the contested decision was adopted, the Commission assumed that the limit values for … lead would be adjusted in good time before that date. None the less, the Commission also wanted to avoid criticism for publishing a decision which did not provide a temporal scope for these two substances. In addition, both dates fell on a weekend. Consequently, the decision (symbolically) grants the German Government an additional period of one day for the adjustment.'

64 Since the bioavailability limit values laid down in Directive 88/378 were to continue to apply until 20 July 2013 and the maintenance of the national provisions on lead was approved only until 21 July 2013, bearing in mind that the difference between these two dates is purely symbolic, it must be held — as the Federal Republic of Germany rightly pointed out — that the contested decision is tantamount, in terms of its practical effect, to a negative decision, which the Commission explicitly admitted during the hearing, even though the Commission stated in that decision that the conditions for the application of Article 114(4) and (6) TFEU had been satisfied (recitals 55, 83, 86, 91 and 94 in the preamble to the contested decision).

65 The contested decision therefore seems to contain an internal inconsistency liable to prevent the reasons underlying it from being properly understood.

66 In the light of this internal inconsistency, and without it being necessary to rule on the Federal Republic of Germany's other pleas in law relating to the alleged unlawfulness of the time-limited approval relating to lead, the second paragraph of Article 1 of the contested decision must be annulled for infringing the second paragraph of Article 296 TFEU, in so far as it approved the national provisions setting the limit values for lead only until 21 July 2013.

Unlawfulness of the refusal to maintain the national provisions on antimony, arsenic and mercury

– Contested decision

67 In the context of its assessment of the Federal Republic of Germany's request under Article 114(4) TFEU, the Commission set out a number of general observations in recitals 19 to 24 in the preamble to the contested decision relating to all of the substances in question, before considering the request in the light of each individual substance.

68 Those preliminary observations are worded as follows:

'(19) The limit values for arsenic, lead, antimony, barium and mercury set out in the Second Equipment and Product Safety Act Ordinance (Verordnung über die Sicherheit von Spielzeug — 2. GPSGV) are those laid down in Directive 88/378/EEC, applicable in the EU since 1990. These limits were set out on the basis of scientific evidence available at that time, namely the scientific opinion of the Scientific Advisory Committee to examine the toxicity and ecotoxicity of chemical compounds from 1985, entitled Report EUR 12964(EN), Chapter III "Chemical properties of toys". To set up limit values, estimated food intakes for adults were used as a basis. It was assumed that children, with an estimated body weight up to 12 kg, would have an intake of maximum 50% of the adults' intake, and that leaking from toys should not contribute more than 10%.

(20) The Directive, adopted in 2009, replaced Directive 88/378/EEC and modernised the legal framework applicable to chemicals, by taking into account the latest scientific evidences available at the time of the revision.

(21) The limit values for arsenic, lead, antimony, barium and mercury set out in the Directive are calculated as follows: based on the recommendations of the Dutch National Institute for Public Health and the Environment (RIVM) made in the 2008 report entitled "Chemicals in Toys. A general methodology for assessment of chemical safety of toys with a focus on elements", exposure of children to chemicals in toys may not exceed a certain level, called "tolerable daily intake". Since children are exposed to chemicals via other sources than toys, only a percentage of the tolerable daily intake should be allocated to toys. The Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) recommended in its 2004 report that a maximum of 10% of the tolerable daily intake may be allocated to toys. However, for particularly toxic substances (for example arsenic, lead, mercury) the Legislator decided that the recommended allocation should not exceed 5% of the tolerable daily intake, in order to ensure that only traces that are compatible with good manufacturing practice will be present. In order to obtain limit values, the maximum percentage of the tolerable daily intake should be multiplied by the weight of a child, estimated at 7,5 kg, and divided by the quantity of toy material ingested, estimated by the RIVM at 8 mg per day for scraped-off toy material, 100 mg for brittle toy material and 400 mg for liquid or sticky toy material. Those ingestion limits were supported by the Scientific Committee on Health and Environmental Risks (SCHER) in its opinion entitled "Risks from organic CMR substances in toys" adopted on 18 May 2010. As the tolerable daily intakes are established by scientific studies, and science may evolve, the Legislator has foreseen the possibility to amend these limits when new scientific evidence is made available.

(22) The Directive establishes migration limits, while the national values Germany wants to maintain are expressed in bioavailability. Bioavailability is defined as the amount of chemicals which actually comes out of a toy and can but may not necessarily be absorbed by the human body. Migration is defined as the amount which actually comes out of a toy and is actually absorbed by the human body. The Commission acknowledges that the bioavailability limits set out in 1990 were transformed in migration limits in standard EN 71-3 — Migration of certain elements.

