Reports of Cases

ORDER OF THE VICE-PRESIDENT OF THE COURT

19 December 2013*

(Appeal — Order for interim measures — Limit values for lead, barium, arsenic, antimony, mercury and nitrosamines and nitrosatable substances in toys — Provisions notified by the Federal Republic of Germany maintaining national limit values for those substances — Commission decision refusing to approve those provisions in their entirety)

In Case C-426/13 P(R),

APPEAL under Article 57, second paragraph, of the Statute of the Court of Justice of the European Union, brought on 26 July 2013,

European Commission, represented by M. Patakia and G. Wilms, acting as Agents, with an address for service in Luxembourg,

applicant,

the other party to the proceedings being:

Federal Republic of Germany, represented by A. Wiedmann, acting as Agent,

applicant at first instance,

THE VICE-PRESIDENT OF THE COURT,

after hearing the First Advocate General, P. Cruz Villalón,

makes the following

Order

1 By its appeal, the European Commission seeks the annulment of the order of the President of the General Court of the European Union of 15 May 2013 in Case T-198/12 R *Germany* v *Commission* [2013] ECR ('the order under appeal'), by which the President ordered the Commission to authorise that the national provisions notified by the Federal Republic of Germany concerning limit values for antimony, arsenic, barium, lead and mercury in toys ('the national provisions') be maintained pending the General Court's decision on the substance of the case before it, seeking annulment of Commission Decision C(2012) 1348 final of 1 March 2012 ('the decision at issue') when giving a ruling on the application to maintain those national provisions.

* Language of the case: German.

2 Paragraph 2 of the order under appeal describes the contested decision as follows:

‘By the [decision at issue], the European Commission granted, for nitrosamines and nitrosatable substances, the German Government’s request, submitted to the Commission under Article 114(4) TFEU, for approval of the maintenance of the national provisions imposing limit values for the abovementioned heavy metals. As regards the limit values for lead, barium, arsenic, antimony and mercury — which correspond to the values which had been established by Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member State concerning the safety of toys (OJ 1988 L 187, p. 1) (“the old toys directive”) –, the Commission essentially rejected the German Government’s request and decided that in future the limit values fixed by [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)] (“the new toys directive”) would be applied.’

Legal context

3 The legal context is presented as follows at paragraphs 3 to 12 of the order under appeal:

‘Primary law

3. Article 114(1) to (7) 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 … 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.

…

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 …, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 36 …, it shall notify the Commission of these provisions as well as the grounds for maintaining them.

…

6. The Commission shall, within six months of the notifications as referred to in paragraphs 4 …, 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 … 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."

Secondary law

The old toys directive

4. Under Article 2 of the old toys directive, toys may be placed on the market only if they do not jeopardise the safety and/or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the normal behaviour of children. In the condition in which it is placed on the market, taking account of the period of foreseeable and normal use, a toy must meet the safety and health conditions laid down in that directive.

5. Annex II ("Essential safety requirements for toys") to the old toys directive, Part II ("Particular risks"), point 3 ("Chemical properties"), sets as the objective limit values of maximum bioavailability per day for, in particular, antimony, arsenic, barium, lead and mercury. The value limits of bioavailability define the maximum acceptable quantity of a chemical substance which may, resulting from the use of the toys, be absorbed and be available for biological processes in the human body. Those limit values of bioavailability make no distinction according to the consistency of the material of which the toy is made. The first sentence of paragraph 2 of point 3 of part II of Annex II to that directive fixes, in particular, the following limit values, which express the maximum acceptable daily bioavailability in μg: antimony: 0.2; arsenic: 0.1; barium: 25.0; lead: 0.7; and mercury: 0.5. As for nitrosamines and nitrosatable substances, the old toys directive does not set any limit value.

6. It was on that basis that, upon instructions from the Commission, the European Standards Committee drew up European harmonised standard EN 71-3 "Safety of toys" ("EN 71-3"), which infers from the limit values of bioavailability "migration limit values" for toy materials and described a procedure enabling them to be determined. The migration limit values stated the maximum permissible quantity of a chemical substance which may migrate, that is to say, pass from a product to the exterior, for example enter the skin or the gastric juices. If the values of EN 71-3 are observed, the limit values of bioavailability of the old toys directive are deemed to be observed as well. EN 71-3 establishes, in particular, the following migration limit values: antimony: 60 mg/kg; arsenic: 25 mg/kg; barium: 1 000 mg/kg; lead: 90 mg/kg; and mercury: 60 mg/kg.

The new toys directive

7. In 2003 the Commission decided to review the old toys directive. Following numerous consultations of experts on a number of projects, it submitted [at the beginning of 2008] the proposal for a directive of the European [Parliament] and of the Council on the safety of toys; that proposal was accepted by the Council on 11 May 2009, in spite of the opposition of the German Government, and adopted on 18 June 2009, becoming the new toys directive. Annex II ("Particular safety requirements"), Part III ("Chemical properties"), point 13, of that directive directly sets migration limits. Henceforth a distinction is drawn according to three consistencies of the toy material, depending on whether it is "dry, brittle, powder-like", "liquid or sticky" or "scraped-off".

8. Point 13 of Part III of Annex II to the new toy directive thus fixes the following migration limit values:

Element	mg/kg in dry, brittle, power-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

9. Under Article 54 of the new toys directive, Member States were to bring into force the laws, regulations and administrative provisions necessary to transpose that directive into their national orders by 20 January 2011 and to apply those measures with effect from 20 July 2011. Article 55 provides for an exception, however, in that Annex II, Part II, point 3 of the old toys directive is to be repealed only with effect from 20 July 2013. The bioavailability limits fixed by the old toys directive, and also the migration limits inferred therefrom for materials used in the manufacture of toys, therefore remain in force until 20 July 2013, notably with respect to antimony, arsenic, barium, lead and mercury.

10. The German Government maintains that Article 55 of the new toys directive is a *lex specialis* that derogates from Article 54, so that, in its submission, Annex II, Part III, point 13 of that directive, the provision at issue in the present case, needs to be transposed only by 20 July 2013. The Commission contends, on the contrary, that the deadline for transposition laid down in Article 54 of the new toys directive also applies to the heavy metals to which the present action relates. It is purely in the interest of the economy that Article 55 provides for a transitional period expiring on 20 July 2013, during which toys whose chemical properties comply with the requirements of the old toys directive may continue to be manufactured and marketed. That provision is not intended to grant a longer transposition period to Member States.

German national law

11. The old toys directive was implemented in German national law by regulation in 1989. The implementing regulation refers to the safety requirements laid down in Annex II to the old toys directive, which set out the bioavailability limit values applicable, in particular, to the five heavy metals antimony, arsenic, barium, lead and mercury.

