



Reports of Cases

ORDER OF THE PRESIDENT OF THE GENERAL COURT

15 May 2013 *

(Interim relief — Limit values for antimony, arsenic, barium, lead and mercury in toys — Commission's refusal to approve in full the national provisions notified by the German authorities and maintaining limit values for those substances — Application for interim measures — Admissibility — Urgency — Prima facie case — Weighing up of the interests)

In Case T-198/12 R,

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 provisional approval of the maintenance of the national provisions notified by the German authorities applying limit values for antimony, arsenic, barium, lead and mercury in toys, pending the decision of the Court in the main action,

THE PRESIDENT OF THE GENERAL COURT

makes the following

Order

Subject-matter of the proceedings

- 1 The present application for interim relief concerns Commission Decision C(2012) 1348 final 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/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 contested decision').
- 2 By the contested decision, 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

* Language of the case: German.

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 ('the new toys directive') would be applied.

Legal context

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, 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.

...

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 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.'

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 the proposal for a directive of the European Council 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 II of Annex III to the new toys directive would produce its effects only from 20 July 2013.

Facts and procedure

- 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, which was notified on 2 March 2012, 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.
- 16 By application lodged at the Court Registry on 14 May 2012, the German Government brought an action for annulment of the contested decision, in so far as the Commission rejected its request to maintain the national provisions on limit values for antimony, arsenic and mercury and approved that request for barium and lead only until 21 July 2013.
- 17 By separate document, lodged at the Court Registry on 13 February 2013, the German Government brought the present application for interim relief, in which it claims, in essence, that the President of the Court should:
- provisionally approve the notified national provisions, maintaining limit values for antimony, arsenic, barium, lead and mercury, pending the Court's decision in the main action;

- in the alternative, order the Commission to approve, provisionally, those national provisions, pending the Court's decision in the main action.
- 18 In its observations on the application for interim relief, which were lodged at the Court Registry on 28 February 2013, the Commission contends that the President of the Court should:
- declare the action inadmissible or, in the alternative, dismiss it as unfounded;
 - order the Federal Republic of Germany to pay the additional costs occasioned by the interlocutory proceedings when a decision as to costs is made in the main proceedings.
- 19 The German Government replied to the Commission's observations in a pleading of 14 March 2013. The Commission adopted a final position on that pleading in a pleading of 27 March 2013.

Law

- 20 Under the combined provisions of Articles 278 TFEU and 279 TFEU, on the one hand, and Article 256(1) TFEU, on the other, the Court may, if it considers that the circumstances so require, order that application of a contested act be suspended or prescribe any necessary interim measures.
- 21 Article 104(2) of the Rules of Procedure of the General Court provides that an application for interim measures is to 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, the judge hearing an application for interim relief may order suspension of operation of an 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 in the main action. The judge hearing the application may also, where appropriate, weigh up the interests involved (see order of the President in Case T-393/10 R *Westfälische Drahtindustrie and Others v Commission* [2011] ECR II-1697, paragraph 12 and the case-law cited).
- 22 In the context of that overall examination, the judge hearing an application for interim relief 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 (see order in *Westfälische Drahtindustrie and Others v Commission*, cited above, paragraph 13 and the case-law cited).
- 23 The judge hearing the application considers that he has before him all the information necessary to determine the present application for interim relief without there first being any need to hear oral argument from the parties.

Admissibility of the application for interim relief

- 24 The Commission contends that the application for interim measures is inadmissible, because the Federal Republic of Germany has no interest in bringing an action. If the main application, which seeks annulment of a negative decision, should succeed, the Commission would be required to adopt a new decision concerning the grant of a derogation, under Article 114(4) TFEU, taking account of the annulment judgment and exercising the wide discretion which it enjoys in such circumstances. By its application for interim relief, the Federal Republic of Germany seeks, in reality, the suspension of operation of a negative decision. Such a claim is in principle inconceivable in the context of interlocutory proceedings (see order of the President of 17 December 2009 in Case T-396/09 R

Vereniging Milieudefensie and Stichting Stop Luchtverontreiniging Utrecht v Commission, not published in the ECR, ‘the order in *Milieudefensie*’, paragraph 34 and the case-law cited). In the Commission’s submission, the Federal Republic of Germany seeks to circumvent that rule relating to admissibility which limits the subject-matter of applications for interim measures and, in order to do so, submits, in the interlocutory proceedings, heads of claim which go far beyond the form of orders which it seeks in the main proceedings, which threatens the institutional equilibrium.

