COMMISSION OF THE EUROPEAN COMMUNITIES

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REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT

on the use of substances other than vitamins and minerals in food supplements

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INTRODUCTION

Directive 2002/46/EC[1] of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements partially harmonises the rules applicable to the placing of food supplements on the market.

The scope of the Directive covers all food supplements, with certain requirements – in particular those concerning labelling information – applying to all food supplements, regardless of their composition.

However, only the rules applicable to the use of vitamins and minerals in the manufacture of food supplements are laid down in the Directive. The use of substances other than vitamins or minerals in the manufacture of food supplements therefore continues to be subject to the rules in force in national legislation, where relevant, which apply within the framework of Articles 28 to 30 of the EC Treaty, without prejudice to any Community provisions of general application which may also concern them.

These principles are mentioned in Recital 8 of the Directive, which states that specific rules concerning nutrients, other than vitamins and minerals, or other substances with a nutritional or physiological effect used as ingredients of food supplements should be laid down at a later stage.

It is also stated that, in any event, such rules cannot be laid down until adequate and appropriate scientific data become available. In view of this, Article 4(8) of the Directive lays down that the Commission shall submit to the European Parliament and the Council a report on the advisability of establishing specific rules, including, where appropriate, positive lists, on categories of nutrients or of substances with a nutritional or physiological effect other than vitamins and minerals.

The present report follows on from that provision and, in accordance with the instructions outlined in the Directive and referred to above, will examine the issues concerning both the necessity and feasibility of the specific rules in question.

In order to clarify matters properly and to set out the necessary information for drawing up the conclusions to this report, the Commission believes it is worthwhile to first describe:

– the characteristics and prospects of the market for the products concerned;

– the existing regulatory framework;

– the status of the available scientific information.

[1] OJ L 183, 12.7.2002, pp. 51-57.

1. CHARACTERISTICS OF THE MARKET FOR FOOD SUPPLEMENTS CONTAINING SUBSTANCES OTHER THAN VITAMINS AND MINERALS

Unlike the market for food supplements containing vitamins and minerals, which appears relatively homogeneous, the market for food supplements containing other substances is characterised by its variety.

A study of the Community market for food supplements[2] containing substances other than vitamins or minerals gives rise to the following observations:

- the Community market for such products is extremely varied, both as regards the substances used and from one Member State to another;
- the market share of products containing vitamins and minerals and that of products containing other substances are almost identical.

Prospects for growth are strongest in the Member States where consumption is still relatively low.

In some Member States, there is a well established tradition of using certain substances, while these same substances are practically absent in other Member States.

More detailed information on the European food supplement market can be found in the Commission's working document on the characteristics and prospects of the market for food supplements containing substances other than vitamins and minerals.

2. THE EXISTING REGULATORY FRAMEWORK

It must be stressed that the substances in question are already covered by various Community legislative texts of general application, or which are applicable to certain categories of product, particularly as regards food safety.

Since Community law does not include specific provisions on the use of substances other than vitamins or minerals in food supplements, the free movement of such products is governed by Articles 28 to 30 of the EC Treaty and can thus be subject to national restrictions or bans within the limits laid down by Article 30.

2.1. Horizontal Community legislation

2.1.1. *How the products concerned are classified in Community legislation*

Food supplements containing substances other than vitamins or minerals are foodstuffs within the meaning of Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council[3], which states that "foodstuff" (or "food") means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

The aforementioned Article 2 explicitly excludes from the definition of foodstuff a series of product categories, including medicinal products within the meaning of

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[2] Source "The use of substances with nutritional or physiological effect other than vitamins and minerals in food supplements", European Advisory Services (EAS), 2007.

[3] OJ L 31, 1.2.2002, pp. 1-24.

Directive 2001/83/EC of the European Parliament and of the Council[4] on the Community code relating to medicinal products for human use.

With regard to food supplements, and in particular those containing substances other than vitamins or minerals, a certain number of borderline cases have given rise, or could give rise, to situations where a given product is authorised for marketing as a food in some Member States, while the same product is classified as a medicinal product in other Member States.