12. German national law was adapted to the new legal situation resulting from the publication of the new toys directive in 2011. However, no amendment was introduced with respect to the limit values of the five heavy metals mentioned above, since Annex II, Part II, point 3 of the old toys directive remained in force. For that reason, the Commission, by formal letter of 22 November 2012, initiated a procedure against the Federal Republic of Germany, in accordance with Article 258 TFEU, for failing to fulfil its obligations by not implementing, in part, the new toys directive. By letter of 21 March 2013 the German Government responded to that formal letter, claiming that it had not failed to fulfil its obligations, on the ground that Part [III] of Annex [II] to the new toys directive would produce its effects only from 20 July 2013.'

Background to the dispute and the procedure before the judge hearing the application for interim relief

4 The background to the dispute was set out as follows in paragraphs 13 to 15 of the order under appeal:

‘13. By letter of 18 January 2011 the German Government requested the Commission, in accordance with Article 114(4) TFEU, read with Article 36 TFEU, to approve the maintenance beyond 20 July 2013 of its national provisions on limit values for antimony, arsenic, barium, lead and mercury (in accordance with point 3 of Part II of Annex II to the old toys directive) and also for nitrosamines and nitrosatable substances, on the ground that those provisions ensured a higher level of protection of children’s health than that put in place by the new toys directive. The German Government referred, in particular, to the migration limit values fixed by the latter directive for toys that might be scraped. According to the German Government, for antimony, arsenic, barium, lead and mercury, a comparison with the EN 71-3 limit values shows that the migration limit values applicable in the future are higher, as may be seen from the following table:

Element	EN 71-3 in mg/kg, which converts the bioavailability limit values of the old toys directive (applied in national law)	New toys directive in mg/kg
Lead	90	160
Arsenic	25	47
Mercury	60	94
Barium	1 000	56 000
Antimony	60	560

14. The German Government claimed that, even if the comparison were limited to the values applicable to the category of “scraped-off toy material”, that comparison alone would suffice to demonstrate, without there being any need to take the other two categories into account, that the application of the provisions of the new toy directive gives rise to a distinct increase in the permissible migration of heavy metals. The directive does not clearly specify in what proportion the migration limit values of each of the three categories stand in relation to the others. It is therefore necessary to begin with the principle that the quantity indicated may migrate every day on the basis of each category. The migration limit values should therefore be assessed cumulatively and added together in order to define total exposure in case a child should come into contact with toys coming within the three categories in the course of the same day.

15. By the contested decision, … the Commission granted the German Government’s request without restrictions for nitrosamines and nitrosatable substances. For barium and lead, it granted the request “until the date of entry into force of EU provisions setting new limits …, or 21 July 2013, whichever comes first”. For antimony, arsenic and mercury, on the other hand, the Commission rejected the request.’

5 By application lodged at the Registry of the General Court on 14 May 2012, the Federal Republic of Germany brought an action seeking annulment of the contested decision in so far as, by that decision, the Commission rejected its request to maintain the national provisions relating to the limit values for antimony, arsenic and mercury and, granted that request only until 21 July 2013 in respect of barium and lead.

6 By separate document, lodged at the General Court Registry on 13 February 2013, that Member State brought proceedings for interim measures, by which it requested, in essence, the President of the General Court to:

— provisionally approve the national provisions, maintaining limit values for antimony, arsenic, barium, lead and mercury, pending the Court's decision on the substance of the action;

— in the alternative, order the Commission to approve, provisionally, those national provisions, pending the Court's decision on the substance of the action.

7 In its observations on the application for interim measures, lodged at the General Court Registry on 28 February 2013, the Commission requested the President of the General Court to:

— declare that application inadmissible or, in the alternative, dismiss it as unfounded;

— order the Federal Republic of Germany to pay the additional costs occasioned by the interim proceedings when a decision as to the costs relating to the substance of the case is made.

8 That Member State replied to the Commission's observations by pleading of 14 March 2013. That institution adopted a position on that pleading by a rejoinder of 27 March 2013.

The order under appeal

9 The President of the General Court observed, at paragraphs 20 to 23 of the order under appeal that the judge hearing the application for interim relief may order suspension of operation of a contested act or other interim measures if it is established that such an order is justified, prima facie, in fact and in law and that it is urgent in so far as, in order to avoid serious and irreparable harm to the applicant's interests, it must be made and produce its effects before a decision is reached on the substance of the action. He observed that the judge hearing the application may also, where appropriate, weigh up the interests involved and that, in the context of that overall examination, that judge has a wide discretion and is free to determine, having regard to the specific circumstances of the case, the manner and order in which those various conditions are to be examined, there being no rule of law imposing a pre-established scheme of analysis within which the need to order interim measures must be assessed. Considering that he had before him all the information necessary to determine the application for interim relief without there being any need to hear oral argument from the parties, the President of the General Court first examined the admissibility of that application.

10 At paragraphs 24 to 39 of the order under appeal, the President of the General Court examined the Commission's argument that the application for interim measures was inadmissible because the Federal Republic of Germany did not have a legal interest in bringing proceedings in so far as the true position was that it sought the suspension of operation of a negative decision, a claim which could not be entertained in the context of interlocutory proceedings.

11 While accepting that an application for interim relief which seeks only to obtain suspension of operation of a negative decision is in principle inadmissible, in that the suspension sought is not in itself capable of altering the applicant's legal position, the President of the General Court observed, in paragraph 28 of the order under appeal, that in that specific case, that Member State had not submitted an application for suspension of application of an act within the meaning of Article 278 TFEU but for the adoption of an interim measure within the meaning of Article 279 TFEU. Relying inter alia on paragraph 41 of the order of the Vice-President of the Court of 7 March 2013 in Case C-551/12 P(R) *EDF* v *Commission* [2013] ECR, he noted that neither Article 279 TFEU, nor

Article 104 of the Rules of Procedure of the General Court, nor, *a fortiori*, Article 47 of the Charter of Fundamental Rights of the European Union permits such an application to be declared inadmissible on the sole ground that the action to which it is attached seeks the annulment of a negative decision.

12 At paragraphs 30 to 38 of the order under appeal, the President of the General Court held that the specific features of that case argued particularly strongly in favour of the interim measure sought by the Federal Republic of Germany being declared admissible. He observed that that party could logically request that the limit values fixed by the national provisions be maintained beyond 20 July 2013 only by means of an interim measure ordered in accordance with Article 279 TFEU. In so far as the Commission claimed that the provisional measure applied for threatened the institutional balance and exceeded the powers of the court dealing with the application on the substance, the President of the General Court pointed out that, in relation to interim measures, the judge hearing an application for interim relief had powers whose impact vis-à-vis the institutions of the European Union went beyond the effects attaching to a judgment annulling a measure, provided that those interim measures apply only for the duration of the proceedings on the substance, do not prejudge the decision to be taken after those proceedings and do not undermine the practical effect of that decision. Having held that those latter conditions were satisfied in the present case, he considered that, in any event, the interim measure sought would remain within the limits of the measures which the Commission would in all likelihood be required to adopt in order to comply with any judgment of annulment.