However, calculations made for the purpose of this transformation were approximate. The tolerable daily intakes used are based on recommendations from 1985. A daily intake of 8 mg of toy material was assumed, and adjustments were made to minimise the exposure of children to toxic elements by lowering, for example, the migration limit for barium, and to ensure analytical feasibility by increasing, for example, the migration limit for antimony and arsenic.

(23) The Commission notes that standards are not mandatory, but used on a voluntary basis by industry in the framework on the conformity assessment procedures set out in the legislation. In addition, standard EN 71-3 is currently under revision in order to give presumption of conformity with the new limits values established in the Directive.

(24) In conclusion, different scientific considerations were taken into account when establishing the limits under the Directive and under standard EN 71-3. Those established under the Directive are based on a consistent and transparent scientific-toxicological approach to ensure safety, and can therefore be considered as more appropriate.'

– Disregard of the assessment criterion under Article 114(4) and (6) TFEU

69 The Federal Republic of Germany submits that, in so far as the Commission based the refusal to maintain the national provisions on antimony, arsenic and mercury on the fact that it had failed to show that the migration limit values under Directive 2009/48 did not offer an appropriate level of protection (recital 43 in the preamble to the contested decision) or that those values were capable of having adverse effects on health (recitals 59 to 62 in the preamble to the contested decision), the contested decision was adopted in disregard of the assessment criterion under Article 114(4) and (6) TFEU, as established by the case-law.

70 As regards the criterion applying to investigative action taken by the Commission under Article 114(4) and (6) TFEU, the Court has stated that a Member State could base a request to maintain its pre-existing national provisions on an assessment of the risk to public health different from that accepted by the EU legislature when it adopted the harmonisation measure from which the national provisions derogate. To that end, it falls to the requesting Member State to prove that those national provisions ensure a level of protection of public health which is higher than that of the European Union harmonisation measure and that they do not go beyond what is necessary to attain that objective (*Denmark* v *Commission*, paragraph 50 above, paragraph 64).

71 In the present case, it is apparent from the contested decision that, for each of the three substances concerned, the Federal Republic of Germany put forward the same line of argument in support of its request under Article 114(4) TFEU, namely that the limit values for these substances in scraped-off materials, as set out in Directive 2009/48, have increased compared to the limits established in standard EN 71-3, that standard having transformed into migration limits the bioavailability limits laid down in Directive 88/378, limits which were reproduced in the national provisions notified (recitals 34, 40, 57 and 58 in the preamble to the contested decision). In its letter of 2 March 2011, the Federal Republic of Germany emphasised that, in the light of the abovementioned increase, the level of protection under Directive 2009/48 was inadequate and the national provisions were more restrictive, with the result that they ensured a higher level of protection for health than under Directive 2009/48.

72 By that line of argument, the Federal Republic of Germany not only alleges that the level of protection ensured by the harmonisation measure is inadequate, but it also claims, as a consequence, that the level of protection afforded by the national provisions is higher, which is in fact a matter for the requesting Member State to prove in accordance with the case-law in this field.

73 The truth is that these two claims are objectively and closely linked and the Commission's response to that line of argument in the contested decision was merely comparative, setting out the reasons why it considered 'the limit values established in [D]irective [2009/48] as more appropriate' (recitals 36, 42 and 62 in the preamble to the contested decision).

74 Likewise, it is not disputed that the Federal Republic of Germany requested the maintenance of the national provisions whilst at the same time acknowledging that no adverse effects on human health were expected from the limits laid down in Directive 2009/48 for antimony and mercury (recitals 40 and 59 in the preamble to the contested decision), of which the Commission merely took note (recitals 43 and 62 in the preamble to the contested decision).

75 Finally, it should be pointed out that, in its assessment relating to antimony and mercury, the Commission clearly stated that the Federal Republic of Germany had not provided any evidence demonstrating that 'the German measures would assure a higher level of protection' (recitals 43 and 62 in the preamble to the contested decision), these words being the precise definition of what the requesting Member State is required to prove. The mere absence of such words so far as concerns arsenic is not, however, sufficient to prove that the assessment criterion under Article 114(4) and (6) TFEU was disregarded, the general scheme of the contested decision as a whole indicating otherwise.

76 This ground for complaint must therefore be dismissed.

– Substantive assessment of the conditions for the application of Article 114(4) and (6) TFEU

77 The Federal Republic of Germany submits that the Commission incorrectly assessed the factual situation and erred in law in its application of Article 114(4) and (6) TFEU by finding that it had not been proven that the national provisions conferred a higher level of protection for children's health than Directive 2009/48.