- 25 As regards the main claim, whereby the German Government asks that the judge hearing the application for interim relief should himself provisionally approve the maintenance of the national provisions at issue, the Commission observes that, in the context of a review of legality, the Courts of the European Union cannot act as an administrative authority or undertake complex assessments of technical questions in the place of such an authority. As for the alternative head of claim, if it should be upheld in the context of the interlocutory proceedings, that would amount to enjoining the Commission to draw specific inferences from the annulment judgment. European Union law does not recognise that type of action for an injunction, which would be tantamount to ordering a measure going beyond the powers of the court dealing with the main application (order in *Milieudefensie*, paragraph 42). Furthermore, the admissibility of an application for interim relief is subject to the existence of a close link between the provisional measure sought and the form of order sought in the main action. The judge hearing the application for interim relief cannot assume powers which the court hearing the main action does not have (order in *Milieudefensie*, paragraph 39 et seq.); yet that is precisely what the applicant seeks to obtain.
- 26 The German Government maintains, on the other hand, that there is indeed a link between the application for provisional measures and the main application. The provisions governing the action for interim relief is an expression of the right to secure justice laid down in Article 47 of the Charter of Fundamental Rights of the European Union (OJ 2010 C 83, p. 389) (‘the Charter’). Those provisions guarantee the applicant the right to obtain provisional judicial protection in so far as that is necessary in order to ensure the full effectiveness of the decision that will be delivered on the main application. Where, as in the present case, the main action concerns, in reality, an application for an injunction, but the applicant is reduced to bringing an action for annulment, provisional judicial protection should be granted either under Article 278 TFEU or under Article 279 TFEU.
- 27 In that regard, it must be recalled that the purpose of interlocutory proceedings is to ensure the full effectiveness of the future decision on the main application (see, to that effect, order of the President in Case C-7/04 P(R) *Commission v Akzo and Akros* [2004] ECR I-8739, paragraph 36). Consequently, those proceedings are necessarily an adjunct to the main proceedings to which they are attached (order of the President in Case T-228/95 R *Lehrfreund v Council and Commission* [1996] ECR II-111, paragraph 61), so that the decision of the judge hearing the application for interim relief must be provisional in the sense that it cannot either prejudice the future decision in the main proceedings or deprive it of all practical effect (orders of the President of the Court of Justice in Case C-313/90 R *CIRFS and Others v Commission* [1991] ECR I-2557, paragraph 24, and of the President of this Court in Case T-203/95 R *Connolly v Commission* [1995] ECR II-2919, paragraph 16). In addition, the protective measure sought must have a sufficiently close link with the subject-matter of the main proceedings and it cannot fall outside the framework of the decision which the Court may reach on the main application (orders of the President in Case T-18/01 R *Goldstein v Commission* [2001] ECR II-1147, paragraph 14, and Case T-78/04 R *Sumitomo Chemical v Commission* [2004] ECR II-2049, paragraph 43).
- 28 As the Commission has correctly observed, 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. However, it is specifically not an application for suspension of application of the contested act within the meaning of Article 278 TFEU that the German Government has submitted. It seeks, rather, the adoption of an interim measure within the meaning of Article 279 TFEU. Neither Article 279 TFEU, nor Article 104

of the Rules of Procedure, nor, *a fortiori*, Article 47 of the Charter 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 (see also, in that regard, order of the Vice President of 7 March 2013 in Case C-551/12 P(R) *EDF v Commission*, not published in the ECR, paragraph 41).

- 29 That is why the case-law contains numerous examples of provisional measures that were adopted in the context of actions for annulment of negative decisions. In those circumstances, the judge hearing the application for interim relief considered it necessary to grant the provisional legal protection sought pending the closure of the main proceedings (see, in particular, the operative parts of the orders of the President of 28 April 2009 in Case T-95/09 R *United Phosphorus v Commission*, not published in the ECR; of 16 November 2012 in Case T-341/12 R *Evonik Degussa v Commission*, not published in the ECR; Case T-345/12 R *Akzo Nobel and Others v Commission* [2012] ECR; and Case T-462/12 R *Pilkington Group v Commission* [2013] ECR).
- 30 It must be stated that the specific features of the present case argue particularly strongly in favour of the interim measure sought by the German Government being declared admissible.
- 31 In fact, Article 55 of the new toys directive provides that point 3 of Part II of Annex II to the old toys directive – which contains the limit values for antimony, arsenic, barium, lead and mercury which the German Government wishes to maintain as set out in national law – is to be repealed only with effect from 20 July 2013. That means that the limit values at issue remain in force until 20 July 2013. In so far as the Commission, in the contested decision, rejected the request to maintain those limit values for antimony, arsenic and mercury and upheld it for barium and lead only until 21 July 2013, the resulting prohibition on maintaining those limit values will take effect only on 21 July 2013. Consequently, the German Government can, in any event, continue to apply the preceding limit values concerned until 20 July 2013, with or without the Commission's authorisation, without prejudice to its eventual obligation to implement, before that date, point 13 of Part III of Annex II to the new toys directive in national law (see paragraph 12 above).
- 32 In those circumstances, the German Government was required to bring an action for annulment of the contested decision within the period prescribed in the sixth paragraph of Article 263 TFEU, that is to say, before mid-May 2012, although it is denied the interim judicial protection provided for in Article 278 TFEU until 20 July 2013 because until that date the legal situation which it wishes to put in place – in the sense of the continuing applicability of the previous limit values – is already ensured by Article 55 of the new toys directive. The German Government can therefore logically request that those limit values be maintained beyond 20 July 2013 only by means of an interim measure ordered in accordance with Article 279 TFEU. The Commission cannot therefore complain that the German Government is seeking unlawfully to circumvent the procedure laid down in Article 278 TFEU.
- 33 In so far as the Commission claims that the provisional measure applied for threatens the institutional balance and exceeds the powers of the court dealing with the main application, it should be borne in mind that, in relation to interim measures, the judge hearing an application for interim relief has powers whose impact vis-à-vis the institutions of the European Union goes beyond the effects attaching to a judgment annulling a measure (see, to that effect, order of the President in Case 118/83 R *CMC v Commission* [1983] ECR 2583, paragraph 53, and operative part of order of the President in Joined Cases T-7/93 R and T-9/93 R *Langnese-Igo and Schöller v Commission* [1993] ECR II-131), provided that those interim measures apply only for the duration of the main proceedings, do not prejudice the decision on the main application and do not undermine the practical effect of that decision.
- 34 As the German Government has correctly observed, the grant of the interim measure which it seeks would not prejudice the decision on the main application. The maintenance of the notified national provisions would be approved only for a limited period, that is to say, pending the adoption of the decision on the main application. That purely provisional approval would entail no assessment of the