13 At paragraph 39 of the order under appeal, the President of the General Court concluded that the application for interim measures had to be declared admissible, but only as regards the head of claim submitted in the alternative since, under Article 114(4) TFEU in conjunction with Article 114(6) TFEU, only the Commission is competent to authorise applications to maintain limit values submitted to it by the Member States, whereas the judge hearing an application for interim relief is, in principle, empowered only to order the institution to take specific measures or to refrain from doing so.

14 In the second place, at paragraphs 40 to 67 of the order under appeal, the President of the General Court examined the condition relating to a prima facie case. He observed, first, that that condition is satisfied where at least one of the pleas put forward by the applicant in support of the action on the substance appears, at first sight, to be relevant and in any event not unfounded. In this respect he considered that it is sufficient that that plea raises complex and delicate issues which, at first sight, cannot be rejected as irrelevant, but require a thorough examination, which is reserved for the court with jurisdiction to determine the substance of the case, or indeed that it follows from the parties' arguments that there is, in the context of the proceedings on the substance, a significant legal controversy, the solution of which is not immediately obvious.

15 As regards the authorisation, granted until 21 July 2013, of the limit values for lead and barium, the President of the General Court observed, at paragraphs 41 and 42 of the order under appeal, that, in the Federal Republic of Germany's submission, the decision at issue infringes Article 114 TFEU in that the Commission, when it approved the national provisions relating to limit values for lead and barium, applied a deadline expiring no later than 21 July 2013, whereas neither the wording of Article 114(6) TFEU nor its scheme allowed the Commission to apply a temporal restriction to a decision approving the maintenance of national provisions. He also observed, in essence, at paragraphs 43 and 44 of that order that, according to the Commission, the authorisation to maintain in force stricter national provisions constitutes a derogation from the harmonisation measures and that it seemed logical, in the present case, to limit the authorisation in time, as that more flexible approach was the only means of taking account of the legitimate concerns of the Member State in question and ensuring that uniform rules would apply consistently to toys marketed in the internal market, while hindering as little as possible the functioning of that market.

16 The President of the General Court observed in essence, at paragraphs 45 and 46 of the order under appeal, that the Commission itself had held, in the contested decision, that the limit values fixed in the national provisions in respect of lead and barium were, first, justified on grounds of major need of protection of human health, since they protected it better than the values fixed in the new toys directive and, secondly, compatible with the internal market, so that it was appropriate to accept them 'subject to a limitation in time'. He inferred, at paragraph 47 of that order, that the Commission had confirmed that all the conditions for the application of Article 114(4) and (6) TFEU were satisfied so far as lead and barium were concerned and he added, in paragraphs 48 to 50 of that order, that it was not certain that the procedures for revision of the values fixed by the new toys directive in respect of those substances which were in progress would end before 21 July 2013, the final date fixed for the maintenance of the national provisions in the decision at issue. The President of the General Court thus concluded, at paragraph 51 of the order under appeal, that the arguments of the Federal Republic of Germany calling in question the approval for a limited period of the limit values applicable to lead and barium were of a very serious nature and raised issues which, prima facie, required thorough examination, which fell within the jurisdiction of the Court dealing with the main application, so that the application for interim relief satisfied the condition relating to a prima facie case.

17 As regards the rejection of the application for approval of the limit values applicable to antimony, arsenic and mercury, the President of the General Court observed, at paragraph 53 of the order under appeal that, according to the Federal Republic of Germany, the decision at issue infringes Article 114(4) and (6) TFEU, in so far as the Commission took issue with that Member State for having failed to establish that the migration limits provided for in the new toys directive did not offer an appropriate level of protection or that they would in all likelihood have harmful effects for health. He observed that such arguments consist in claiming that a Member State need only establish that its national rules ensure a higher level of protection of public health than does the EU law harmonisation measure and that they do not go beyond what is necessary to attain that objective. He observed, at paragraphs 54 and 55 of that order, that that Member State considered itself to have satisfied all its obligations in relation to evidence, since it had established, on the basis of its own calculations, that the limit values, expressed in bioavailability terms provided for by the national provisions, which are the same as those fixed by the old toys directive, are lower so far as those three substances are concerned and that they therefore protect human health better than the migration limit values arising under the new toys directive, regardless of the consistency of the material of which the toy is made.

18 The President of the General Court drew attention, at paragraphs 56 to 59 of the order under appeal, to the Commission's arguments seeking to demonstrate that, according to its calculations, the migration values which result from the national provisions are clearly higher than those of the new toys directive in respect of liquid and dry materials and are only lower than those latter values in respect of 'scraped-off' materials, which are generally less readily available since they first need to be scraped off. He observed that the Commission took issue with the Federal Republic of Germany, in essence, for having failed to calculate the bioavailability per day attained in practice, in respect of the three consistencies which are dealt with separately in the new toys directive, by the application of single values fixed by the old toys directive, whereas that Member State calculated such a bioavailability per day in respect of the migration values fixed by the new toys directive and subsequently compared the various bioavailabilities, thereby using rates of bioavailability which are not comparable.

19 At paragraphs 60 and 61 of the order under appeal, the President of the General Court observed that the dispute between the Federal Republic of Germany and the Commission concerning the 'correct' limit values for antimony, arsenic and mercury in toys raised highly technical questions, in particular, for the conversion of the migration and bioavailability limit values, in so far as that Member State disputes the relevance of the 'bioavailability limit values likely to be attained in practice' adopted by the Commission. He noted, at paragraph 62 of the order, that the Commission itself acknowledged that the values fixed by the national provisions are, for scraped-off material, lower than those fixed in the new

toys directive, but that the Commission did not explain the relevance, in that regard, of its claim that scraped-off material is less readily accessible to the child, because it must first be scraped off. He also held, at paragraph 63 of the order under appeal, that the Commission was wrong to criticise the method used by that Member State in support of its arguments since the Commission itself had used it for 30 years, including in the decision at issue, in order to authorise, provisionally, the values relating to barium and to lead.

20 Having concluded, at paragraph 65 of the order under appeal that the arguments which the Federal Republic of Germany had put forward concerning the refusal to approve the limit values applicable to antimony, arsenic and mercury raised complex questions which prima facie could not be rejected as irrelevant, the President of the General Court held, at paragraph 66 of the same order, that there was no reason to assume, in the present case, that the national provisions were incompatible with the internal market so far as antimony, arsenic and mercury are concerned. He therefore held, at paragraph 67 of the order under appeal that the condition relating to a prima facie case was satisfied with respect to the refusal to approve the limit values applicable to antimony, arsenic and mercury.

21 Thirdly, the President of the General Court examined, at paragraphs 68 to 79 of the order under appeal, the condition relating to urgency. He noted, at paragraph 68, that the purpose of proceedings for interim relief is to ensure the full effectiveness of the future decision on the merits of the case and that the urgency of an application for the adoption of interim measures must therefore be assessed in the light of the extent to which an interlocutory order is necessary in order to avoid serious and irreparable damage to the party seeking the adoption of the interim measure, the foreseeability of the occurrence of that damage having to be shown by that party with a sufficient degree of probability. At paragraphs 69 and 70, he observed that the Federal Republic of Germany put forward the occurrence of damage affecting children's health after 20 July 2013, which is a serious claim since health is, in itself, a particularly important issue because, once it has occurred, such damage is irreversible and injuries to health cannot be eliminated retroactively. In this connection, the Commission points out, essentially, that even if the limit values of the old toys directive did lead to a higher level of protection, that would not mean that the implementation of the provisions of the new toys directive would entail serious and irreparable damage with effect from 20 July 2013.