78 In the arguments put forward in the first part of its plea in law, entitled 'The reasons for maintaining the national provisions notified (concept of a Member State's own national protection)', the Federal Republic of Germany makes various observations on the principle of good manufacturing practice and the precautionary principle, which it claims the Commission did not sufficiently take into account during the preparation of Directive 2009/48.

79 In the first place, the Federal Republic of Germany submits that the specific level of the limit values set out in the notified provisions corresponds to what is necessary from a toxicological perspective and to what is feasible from a technological perspective and, therefore, it acted consistently on the basis of the 'principle of good manufacturing practice'. However, that principle was not sufficiently taken into account during the preparation of Directive 2009/48, the migration limit values of which are founded on the RIVM report, which was intended to be a mere basis for discussion. Directive 2009/48 is also at odds with other provisions of secondary legislation which use that principle as regards the issue of residues of harmful substances in consumer products.

80 It must be noted that this line of argument is inconsistent with the language of Directive 2009/48 — in particular recitals 3, 20 and 22 in the preamble thereto — which shows that the technological question was taken into account.

81 Thus, recital 3 in the preamble to Directive 2009/48 provides, first, that '[t]echnological developments in the toys market have, however, raised new issues with respect to the safety of toys and have given rise to increased consumer concerns' and '[i]n order to take account of those developments and to provide clarification in relation to the framework within which toys may be marketed, certain aspects of Directive 88/378/EEC should be revised and enhanced and, in the interests of clarity, that Directive should be replaced by this Directive'. Recital 20 in the preamble to Directive 2009/48 subsequently

states that '[c]ertain essential safety requirements which were laid down in Directive 88/378/EEC should be updated to take account of technical progress since the adoption of that Directive' and '[i]n particular, in the field of electrical properties, technical progress has made it possible to allow the limit of 24 volts set in Directive 88/378/EEC to be exceeded, while guaranteeing the safe use of the toy concerned'. Lastly, recital 22 in the preamble to Directive 2009/48, recalled in paragraph 10 above, expressly refers to the need, when establishing the limit values, 'to ensure that only traces that are compatible with good manufacturing practice will be present'.

82 It is also undisputed that, in order to prepare the proposal for Directive 2009/48, the Commission relied on the RIVM report, which clearly states that its purpose is, inter alia, 'to examine how the limit values for certain elements that are contained in toys, laid down in Annex II.II.3 of Directive 88/378/EEC on the Safety of Toys should be revised according to recent scientific knowledge'. The authors also stated that in their report they presented 'a *risk based* methodology that can be used to assess the safety of exposure to chemicals in toys'. These quotes are inconsistent with the applicant's claim that the RIVM report 'was never intended to be applied or to serve as a basis for application in practice'.

83 The mere fact that the application of that method might lead, for some elements, to higher migration limit values than those permitted under Directive 88/378 does not necessarily mean — as the Federal Republic of Germany suggests — that the principle of good manufacturing practice was not sufficiently taken into account during the preparation of Directive 2009/48.

84 Therefore, the Federal Republic of Germany's claim that the measure in question is also inconsistent with other provisions of secondary legislation which use the principle of good manufacturing practice is based on an unsubstantiated premiss.

85 In the second place, the Federal Republic of Germany claims that the precautionary principle, which is to apply as a matter of course, particularly where there is scientific uncertainty, was not sufficiently taken into account during the preparation of Directive 2009/48, as evidenced by the limit values in that directive for antimony, arsenic and mercury, as well as by how the specific question of the tolerable daily intake of arsenic is handled. For arsenic, Directive 2009/48 provides for a tolerable daily intake of 1 μg per kg of body weight per day, even though EFSA considers it impossible to specify any tolerable intake whatsoever for that substance without posing a risk to health.

86 In its request under Article 114(4) TFEU, the Federal Republic of Germany put forward the same legal arguments as regards the question of the tolerable daily intake of arsenic.

87 In the contested decision (recitals 31 to 33 in the preamble thereto), the Commission replied to those arguments as follows:

> '(31) The Commission was made aware of the 2009 EFSA study on arsenic, and considered it as new scientific evidence which may trigger the revision of the arsenic limit values. The study was sent to the SCHER committee. In its opinion …, SCHER notes that EFSA has not derived a tolerable daily intake, but used a risk-based value. SCHER concluded in previous opinions … that "arsenic shows a non-linear dose response regarding cancer". Using the present legal limit for drinking water (10 μg/L) and the food exposure defined by EFSA for the average consumer, SCHER concludes that the daily human exposure to arsenic is approximately 1 μg/kg body weight/day and does not increase tumour incidence. This value can be used as a pragmatic tolerable daily intake, and exposure of children via toys should not exceed 10%.

