OPINION OF MR ADVOCATE GENERAL DARMON
delivered on 9 July 1985 *

Mr President,
Members of the Court,

1. The rules submitted for the consideration of the Court arise from an amendment of the German legislation relating to feedingstuffs by which the Government of the Federal Republic of Germany prescribed minimum iron contents and maximum permitted levels of sodium for milk-replacer feed used for the rearing and fattening of calves.

The Commission considers that those requirements were adopted in breach of the substantive and procedural rules laid down by the directives harmonizing national laws in that field. In essence, the Court is requested to decide on the effective scope of Community harmonization in order to determine the precise extent of the residual powers of the Member States.

It is necessary, in the first place, to examine the German rules at issue in this case.

Relevant legal provisions

2. Paragraph 7 (2) of the Futtermittelverordnung (Feedingstuffs regulation) of 16 June 1976 (BGBl. I, p. 1497), as amended by the Verordnung of 19 July 1979 (BGBl. I, p. 1122), which has become Paragraph 8 (3) of the Verordnung in the amended version in force since 8 April 1981 (BGBl. I, p. 352), provides that milk-replacer feed used as *complete feedingstuffs* must contain per kg of dry matter:

(i) at least 60 mg of iron, if they are intended for calf-rearing, and

(ii) at least 40 mg of iron and no more than 6 000 mg of sodium if they are intended for the fattening of calves.

According to Paragraph 14 (1) of the Futtermittelgesetz [Law on feedingstuffs] (BGBl. I, p. 1745) feedingstuffs which fail to comply with those requirements may not be marketed in the territory of the Federal Republic of Germany.

According to the information provided by the German Government during the preliminary procedure those rules are justified for the protection of animal and human health. The requirement of a minimum iron content is necessary to combat the practice of feeding calves with feedingstuffs which have a low iron content in order to obtain artificially white meat which is wrongly regarded by consumers as an indication of quality. Such a practice leads to anaemia in animals and is indirectly a threat to human health. The maximum permitted level of sodium is intended to eliminate the practice of putting excessive quantities of salt into feedingstuffs in order to force calves to consume more feedingstuffs in liquid form. An excessive concentration of sodium causes paralysis and other problems in the nervous system capable of resulting in the animal's death.

* Translated from the French.

Those are the German legal provisions, and the underlying facts, which form the backcloth of this action. It must be pointed out that although the Commission does not underestimate the theoretical danger for the health of animals which by a lack of iron or an excess of sodium may present, it disputes the actual effect thereof and objects to the methods adopted by the German Government to counter that danger in view of the binding legal framework of the directives which have harmonized the law relating to animal feedingstuffs.

It is therefore necessary to consider the relevant provisions of Community law in the matter.

3. As already stated, the rules at issue relate to *complete feedingstuffs for calves.*

Their use is governed by the following three Council Directives:

(i) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs, hereinafter referred to as 'the additives directive' (Official Journal, English Special Edition 1970 (III), p. 840), as amended by Council Directives 73/103/EEC of 28 April 1973 (Official Journal 1973, L 124, p. 17) and 75/296/EEC of 28 April 1975 (Official Journal 1975, L 124, p. 29);

(ii) Council Directive 74/63/EEC of 17 December 1973 on the fixing of maximum permitted levels for undesirable substances and products in feedingstuffs, hereinafter referred to as 'the undesirable substances directive' (Official Journal 1974, L 38, p. 31), as amended by Council Directive 80/502/EEC of 6 May 1980 (Official Journal 1980, L 124, p. 17);

(iii) Council Directive 79/373/EEC of 2 April 1979 on the marketing of compound feedingstuffs, hereinafter referred to as 'the compound feedingstuffs directive' (Official Journal 1979, L 86, p. 30).

Feedingstuffs are defined by those directives as 'organic or inorganic substances, used singly or in mixtures, whether or not containing additives, for oral animal feeding' (see, in particular, Article 2 (a) of Directive 79/373).

The first two directives define authorized additives and prohibited undesirable substances. The third directive relates to compound feedingstuffs which, together with straight feedingstuffs, constitute one of the two main categories of feedingstuffs. The characteristic of compound feedingstuffs is that they are a mixture 'in the form of complete feedingstuffs or complementary feedingstuffs' (Article 2 (b) of Directive 79/373). In this case the complete feedingstuffs to which the German rules relate are those described in Directive 79/373 as 'mixtures of feedingstuffs which, by reason of their composition, are sufficient for a daily ration', that is to say 'the average total quantity of feedingstuffs . . . required daily by an animal . . . to satisfy all its needs' (Article 2 (d) and (c) respectively of Directive 79/373).

In short, therefore, complete feedingstuffs for calves fall within the first two directives, namely the 'specialized' directives, inasmuch as they relate to all feedingstuffs, and within Directive 79/373 inasmuch as complete feedingstuffs constitute one of the forms of animal feeding through compound feedingstuffs.