22 At paragraphs 71 to 74 of the order under appeal, the President of the General Court held that the assessment of whether serious and irreparable damage was likely to occur in the present case, allegedly resulting from risks to human health, must be made in the light of the precautionary principle and he held that the existence of a prima facie case is relevant to that assessment in the context of the present case. In respect of the values applicable to barium and to lead, he observed, at paragraph 75 of the same order, that, according to the Commission itself, the national provisions were justified by serious needs related to the protection of health, in so far as they offer a better level of protection in that regard than that guaranteed by the new toys directive. He noted, at paragraphs 76 and 77 of that order, that the refusal of entitlement to that better level of protection, so far as concerns the exposure of children to heavy metals, must be regarded as giving rise to serious and irreparable harm and he expressly rejected the argument that the new toys directive ensures a sufficient level of protection, such an argument being inappropriate in the light of the 're-nationalisation' of health policy, the principle of which is recognised in Article 114(4) TFEU.

23 As regards the values applicable to antimony, arsenic and mercury, the President of the General Court held, at paragraph 78 of the order, that the possibility could not be ruled out that, following a thorough examination, the Court dealing with the main application might answer the complex questions which the Federal Republic of Germany had raised on that point by stating that the national provisions applicable to antimony, arsenic and mercury ensure, so far as those substances are concerned, a higher level of protection than that put in place by the new toys directive, so that children would be exposed to risks of serious and irreparable damage to their health if they were denied that level of protection. He therefore concluded, at paragraph 79 of that order, that that Member State had shown that the condition relating to urgency was satisfied in the present case.

24 Lastly, as regards the weighing up of interests, the President of the General Court held, at paragraphs 80 to 83 of the order under appeal, that the Commission's interest in the application for interim relief being dismissed in order to protect the coherence of the internal market must give way to the Federal Republic of Germany's interest in the national provisions being maintained in order to ensure the best possible protection of children's health, *a fortiori* because the interim measure sought would merely maintain a legal situation which had prevailed since 1988, and the provisions in question were to be maintained for only a limited period.

25 It was on the basis of all those grounds that the President of the General Court decided to grant the interim measure applied for in the alternative by the Member State. In that connection, point 1 of the operative part of the order under appeal is worded as follows:

'The European Commission shall authorise that the national provisions notified by the Federal Republic of Germany concerning limit values for antimony, arsenic, barium, lead and mercury in toys be maintained pending the Court's decision in the main proceedings.'

Forms of order sought

26 The Commission claims that the Court of Justice should:

— primarily, set aside the order under appeal, and

— reject the Federal Republic of Germany's application seeking that the Commission be ordered to authorise, provisionally, the maintenance of the national provisions containing limit values for antimony, arsenic, barium, lead and mercury until the General Court has ruled on the substance of the action; or

in the alternative:

— set aside the order under appeal in so far as it orders the Commission;

  — to approve, provisionally, the limit values notified by the Federal Republic of Germany for antimony and mercury until the General Court has ruled on the substance of the action;

  — to approve, provisionally, the limit values notified by that Member State for arsenic and lead in dry materials and liquids, until the General Court has ruled on the substance of the action;

— reject the application of the Federal Republic of Germany seeking that the Commission be ordered to authorise, provisionally, the maintenance of the national provisions containing limit values for antimony and mercury until the General Court has ruled on the substance of the action;

— reject the application of that Member State seeking that the Commission be ordered to authorise, provisionally the maintenance of the national provisions containing limit values for arsenic and lead until the General Court has ruled on the substance of the proceedings, in so far as it is based on limit values for arsenic and lead in dry materials and liquids, and

— order the Federal Republic of Germany to pay the costs of both sets of proceedings.

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

— dismiss the appeal so far as concerns the claims submitted both primarily and in the alternative, and

— order the Commission to pay the costs.

The appeal

28 In support of its appeal, the Commission raises five grounds of appeal, alleging, respectively:

— an error of law concerning the burden of proof in the context of the procedure provided for in Article 114(4) and (6) TFEU;

— a distortion of the facts concerning the availability of 'scraped toys';

— an inadequate statement of grounds for the order under appeal;

— inconsistency of the grounds of that order, and

— errors of law so far as concerns the weighing-up of interests.

29 It is appropriate, first, to examine the first and fourth pleas together.

The first plea, alleging an error of law concerning the burden of proof, and the fourth plea, alleging inconsistency of the grounds of the order under appeal

Arguments of the parties

30 By its first plea, the Commission claims that the President of the General Court misinterpreted the burden of proof which is borne by the Member State which applies, pursuant to Article 114(4) TFEU, for authorisation to maintain a provision derogating from a harmonisation directive, that State having to prove that that provision guarantees better health protection than that ensured by the provisions of such a directive. In the present case, that allocation of the burden of proof is all the more necessary since the values of the old toys directive have been replaced by the values of the new toys directive, the EU legislature having made a decision, in full knowledge of the facts and in accordance with the obligation on it under Article 114(3) TFEU to take as a base a high level of protection, taking account in particular of any new development based on scientific facts, to replace by new values the old values which the Federal Republic of Germany wishes to maintain.

31 The Commission submits that, in the order under appeal, the President of the General Court did not take account of those specific features of the procedure provided for under Article 114(4) TFEU, inter alia by observing, in his analysis of whether there was a prima facie case and, in particular, at paragraphs 61 and 64 of that order, that the grounds for annulment raised by the Federal Republic of Germany before the General Court were not 'prima facie' irrelevant. Likewise, in respect of the condition relating to urgency concerning antimony, arsenic and mercury, the judge hearing the application for interim relief held, at paragraphs 78 and 79 of that order, that the fact that a finding that the national provisions ensure a better level of health protection 'cannot be precluded' is sufficient for the measure sought to be granted. That incorrect reversal of the burden of proof is apparent in particular from paragraph 76 of that order, in which the President of the General Court refers to a 're-nationalisation' of health policy under Article 114(4) TFEU. That error of law has consequences for the assessment of the prima facie case, of the issue of urgency and of the weighing-up of interests and it has also led the judge hearing the application for interim relief not to take account of the limits of his power of review.

32 As regards the question of a prima facie case, the Commission maintains that, in the order under appeal, the President of the General Court failed to have regard to the specific relationship between the rule and the derogation which is inherent in the procedure provided for in Article 114(4) TFEU by applying to that procedure the same rules relating to the burden of proof as those applicable in other contexts, inter alia in the competition field. The approach thus taken by the judge hearing the application for interim relief forces the Commission to adopt new values by relying deliberately on measures other than the latest scientific knowledge and undermines the institutional balance between the Commission and the EU legislature.