(32) The value on which SCHER concluded corresponds to the tolerable daily intake recommended by RIVM and used to calculate migration of arsenic from toys in the Directive. Therefore, the Commission concluded that the limit values for arsenic should not be amended, as no new tolerable intake, which may question the level of protection granted by the Directive, was established.

(33) Furthermore, the Commission would like to stress that the German authorities justified their request to maintain national levels for arsenic by referring to the range of daily intake doses established in the 2009 EFSA study. The Commission notes that the measures notified do not appear consistent with this justification. The limits notified are derived from estimated food intakes established in 1985, not from the doses recommended by EFSA in 2009.'

88 It must be stated that, in its pleadings, the Federal Republic of Germany did not submit any observations on that part of the contested decision and, therefore, any information capable of disproving the findings of the Commission based on an opinion of the Scientific Committee on Health and Environmental Risks (SCHER). In addition, the Federal Republic of Germany cannot simply refer to the limit values laid down in Directive 2009/48 for antimony, arsenic and mercury to show that the precautionary principle was not sufficiently taken into account.

89 In any event, it should be made clear that, by this line of argument, recalled in paragraphs 79 and 85 above and set out in the applicant's pleadings under the heading 'The reasons for maintaining the national provisions notified (concept of a Member State's own national protection)', the Federal Republic of Germany has not shown or even claimed that it discharged its burden of proof, namely proof that the national provisions notified offered a higher level of protection than Directive 2009/48. It is also apparent from the application that this issue was the subject of a specific argument, formally separate from the abovementioned section of the pleadings.

90 In the arguments put forward in the second part of its plea in law, the Federal Republic of Germany claims to have shown that the national provisions notified setting limit values for arsenic, antimony and mercury ensured a higher level of protection for children's health than Directive 2009/48.

91 The Federal Republic of Germany asserts that the migration limit values of the notified provisions, resulting from the conversion based on the requirements of standard EN 71-3, are lower than those laid down in Directive 2009/48, which permits the exposure of children to harmful substances to be higher. According to the Federal Republic of Germany, this fact 'on its own' demonstrates that it has credibly established that the national provisions notified ensured a higher level of protection than Directive 2009/48. One of the ways in which the Federal Republic of Germany substantiates its assertions is by converting the migration limit values contained in Directive 2009/48 into bioavailability limit values, and it states that the limit values laid down in the national provisions, in the case of both individual and overall assessments, are lower than the bioavailability limit values under Directive 2009/48, after conversion, regardless of the substance and consistency of the toy material in question.

92 As a preliminary point, it was noted in paragraph 70 above that, according to the case-law of the Court, a Member State may base a request to maintain its pre-existing national provisions on an assessment of the risk to public health different from that accepted by the EU legislature when it adopted the harmonisation measure from which the national provisions derogate. To that end, it falls to the requesting Member State to prove that those national provisions ensure a level of protection of public health which is higher than that of the EU harmonisation measure and that they do not go beyond what is necessary to attain that objective.

93 In the first place, it is necessary to examine the Federal Republic of Germany's assertion that the migration limit values of the notified provisions, resulting from the conversion based on the requirements of standard EN 71-3, are lower than those laid down in Directive 2009/48, which shows that those provisions ensure a higher level of protection of public health than the harmonisation measure.

94 In support of that claim, the Federal Republic of Germany produced an overview in table form which was previously included in the letter of 2 March 2011 ('table 1'), corresponding to an assessment carried out by BfR, in which BfR concluded that the application of the migration values of Directive 2009/48 led to a higher degree of absorption in children of arsenic, antimony and mercury than the national provisions notified, even though those provisions make no distinction according to the consistency of the material of which the toy is made. This table includes data comparing the migration limit values of Directive 2009/48 for toys composed of material than can be scraped off with the limit values of standard EN 71-3, which transforms into migration limit values the bioavailability limit values of Directive 88/378, values that are identical to the national provisions notified. The Federal Republic of Germany also states that its demonstration is not simply a comparison with scraped-off toy material, to which reference was made solely by way of guidance since most toys are made of materials than can be scraped off.

95 Table 1 includes the following data:

Element	EN 71-3 in mg/kg	Directive 2009/48 in mg/kg
Arsenic	25	47
Mercury	60	94
Antimony	60	560

96 It should be noted that the limit values for the harmful substances are not established in the same way in the second GPSGV 2011, which reproduces the values of Directive 88/378, and in Directive 2009/48. Thus, Directive 2009/48 lays down different migration limit values according to the three types of toy material used, while the national provisions set out bioavailability limit values which apply to all types of toy, regardless of the consistency of the material of which the toy in question is made.

97 The Federal Republic of Germany's need to adduce evidence enabling comparisons to be drawn between the data in question led it to use the conversion of bioavailability limit values into migration limit values, as carried out in standard EN 71-3.