The purpose of those directives, which are based on Articles 43 and 100 of the EEC Treaty, is, according to Article 100, to approximate 'such provisions laid down by law, regulation or administrative action in Member States as directly affect the establishment or functioning of the common market,' in this case the common

agricultural market, and to contribute thereby to the strengthening of the implementation of the principle of free movement of agricultural products (Article 38 (1) and (2) of the EEC Treaty). The structure of the three directives is very similar as regards the scope of the intended harmonization and the procedures for adaptation where necessary.

Let us examine those two aspects.

(a) Scope of the various directives

Annex I to Directive 70/524 lists the authorized additives and states either the maximum and minimum permitted contents or solely the minimum content. The directive imposes an obligation on the Member States to provide that 'only those additives which are listed in Annex I may be incorporated in feedingstuffs and only subject to the requirements set out therein' (Article 3 (1)). It should be pointed out that the annex includes, under heading I 'Trace elements', a list of iron additives classified under No. E 1, the maximum permitted level of which is 1 250 mg per kg (ppm) of complete feedingstuffs.

The undesirable substances directive applies without prejudice to the preceding directive (Article 1 (2) (a)) and provides that the 'Member States shall prescribe that the substances and products listed in the annex shall be tolerated in feedingstuffs only under the conditions therein set out' (Article 3 (1)).

The compound feedingstuffs directive also applies without prejudice to the two preceding directives (Article 1 (2) (b) and (c)) and has far wider scope. The Member States are obliged to prescribe that compound feedingstuffs 'may be marketed only if they are wholesome, unadulterated and of merchantable quality' and 'may not represent a danger to animal or human health and may not be presented or marketed in a manner liable to mislead' (Article 3).

To that end Directive 79/373 lays down the provisions to be prescribed with regard to the packaging of compound feedingstuffs, in particular with regard to the package or container (Article 4) and labelling (Article 5).

In relation to those provisions the annex contains a list of the contents as regards analytical constituents which have to be declared (Points 5 to 8) as well as the tolerances applicable in the case of departure from the declared content (Points 9 and 10).

The directive includes several provisions concerning the composition of compound feedingstuffs. Articles 6 and 7 refer to the maximum moisture and ash contents. Article 8 authorizes the Member States:

'In so far as their national laws so provide at the time of adoption of this Directive . . . to limit the marketing of compound feedingstuffs to those:

obtained from certain ingredients, or

free from certain ingredients'.

Finally, Article 14 (a) provides that the directive 'shall not affect the right of Member States . . . to recommend types of compound feedingstuffs which meet certain analytical characteristics'.

Observance of the requirements laid down by the directives is ensured by official inspections carried out by the Member States (Articles 15, 8 and 12 of the respective directives). In addition, according to Article 13 of the additives directive Article 7 of the undesirable substances directive and Article 9 of the compound feedingstuffs directive, feedingstuffs may not be subjected by the Member States to marketing restrictions other than those expressly provided for by those directives. Nevertheless, provision was made for certain procedures to ease those provisions.

(b) Adaptation procedures

The additives directive and undesirable substances directive contain the same procedure where there is a threat to animal or human health: the Member States may derogate 'temporarily' from the provisions of the directives and adopt unilateral protective measures (Article 7 (1) of Directive 70/524, as amended by Directive 73/103 and Article 5 of Directive 74/63). Those measures set in motion an emergency procedure whereby the Commission or the Council, as the case may be, after consulting the Standing Committee for Feedingstuffs, decides forthwith whether the Annex should be amended (Article 7 (2) of Directive 70/524, as amended by Directive 73/103, and Article 5 (2) of Directive 74/63).

In addition, in order to take account of developments in scientific and technical knowledge, provision is made in the same terms by the two directives for a similar procedure for revising the list of authorized additives and prohibited undesirable substances (Article 6 of Directive 70/524, as amended by Directive 75/296, and Article 6 of Directive 74/63).

The compound feedingstuffs directive provides for a similar procedure for the same purposes (Articles 10 (a) and 13). In addition, it contains a special provision: Article 15 obliges the Commission to make proposals for amendments to the directive within three years of notification thereof 'on the basis of experience acquired . . . such as to achieve free movement of compound feedingstuffs and to eliminate certain disparities concerning the use of ingredients and labelling in particular'. The Council is obliged to act on those proposals within five years of notification of the directive.

The parties' submissions

4. In support of its action under Article 169 of the EEC Treaty the Commission has submitted the following arguments:

(a) The body of Community provisions laid down by the three directives is exhaustive and therefore leaves no room, other than on the conditions laid down therein, for unilateral action on the part of the Member States such as the German measures complained of.

(b) In addition, the German rules impose restrictions which are contrary to the substantive and procedural rules severally laid down by the Community directives.

(c) Finally, and in the alternative, the restrictions imposed by the German rules are contrary to Article 30 of the EEC Treaty and cannot be justified by reference to Article 36 thereof on the ground of the protection of animal and human health.

Let us examine each of those three arguments which are all contested by the Federal Republic of Germany.