33 As regards the issue of urgency, regardless of whether the national provisions ensure a better level of protection than the provisions of the new toys directive, which the Commission disputes, that party argues that the issue is to ascertain to what extent those latter provisions not only provide for a lower level of protection than that ensured by the national provisions, but furthermore put in danger children's health in a serious and irreparable way. It observes that, according to case-law, it is for the party requesting the adoption of an interim measure to show that it cannot wait for the end of the proceedings on the merits without suffering serious and irreparable harm. Moreover, the Federal Republic of Germany expressly accepted, in a letter of 2 March 2011 to the Commission, which set out the grounds for its request for a derogation brought on 18 January 2011 ('the letter of 2 March 2011'), that the values fixed by the new toys directive in respect of antimony and mercury did not exceed the total tolerable daily quantity of absorption, which was indeed confirmed by the opinion of the German Federal Institute for Risk Evaluation of 12 January 2011.

34 Lastly, the Commission observes that it had a wide discretion so far as concerns complex scientific assessments and argues that the judicial review carried out in the present case significantly exceeded that framework. In its view, the President of the General Court overstepped the limits of his powers as the judge hearing the application for interim relief, by holding, impliedly, that the new toys directive is, in part, unlawful.

35 In connection with the fourth ground of its appeal, the Commission takes issue with the judge hearing the application for interim relief on account of the fact that the order under appeal does not make any distinction between the various materials of which toys are made. It claims that, even if the arguments of the President of the General Court are correct, that order should have allowed the application to maintain the national provisions only in respect of scraped-off material, since, as it has shown, the new toys directive was much stricter so far as liquid and dry materials were concerned.

36 Failing to take any account of the demonstration of that fact, based on the latest scientific knowledge, in accordance with the requirements of Article 114(3) TFEU, the order under appeal obliges the Commission to authorise, so far as concerns antimony, arsenic, lead and mercury, in liquid and dry materials of which toys are made, limit values which do not protect children's health nearly as well as those provided for by the new toys directive.

37 As regards scraped-off material, it is true that the migration limit values which result from the bioavailability limit values fixed by the national provisions are lower than those of the new toys directive, but, having regard to the latest scientific knowledge, the maintenance of those national values is not necessary, since children's health would be protected as effectively by the new values, as the Federal Republic of Germany has itself acknowledged in its letter of 2 March 2011, with respect to antimony and mercury. In the alternative, the Commission requests the Court, in the event that that argument is not accepted, to set aside the order under appeal only in respect of liquid and dry materials.

38 In response to the first plea, the Federal Republic of Germany submits, first of all, that that plea is inadmissible because the true position is that the Commission is calling into question factual assessments made by the President of the General Court. In any event, the President did not reverse the burden of proof in any way, but merely held that the arguments put forward by that Member

State in support of its application for interim relief were plausible and coherent. Thus, the order under appeal does not in any way prejudice the decision to be taken on the merits of the case. In so far as the Commission calls into question the power of the judge hearing the application for interim relief to adopt an interim measure such as that ordered at point 1 of the operative part of that order, that Member State submits that the Commission is merely repeating the arguments already raised at first instance and that, for that reason also, that part of its arguments should be rejected as inadmissible.

39 As regards the fourth ground of the appeal, the Federal Republic of Germany again argues that the arguments put forward by the Commission in support of that ground are inadmissible because the true position is that the Commission is calling into question factual assessments made by the President of the General Court. Moreover, it claims, in essence, that the Commission has committed errors in the method used for its calculations, in particular in so far as it used for that purpose the migration limit values fixed in the EN 71-3 standard. Those errors led it to make an inaccurate comparison between the level of health protection ensured by the national provisions and that guaranteed by the provisions of the new toys directive.

Findings of the Court

40 Article 104(2) of the Rules of Procedure of the General Court provides that applications for interim measures shall state 'the subject-matter of the proceedings, the circumstances giving rise to urgency and the pleas of fact and law establishing a prima facie case for the interim measures applied for'. Thus, suspension of the operation of an act or other interim measures may be ordered if it is established that such an order is justified, prima facie, in fact and in law and that it is urgent in so far as it must, in order to avoid serious and irreparable harm to the interests of the party requesting it, be made and produce its effects before a decision is reached on the substance of the application. Those conditions are cumulative, so that an application for interim measures must be dismissed if any one of them is absent (order of the President of the Court in Case C-268/96 P(R) *SCK and FNK* v *Commission* [1996] ECR I-4971, paragraph 30). Where appropriate, the judge hearing such an application must also weigh up the interests involved (order of the President of the Court in Case C-445/00 R *Austria* v *Council* [2001] ECR I-1461, paragraph 73).

– The prima facie case

41 It must be recalled, first of all, that the condition of a prima facie case is satisfied where there is, at the stage of the interim proceedings, a major legal disagreement whose resolution is not immediately obvious, so that the action is not prima facie without reasonable substance (see, to that effect, orders of the President of the Court in Case 56/89 R *Publishers Association* v *Commission* [1989] ECR 1693, paragraph 31, and Case C-39/03 P-R *Commission* v *Artegodan and Others* [2003] ECR I-4485, paragraph 40). Since the purpose of the interim proceedings is to guarantee that the final decision to be taken is fully effective, in order to avoid a lacuna in the legal protection ensured by the Court, the court hearing the application for interim relief must restrict itself to assessing 'prima facie' the merits of the grounds put forward in the main proceedings in order to ascertain whether there is a sufficiently large probability of success of the action.

42 In so far as the Commission claims, in the present case, that the President of the General Court misinterpreted the burden of proof which is borne by the Member State which applies, on the basis of Article 114(4) TFEU, for the option to maintain a provision derogating from a harmonisation directive, that State having to prove, according to the Commission, that that provision guarantees better health protection than the provisions of the harmonisation directive in question, it must be stated that the Commission is mistaken as to the nature of the assessment which must be carried out by the judge hearing the application for interim relief, irrespective of the subject-matter of the case before the General Court.

43 Admittedly, the specific context of the procedure provided for in Article 114(4) TFEU and, inter alia, the fact that it is for the Member State to prove that the derogation which it requests from the provisions of a harmonisation directive is justified, and the discretion which the Commission has in this respect, are relevant for the purposes of the examination of whether there is a prima facie case. However, that relevance means only that the judge hearing the application for interim relief, in ascertaining whether the Member State requesting the adoption of an interim measure has submitted grounds which may, prima facie, establish that the Commission acted unlawfully, and consequently, that there is a prima facie case, must take account of the fact that it is for the Member State to establish, during the administrative proceedings, that the conditions for the grant of the derogation sought are satisfied. That relevance does not mean, on the other hand, that the Member State is required to establish definitively, at the stage of the interim proceedings, that those conditions are fulfilled. Were the judge hearing the application for interim relief to adopt a position on that latter issue, he would be obliged to rule on an aspect of the merits of the main proceedings brought by the Member State concerned and would thereby exceed the limits of his own powers.