98 In recital 22 in the preamble to the contested decision, the Commission observed that 'the bioavailability limits set out in 1990 [had been] transformed in migration limits in standard EN 71-3 — Migration of certain elements', but that '[h]owever, calculations made for the purpose of this transformation were approximate'.

99 For each substance concerned, the Commission disputed the assessment of the risks for human health accepted by the Federal Republic of Germany based on the observed increase of the migration limit values of those substances in scraped-off toy material. In the contested decision, the Commission therefore took the following view as regards arsenic (recital 36), antimony (recital 42) and mercury (recital 61):

'The migration limits for [these substances] in standard EN 71-3 were derived from the bioavailability limits established in Directive 88/378/EEC, based on estimated food intakes established in 1985. The calculation method applied did not take into account the weight of the child nor the differences between toy materials, as does the Directive. Thus, the Commission considers the limit values established in the Directive as more appropriate.'

100 Although the Federal Republic of Germany rightly recalls that the requesting Member State may, in order to justify maintaining national provisions, put forward the fact that its assessment of the risk to public health is different from that made by the EU legislature in the harmonisation measure, and that divergent assessments of those risks can legitimately be made, without necessarily being based on new or different scientific evidence (*Denmark* v *Commission*, paragraph 50 above, paragraph 63), it is for that Member State to show in what respect the evidence previously submitted to the Commission was wrongly assessed by it and how it should be interpreted differently by the Court.

101 First, it should be recalled that Directive 2009/48 lays down migration limits, the risk to health being regarded as linked to the quantity of a given harmful substance that may be released by a toy before being absorbed by a child. The migration limit values of Directive 2009/48 for substances such as antimony, arsenic and mercury were set on the basis of the RIVM report, which established the estimated quantity of toy material ingested by a child, in this instance 8 mg per day for scraped-off toy material, 100 mg per day for brittle toy material and 400 mg per day for liquid or sticky toy material. Those ingestion limits were supported by SCHER in its opinion entitled 'Risks from organic CMR substances in toys' adopted on 18 May 2010 (recital 21 in the preamble to the contested decision) and correspond to the 'assumed worst-case oral intake scenarios', according to SCHER's opinion of 1 July 2010.

102 The quantity that may be absorbed therefore depends on the consistency of the material of which the toy is made, a distinction not drawn in standard EN 71-3, which uses the same measurement for all types of material. Indeed, standard EN 71-3 states that a 'combined average daily intake of 8 mg of the different toy materials was taken as a working hypothesis, in the knowledge that, in certain specific cases, that value could be higher'.

103 Second, even though the Federal Republic of Germany did not submit any observations in its pleadings concerning the fact that the child's weight was not taken into account in the calculation method used in standard EN 71-3, it stated — in reply to a written question from the Court — that the calculation method used in standard EN 71-3 took account of children's lower weight compared to that of adults since it was based on bioavailability limit values inferred for children under the age of 12. It contends that the definition of bioavailability as provided for in Directive 88/378 is based on the view of the Scientific Advisory Committee to examine the toxicity and ecotoxicity of chemical compounds, which specifically evaluated ingested daily intakes for children and sought to ensure that the contribution of toys to the total intake of heavy metals absorbed by children was limited to a set proportion. Children's lower weight was therefore taken into account by means of a reduced daily intake and was therefore also incorporated into the migration values as provided for in standard EN 71-3.

104 In this connection, the Commission's reference to the fact that the child's weight was not taken into account in the calculation method must be viewed in the light of recitals 19 to 21 in the preamble to the contested decision (see paragraph 68 above), according to which, in Directive 88/378, it 'was assumed that children, with an estimated body weight up to 12 kg, would have an intake of maximum 50% of the adults' intake', whereas, in Directive 2009/48, in order to obtain limit values, 'the maximum

percentage of the tolerable daily intake should be multiplied by the weight of a child, estimated at 7,5 kg, and divided by the quantity of toy material ingested, estimated by the RIVM at 8 mg per day for scraped-off toy material, 100 mg for brittle toy material and 400 mg for liquid or sticky toy material'. The Commission was therefore right to consider that the calculation method of standard EN 71-3 did not sufficiently take account of the weight of the child, even though it did note, in recital 22 in the preamble to the contested decision, the adjustments made in that standard to minimise the exposure of children to toxic elements.

105 Third, the argument put forward by the Commission regarding the value of the calculation method used to establish the migration limits in standard EN 71-3 is clearly justified from a scientific standpoint in SCHER's opinion of 1 July 2010, which was drawn up for the Commission to ascertain whether the migration limits laid down in Directive 2009/48 were a sound scientific basis for setting safe migration limits for 19 chemical elements.