(a) Exhaustive nature of the harmonized provisions of Community law

The *Commission* does not maintain that the harmonization of national legislation concerning feedingstuffs is *altogether complete.* In particular, the provisions relating to pathogenic micro-organisms still remain to be harmonized. However, since Directive 79/373 came into force on 1 January 1981 the substantive provisions resulting from the three directives constitute an exhaustive set of rules on the *composition* of compound feedingstuffs. The first two directives govern the use of substances which are really 'problematical' and fix content levels for those substances; they expressly exclude the introduction by the Member States of marketing restrictions other than those provided for in those directives, or at least adopted pursuant to the procedures specified therein. For its part the compound feedingstuffs directive, which is limited essentially to requirements regarding the packaging and labelling of feedingstuffs, manifests an intention on the part of the legislature to provide for the unrestricted marketing within the Community of all feedingstuffs which comply with the requirements laid down therein, leaving the manufacturer to choose the appropriate composition; in this field the directive merely prohibits the Member States from introducing any new restrictions regarding the presence or absence of ingredients and authorizes them to recommend types of compound feedingstuffs which meet certain analytical characteristics.

Finally, the Commission claims, apart from authorized additives and prohibited undesirable substances, it follows from the compound feedingstuffs directive that, save as otherwise provided, the composition of such feedingstuffs is deliberately placed by the Community legislature outside the ambit of any national rules so that the contested German provision has the effect of hindering the free movement of all compositions of compound feedingstuffs. The counterpart to the manufacturer's freedom to determine the composition is the right given to the Member States on the basis of Article 3 of the directive to impose sanctions in respect of individual cases of abuse. That provision could not give the Member States general powers to adopt unilateral preventive measures without going back on the harmonization which has already been achieved.

Contrary to the Commission, the *Federal Republic of Germany* takes the view that the three directives have not *completely* harmonized the rules relating to the composition of compound feedingstuffs, in particular those relating to the 'constitutive elements' of feedingstuffs, such as iron and sodium, which, in its opinion, cannot be regarded as additives or undesirable substances.

That view is confirmed, it alleges, in particular by the wording of Directive 79/373 itself, Articles 8 and 15 of which show that in the absence of Community rules the Member States are authorized to maintain their own rules regarding ingredients. Despite the obligation contained in Article 15, the Commission has not yet proposed any amendments so that the harmonization of the rules relating to the ingredients of compound feedingstuffs is incomplete. The non-exhaustive nature of the directives from other provisions of Community law, in particular Directive 82/471 concerning bioproteins, which

regulated for the first time the use of certain ingredients. In addition, the Court has held that directives are recognized as being exhaustive only if the harmonization effected by them is complete.

In fact, the Federal Republic of Germany maintains, the three directives have only dealt in a fragmentary manner with the question of the composition of compound feedingstuffs. The Member States therefore retain the power to adopt any appropriate provisions, at least whenever measures are necessary for the protection of animal or human health. In that connection the defendant notes that, contrary to the other two directives, Directive 79/373 does not contain any special procedure enabling the Member State to meet such a need. To accept that the harmonization provisions are exhaustive would mean giving manufacturers a completely free hand and denying the Member States the possibility of adopting any urgent measures that may be needed in the field.

That is certainly not the meaning of Article 3, the second sentence of which generally empowers the Member States to adopt any measure — that may be necessary for the protection of animal and human health against the dangers which may result from the absence or excessive concentration of certain analytical constituents, such as iron and sodium.

Finally the defendant contends that the prohibition of additional marketing restrictions laid down by Article 9 of Directive 79/373 cannot limit the prerogatives of the Member States under the second sentence of Article 3 and Articles 8 and 15.

(b) Applicability of the several directives

In the *Commission's* opinion the German rules are in breach of the provisions of the additives directive and the undesirable substances directive as well as the compound feedingstuffs directives.

The Commission considers that a manufacturer, who is free to choose how he will meet the minimum iron requirement will necessarily be prompted to have recourse to the iron additives referred to in Directive 70/524 rather than to choose ingredients which are rich in iron. If he used those ingredients in preference to additives he would to a considerable extent have to stop using the usual basic products with an iron content of approximately 30 mg per kg (ppm) and in particular milk powder subsidized by the Community. With regard to iron additives the directive lays down only a maximum level and prohibits all marketing restrictions other than those contained therein so that, at least indirectly, the German rules infringe those provisions and are thereby in breach of Article 5 of the EEC Treaty.

Sodium must, in the Commission's view, be regarded as an undesirable substance which is covered by Directive 74/63 alone since, above a certain concentration, it involves a health risk. Since the directive does not contain any provision concerning sodium, it follows that a restriction of the type established by the German rules is prohibited.

Furthermore, the Commission alleges that the provisions at issue were deliberately adopted in a manner other than by the appropriate procedures prescribed by the said two directives either to deal with a threat to animal or human health or to take account of scientific or technical developments.