44 It follows that the President of the General Court did not commit any error of law and, in particular, did not reverse the burden of proof by holding in the order under appeal, inter alia at paragraphs 61 and 65 thereof, that the grounds for annulment raised by the Federal Republic of Germany before the General Court were not 'prima facie' irrelevant.

45 As regards the Commission's argument that the order under appeal will force it to adopt new provisions by relying on information other than the latest scientific knowledge and, thereby, to infringe its obligation under Article 114(3) TFEU, according to which it must 'take as a base a high level of protection, taking account in particular of any new development based on scientific facts', it must be observed that the President of the General Court held, at paragraphs 41 to 52 of the order under appeal so far as concerns lead and barium and at paragraphs 53 to 67 so far as concerns antimony, arsenic and mercury, that the Federal Republic of Germany had submitted arguments which were capable of demonstrating that its pleas in the main action, seeking to support the opposite line of argument to that adopted by the Commission, were not unfounded. In the context of the present appeal relating to interim proceedings, the judge hearing the application for interim relief could be alleged to have infringed that provision only if it were established by the party making the claim that that finding seemed to be manifestly incorrect.

46 It must be noted, in this connection, as the Federal Republic of Germany set out in detail in the response to the appeal, that its arguments as to the merits are based, in essence, on the allegedly more protective nature, so far as concerns children's health, of the bioavailability limit values fixed in the national provisions than those obtained from the migration limit values fixed by the new toys directive.

47 That Member State points out, inter alia, that although the bioavailability limit values in micrograms of poisonous substance absorbed per day, namely the daily tolerable absorption doses, fixed by the national provisions, are identical to those fixed by the old toys directive, the migration limit values for the materials of which toys are made, which the EN 71-3 standard took from that directive, were not transposed in those provisions. Thus, according to that Member State, the Commission distorted the content of the national provisions by using the migration limit values fixed by the EN 71-3 standard in order to calculate the bioavailability limit values which it subsequently attributed to the national provisions for the purposes of comparing those national provisions to the bioavailability limit values calculated from the migration limit values fixed by the new toys directive, in respect of the three types of material defined there.

48 The Federal Republic of Germany submits that the bioavailability limit values thus determined, which the Commission attributed to the national provisions for the purposes of its comparison, are higher than the bioavailability limit values actually fixed by the national provisions themselves. According to the comparison made by that Member State between, on the one hand, the bioavailability limit values

fixed by the national provisions and, on the other, those obtained from the migration limit values fixed by the new toys directive, the national provisions offer a level of protection higher than that ensured by the new toys directive, the directive providing for a higher daily tolerable absorption dose in respect of all the substances used and in the three materials — scraped-off, dry and liquid.

49 Thus, according to the Federal Republic of Germany, the method adopted by the Commission for the purposes of its calculations of the limit values is incorrect, which led it to make an inaccurate comparison between the level of health protection ensured by the national provisions and that guaranteed by the new toys directive.

50 Without it being necessary to rule on the merits of the arguments put forward as to the merits by the Federal Republic of Germany or on the contrary arguments of the Commission, a task which falls within the jurisdiction solely of the court ruling on the substance of the action, it must be observed that the arguments of that Member State are sufficiently plausible to show, in the present appeal, that the President of the General Court did not infringe Article 114(3) TFEU by concluding, at paragraph 51 of the order under appeal, so far as concerns lead and barium, and at paragraph 65, as regards antimony, arsenic and mercury, that the grounds raised by that Member State before the General Court were not 'prima facie' irrelevant. It also stems from the foregoing that that order is not inconsistent, in the sense intended by the Commission in the title of its fourth ground of appeal, on account of the fact that the President of the General Court reached those findings notwithstanding the arguments to the contrary put forward by the Commission. Without prejudice to the merits of his assessment of urgency and the weighing-up of interests, nor has he exceeded the limits of his powers, as the judge hearing the application for interim relief, or infringed the provisions of Article 114 TFEU, by drawing the appropriate inferences from such findings as regards the prima facie case and thereby ordering, merely on a provisional basis, the Commission to allow the national provisions to be maintained.

– Urgency and the weighing-up of interests

51 In so far as the Commission criticises the President of the General Court, as regards antimony, arsenic and mercury, for having reversed the burden of proof in so far as he held, at paragraphs 78 and 79 of the order under appeal, that the finding that the national provisions ensure a better level of health protection than that guaranteed by the new toys directive 'cannot be precluded', it must be pointed out at the outset that it was logical for the President of the General Court to postulate, for the purposes of the assessment of the existence of serious and irreparable damage, that the grounds submitted in the main proceedings by the Federal Republic of Germany might be accepted (see, by analogy, order of the Vice-President of the Court in Case C-278/13 P(R) *Commission* v *Pilkington Group* P(R) [2013] ECR, paragraph 38).

52 The serious and irreparable damage whose likely occurrence must be proven is that which would result, where relevant, from the refusal to grant an application for interim measures in the event that the action in the main proceedings was subsequently successful, and it must be assessed on the basis of that premiss, although that does not entail the judge hearing the application for interim relief adopting a position as regards the pleas in the main proceedings. Thus, the arguments put forward by the Commission, based on the burden of proof borne, in the administrative proceedings, by the Member State seeking a derogation to a harmonisation directive under Article 114(4) TFEU cannot cast doubt on the assessment by the judge hearing the application for interim relief of the condition relating to urgency. As regards the more specific argument relating to the fact that the President of the General Court referred, at paragraph 76 of the order under appeal, to a 're-nationalisation' of health policy, the principle of which is acknowledged in Article 114(4) TFEU, it is sufficient to note that, for the same reasons as those mentioned above, that complaint cannot affect that assessment, without there being any need to adopt a position on the relevance of that description of the procedure laid down in that provision.

53 In respect of the Commission's argument that, even if the national provisions ensure a better level of protection than those of the new toys directive, it is still necessary that those latter provisions pose a threat of serious and irreparable damage to children's health, it must be observed that the President of the General Court was correct to draw attention, at paragraphs 71 to 73 of the order under appeal, to the relevance of the precautionary principle in the present context.

54 In accordance with that principle, where there is uncertainty as to the existence or extent of risks to human health, the EU institutions, pursuant to that principle, may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent (Case C-157/96 *National Farmers' Union and Others* [1998] ECR I-2211, paragraph 63, and Case C-504/04 *Agrarproduktion Staebelow* [2006] ECR I-679, paragraph 39). It follows that the judge hearing the application for interim relief did not commit any error of law in the present case in considering, for the purposes of his assessment of the likelihood of serious and irreparable damage, and subject to that of the weighing-up of interests, that the application, even provisionally, of values which might not be the most effective for the purposes of protecting human health and, specifically, children's health, was sufficient to prove, with a sufficient degree of probability, the future occurrence of serious and irreparable damage.