It should also be pointed out that some substances, in particular certain herbal extracts, are used both in food supplements and for manufacturing proprietary medicinal products, in particular traditional herbal medicinal products. Such difficulties must be dealt with on a case-by-case basis, since the legislation on medicinal products lays down rules and procedures for the placing of medicinal products on the market and provides for marketing authorisation to be issued by the Member States' competent authority or, for certain types of medicinal product, at Community level.

For traditional herbal medicinal products, a so-called simplified registration procedure is provided for by Directive 2004/24/EC of the European Parliament and of the Council[5] amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.

In this context, the Court of Justice has stated on several occasions that so long as harmonisation of the measures necessary to ensure the protection of health is not more complete, it is difficult to avoid the existence of differences between Member States in the classification of products as medicinal products or foodstuffs. Thus, the fact that a product is classified as a foodstuff in another Member State cannot prevent it from being classified as a medicinal product in the Member State of importation, if it displays the characteristics of such a product.

Correspondingly, the Court also concluded long ago that a product which satisfies the definition of "medicinal product" within the meaning of Directive 2001/83/EC must be held to be a medicinal product and be made subject to the corresponding rules even if it comes within the scope of other, less stringent Community rules (see paragraphs 37 and 38 of case C-319/05 of 15 November 2007).

This principle also figures in the legislation itself, since Article 2(2) of Directive 2001/83/EC, as amended by Directive 2004/27/EC[6], lays down that, in cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a "medicinal product" and within the definition of a product covered by other Community legislation, the provisions of the legislation on medicinal products shall apply.

As a result, the provisions of the legislation applicable to medicinal products will apply to a product which fulfils the definition of food supplement, as laid down in Article 2(a) of Directive 2002/46/EC, but which, at the same time, taking into account all its characteristics, may also fall within one of the definitions of medicinal product contained in Article 1 of Directive 2001/83/EC, which defines medicinal products with reference to both their presentation and their function.

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4 OJ L 311, 28.11.2001, pp. 67-128.

5 OJ L 136, 30.4.2004, pp. 85-90.

6 OJ L 136, 30.4.2004, pp. 34-57.

With regard to the definition of medicinal product by presentation, "any substance or combination of substances presented as having properties for treating or preventing disease in human beings" must be classified as a medicinal product.

As regards the definition of medicinal product by function, "any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis" must be classified as a medicinal product.

On first examination, this definition could be understood as potentially applying to certain foodstuffs, particularly food supplements, which constitute a concentrated source of substances having a physiological effect.

However, the Court of Justice ruled that this definition of medicinal product by function should be interpreted restrictively, since it is designed to cover only products whose pharmacological properties have been scientifically observed, and not substances which, while having an effect on the human body, do not significantly affect the metabolism and thus do not strictly modify the way in which it functions (see paragraphs 60 to 65 of the aforementioned case C-319/05).

By contrast, according to settled case law, the definition of medicinal product by presentation is subject to broad interpretation, so as to avoid consumers being misled by improper presentation.

Accordingly, it is more specifically as regards presentation that some food supplements are liable to fall within the definition of medicinal product. It will be possible to significantly reduce this risk of a conflict of classification by applying the rules on health claims concerning foodstuffs (see section 2.1.2(c) below).

2.1.2. *Food safety legislation*

As foodstuffs, food supplements, including those containing substances other than vitamins and minerals, are covered by legislative texts of general application in the area of food safety legislation, some of which were adopted or entered into force subsequent to the adoption of Directive 2002/46/EC. Taken together, these provisions constitute a substantial framework in relation to the movement of the products in question on the Community market consistent with the requirements of food safety.

a) Regulation (EC) No 178/2002

Regulation (EC) No 178/2002 lays down the general legal framework and requirements of food law and the procedures applicable in the area of food safety.

It also established the European Food Safety Authority (EFSA).

As such, this Regulation has a very wide scope, covering not only any product included in the definition of "foodstuff" (see section 2.2.1.), but also any substance introduced into the food chain for the purposes of manufacturing a foodstuff, irrespective of the existence of specific provisions applicable to that substance. Accordingly, all the relevant provisions of Regulation (EC) No 178/2002 apply directly to the substances involved in the manufacture of food supplements.