106 In the statement of reasons for its opinion, SCHER stated, inter alia, that standard EN 71-3 had been tested in an inter-laboratory exercise for eight chemical elements, revealing up to tenfold inter-laboratory variations in the measurements, which raised some concern about the reliability of the method and the suitability of continuing to use the currently applied correction factors. It also pointed out that the method of measuring the migration of chemical elements used in standard EN 71-3 was not reliable.

107 SCHER's unequivocal findings disprove the reliability of the foundation for the comparative analysis set out in table 1, based on the migration measurement method of standard EN 71-3, and, therefore, disprove the validity of the findings of that analysis. Even though the Federal Republic of Germany claimed — in reply to a written question from the Court — that the significance and purpose of the comparative study of the laboratories was not to demonstrate the reliability of the method, the fact remains that it listed 'the identification of problems linked to the technique and the methodology' as one of the objectives of that comparative study.

108 In any event, even if the migration limit values resulting from the conversion of the bioavailability limit values of Directive 88/378 carried out in standard EN 71-3, as referred to in table 1, could be taken into account, the pleadings of the Federal Republic of Germany do not contain a complete assessment of the health risk.

109 In these proceedings, the Commission provided a table ('table 2') with the same comparison as that contained in table 1, but covering all toy materials referred to in Directive 2009/48. The table is presented as follows:

Element	Liquid or sticky material Migration (mg/kg)	Dry, brittle, powder-like or pliable material Migration (mg/kg)	Scraped-off material Migration (mg/kg)	Notified measures Bioavailability (μg)	Values of the notified measures converted into migration values (standard EN 71-3) (mg/kg)
Antimony	11.3	45	560	0.2	60
Arsenic	0.9	3.8	47	0.1	25
Mercury	1.9	7.5	94	0.5	60

110 The abovementioned table clearly shows that, for liquid or sticky material and for dry, brittle, powder-like or pliable material, the values notified by the Federal Republic of Germany, converted into migration limit values on the basis of standard EN 71-3, are considerably higher than the values of Directive 2009/48.

111 In this connection, it must be noted that the statement of reasons for the request submitted by the Federal Republic of Germany under Article 114(4) TFEU is based solely on account being taken of the migration limit values relating to scraped-off toy material.

112 In the light of the data set out in table 2, which reflects in full the numerical results of the Federal Republic of Germany's own comparative reasoning, that Member State cannot legitimately make the general assertion that Directive 2009/48 permits a higher migration of the harmful substances in question than that allowed under the national provisions notified, that children are accordingly more exposed to those substances, and that this fact 'on its own' demonstrates that the Federal Republic of Germany has credibly established that those provisions ensured a higher level of protection than Directive 2009/48.

113 It is true that, for scraped-off material, the migration limit values set out in Directive 2009/48 are indeed higher than those resulting from the conversion of the bioavailability limit values provided for in the national provisions notified.

114 However, as the Commission correctly points out, the quantity that may be absorbed depends on the consistency of the material used (also see paragraphs 101 and 102 above). Thus, scraped-off material is less readily accessible by a child than dry or liquid material, which can easily be swallowed and therefore absorbed in higher quantities by the child.

115 The Federal Republic of Germany has not submitted any critical remarks on the lower accessibility of scraped-off toy material. However, it did claim that since Directive 2009/48 does not clearly explain the relationship between the migration limit values for the three categories of material *inter se*, the starting premiss had to be that the quantity indicated could migrate every day from each of the categories and that those values had to be added up in order to ascertain the total exposure 'in the event that' a child should come into contact, during the same day, with toys made from the three materials in question.

116 This line of argument of the Federal Republic of Germany does not demonstrate that the national provisions notified indeed ensure a higher level of protection for human health than that resulting from the application of Directive 2009/48, bearing in mind that neither those provisions nor standard EN 71-3, which transforms the bioavailability values provided for in the national provisions notified into migration limit values, makes any distinction according to the consistency of the materials of which the toys are made. The comparative analysis set out in table 1 (paragraph 95 above) cannot effectively be relied on in support of the arguments recalled in paragraph 115 above.

117 The Federal Republic of Germany's arguments seem to be based on the emphasis placed on a specific situation, presented as a premiss, namely where a child is exposed, at the same time, to the three toy materials referred to in the directive. It is noted that the Federal Republic of Germany simply refers to such a situation in its pleadings without citing any scientific study.