55 As regards the Commission's argument that the German Government expressly accepted, in its letter of 2 March 2011, that the values fixed by the new toys directive in respect of antimony and mercury do not exceed the daily quantity of total tolerable absorption, which was indeed allegedly confirmed by the opinion of 12 January 2011 of the German Federal Institute for Risk Evaluation, it must be held that the Commission is thereby raising a question of assessment of the facts which the General Court did not expressly examine in the order under appeal, without however claiming that the facts were distorted in that respect.

56 Therefore, that complaint must be dismissed as inadmissible. Under Article 256 TFEU and Article 58 of the Statute of the Court of Justice of the European Union, which apply also to appeals brought under the second paragraph of Article 57 of that Statute, an appeal is limited to points of law, to the exclusion of appraisal of the facts. Therefore, the General Court has exclusive jurisdiction to find the facts and to appraise those facts. That appraisal thus does not, save where the clear sense of the evidence has been distorted, constitute a point of law which is subject, as such, to review by the Court of Justice at the appellate stage (see, to that effect, order of the President of the Court in Case C-233/03 P(R) *Linea GIG* v *Commission* [2003] ECR I-7911, paragraphs 34 to 36).

57 In any event it must be observed that the Federal Republic of Germany has stated, both before the General Court and before the Court of Justice in the present interim proceedings, the reasons for which it considers that the probable occurrence of serious and irreparable damage is established in the present case, so far as concerns the five substances at issue. It submitted, inter alia, that human health, in particular children's health, is, in itself, a particularly important value. Irrespective of the factors and the arguments which that Member State put forward at the stage of the administrative proceedings, it is sufficient to observe that, in accordance with what was held at paragraph 54 of the present order, the President of the General Court, in relying inter alia on the precautionary principle, did not commit any error of law in this respect.

58 Lastly, in so far as the Commission claims that the error of law which it alleges so far as concerns the burden of proof also affects the assessment of the weighing-up of interests carried out by the judge hearing the application for interim relief, it must be observed that it does not put forward any specific arguments in this connection. The issue of the weighing-up of interests will consequently be examined in the context of the fifth ground of appeal which concerns that aspect of the order under appeal.

59 It follows from the foregoing that the first and fourth grounds of appeal relied on by the Commission in support of its appeal must be rejected.

The second ground of appeal, alleging distortion of the facts

Arguments of the parties

60 According to the Commission, the President of the General Court distorted the facts, at paragraph 62 of the order under appeal, by assuming that the lower limit values set out in the national provisions concerned 'scraped' toys, in the sense that those toys would be particularly worn, whereas, in fact, those provisions concerned materials of which toys are made which cannot be absorbed by children unless they have been scraped-off by them. The Commission maintains that, had he not distorted the facts, the President of the General Court could have allowed the application for scraped-off material only, and rejected it for liquids or materials in powder form. Since he distorted the facts, the President of the General Court therefore deprived himself of that possibility in his order.

61 The Federal Republic of Germany submits that the President of the General Court did not distort the facts and submits that, in any event, the paragraph of the order under appeal which is criticised in this connection by the Commission does not provide the necessary support for the finding reached by the judge hearing the application for interim relief so far as concerns the prima facie case.

Findings of the Court

62 It must be held that the distortion of the facts alleged by the Commission so far as concerns paragraph 62 of the order under appeal had no effect on the overall assessment of the prima facie case made by the President of the General Court at paragraphs 53 to 67 thereof so far as concerns antimony, arsenic and mercury. Even if the President misinterpreted the references, in the file, to the concept of the availability of scraped toys, by assuming that those toys had to be particularly worn, he also held, correctly, at paragraph 62, that the Commission had itself acknowledged that, even according to its own method of conversion, the limit values contained in the national provisions offer, in respect of scraped-off matter, better children's health protection than those fixed in the new toys directive. That statement is a sufficient basis, in that regard, for the finding reached by the President of the General Court at paragraph 67, according to which the condition relating to a prima facie case is satisfied, so far as concerns scraped-off material, with regard to the three substances at issue.

63 It follows that the second ground relied on by the Commission in support of its appeal is inoperative and must be rejected as such.

The third ground of appeal, alleging an inadequate statement of grounds

Arguments of the parties

64 The Commission criticises the President of the General Court for not having explained the grounds on which he held that the Commission's arguments, according to which the new toys directive grants a better level of protection to children's health, were not relevant, since such an explanation is necessary having regard to the relationship existing between the rule and the derogation to that rule in the context of Article 114(4) TFEU. The Commission identifies a second inadequacy in the grounds stated for the order under appeal, by observing that, in the decision at issue, it did not check, so far as concerns antimony, arsenic and mercury, whether or not there was arbitrary discrimination or a disguised restriction on trade or an obstacle to the functioning of the internal market, whereas, in that order, the President of the General Court himself carried out that assessment by merely, in that regard, repeating the arguments of the Federal Republic of Germany according to which the reasoning relating to those conditions seeking to guarantee undistorted competition, upheld in respect of lead, barium, nitrosamines and nitrosatable substances, could be easily transposed to other substances, the national provisions being, in his view, identical. That statement of grounds is inadequate, since the

determining factor is not the fact that those provisions are identical but the situation on the market. Once again the judge hearing the application for interim relief substituted his own assessment for that of the competent decision-making bodies.

65 The Federal Republic of Germany submits that none of the arguments put forward by the Commission in that regard establishes that there were inadequate grounds stated capable of vitiating the assessment made in the order under appeal.

Findings of the Court

66 It is settled case-law that judgments of the General Court must contain an adequate statement of reasons to enable the Court of Justice to exercise its power of review (see, to that effect, inter alia, Case C-259/96 P *Council* v *de Nil and Impens* [1998] ECR I-2915, paragraph 32; Joined Cases C-395/96 P and C-396/96 P *Compagnie maritime belge transports and Others* v *Commission* [2000] ECR I-1365, paragraph 106; and Joined Cases C-101/11 P and C-102/11 P *Neuman and Others* v *José Manual Baena Grupo* [2012] ECR, paragraph 80). In that regard, it is sufficient that the reasoning is clear and comprehensible and that it is moreover such as to justify the finding which it seeks to substantiate (judgment of 4 October 2007 in Case C-311/05 P *Naipes Heraclio Fournier* v *OHIM*, paragraph 53).

67 In respect of the Commission's complaint that the President of the General Court did not state adequate grounds for the rejection of the arguments by which the Commission claimed that the new toys directive granted a better level of protection for children's health than the national provisions, it must be observed that the President, whose examination as to the merits had to limit itself exclusively to the question whether there was a prima facie case, stated to the requisite legal standard, at paragraphs 40 to 67 of the order under appeal, the reasons for which he considered, notwithstanding those arguments, that the condition relating to a prima facie case was fulfilled. As regards the alleged relevance, in that regard, of the relationship between the rule and the derogation to that rule in the context of Article 114(4) TFEU, it is sufficient to refer to paragraphs 42 to 44 of this order, from which it is apparent that the President of the General Court did not commit any error of law so far as concerns the burden of proof borne by the Federal Republic of Germany in the context of the interim proceedings.