merits of the contested decision, since that assessment will form the subject-matter of the decision on the main application. Moreover, the application for interim relief, whereby the German Government seeks, in essence, to be able to apply the previous limit values beyond 20 July 2013, has a sufficiently close link with the action for annulment of the contested decision, since that decision *de facto* prohibits the German Government from maintaining those limit values beyond that date.

- 35 As for the practical effect of the decision to be taken on the main application, it is clear that the grant of the interim measure sought would not adversely affect the effect of a judgment rejecting the German Government's action for annulment, since, in accordance with Article 107(3) of the Rules of Procedure, that measure would automatically lapse as soon as judgment is delivered. If the Court were to annul the contested decision, the Commission would be required, in accordance with Article 266 TFEU, to take the measures entailed by that annulment, in compliance with the grounds of the judgment. On the assumption that the Commission should again reject the German Government's request to maintain the existing limit values, relying, for example, on fresh grounds, the measure, which would have lapsed by the effect of Article 107(3) of the Rules of Procedure, would not constitute an obstacle to that consequence of the judgment. On the other hand, if the Commission were to grant the request to maintain the limit values in order to comply with the grounds of the judgment, the interim measure sought would be particularly apt to ensure, at present, the full effect of an annulment judgment that would form the object of such enforcement.
- 36 Nor, in those circumstances, can the Commission properly claim that the interim measure sought would go beyond what the Court would be able to grant in a future annulment judgment. In that regard, it is sufficient to observe, for the purpose of the present examination of the admissibility of the application for interim relief, that the German Government has pertinently stated (see Case 169/84 *Cofaz and Others v Commission* [1986] ECR 391, paragraph 28) that the national limit values notified to the Commission with a view to their being maintained ensured a higher level of protection of children's health than that resulting from the implementation of the limit values in the new toys directive, that to refuse to grant it the interim measure which it seeks for the period between 21 July 2013 and the date of delivery of the judgment on the main application would expose children's health to the threat of serious and irreparable harm and that the interest for which protection is claimed, namely public health, is of crucial importance.
- 37 That conclusive account provided by the German Government enables the judge hearing the application for interim relief, for the purposes of the examination of the admissibility of the application before him, to be sufficiently certain that, in order to discharge the obligations entailed by an annulment judgment, the Commission should grant the application to maintain the value limits at issue. The interim measure sought would thus remain within the limits of the measures which the Commission would in all likelihood be required to adopt in order to comply with such a judgment.
- 38 On that point, the present case should be distinguished from that giving rise to the order in *Milieudefensie*, which had as its subject-matter an authorisation to derogate whereby the Commission had exempted a Member State from complying with certain limit values in relation to air quality. The Commission had rejected as inadmissible an application whereby an environmental protection organisation had requested it to carry out an 'internal reconsideration' of that authorisation. It was against that rejection decision, and not against the actual authorisation to derogate, that the applicant organisation had brought an action for annulment. It had also lodged an application for interim relief, seeking, in particular, that the Commission should be enjoined to order the Member State concerned to comply with the limit values forthwith. At paragraphs 37 to 41 of the order in *Milieudefensie* the application for interim relief was declared inadmissible, on the ground that the grant of the provisional measure sought would have amounted *de facto* to requiring the Commission to withdraw the derogation, whereas a judgment annulling the rejection decision would have obliged it only to take action and to undertake, without prejudice to the outcome, the reconsideration initially refused, *a fortiori* because the discussion between the parties, far from being aimed at that result, related solely to questions of admissibility. Thus, withdrawal of the derogation would not in any way have been the

necessary consequence of that judgment, so that the interim measure sought would have gone far beyond the measures that the Commission would have been required to adopt in order to comply with the annulment judgment, pursuant to Article 266 TFEU (see, with respect to a similar situation relating to EU State aid law, order in *CIRFS and Others v Commission*, paragraphs 20 to 23).

- 39 It follows from all of the foregoing that the application for interim measures must be declared admissible, but only as regards the head of claim submitted in the alternative. 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.

A prima facie case

- 40 It follows from the case-law that the condition relating to a prima facie case is satisfied where at least one of the pleas put forward by the applicant in support of the main action appears, at first sight, to be relevant and in any event not unfounded. It is sufficient that the 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 main proceedings, a significant legal controversy, the solution of which is not immediately obvious (see, to that effect, order in *Westfälische Drahtindustrie and Others v Commission*, paragraph 54, and order of the President of 19 September 2012 in Case T-52/12 R *Greece v Commission*, ECR, paragraph 13 and the case-law cited).