Finally, if the provisions in question are to be regarded, as is maintained by the defendant, as not relating to the use of iron and sodium as additives or undesirable sub-

stances but as the analytical constituents of ingredients, the Commission maintains that Article 8 of Directive 79/373 prohibits the Member States, from 2 April 1979, from adopting, as the Federal Republic of Germany has done by the Verordnung at issue, any new rules prescribing or prohibiting the use of certain ingredients. It cannot justify such unlawful conduct by alleging that the Commission had not implemented the procedure provided for in Article 15 of Directive 79/373.

For its part the *German Government* denies that the specialized directives are applicable.

In its view Directive 70/524 applies only to iron in the form of additives, that is to say iron compounds such as those listed in the annex to that directive, which are intentionally added to feedingstuffs, and does not apply to iron in the form of analytical constituents naturally present in certain ingredients. The German rules in fact leave manufacturers free to choose ingredients which are rich in iron (for example fishmeal) in order to meet the minimum iron requirement for complete feedingstuffs intended for calves. The additives directive is not therefore applicable to the German rules.

The German Government argues that Directive 74/63 prohibits only substances which are undesirable regardless of their concentration in feedingstuffs. Sodium, however, is a necessary substance in an animal's diet; its presence is desirable since it is an essential element in the nutritive value of feedingstuffs. Consequently, sodium is not to be classified as an undesirable substance merely on the ground that an excessive dose could prove to be dangerous.

Finally, the German Government contends that the additives directive, which relates only to substances intentionally added to feedingstuffs, and the undesirable substances directive, which relates only to substances which are naturally harmful, cannot apply to the analytical constituents or ingredients of compound feedingstuffs which are present in the natural state and which give them their nutritive value.

The *Commission* contests the extent of the distinction drawn by the German Government, maintaining that the borderline between constituents, undesirable substances and additives is blurred so that a substance cannot necessarily straightaway be classified in one or the other of those categories. The concept of constituents applies to all substances contained in feedingstuffs. Accordingly, depending on the particular case, the same substance may be present as an undesirable substance — when the concentration is excessive — or as an additive — if it is intentionally added — or as a mere constituent having no particular property.

(c) Justification for animal or human health reasons

According to the *Commission* the exhaustive nature of the harmonization effected in the field by the three directives means that it is no longer lawfully possible, according to the settled case law of the Court, to lay down by means of a derogation under Article 36 of the EEC Treaty a marketing restriction not expressly provided for by the directives.

The adaptation procedures provided for by the additives directive and the undesirable substances directive cannot be relied upon by the defendant since in this case it deliberately placed itself outside their field

of application. For its part, Article 3 of Directive 79/373 merely authorizes the Member States to adopt measures against individual abuses.

The Commission contends that in any case the German rules cannot be justified by the desire to ensure the protection of animal and human health. In that connection it observes that the defendant has been unable to show that any danger actually existed or even that the alleged practices existed. It points out that, in view of the average iron content of feedingstuffs in the Community, namely approximately 30 mg/kg (ppm), a small level of iron in compound feedingstuffs for calves is not necessarily dangerous for the animals. Furthermore, it is not clear what commercial interest manufacturers might have in the excessive use of sodium. Finally, the Commission points out that Directive 79/373 offers the defendant less radical means of countering the alleged risks, namely by appropriate labelling or by exercising the right to make recommendations provided for by Article 14 (a). Moreover, it recalls that when, after receiving the reasoned opinion, the Federal Republic of Germany submitted a proposal for substantive amendments to the contested rules, the Standing Committee for Feedingstuffs rejected it on grounds which were based essentially on the same analysis as that put forward by the Commission.

The *Federal Republic of Germany* maintains that the contested rules seem more appropriate to deal with the aforementioned malpractices than the measures suggested by the Commission and points out that the latter does not dispute the dangers which the German measures sought to counter. Consequently, the German Government was justified in adopting the contested measures, either on the basis of the second sentence of Article 3 of Directive 79/373 or on the basis of the derogations provided for by Article 36 of the EEC Treaty.

Consideration of the submissions

5. The solution to this dispute must be found in the scope of the harmonization effected by the three directives in question in relation to compound feedingstuffs.

As has already been stated, the three directives are part of the extensive framework of rules for the free movement of agricultural products which are indispensable to the proper functioning of the common market in agricultural products and which are based on the principle that all persons concerned, in particular producers of such products, have free access to the market (judgment of 5 October 1977 in Case 5/77 *Tedeschi* v *Denkavit Commerciale* [1977] ECR 1555, paragraph 32 of the decision; and judgment of 29 November 1978 in Case 83/78 *Pigs Marketing Board* v *Redmond* [1978] ECR 2347, paragraph 57 of the decision). In this case, however, that freedom relates only to feedingstuffs which satisfy the composition and packaging requirements laid down by the additives directive, the undesirable substances directive and the compound feedingstuffs directive, in accordance with Articles 14, 7 and 9 respectively of those directives (judgment of 27 March 1985 in Case 73/84 *Denkavit* v *Land Nordrhein-Westfalen* [1985] ECR 1019, paragraph 11 of the decision). Those requirements were adopted on account of the important rôle of animal feed in Community agriculture and of the need to guarantee the use of appropriate good-quality feedingstuffs: such requirements are therefore 'essential to an increase in agricultural productivity' (the first and second recitals in the preambles to Directives 70/524 and 74/63; similar terms figure in Directive 79/373).