68 As regards the claim that the President of the General Court did not state adequate grounds, at paragraph 66 of the order under appeal, for his reasoning concerning whether or not there was arbitrary discrimination, a disguised restriction on trade or an obstacle to the functioning of the internal market concerning antimony, arsenic and mercury, in so far as he merely repeated the arguments of the Federal Republic of Germany according to which the reasoning relating to those conditions seeking to guarantee undistorted competition, upheld in respect of lead, barium, nitrosamines and nitrosatable substances, can be easily transposed to other substances since the national provisions are identical, it must be pointed out that the President of the General Court, as the judge hearing the application for interim relief, had to assess only whether there was a prima facie case in relation to the absence of those conditions, and not the definitive existence of those conditions as such. Moreover, the fact that the judge hearing the application for interim relief used, on a particular point of fact or law, the arguments of one or other of the parties in his reasoning cannot, as such, constitute a failure to state reasons.

69 In the context of the application for interim measures before him, the President of the General Court therefore adopted an adequate statement of reasons allowing the Court of Justice to understand why he was led to conclude that there was a prima facie case having regard to the absence of arbitrary discrimination, a disguised restriction on trade or an obstacle to the functioning of the internal market concerning antimony, arsenic and mercury, since, in his view, the Commission's reasoning

concerning those conditions seeking to guarantee undistorted competition for lead, barium, nitrosamines and nitrosatable substances was transposable to the three other substances mentioned above, given that the national provisions are identical, in this respect, for all those substances.

70 It follows that the third ground relied on by the Commission in support of its appeal must be rejected.

The fifth ground of appeal, alleging errors of law in the weighing-up of interests

Arguments of the parties

71 The Commission submits that, in the order under appeal, the President of the General Court merely followed the arguments of the Federal Republic of Germany, according to which that institution's interest was limited to the functioning of the internal market. The Commission disputes that contention and maintains that the interest which it is defending in the present case consists in the observance of the intention of the EU legislature, as it is expressed in the new toys directive. In practice, the primary aim of that interest is to protect children's health and not only the internal market. In order to guarantee that health protection in the most effective manner, that directive is based, as the Commission submitted in the context of its first and fourth pleas and in accordance with the requirements of Article 114(3) TFEU, on the latest scientific knowledge. The Commission submits that the order under appeal does not take into account that interest in the weighing-up of interests.

72 The Federal Republic of Germany claims that the new toys directive, as a harmonising measures adopted on the basis of Article 114(1) TFEU and seeking to ensure the establishment of the internal market so far as concerns the safety of toys, does not have as its primary objective the protection of children's health, contrary to what the Commission maintains. Thus, since the President of the General Court has not committed any error in that regard, the fifth ground of appeal cannot succeed.

Findings of the Court

73 It must be observed that, in the context of the interim proceedings brought before the President of the General Court by the Federal Republic of Germany, the Commission sought to obtain the rejection of the application for interim measures in order to permit the application, from 21 July 2013, of the migration limit values fixed in the new toys directive throughout the European Union, given that it had rejected the application for a derogation submitted by that Member State under Article 114(4) TFEU.

74 It is not disputed between the parties that the new toys directive is a harmonisation measure within the meaning of Article 114(4) TFEU. Moreover, it was adopted on the basis of Article 95 EC, a provision which was reproduced in Article 114(1) TFEU. That provision sets out the rules applicable for the purpose of attaining the objectives set out in Article 26 TFEU, namely, in essence, those which enable the establishment of the internal market. Thus, taking account of the legal basis used for its adoption, the main objective of the new toys directive is therefore necessarily the harmonisation of the national rules in the field which it governs, namely that of toy safety, and therefore that is the underlying objective behind the Commission's interest in obtaining the application of that directive without delay.

75 Article 168(5) TFEU excludes any harmonisation of laws and regulations of the Member States designed to protect and improve human health. Admittedly, as the Court has already held, harmonisation measures adopted on the basis of other provisions of primary law can have an effect on the protection of human health. The first subparagraph of Article 168(1) TFEU provides, moreover, that a high level of human health protection is to be ensured in the definition and implementation of all European Union policies and activities and Article 114(3) TFEU states that the

European Parliament and the Council are to seek to achieve this objective in the exercise of their powers relating to the establishment of the internal market (see, to that effect, Case C-376/98 *Germany* v *Parliament and Council* [2000] ECR I-8419, paragraphs 77 and 78, and Case C-380/03 *Germany* v *Parliament and Council* [2006] ECR I-11573, paragraphs 93 to 95). Other provisions of primary law may not, however, be used as a legal basis in order to circumvent the express exclusion of harmonisation seeking to protect and improve human health laid down in Article 168(5) TFEU (see, to that effect, Case C-376/98 *Germany* v *Parliament and Council*, paragraph 79).

76 It thus stems from the Court's case-law that, for the purposes of interim proceedings such as those which are the subject of present appeal, it is the objective of harmonisation of national legislation in the field of toy safety, and not the objective of the protection of children's health as such, which must actually be regarded as underlying the interest defended by the Commission in those proceedings.

77 It follows from the foregoing that the President of the General Court was correct, after having, at paragraphs 82 and 83 of the order under appeal, weighed-up the interests by means of a comparison between the Federal Republic of Germany's interest in maintaining the national provisions with the aim of the protection of children's health and the Commission's interest in the rejection of the application for interim measures, in order that the harmonised provisions adopted by the EU legislature in the new toys directive might apply from 21 July 2013 thoughout the internal market, including in Germany, to conclude, at paragraph 83, that the Commission's interest should give way to that Member State's interest in obtaining the maintenance of the national provisions.

78 Accordingly, the fifth ground of appeal put forward by the Commission in support of its appeal must be rejected.

The Commission's observations on the recent steps taken so far as concerns barium and lead

79 In so far as the Commission informed the Court, at the end of its statement of appeal, that, by Commission Regulation (EU) No 681/2013 of 17 July 2013 amending part III of Annex II to Directive 2009/48 (OJ 2013 L 195, p. 16), it reduced the migration limit values for barium, it is sufficient to note that, since the Federal Republic of Germany informed the Court that, in its view, that measure did not go far enough, this does not affect the framework of the present proceedings. *A fortiori*, the fact that a possible reduction of the values relating to lead is envisaged does not have an effect on the present proceedings.

80 As none of the eight grounds of appeal relied on by the Commission in support of its appeal can be upheld, the appeal must be dismissed in its entirety.

Costs

81 Under Article 138(1) of the Rules of Procedure, which applies to appeal proceedings pursuant to Article 184(1) thereof, 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 Federal Republic of Germany has applied for costs and the Commission has been unsuccessful in its submissions, the latter must be ordered to pay the costs.

On those grounds, the Vice-President of the Court hereby:

1. Dismisses the appeal;

2. Orders the European Commission to pay the costs.

[Signatures]