The temporary authorisation of the limit values of lead and barium

- 41 In the German Government's submission, the contested decision infringes Article 114 TFEU in that the Commission, when it approved the notified national provisions relating to the limit values for lead and barium, applied a deadline expiring no later than 21 July 2013. The first subparagraph of Article 114(6) TFEU does not provide for such a restriction in time, so that the Commission is able to choose only between approval and rejection. The period within which it must adopt its decision is expressly limited to six months. The wording of that provision does not allow the Commission to impose a temporal restriction, *a fortiori* an abrupt restriction such as the one it imposed in the present case, which leaves its departments free to proceed to examine any adaptations of the harmonisation measure.
- 42 The German Government adds that the wording of the first subparagraph of Article 114(6) TFEU also argues against the possibility for the Commission to impose a time limitation when it adopts a decision on the basis of that provision. First, the second subparagraph of Article 114(6) TFEU creates a presumption of approval where the Commission has not acted within the six-month period provided for in the preceding subparagraph. Second, in accordance with the third subparagraph of that provision, the Commission can extend the initial period by a further six months only in exceptional circumstances. Third, Article 114(7) TFEU requires the Commission, where it approves the notified national provisions, to examine immediately whether it is appropriate to propose an adaptation of the harmonisation measure. The purpose of that rule is to ensure that the slow pace of a procedure for maintaining national provisions is not prejudicial to the requesting Member State. The Commission is therefore expressly required to examine the appropriateness and the scope of any adaptation immediately after it has granted its approval.
- 43 The Commission replies that the German Government's argument fails to understand the system put in place by Article 114 TFEU. The authorisation of stricter national provisions specifically constitutes a derogation from the harmonisation measures. Far from relying on an exception, the Commission

makes its approval subject to a restriction in time only in order to create a situation compatible with the harmonisation measure while approving, for a limited period, a higher level of protection. The limitation in time enables the procedure to be closed quickly and a possible second procedure based on Article 114(4) TFEU to be avoided. The Commission adopted that solution because the Federal Republic of Germany had demonstrated at a very early stage its disapproval of the approach chosen by the Commission, in spite of the fact that the Commission had already taken steps with a view adapting the limit values to the latest scientific knowledge. It therefore seemed logical to limit the authorisation in time, as that was the only means of ensuring that uniform rules would apply consistently to the substances in question in toys marketed in the internal market.

- 44 The Commission claims that to block any measure seeking to introduce stricter provisions at EU level pending the closure of the procedure provided for in Article 114(6) TFEU would be contrary to the objective of protection pursued by the new toys directive and to the importance which EU law has accorded to the protection of health. Such an outcome would clearly be absurd. By limiting its authorisations in time, on the contrary, the Commission is able, where necessary, to find more flexible solutions which impede as little as possible the functioning of the internal market and the uniform application of EU law. That enables the Commission, at the same time, to take Member States' legitimate concerns into account.
- 45 In that regard, the judge hearing the application for interim relief observes, first of all, that at paragraph 54 of the contested decision the Commission expressly acknowledged that the migration limits established for lead in the new toys directive did not offer an appropriate level of protection for children, which led it to undertake a procedure for the revision of the limit values in question. For that reason, the Commission considered, at paragraph 55 of the contested decision, that the notified national provisions relating to lead were justified on grounds of major need of protection of human health. The same applies, next, with respect to barium: at paragraph 48 of the contested decision the Commission also expressly acknowledged that the values recommended by the German Government together ensured a higher level of protection for children's health. For that reason, the Commission declared at paragraph 51 of the contested decision that the notified national provisions relating to barium were justified by significant requirements of protection of human health.
- 46 It should be added, last, that at paragraph 94 of the contested decision the Commission observed that the national measures notified by the Federal Republic of Germany in relation to lead and barium did 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 concluded that it had reasons to consider that those measures could be approved, 'subject to a limitation in time'.
- 47 It thus appears that the Commission 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. Furthermore, it acknowledged being in agreement with the Federal Republic of Germany that approval should be granted when the conditions laid down in Article 114(4) and (6) TFEU were satisfied. It none the less stated that those conditions included the requirement that the national provisions be necessary, which was the case in this instance until the adoption of the limit values resulting from the new toys directive. Beyond that limit in time, the national provisions would cease to be necessary. That situation argues in favour of the limitation in time which it attached to its approval.
- 48 As regards the review of the limit values established in the new toys directive, the Commission stated in its observations on the application for interim relief that on 3 January 2013 it had notified to the World Trade Organisation a proposal for a regulation amending that directive and adapting the limit values applicable to barium. Once that proposal had been notified, the Commission was required to comply with a deadline of 60 days, that is to say, until 4 March 2013, before being able to adopt it. Upon expiry of that deadline, and after any observations had been taken into account, it could submit the proposal in question to the regulation committee, which it 'envisaged doing' in March 2013,

following the written procedure. 'If the regulation committee approves the proposal by a qualified majority', a period of three months will begin to run, during which the European Parliament and the Council of the European Union will be able to make objections. 'If they do to submit [any objections]', the Commission could adopt the proposal. The new migration limits for barium could then enter into force in July 2013.