Within that framework and in view of the uncontestable health risk for animals of a complete lack of iron and of an excessive level of sodium in their feed, are the Member States still authorized to impose limits on the levels of certain substances present in compound feedingstuffs in order to protect animals and humans?

It cannot seriously be denied that the German rules constitute a measure having an effect equivalent to a quantitative restriction on imports, which is prohibited by Article 30 of the EEC Treaty, since they deny access to the German territory to complete feedingstuffs which do not satisfy the conditions laid down therein. The Court has stated that 'it is enough for the measures in question to be capable of acting as a direct or indirect, real or potential hindrance to imports between Member States' (judgment of 8 July 1975 in Case 4/75 *REWE-Zentralfinanz* v *Landwirtschafts-kammer* [1975] ECR 843, paragraph 3 of the decision). Such a marketing restriction may nevertheless fall within the derogations provided for by Article 36 of the EEC Treaty if it satisfies the conditions laid down therein and is for the protection of animal or human health. However, recourse to the exception provided for by Article 36 is no longer justified where,

'in application of Article 100 of the Treaty, Community directives provide for the harmonization of the measures necessary to ensure the protection of animal and human health and establish Community procedures to check that they are observed'.

In such a case

'the appropriate checks must be carried out and the measures of protection adopted within the framework outlined by the harmonizing directive' (Case 5/77, cited above, paragraph 35 of the decision).

That is therefore the context within which the lawfulness of the national measures must be assessed.

According to the terms of that alternative the legality of the rules at issue is to be reviewed in the light of the 'degree' of harmonization effected by the three directives governing the use of compound feedingstuffs in animal feed. As the Commission has itself recognized the harmonization of national legislation applicable to all types of animal feed cannot be regarded as absolutely exhaustive. That is confirmed by Article 1 (2) of Directive 79/373 which refers to 'the fixing of maximum permitted levels for pesticide residues', which has not yet been effected. In addition, it must be noted that the Court has stated, when examining that very directive, that it is not applicable to health inspections on compound feedingstuffs (Case 73/84, cited above, paragraph 12 of the decision). Such restrictions do not mean that the three directives have not achieved a certain degree of harmonization with regard to the *composition of compound feedingstuffs.*

It is clear that the two 'specialized' directives relate to the composition of animal feed. It cannot be disputed that the principle aim of the third directive is to regulate the *packaging and presentation* of feedingstuffs of the type to which the

German rules relate: compound feedingstuffs in the form of complete feedingstuffs. It deals only incidentally with the *composition* of compound feedingstuffs.

As has been seen the Federal Republic of Germany is essentially relying on the following arguments:

(i) It considers that the specialized directives are not applicable to the substances whose contents it sought to regulate: the contested rules relate to a type of substance — analytical constituents — which is not covered by those directives;

(ii) It concludes from the 'lacunae' in Directive 79/373 with regard to composition that, under the second sentence of Article 3 of that directive, the Member States have the power to adopt unilateral measures which are justified in this case by the desire to ensure protection of animal and human health.

Those arguments cannot be accepted. Analysis of the secondary law in this field demonstrates that the incompatibility with that law of the German rules is established by each of the aforementioned directives *taken individually*, and also that the *coherent body of law formed by the three directives together* is such as to preclude generally any intervention by the Member State in the field in question other than that for which express provision is made by the Community legislature.

6. At this stage and in view of the importance attached to them by the defendant it is necessary to define the concepts of 'analytical constituents' and 'ingredients'.

Without considering in detail the terms used sucessively in the course of the proceedings by the German Government, all of which it considers equivalent — 'constituent elements', 'constituents', 'analytical constituents', 'ingredients' — we may, like the Commission, treat analytical constituent as meaning any mineral or vegetable matter present in animal feed. As is clear from Directive 79/373 some of those substances determine the quality of the feedingstuff to such an extent that their levels should be declared (fourth recital); these include sodium, crude fibre, calcium and sugar (Article 5 (1) (e) and Point 5 of the Annex to the directive). As was emphasized by the Commission, outside that basic category analytical constituents may be classified either as additives where they are incorporated in feedingstuffs in a concentrated form or as undesirable substances where, in certain concentrations, they constitute a health risk. For its part the defendant maintains that iron and sodium may be defined as analytical constituents substantially determining the quality of compound feedingstuffs for calves.

It is necessary to make a distinction between the concept of 'analytical constituents' and that of 'ingredients', as is absolutely clear from the provisions of Directive 79/373 (fifth, sixth and seventh recitals, Article 5 (1) (e), Article 5 (4) (b) and (f), Article 8, Article 14 (a) and Article 15). As indicated by the Commission, ingredients may be defined as the basic products such as cereals or milk powder (Article 5 (4) (f)) the

mixture of which determines the particular nature of the compound feedingstuff. That definition may also be deduced from Directive 79/373 (the final subparagraph of Article 5 (1), Article 5 (4) (f), and Article 5 (7)).