In this connection, mention can be made of the ban on the placing on the market of products which are injurious to health or unfit for human consumption (Article 14), the primary responsibility of food business operations to ensure that products comply with food law (Article 17), their obligation to put in place a product traceability system (Article 18) and their obligation to be able to immediately initiate procedures to withdraw non-compliant products from the market and inform the competent authorities in such cases (Article 19).

It is important to note that Article 14(9) of the Regulation lays down that, "where there are no specific Community provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof".

b) Regulation (EC) No 258/97[7] on Novel Foods

The objective of this Regulation is to make subject to an authorisation procedure, and thus to a safety assessment, all foods and food ingredients covered by its scope, i.e. those covered by the definition of "novel food" or "novel ingredient", which, within the meaning of the Regulation, covers all foods and food ingredients which had not been used for human consumption to a significant degree within the Community prior to the entry into force of the Regulation.

This definition covers foods and food ingredients with a new or intentionally modified primary molecular structure, those consisting of or isolated from micro-organisms, fungi or algae, those consisting of or isolated from plants and food ingredients isolated from animals obtained by non-traditional propagating or breeding practices.

The production process is also covered if it gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.

In order to facilitate the provision of information to operators concerning the scope of these definitions, and in particular the concept of "consumption to a significant degree", the Commission recently drew up and published a "Novel Food Catalogue"[8]. This is a non-exhaustive database, the aim of which is to provide an initial indication as to whether a given product is "novel" with reference to the criterion mentioned above. The catalogue will be updated on a regular basis.

In the context of this report, it is also relevant to stress that, in view of the food safety objective of Regulation (EC) No 258/97, the concept of "novel food" is broadly interpreted. This explains how a plant extract which was not on the Community market, or not produced, as at the date of entry into force of the Regulation, will, in principle, be considered a "novel ingredient", even though the plant from which it is extracted would not be considered "novel".

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7 OJ L 43, 14.2.1997, pp. 1-6.

8 http://ec.europa.eu/food/food/biotechnology/novelfood/nfnetweb/index.cfm

This Regulation, which was recently the subject of a proposal[9] for revision, is thus an important factor in the issue dealt with in this report, since it permits the safety assessment and free movement of any "novel substance" used in food supplements or as a food supplement.

c) Regulation (EC) No 1924/2006[10] on nutrition and health claims

This Regulation lays down the conditions for the use of nutrition and health claims on food packaging. While the Regulation has been in force since 1 July 2007, it necessarily includes a transitional period for the circulation of products which were on the market when it entered into force but do not comply with its provisions. Furthermore, several implementing measures are being prepared. This Regulation is very important for the food supplement sector, in which claims, and in particular health claims, are a favoured means of communication with consumers.

The decisive criterion for use of a health claim is that the health effect claimed in relation to a nutrient or substance must absolutely be based on scientific evidence. It can thus be expected that the legal framework applicable to health claims will ultimately constitute, directly or indirectly, an element of harmonisation of the substances enjoying mutual recognition by the Member States, for which these claims will be authorised at the Community level.

Moreover, as suggested at the end of section 2.1.1., health claims authorised pursuant to Regulation (EC) No 1924/2006 will constitute a presumption that the product to which they refer belongs in the category of foodstuffs, thereby reducing the risk of conflicts of classification. Indeed, function claims and reduction of disease risk claims clearly establish that the product to which they refer is not liable to fall within the definition of medicinal product by presentation. However, they will not make it possible to completely exclude the risk of conflict of classification in cases where it could be claimed that the product concerned is liable to fall within the definition of medicinal product by function.

d) Regulation (EC) No 1925/2006[11] on the addition of vitamins and minerals and of certain other substances to foods

This Regulation, which has been in force since 1 July 2007 subject to a transitional period, concerns all foodstuffs, including food supplements. However, it is specifically stated that the provisions regarding vitamins and minerals shall not apply to food supplements covered by Directive 2002/46/EC. The definition in Article 1 implies, therefore, that the provisions concerning other substances shall apply to all foodstuffs, including food supplements. With regard to these other substances, Regulation (EC) No 1925/2006 does not contain a list of authorised substances. Instead it establishes, in Article 8, a procedure to be used in cases where a substance other than vitamins or minerals, or an ingredient containing a substance other than vitamins or minerals, is added to foods or used in the manufacture of foods under conditions that would result in the ingestion of amounts of this

9 COM/2007/0872 final - COD 2008/0002

10 OJ L 12, 18.1.2007, pp. 3-18.

11 OJ L 404, 30.12.2006, pp. 26-38.

substance greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or would otherwise represent a potential risk to consumers.