- 49 As may readily be seen from that account, the entry into force of the new migration values for barium envisaged by the Commission depends on a number of imponderable factors. By making its approval subject to a compulsory deadline '[not later than] 21 July 2013', as it did in Article 1 of the contested decision, the Commission therefore, at first sight, created the risk that the Federal Republic of Germany would have to waive its national rules before the entry into force of any new migration values, whereas those rules undeniably ensure a higher level of protection than that offered by the current values of the new toys directive and the maintenance of those rules is therefore justified by major needs relating to the protection of health. Consequently, the German Government's argument – that the imposition of such a deadline does not correspond to 'maintain[ing]' within the meaning of Article 114(4) TFEU and amounts to circumventing the system of time limits and the presumption of approval established in Article 114(4) to (7) TFEU – seems at first sight not to be unfounded.
- 50 That applies *a fortiori* to the adaptation of the limit values applicable to lead envisaged by the Commission. The Commission itself proceeds from the principle that the new values will not be able to be adopted until January 2014 at the earliest, that is to say, in any event, after the expiry of the compulsory deadline to which it made its approval subject, which expires on 21 July 2013.
- 51 It must therefore be held that the arguments which the German Government has submitted concerning the approval for a limited period of the limit values applicable to lead and barium are very serious and raise issues which, *prima facie*, require thorough examination, which falls within the jurisdiction of the Court dealing with the main application. In that regard, the application for interim relief therefore constitutes a *prima facie* case.
- 52 It should be observed at this juncture that if the application for interim relief should be upheld on this point, the Commission could at any time lodge an application under Article 108 of the Rules of Procedure, if it considered that the circumstances had changed in a way capable of justifying a variation or cancellation of the interim measure, which would be the case, for example, if the limit values applicable to lead or barium, or to both of those elements, should in the meantime be adapted.

The rejection of the request for approval of limit values applicable to antimony, arsenic and mercury

- 53 In the German Government's submission, the contested decision infringes Article 114(4) and (6) TFEU, in that the Commission disregarded the relevant criterion of assessment when, in order to justify its refusal to maintain the national provisions applicable to antimony, arsenic and mercury, it took issue with the German Government for having failed to demonstrate 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. As may be seen from Case C-3/00 *Denmark v Commission* [2003] ECR I-2463, paragraphs 63 and 64, a Member State may, in order to justify maintaining its 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 concerned. The applicant Member State need only establish, on that occasion, 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.
- 54 The German Government maintains that, contrary to the Commission's assertions, it satisfied all its obligations in relation to evidence. The national limit values, which are the same as those in point 3 of Part II of Annex II to the old toy directives, and the limit values laid down in point 13 of Part III of

Annex II to the new toys directive can be compared only after conversion, because the former are expressed in terms of bioavailability, while the latter are expressed in terms of migration limit values. The German Government carried out the conversion into migration limit values on the basis of the EN 71-3 standard (see paragraph 6 above), then it compared the bioavailability limit values after exhaustion of the maximum migration limit values authorised by the new toys directive for the three categories of toy consistency with those of the old toys directive (independently of the consistency of the toys). After that conversion, the migration limit values provided for in the notified national provisions proved to be lower than those provided for in the new toys directive. For the elements in question, that directive therefore authorises a higher migration than is permitted by the national provisions, which means that children have greater exposure to harmful substances. That shows that the same national provisions ensure a higher level of protection than that resulting from the application of the new toys directive, as the following table confirms:

| Element | Limit value of bioavailability under German national law (corresponds to the old toys directive) | Limit value of bioavailability under the new toys directive | | |
|----------|--|---|---|---|
| | | µg/day whatever the consistency of the toy material | µg/day in dry, brittle, powder-like or pliable toy material | µg/day in liquid or sticky toy material |
| Antimony | 0.2 | 4.5 | 4.5 | 4.5 |
| Arsenic | 0.1 | 0.38 | 0.36 | 0.38 |
| Mercury | 0.5 | 0.75 | 0.76 | 0.76 |

- 55 In the German Government's submission, that shows that, for each element and each consistency, the availability limit values provided for in the old toys directive are lower than those provided for in the new toys directive. Consequently, it is already clear when each consistency is examined separately that the notified national provisions ensure a higher level of protection of the health of children than the requirements of the new toys directive. That finding would be reinforced if, for each element, a global examination was carried out by adding the availability limit values provided for in the new toys directive, after conversion, for the three consistencies of toy material.

56 The Commission contends, on the other hand, that the notified national provisions (and the limit values provided for in the old toys directive on which those provisions are based) do not protect health more effectively than the provisions of the new toys directive do and that, on the contrary, in most cases the German standards ensure much less protection against antimony, arsenic and mercury, as shown in the following table, in which the migration limit values provided for in the new toys directive are compared with the measures notified by the German Government, the figures referring to the maximum acceptable quantity in mg of each element that may be released (that may ‘migrate’) from one kg of toy material:

| Element | New toys directive Migration on the basis of toy materials, in mg/kg | | | Measures notified, expressed in the form of migration in mg/kg EN 71-3 |
|----------|---|---|-------------------------|--|
| | Liquid or sticky material | Dry, brittle, powder-like or pliable material | Scraped-off material | |
| Antimony | 11.3 | 45 | 560 | 60 |
| Arsenic | 0.9 | 3.8 | 47 | 25 |
| Mercury | 1.9 | 7.5 | 94 | 60 |

57 In the Commission’s submission, it is clear from that table that, for liquid and dry materials, the values notified by the German Government are significantly higher than those prescribed in the new toys directive. The notified limit values are lower only for scraped-off materials, which are generally less readily available, precisely because they first need to be scraped off.