Finally, as was stated by the Commission at the hearing, iron and sodium should be classified as *analytical constituents of the ingredients* making up complete feed for calves. According to the German Government such a definition means that they fall outside the scope of the two specialized directives since the harmonization effected by the third directive is still incomplete in that respect.

7. Let us consider first the problem of the *applicability of Directive 74/63 to sodium,* which appears to raise hardly any difficulties. In relation to the prescribing of maximum sodium levels the Federal Republic of Germany, it must be recalled, maintains that it is necessary to distinguish, for the purpose of applying that directive, between substances that are intrinsically undesirable, which are covered by the directive, and substances, such as sodium, whose presence is, on the contrary, desirable in complete feed and which therefore do not fall within the scope of the directive.

That distinction must be rejected in the light of the views expressed in the Court's judgment in the *Tedeschi* case. In contrast to additives which are 'intentionally' added 'so as to produce a favourable effect' on the characteristics of the feedingstuffs, the Court defined undesirable substances as those 'which are inevitably present in those feedingstuffs either in the natural state or as residues from processing previously undergone by those feedingstuffs or by the constituents of those feedingstuffs' (Case 5/77, cited above, paragraph 28 of the decision). Going on to consider the procedure for adopting protective measures in the event of a danger to animal or human health, the Court stated that that eventuality

'covers the case in which substances which were previously considered not to be harmful prove to be so, in particular if, considered in a previous stage as not harmful because they are only present in minute quantities, it appeared that in other feedingstuff mixtures or in mixtures made in new proportions, they are present in a proportion which may make them undesirable' (Case 5/77, cited above, paragraph 39).

Contrary to the defendant's assertion undesirable substances must therefore be regarded as covering not only substances which are *intrinsically* undesirable but also those that are undesirable '*because of their level*' (Case 5/77, paragraph 43 of the decision, emphasis added), that is to say, they become undesirable although, as in the case of sodium, they are inoffensive or even necessary in smaller quantities.

In view of that definition, the compatibility of the unilateral fixing of a maximum sodium level must be assessed within the framework of the Community legislation since it is incontestable that the field has been harmonized by Directive 74/63.

The annex to Directive 74/63 contains no provision with regard to sodium levels in animal feed. According to Article 3, the Member States are to prescribe that 'the

substances and products listed in the Annex shall be tolerated in feedingstuffs *only under the conditions therein set out*' (emphasis added). The absence of any reference to sodium in the annex must therefore be interpreted, unless the provision is to be deprived of any meaning whatsoever, as signifying that in principle feedingstuffs comply with Community law *regardless of their sodium content.* Accordingly, the fixing of a maximum permitted level of sodium must be regarded as a marketing restriction not expressly provided for by the directive and therefore as an infringement of Article 7, according to which the Member States are to ensure

'that feedingstuffs *which conform to this Directive* are not subject to any other marketing restrictions as regards the *presence* of undesirable substances and products' (emphasis added).

However, that does not deprive the Member States of any powers whatsoever, provided that they act within the framework established by the directive and in accordance with the procedure and substantive rules laid down therein. Thus:

(i) the procedure for taking urgent action provided for in Article 5, in conjunction with Article 10, provides the Member States with 'the means of remedying a lacuna in the harmonized legislation when a danger requiring immediate action arises' (Case 5/77, cited above, paragraph 38 of the decision);

(ii) the procedure provided for in Article 6, in conjunction with Article 9, gives the Member States the possibility of having the directive adapted in the light of developments in scientific or technical knowledge.

In this case the German Government did not consider it necessary to have recourse to those procedures. Accordingly, by adopting its rules concerning sodium the Federal Republic of Germany has failed to comply with the formal and substantive provisions of Directive 74/63.

8. The question whether the *prescription of a minimum iron content* is compatible with Community law is more complex. According to the defendant's arguments it is not necessary to use iron additives in complete feedingstuffs for calves in order to secure the levels laid down since manufacturers can select ingredients rich in iron which, as such, fall outside the scope of the additives directive and only fall within that of the compound feedingstuffs directive. However, Paragraph 7 (2) (now Paragraph 8 (3)) of the German rules concerning animal feedingstuffs does not specify the manner in which the manufacturers concerned are to comply with the provisions. Since it is left to the manufacturers to choose between recourse to iron additives and use of ingredients rich in iron, both eventualities must be considered.

Recourse to additives is not hypothetical. The Commission's view may be shared that, rather than use ingredients rich in iron, manufacturers will tend to prefer to incorporate iron additives which have the advantage of not affecting the feed formula, that is to say the mixture of ingredients making up the complete feedingstuff, which

consists to a substantial extent of milk powder. They are encouraged to do so by the Community subsidies for milk powder. In that case Directive 70/524 is applicable since it relates to all substances which are 'intentionally added' to feedingstuffs 'so as to produce a favourable effect on their characteristics' (Case 5/77, cited above, paragraph 28 of the decision).