118 The Commission has argued that that approach was not realistic and refers to SCHER's opinion of 1 July 2011, in which SCHER stated that the specific limits for the chemical elements concerned had been established, in Directive 2009/48, in the light of health-based limit values, tolerable daily intakes and assumed worst-case oral intake scenarios, that is 8 mg/day for scraped-off toy material, 100 mg/day for dry, brittle, powder-like or pliable toy material, and 400 mg/day for liquid or sticky toy material. Since children are exposed to chemical products from sources other than toys, SCHER recalls its opinion according to which the total contribution from toys should not exceed 10% of the tolerable daily intake. However, as regards particularly toxic elements such as arsenic, cadmium,

chromium, lead, mercury and organic tin, the legislature decided that the proportion represented by toys should not exceed 5% of the tolerable daily intake, in order to ensure that only traces which are in line with good manufacturing practice would be present. SCHER also stated that 'in a worst-case scenario with a concomitant exposure from all three sources [that is, scraped-off material, brittle, powder-like or pliable material, and liquid or sticky material], the total oral exposure for the chemical elements [was] 30% and 15% of the TDI [tolerable daily intake]' and that '[h]owever, it [was] unlikely that exposure [would] occur… through all three sources simultaneously'.

119 The very basis of the Federal Republic of Germany's arguments is therefore called in question by SCHER, without this being disputed by the Member State. It is true that the Federal Republic of Germany asserted, in reply to a written question from the Court, that the RIVM report — on the basis of which the migration limit values were established according to the type of material of which the toy was made (recital 21 in the preamble to the contested decision) — stated that, for dry toy material and liquid toy material, the respective values of 100 mg and 400 mg were rough estimates which required further research.

120 However, RIVM's comments are only quoted in part by the Federal Republic of Germany, whose arguments cannot succeed since RIVM had the following to say in relation to dry material:

'The ingestion of 100 mg by children is considered reasonable, but may not occur daily. For exposure assessment refinement purposes, we propose to use a frequency of 1/week for this ingestion default … This is a rough estimate and needs further research. [For liquid material] … an ingestion of 400 mg may occasionally occur, but not daily. For the purpose of an exposure assessment refinement … we propose to use a frequency of 1/week as a default. This is a rough estimate and needs further research.'

121 Furthermore, even if the Court were to rely solely on the numerical data from the BfR study contained in table 1, it would still be unable to find that the contested decision was unlawful. Since the migration limit values of Directive 2009/48 are higher than those of the national provisions resulting from conversion by means of standard EN 71-3 in one situation only, in this case for scraped-off toy material, the Commission cannot be criticised for having rejected the request to maintain national provisions which make no distinction according to the consistency of the materials of which the toy is made.

122 In the second place, for the purpose of this action, the Federal Republic of Germany also submitted a second table containing a comparison between, of the one part, the bioavailability limit values resulting from Article 10(3) of the second GPSGV 2011, which are the same as those resulting from the national provisions notified and Directive 88/378, and, of the other part, the bioavailability limit values resulting from the conversion of the migration limit values provided for in Directive 2009/48 for the three categories of toy material ('table 3'). According to the Federal Republic of Germany, the bioavailability limit values of the second GPSGV 2011 are, for each chemical substance in question and for each consistency of toy material, lower than the bioavailability limit values of Directive 2009/48 after conversion, which also shows that the national measures notified ensure a higher level of protection for children's health than Directive 2009/48.

123 Table 3 is presented as follows:

Element	Bioavailability limit value under Article 10(3) of the second GPSGV 2011	Bioavailablity limit value — resulting from conversion — under Annex II, point III, paragraph 13 of Directive 2009/48		
	µg/day irrespective of the consistency of the toy material	µg/day of dry, brittle, powder-like or pliable toy material	µg/day of liquid or sticky toy material	µg/day of scraped-off toy material
Antimony	0.2	4.5	4.5	4.5
Arsenic	0.1	0.38	0.36	0.38
Barium	25	450	450	448
Lead	0.7	1.35	1.36	1.3
Mercury	0.5	0.75	0.76	0.76

124 Table 3 is based on the figures contained in a table drawn up by BfR entitled 'Comparison of the absorbed intakes and tolerable migration limits under Directive 88/378/EEC, Directive 2009/48/EC and standard EN 71-3'.

125 However, it must be stated, first of all, as the Commission notes, that the purpose of table 3 is to compare the daily absorption values set out in Directive 2009/48 for the three consistencies of toy material with the values resulting from standard EN 71-3, even though only one toy consistency is taken into account in the calculation thereof and the migration limits of standard EN 71-3 for dry toy material and liquid toy material have been omitted. Thus, as the Commission rightly points out, the explanation provided by BfR that it 'only [takes] into account the migration limits set out in standard EN 71-3 for toy material that can be scraped off, as the quantity of 8 mg of toy material capable of ingestion only applies to this type of material and the only possible comparison in that regard is the comparison with the relevant migration limits of Directive 2009/48/EC' is not convincing, as the quantitative data in Directive 2009/48 for dry and liquid materials could have, for example, been used for that purpose.