58 The Commission disputes the comparison which the German Government made in the table which it has submitted (see paragraph 54 above). The second column indicates bioavailability sought as an objective by the German national provisions (and by the old toys directive), whereas the three columns further to the right show bioavailability attained in practice under the new toys directive, that is to say, taking into account the quantity of toy material absorbed. In order for the comparison to be correct, it would be necessary to calculate, for the old toys directive as well, bioavailability likely to be attained in practice, for the three consistencies of toy material. To that end, it would be necessary to multiply the migration limit value for a given element, that is to say, the maximum quantity of that element which can acceptably be released per kg of toy material, by the quantity of toy material swallowed by the child playing with the toy: 100 mg for dry (and other) material, 400 mg for modelling clay and finger paints or liquid (and other material and 8 mg for scraped-off material. The following table illustrates that result:

| Element | Old toys directive | | | | New toys directive | | |
|----------|---|--|--|-------------------------------------|--|------------------------------|-------------------------------------|
| | Bioavail- ability in µg/day, as objective | Bioavailability in µg/day achieved in practice by EN 71-3 standard for ... | | | Bioavailability in µg/day achieved in practice by the new toys directive for ... | | |
| | | Dry material: 100 mg | Modelling clay and finger paint 400 mg | Scraped- off material 8 mg | Dry material: 100 mg | Liquid material 400 mg | Scraped- off material 8 mg |
| Antimony | 0.2 | 6 | 24 | 0.5 | 4.5 | 4.5 | 4.5 |
| Arsenic | 0.1 | 2.5 | 10 | 0.2 | 0.4 | 0.36 | 0.38 |
| Mercury | 0.5 | 2.5 | 10 | 0.5 | 0.75 | 0.76 | 0.76 |

- 59 That comparison shows that for antimony, arsenic and mercury the new toys directive is, except for scraped-off material, stricter overall than the rules that the Federal Republic of Germany seeks authorisation to maintain. The notified provisions therefore do not serve the protection of health, so that the decisive element required by Article 114(4) TFEU, namely that the measure be appropriate, is not present in the main action.
- 60 In that regard, the judge hearing the application for interim relief finds that the controversy between the German Government and the Commission concerning the ‘correct’ limit values for antimony, arsenic and mercury in toys raises highly technical questions. That is so, in particular, for the conversion of the migration and bioavailability limit values.
- 61 As regards that conversion, the German Government disputes the relevance of the ‘bioavailability limit values likely to be attained in practice’ that the Commission obtained by multiplying the migration limit values corresponding to the EN 71-3 standard by the estimates of quantities absorbed, namely 100 mg, 400 mg and 8 mg. That objection is not *prima facie* unfounded, in so far as the German Government observes that the migration limit values of the EN 71-3 standard were prepared on the basis of the hypothesis that the daily quantity of toy material absorbed is only 8 mg and the old toys directive (and also the national provisions based thereon) already impose the applicable availability value limits and also define the maximum daily bioavailability caused by the use of the toys and prohibit its being exceeded. In so far as the German Government adds that the ‘bioavailability limit values likely to be attained in practice’ fixed by the Commission are not correct, because the values as thus calculated are much higher than those permitted, in absolute terms, by the old toys directive, so that the premiss on which the Commission based its conversion is incompatible with the very provisions of that directive, that argument also does not appear *prima facie* to be irrelevant.
- 62 Furthermore, the Commission itself acknowledges that, even according to its own conversion method, the notified limit values are, for scraped-off material, lower than that fixed in the new toys directive, although scraped-off material is less readily accessible by the child, because it must first be scraped off. When questioned on that point, the Commission cited, by way of example, surface coatings (paint, varnish), plastic materials and other materials, such as leather, cardboard, wood and textiles such as fluff, but also glass or steel. It explained that it was the child himself who, while playing, bit the toy, scraped it with his teeth, sucked it or licked it and could thus swallow the scraped-off material. However, those explanations do not allow it to be determined *prima facie* why toys which are scraped – that is to say, heavily used toys, as may often be found in kindergartens, nurseries and large families – would be less readily available than other consistencies of material or why the resulting risk to health should be negligible. In any event, the Commission has produced no figures to illustrate the degree of rarity of such toys. Accordingly, it can scarcely be asserted that, in the case of material scraped off the toy, the notified national provisions would not be likely to ensure the protection of health, within the meaning of Article 114(4) TFEU.
- 63 Although the Commission further claims that the provisions for which the German Government seeks approval are based on methods dating back almost 30 years, it is sufficient to observe that in the new toys directive the legislature itself expressly allows the limit values based on those methods to remain in force until 20 July 2013. The national limit values which, in the contested decision, the Commission authorised for a specific period for barium and lead are also based on those methods. The Commission is therefore not *prima facie* justified in claiming that the regime of limit values established by the old toys directive is wholly outmoded, scientifically obsolete and therefore manifestly inappropriate.
- 64 Nor can the Commission’s argument that no other Member State has expressed the slightest reservation about the new limit values be upheld. It is perfectly open to a Member State, in particular in the health sector, to evaluate the risk that certain substances may represent for the population differently from the European Union legislature when it draws up a harmonisation measure, which authorises that State to maintain its national provisions in force in so far as it can show that they

protect (national) health better than the harmonisation measure at issue and that they do not exceed what is necessary to attain that objective (see, to that effect, *Denmark v Commission*, cited above, paragraphs 63 and 64).