The incorporation of iron additives corresponds precisely to that objective in the view of the German legislature. But Directive 70/524 authorizes the use only of the additives which it lists and for which it fixes the content level. That follows from Article 3 (1), according to which the

'Member States shall provide that ... *only* those additives which are listed in Annex I may be incorporated in feedingstuffs and *only* subject to the requirements set out therein' (emphasis added),

and also from Article 13 which obliges the Member States to ensure that feedingstuffs which conform to the provisions of the directive

'shall be subject, as regards the *presence* or absence of additives . . . , to no marketing restrictions other than those provided for in this directive' (emphasis added).

In other words, whereas the undesirable substances directive prohibits only the undesirable substances listed therein, and those which are not expressly mentioned may be regarded as authorized, the additives directive permits the incorporation up to prescribed levels of only those additives listed in the annex thereto so that only the levels expressly laid down are authorized. Point I of the annex lays down only a *maximum* permitted level in respect of the trace elements to which it refers. It must be concluded that the Member States have no power to lay down a minimum iron content for animal feed except within the framework of the adaptation procedures provided for by the directive itself where there is a danger to animal or human health or in order to take account of developments in scientific or technical knowledge. In this case only the latter procedure, which the defendant did not attempt to institute, was applicable since Article 7, which provides for the emergency procedure, permits a Member State only to suspend the use of the additive or to reduce the maximum permitted level thereof in the event of a danger to health.

Since the provisions at issue *do not exclude* the incorporation by manufacturers of iron additives into feed for calves in order to attain the minimum iron level required by those provisions, the Federal Republic of Germany, in view of the exhaustive nature of the harmonization effected in this field, has failed to fulfil its obligations under Directive 74/63. The uncertainty arising from the lack of such a provision means, in my opinion, that it may be declared that, with regard to the minimum content of iron as well, the Federal Republic of Germany has failed to fulfil its obligation as alleged by the Commission.

9. Let us, however, examine the other option open to manufacturers according to the defendant: the use, not of iron additives, but of ingredients rich in iron. In

the defendant's view the compound feedingstuffs directive alone is applicable and that directive contains lacunae with regard to the *composition* of feedingstuffs.

This argument no more stands up to examination than did the preceding ones.

The objective of Directive 79/373 is different from those of the specialized directives. Whereas the Community legislature sought, by means of the additives directive and the undesirable substances directive, to harmonize the rules applicable within the Community to the use of *specific analytical constituents*, the compound feedingstuffs directive relates above all to the conditions for putting on the market a *specific type of animal feed*, namely compound feedingstuffs. To that extent it is intended to harmonize the substantive conditions with regard to the information to be given to the user and the presentation of the product. As has already been stated when analysing those provisions, it is only *incidentally* concerned with the question of their composition.

Did the Community legislature intend to leave it to the Member States to fill in the 'lacunae' in that directive? There is no reason to think that it did: various provisions demonstrate, on the contrary, its desire to rule out any unilateral steps on the part of the Member States capable of compromising not only what had already been attained by the directive but also that which remained to be enacted.

First of all it is in that sense that the 'standstill' obligation contained in Article 8, which 'freezes' the domestic law of the Member States applicable to ingredients as it stood when the directive was adopted, namely *2 April 1979*, must be interpreted. Any new rules governing ingredients are therefore prohibited. In so far as they oblige manufacturers of complete feedingstuffs to use a certain type of ingredient rich in iron, the German rules of *19 July 1979* therefore constitute, with effect from 1 January 1981, the date on which the directive entered into force, a breach of the obligation *to desist from any further act* laid down by Article 8 thereof.

Secondly, the Community procedure for adjustments to take account of developments in scientific and technical knowledge, which allows for amendments to the annex to the directive, requires the Member States to act within the framework laid down in the directive. By submitting a proposal for the amendment of Directive 79/373 during the course of the preliminary procedure, the Federal Republic of Germany seems to have then taken account of the process prescribed by that procedure.

Thirdly, by leaving the Member States the power to '*recommend* types of compound feedingstuffs which meet certain analytical characteristics' (emphasis added) the Community legislature clearly intended to deprive them of the possibility of *obliging* manufacturers to use a particular type of compound feedingstuffs, for example a type rich in iron (Article 14 (a)).

Fourthly, by providing in Article 15 that within specified periods the Commission was to propose and the Council was to decide on amendments to be made to the directive, in particular with regard to 'the use of ingredients', the Community legislature intended to reserve *exclusively* to the Community institutions the power to

adopt supplementary common rules, thus precluding any unilateral act on the part of the Member States. In that connection, the delay by the institutions in complying with that obligation may be regretted but it cannot justify the introduction of new national provisions laid down unilaterally in breach of Article 8 of the directive.

The purport of those provisions is confirmed by Article 9 according to which compound feedingstuffs are not to be subject '*for reasons concerning the provisions included in this directive*' (emphasis added) to marketingrestrictions other than those provided for by the directive.