126 Second, in the table drawn up by BfR, the tolerable daily intakes for the three materials identified in Directive 2009/48 are added up, before being compared to the only material that can be scraped off, referred to in standard EN 71-3. Thus, BfR compared the permitted substance intake in 8 mg of toy material, in accordance with Directive 88/378, and the sum of tolerable intakes in 508 mg of toy material, that is 8 mg of scraped-off toy material, 100 mg of dry toy material and 400 mg of liquid toy material, which alters its conclusions.

127 Third, it must be pointed out that the comparison of the bioavailability limits, raised by the Federal Republic of Germany, conveys an assessment of the health risk that is contrary to the assessment based on the most recent scientific knowledge, knowledge which served as the foundation for the specific requirements relating to chemical properties set out in Annex II, point III, of Directive 2009/48. In this connection, it is appropriate to quote SCHER's opinion of 1 July 2010, according to which 'the total amount of the chemical elements present in a toy per se does not necessarily represent a risk as most of the chemical elements will remain in the toy even after mouthing or swallowing parts of it', and '[t]herefore, the risk assessment should be based on examining the migration levels of the chemical elements'. That opinion also states that 'SCHER reiterates its recommendation that toy safety should be based on migration limits'.

128 It should also be noted that the Federal Republic of Germany stated that, on 10 April 2008, it had 'proposed, using the bioavailability limit values of Directive 88/378 as a starting point, updated bioavailability limit values for lead, arsenic, mercury, barium and antimony, on the basis of which migration limit values were to be subsequently drawn up' and pointed out, on that occasion, that the 'level of protection of Directive 88/378 was to be maintained, at least, and improved in certain respects'. It also made clear in its pleadings that 'it [was] not opposed to the establishment of migration limit values or to distinctions being made according to the different consistencies of the toy material, as inserted into Directive 2009/48'.

129 Accordingly, the Federal Republic of Germany cannot legitimately rely on a comparison of the bioavailability limits to claim that the national provisions notified ensure a higher level of protection for human health than Directive 2009/48.

130 It follows from the above considerations that the Federal Republic of Germany has not discharged the burden of proof falling on it, namely proof that the national provisions notified ensure, as regards arsenic, antimony and mercury, a higher level of protection than Directive 2009/48.

131 It follows from all of the foregoing arguments that the action must be dismissed in so far as it seeks the annulment of the Commission's refusal to maintain the national provisions notified laying down limit values for arsenic, antimony and mercury, without it being necessary to examine the Federal Republic of Germany's arguments relating to the proportionality of those provisions and the fact that they are not a means of arbitrary discrimination, a disguised restriction on trade between Member States, or a disproportionate obstacle to the functioning of the internal market.

132 In so far as the Federal Republic of Germany failed to show that the national provisions notified ensured, as regards arsenic, antimony and mercury, a higher level of protection than Directive 2009/48, the arguments referred to in the previous paragraph are irrelevant.

Costs

133 Under Article 87(3) of the Rules of Procedure, where each party succeeds on some and fails on other heads, or where the circumstances are exceptional, the Court may order that the costs be shared or that each party bear its own costs. Furthermore, under Article 87(6) of those rules, where a case does not proceed to judgment, the costs are in the discretion of the Court.

134 As has been stated at paragraphs 33 and 34 above, since the action has become devoid of purpose to the extent that it seeks to annul the contested decision in so far as it concerns barium, it is no longer necessary to adjudicate on the application for annulment of that decision in so far as it concerns barium.

135 In those circumstances, in view of the fact that each of the parties has been partly successful, the Commission must be ordered to bear its own costs and to pay one half of those incurred by the Federal Republic of Germany.

On those grounds,

THE GENERAL COURT (Eighth Chamber),

hereby:

1. **Declares that there is no need to adjudicate on the lawfulness of Commission Decision 2012/160/EU of 1 March 2012 concerning the national provisions notified by the German Federal Government maintaining the limit values for lead, barium, arsenic, antimony,**

mercury and nitrosamines and nitrosatable substances in toys beyond the date of entry into force of Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, in so far as it concerns barium;

2. **Annuls the second paragraph of Article 1 of Decision 2012/160 in so far as it approved the national provisions setting the limit values for lead only until 21 July 2013;**

3. **Dismisses the action as to the remainder;**

4. **Orders the European Commission to bear its own costs and to pay one half of the costs incurred by the Federal Republic of Germany.**

Martins Ribeiro Popescu Berardis

Delivered in open court in Luxembourg on 14 May 2014.

[Signatures]

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