- 65 It must therefore be concluded that the arguments which the German Government has put forward concerning the refusal to approve the limit values applicable to antimony, arsenic and mercury raise complex questions which *prima facie* cannot be rejected as irrelevant, but require a thorough examination, which will have to be carried out in the context of the main proceedings, if necessary after consultation of an expert in accordance with Article 65(d) of the Rules of Procedure.
- 66 Last, it should be emphasised that in the contested decision the Commission declined to examine the existence of any arbitrary discrimination, any disguised restriction on trade between Member States or any obstacle to the functioning of the internal market. However, as the German Government correctly observes, the Commission itself acknowledged in that decision that the German national provisions relating to lead, barium, nitrosamines and nitrosatable substances apply without distinction to all products and do not entail either arbitrary discrimination, or restriction on trade between Member States, or obstacle to the functioning of the internal market. There is no reason why it should be different for antimony, arsenic and mercury, although the national provisions notified are the same in that regard.
- 67 The condition relating to a *prima facie* case is there also satisfied with respect to the refusal to approve the limit values applicable to antimony, arsenic and mercury.

Urgency

- 68 It should be borne in mind that the purpose of proceedings for interim relief is to ensure the full effectiveness of the definitive future decision, in order to ensure that there is no lacuna in the legal protection provided by the Courts of the European Union (order of the President in Case C-399/95 R *Germany v Commission* [1996] ECR I-2441, paragraph 46). To attain that objective, 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 (order of the President in Case C-329/99 P(R) *Pfizer Animal Health v Council* [1999] ECR I-8343, paragraph 94). It is for the party that relies on the threat of such damage to demonstrate that its occurrence is foreseeable with a sufficient degree of probability (see, to that effect, order of the Court in Case C-280/93 R *Germany v Council* [1993] ECR I-3667, paragraph 34, and order of the President in Case C-180/01 P-R *Commission v NALOO* [2001] ECR I-5737, paragraph 53).
- 69 In the present case, the Federal Republic of Germany maintains that, in the absence of the interim measures sought, it is at risk of sustaining serious and irreparable damage in the period between 20 July 2013 and the Court's decision in the main action. The legal interest threatened is the health of children, who are likely to come into contact with toys that were not produced in compliance with the limit values provided for in the notified national provisions, which offer a higher level of protection than that ensured by the new toys directive. The harm is serious, because health is in itself a particularly important value and because children, who are the most sensitive consumers, cannot themselves decide on the dangers to which they are exposed. Once it has occurred, the damage is irreversible, since, owing to their nature, the injuries to health cannot be eliminated retroactively.
- 70 The Commission contends, in essence, 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 provisions of the new toys directive would entail serious and irreparable damage with effect from 20 July 2013. Furthermore, in the absence of a *prima facie* case, the Federal Republic of Germany cannot rely on urgency.

- 71 In that regard, it must be held that the present case concerns the protection of the health of children, who are likely to come into contact with toys containing certain heavy metals. As regards the setting of limit values for the presence of those metals in toys, Article 114(4) TFEU provides for the possibility of maintaining national provisions justified by serious needs, listed in Article 36 TFEU, that is to say, requirements linked, *inter alia*, to the protection of health of persons. In accordance with Article 191(1) and (2) TFEU, which also refers to the protection of human health, policy to be carried out in this sphere is to be based, in particular, on the precautionary principle.
- 72 The precautionary principle, which is a general principle of European Union law, allows the EU institutions to take protective measures where there is uncertainty as to the existence or extent of risks to human health without having to wait until the reality and seriousness of those risks become fully apparent (see order of the judge hearing the application for interim relief of 28 September 2007 in Case T-257/07 R *France v Commission* [2007] ECR II-4153, paragraphs 60 and 61 and the case-law cited). The institutions are even required to take appropriate measures to prevent specific potential risks to public health arising from a given product, and need do no more than provide solid and convincing evidence which, while not resolving the scientific uncertainty, may reasonably raise doubts as to the safety of the product (Case T-539/10 *Acino v Commission* [2013] ECR II, paragraphs 63 and 66).
- 73 The judge hearing the application for interim relief must also take account of those considerations, based on the precautionary principle and relating to the existence and seriousness of potential risks for health, when he is called upon to settle the question whether the legal measure at issue is, with a sufficient degree of probability, likely to cause serious and irreparable damage to health. In particular, he cannot dismiss such damage as being purely hypothetical on the sole ground that scientific uncertainty remains as to the possible risks to health.
- 74 In the present case, in order to examine urgency, it is appropriate, first of all, to take account of the fact that the German Government has established the existence of a *prima facie* case.
- 75 Next, as regards the limit values applicable to barium and lead, the Commission itself has acknowledged, in the contested decision, that the notified national provisions were justified by serious needs related to the protection of health; it therefore authorised their being maintained. It follows that the German Government, which was entitled to assess the existence of a risk to public health, in principle, differently from the EU legislature in the context of the new toys directive (see, to that effect, *Denmark v Commission*, cited above, paragraphs 63 and 64), has demonstrated to the requisite legal standard that its national provisions, at first sight, ensured a better protection of public health than the requirements of the new toys directive and that they did not go beyond what was necessary to attain that objective.
- 76 Since the notified national provisions ensure, at first sight, for barium and lead, a higher level of protection than that ensured by the new toys directive, it may be concluded that the children whose health is to be protected would be exposed to risks likely to affect their health in a serious and irreparable way if they were denied that level of protection. In so far as the Commission contends that the new toys directive already ensures a high level of protection, so that the harm caused by the difference between those two levels would be neither serious nor irreparable, it calls into question the nature and the extent of the national level of protection, although it has itself attested that the national provisions at issue were justified by ‘serious needs relating to the protection of health’. Be that as it may, that line of argument, which is contradictory in itself, is inappropriate in the light of the ‘re-nationalisation’ of health policy, the principle of which is recognised in Article 114(4) TFEU.