Far from leaving a legal void in relation to the composition of compound feedingstuffs, Directive 79/373 confirms in this field the principle of the free movement of compound feedingstuffs whilst making available to the Member States a number of possibilities for lawful intervention. In addition to the power to propose, in accordance with the Community procedure provided therefor (Articles 10 and 13), appropriate amendments to the annex with regard to iron, which is not referred to therein, the Federal Republic of Germany could, in accordance with Article 14 (a), recommend the use of feedingstuffs with a certain iron content.

Article 3, which provides a basis for national measures to sanction practices which are unfair or a danger to animal health, cannot be interpreted as giving the Member States power to regulate the composition of feedingstuffs generally. As the Court stated in its judgment in the *Denkavit* case, cited above, that provision, in conjunction with the other provisions of the directive

'merely imposes on Member States a general obligation to adopt all appropriate measures, whether legislative, administrative or judicial, to enforce compliance with certain rules relating to quality, to ensure that health inspections are carried out on feedingstuffs and to guarantee fair trading, regardless of the origin of the applicable rules' (paragraph 12).

Article 3 therefore clearly obliges the Member States, in relation to all the matters regulated by the directive and to the national provisions to which it may refer, not only to *guarantee* the quality of compound feedingstuffs manufactured in their territory but also to *impose a sanction* on any breach of those rules by manufacturers, in particular if the latter endanger animal or human health by manipulations proscribed by the rules at issue. The Member States are therefore under an obligation to *take steps against* abuses but may not unilaterally introduce *general* rules of a *preventative* nature.

Finally, Articles 3, 8 and 15 of the directive all correspond to the legitimate concerns of Member States: Article 8 provides for a 'freeze' of domestic law with regard to ingredients, Article 15 lays down a time-limit for the elimination of the resulting disparities and Article 3 imposes an obligation to guarantee fair trading and to ensure that the product does not endanger animal or human health.

An analysis of Directive 79/373 therefore shows that, by adopting rules which oblige manufacturers to use ingredients rich in iron in complete feedingstuffs for calves, the German Government has failed to fulfil its substantive and procedural obligations under that directive. That final conclusion bears out the Commission's contention that the Federal Republic of Germany has failed to fulfil its obligations.

10. Is it necessary, as is proposed by the Commission, to take a further step and consider that with the adoption of Directive 79/373 the harmonization of the rules relating to the composition of compound feedingstuffs is complete? To reply to that question, the examination of the directives, which has hitherto treated each one individually, must be extended to the whole system created by them.

That system may be described in the following manner:

(i) Directives 70/524 and 74/63 laid down prescriptions concerning analytical constituents the regulation of which appeared *indispensable* on account both of their use as additives and of their harmful nature; as regards analytical constituents other than additives and undesirable substances, prescriptions were laid down concerning moisture level and ash content; Member States were given the right to 'recommend/the use of/ types of compound feedingstuffs which meet certain analytical characteristics' (Article 14 (a) of Directive 79/373);

(ii) With regard to the ingredients, Member States were permitted to maintain the *status quo* until completion of the enactment of Community rules in the matter (Articles 8 and 15 of Directive 79/373).

Furthermore, the Community procedures for complementing the provisions of the directives by setting in motion the process for adaptation to scientific and technical developments, or, in the case of the most sensitive constituents (additives and undesirable substances), by dealing with emergency situations by means of a procedure which is subject to strict control by the Community institutions. If no provision is made for such a procedure in the compound feedingstuffs directive it is precisely because the risks to animal and human health normally arise in the fields regulated by the specialized directives. We have already seen how, in the context of Directive 79/373, the protection of health may be ensured.

In the light of all the foregoing considerations it is apparent that in relation to the composition of compound feedingstuffs the essential measures needed for the protection of animal and human health and the Community procedures for verifying compliance therewith have been adopted. The harmonization of national rules on the composition of compound feedingstuffs has been definitively completed or is in any case so advanced that the Member States are no longer able to intervene without jeopardizing 'the attainment of the objectives of this Treaty' (second paragraph of Article 5 of the EEC Treaty), except within the framework of the established body of rules. Any other solution would open the way to the progressive dismantling of those rules and would thus compromise the process of adaptation of the directives over which the Community legislature intended to retain control.

11. Accordingly, it is unnecessary to consider the defendant's argument based on the provisions of Article 36 of the EEC Treaty and I propose that the Court should:

(i) Declare that, by adopting rules prohibiting the marketing on its territory of compound feedingstuffs which do not contain a minimum level of iron or which exceed a maximum permitted level of sodium, the Federal Republic of Germany has failed to fulfil its obligations under Directive 70/524 of 23 November 1970 concerning additives in feedingstuffs (Official Journal, English Special Edition 1970 (III), p. 840), Directive 74/63 of 17 December 1973 on the fixing of maximum permitted levels for undesirable substances and products in feedingstuffs (Official Journal 1974, L 38, p. 31) and Directive 79/373 of 2 April 1979 on the marketing of compound feedingstuffs (Official Journal 1979, L 86, p. 30);

(ii) Order the defendant to bear the costs.