In such cases, on its own initiative or on the basis of information provided by the Member States, the Commission may take a decision, following an assessment of available information by the European Food Safety Authority, to include the substance in Annex III to the Regulation.

Annex III, which does not currently include any substances, as the procedure under Article 8 has not yet been used, will make it possible to draw up a list of substances whose use in foods is prohibited, restricted or under Community scrutiny.

Any decision to place a substance in one of these three headings will thus be taken on the basis of the results of an assessment of the available scientific information, having regard only to the safety of the substances concerned in food. With regard to substances other than vitamins or minerals added to foodstuffs, including food supplements, or used in the manufacture of foodstuffs, the procedure described above constitutes, on first examination, a safety net as regards health protection and can allow, with a precautionary approach, harmonisation of the possibilities or conditions of use of a certain number of substances.

This procedure can be used on a case-by-case basis, provided that the conditions laid down in Article 8(1), referred to above, have been met.

2.2. **National legislation**

A large majority of the Member States have drawn up positive or negative lists of substances other than vitamins and minerals which can be used in food supplements.

In some cases, use of the substances in question is subject to compliance with technical conditions, such as maximum limits, type of extract or combination of ingredients. Furthermore, entry of new substances onto these lists is liable to be subject to an assessment.

2.3. **Mutual recognition**

Mutual recognition remains an important tool for ensuring the free movement of products, including foodstuffs, on the Community market.

As already stated in section 2.1.2., Article 14(9) of Regulation (EC) No 178/2002 lays down that, where there are no specific Community provisions, food shall be deemed to be safe when it conforms to specific national provisions, without prejudice to the Treaty, in particular Articles 28 and 30 thereof.

Mutual recognition is not free from the risk that technical obstacles to the free movement of the products concerned can be maintained or created.

However, these risks should be put into perspective, in that the Court of Justice, as part of its judicial supervision, has set precise limits within which the Member States may validly exempt themselves from mutual recognition by availing themselves of Article 30 EC, including in the area of foodstuffs.

Accordingly, the Court frequently reiterates that, it is for the Member States, in the absence of harmonisation and to the extent that uncertainties continue to exist in the current state of scientific research, to decide on their intended level of protection of

human health and life and on whether to require prior authorisation for the marketing of foodstuffs, always taking into account the requirements of the free movement of goods within the Community.

However, in exercising their discretion relating to the protection of public health, the Member States must comply with the principle of proportionality. The means which they choose must therefore be confined to what is actually necessary to ensure the safeguarding of public health; they must be proportional to the objective thus pursued, which could not have been attained by measures which are less restrictive of intra-Community trade.

Furthermore, since Article 30 EC provides for an exception, to be interpreted strictly, to the rule of free movement of goods within the Community, it is for the national authorities which invoke it to show in each case, in the light of national nutritional habits and in the light of the results of international scientific research, that their rules are necessary to give effective protection to the interests referred to in that provision and, in particular, that the marketing of the products in question poses a real risk for public health (see, most recently, paragraphs 86 to 88 of the judgment in the aforementioned case C-319/05, Commission v Germany).

In other words, the Member States are entitled to invoke the need to protect the interests referred to in Article 30 EC, including health protection, only when the conditions laid down by the Court and referred to above have been met, and to the extent that there is no harmonised Community legislation capable of protecting the same interests.

In this context, it should be stressed that, with effect from 13 May 2009, refusals of mutual recognition will be subject to the conditions laid down in Regulation (EC) No 764/2008[12] of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC of the European Parliament and the Council establishing a procedure for the exchange of information on national measures derogating from the principle of the free movement of goods within the Community.