- 77 In the light of the precautionary principle, moreover, it seems essential that the harm to health that contact with heavy metals, such as barium and lead, can cause should be described as serious and irreparable, particularly when the at-risk group to be protected consists of children who handle toys. The argument which the German Government has put forward in order to establish urgency (see paragraph 69 above) must therefore be upheld.
- 78 That also applies to the limit values applicable to antimony, arsenic and mercury, although the Commission has not acknowledged that the national provisions relating to those elements were justified by serious needs relating to the protection of health. It cannot be precluded that, following a thorough examination, the Court dealing with the main application should answer the complex questions which the German Government has raised on that point (see paragraph 65 above) by stating that the national provisions at issue applicable to antimony, arsenic and mercury also ensure a higher level of protection than that put in place by the new toys directive, so that the children to be protected would be exposed to risks of serious and irreparable damage to their health if they were denied that level of protection. While it is not certain that the Court dealing with the main application will in fact reach a decision to that effect, that uncertainty does not allow the judge dealing with the application for interim relief, in the light of the precautionary principle, to deny the existence of a risk of serious and irreparable harm to health, particularly when the German Government has put forward serious and convincing arguments that cast doubt on the level of protection ensured by the new toys directive (see paragraph 61 above) and when the Commission itself has admitted, with respect to scraped-off toy material, that the national limit values notified were lower than those imposed by that directive.
- 79 It follows from all of the foregoing that the German Government has demonstrated to the requisite legal standard the urgency which had to be recognised to the interim measure sought.

The weighing up of the interests

- 80 According to settled case-law, the weighing up of the various interests involved requires the judge hearing the application for interim relief to determine whether or not the applicant's interest in obtaining the interim measures sought outweighs the interest in immediate application of the contested measure by also examining whether annulment of that measure by the Court when ruling on the main application would allow the situation which would have been brought about by its immediate operation to be reversed and, conversely, whether the grant of the interim measures sought would prevent the contested measure from being fully effective in the event of the main application being dismissed (see, to that effect, orders of the President of 18 March 2011 in Case T-457/09 R *Westfälisch-Lippischer Sparkassen- und Giroverband v Commission*, not published in the ECR, paragraph 69, and in Case T-345/12 R *Akzo Nobel and Others v Commission* [2012] ECR, paragraph 24 and the case-law cited).
- 81 In the present case, as the German Government has shown both the urgency of its application for interim relief and the existence of a *prima facie* case, it must be recognised as having a legitimate interest in obtaining the interim measure which it seeks.
- 82 Next, the German Government correctly observes that the grant of an interim measure following the dismissal of the main action would indeed adversely affect the interest associated with the harmonisation of laws in the internal market, within the meaning of Article 114(1) TFEU in conjunction with Article 26 TFEU, but that the ensuing inconvenience for the internal market must be regarded as relatively minor. The limit values provided for in the notified national provisions, which are identical to those in the old toys directive, have already been known and established for decades in the toy sector, with the consequence that that sector is capable of applying them and complying with them without difficulty. In any event, and above all, that inconvenience for the internal market would not be irreversible, but only temporary, because, after the decision on the main

action, toys could again be imported and distributed. Conversely, if the application for interim relief should be dismissed, but the Court dealing with the main application were to uphold the action, children's health would in the meantime be likely to suffer serious and irreversible harm.

- 83 For that reason, the Commission's interest in the application for interim relief being dismissed must give precedence to the German Government's interest in the notified national provisions being maintained, *a fortiori* because the interim measure sought will merely maintain a legal situation which has already prevailed since 1988, and the provisions in question will be maintained for only a limited period. The written procedure in Case T-198/12 has been closed since 14 December 2012 and the Court can therefore be expected to adjudicate in the main proceedings within the next few months.
- 84 As all the conditions permitting the grant of the interim measure sought in the alternative are satisfied, the corresponding head of claim must be upheld.

On those grounds,

THE PRESIDENT OF THE GENERAL COURT

hereby orders:

1. **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;**
2. **The application for interim relief is dismissed as to the remainder;**
3. **Costs are reserved.**

Luxembourg, 15 May 2013.

E. Coulon
Registrar

M. Jaeger
President