3. AVAILABLE SCIENTIFIC INFORMATION

With regard to scientific information, a distinction should be drawn between substances of vegetable origin (plants or plant extracts) and other categories of substance. Scientific assessments have been, or are being, carried out for a significant number of substances other than those of vegetable origin, within the framework of the legislation on foodstuffs for particular nutritional uses. This is the case for some amino acids and other substances, a list of which features in the Annex to Commission Directive 2001/15/EC[13] on substances that may be added for specific nutritional purposes in foods for particular nutritional uses.

With regard to substances of vegetable origin, work is ongoing at the European Food Safety Authority[14] and the Council of Europe's Nutrition Committee[15].

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12 OJ L 218, 13.8.2008, pp. 21-29.

13 OJ L 52, 22.2.2001, pp. 19-25.

14 http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178717026833.htm

However, it should be pointed out that this work is more specifically concerned with methodology and not with assessing the safety of substances of vegetable origin.

The Commission believes that this high-quality work will make new tools available to the Member States, thereby facilitating consensus building in relation to the proper approach to be taken for each product. It will also be a benchmark for the Court's analysis, in the light of the aforementioned articles of the Treaty.

A brief description of the ongoing work at the European Food Safety Authority and the Council of Europe's Nutrition Committee is available in the Commission's working document on the available scientific information concerning the use of substances other than vitamins and minerals in food supplements.

4. CONCLUSIONS

Considering all the issues described and analysed in this report, the Commission concludes that laying down specific rules applicable to substances other than vitamins and minerals for use in food supplements is not justified.

Moreover, the Commission doubts the feasibility of such a measure, which, in any case, is not necessary in the short term.

a) Feasibility.

Unlike vitamins and minerals, the use of which is fairly similar throughout the Member States, the other substances correspond to very varied consumption habits. Moreover, given the available scientific information, which is essentially limited to substances that may be added for specific nutritional purposes to foods for particular nutritional uses, the Commission believes that a proposal for harmonisation in this area could only be limited to some substances, thus restricting its usefulness.

Taking account, also, of the scientific and methodological difficulties which would have to be overcome, the Commission believes that the prospect of extending Directive 2002/46/EC to substances other than vitamins and minerals could only be envisaged in the light of the experience gained when the rules on the use of vitamins and minerals were being laid down, bearing in mind that these rules still need to be supplemented by laying down maximum quantities in accordance with Article 5 of the Directive.

b) Necessity.

Reference has been made in this report to existing instruments, in particular the recently adopted legislation on the enrichment of foodstuffs with vitamins, minerals and other substances and that on nutritional and health claims. This suggests that the possibilities or conditions of use of the substances in question in foodstuffs, including food supplements, or their prohibition, can undergo harmonisation over time in the framework of the procedures provided for in those instruments. In this connection, the Commission would refer in particular to the procedure laid down in Article 8 to Regulation (EC) No 1925/2006, which allows a substance to be placed under scrutiny for a given period if the

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[15] http://www.coe.int/t/e/social_cohesion/soc-sp/public_health/nutrition_food_consumer_health/Nutrition,%20food%20and%20consumer%20health_%20EN.asp#TopOfPage

available scientific information is insufficient. The Commission believes that this type of procedure is particularly well suited to plants and plant extracts, for which sufficient and appropriate scientific data are not always available, and for which the safety assessment methodology is still being developed.

Furthermore, the legislation on novel foods is another factor likely to contribute to such harmonisation, within the limits of its specific scope.

Lastly, the Commission would point out that, in general terms, despite certain limitations, mutual recognition is a useful instrument for facilitating the free movement of the products concerned.

To conclude, the Commission believes that the Community legal instruments described in this report already constitute a sufficient legislative framework for regulating this area and does not consider it opportune to lay down specific rules for substances other than vitamins or minerals for use in foodstuffs.

However, since substances other than vitamins or minerals, including substances derived from plants, are now being added to ordinary foodstuffs and not only to food supplements, the Commission does not rule out the possibility, at a later state, of carrying out a supplementary analysis to this report, examining the conditions for the addition of these substances to foodstuffs in general.