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REPORT

from :	Permanent Representatives Committee
to :	Council
No. prev. doc. :	11690/01 DENLEG 38 CODEC 850
No. Cion prop. :	7340/01 DENLEG 9 CODEC 266
Subject :	Amended proposal for a European Parliament and Council Directive on the approximation of the laws of the Member States relating to food supplements

I. INTRODUCTION

1. On 11 May 2000 the Commission submitted to the Council the above proposal for a Directive [1], based on Article 95 of the Treaty. That proposal had been promised in the Commission's White Paper on food safety.

   It was the Commission's belief that barriers to free movement had been created as a result of the proliferation of national rules governing a great many products known as "food supplements" which had been marketed in the Community for a number of years.

[1] OJ C 311 E, 31.10.2000, p. 207.

The Commission had received many complaints from economic operators following decisions by national regulatory authorities, and after consulting widely with the parties involved, it had concluded that it was necessary to adopt Community rules in this area.

2. The Economic and Social Committee and the European Parliament delivered their Opinions on 19 October 2000 [2] and 14 February 2001 [3] respectively.

   On the occasion of the European Parliament vote, the Commission accepted 16 of the 38 amendments adopted, and forwarded an amended proposal [4] to the Council on 21 March 2001, following the above European Parliament Opinion.

3. The Council (Internal Market, Consumer Affairs and Tourism) of 30 and 31 May 2001 discussed this text on the basis of an overall compromise proposal by the Presidency (9142/01 + COR 1). After the discussion, the Presidency concluded that its proposals had not received sufficient support and that the Council would therefore come back to this issue at a future meeting.

4. With a view to reaching agreement, the Presidency presented further compromise suggestions for Articles 2 and 5.
   The text, as it stands following the meeting of the Permanent Representatives Committee on 12 and 19 September 2001, is set out in the Annex.

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2 OJ C 14, 16.1.2001, p. 42.
3 Not yet published in the OJ.
4 OJ C 180 E, 26.6.2001, p. 248.

II. PRESIDENCY COMPROMISE

1. Compromise suggestions

(a) Setting amounts of vitamins and minerals present in food supplements (Article 5(1) and (2) – cf. also recital 14)

Delegations differed on the criteria for setting these amounts.
Some delegations preferred a safety-based approach (as proposed by the Commission), accompanied by adequate provisions on labelling, while others preferred a nutritional approach, whereby nutritional requirements would also be an essential criterion.

The Presidency's compromise text proposed that these maximum amounts should be set after scientific risk assessment on the basis of intake from other food sources within the overall context of reference intake figures for the whole population.

(b) Definition of food supplements (Article 2(a))

To resolve the problems raised by a number of delegations, the Presidency suggested a definition which would avoid possible ambiguity regarding the scope of the proposal, by referring to substances with a nutritional or physiological "effect" as opposed to "function".

2. Delegations' positions

At the Committee meeting the Danish, Spanish and Austrian delegations maintained their reservations on this compromise, specifically because they felt that the nutritional approach should be consolidated.
The United Kingdom delegation, which was in favour of a safety-based approach, maintained a scrutiny reservation.
The Greek delegation maintained reservations on the definition of "food supplements" as suggested by the Presidency in Article 2, and in particular on the reference to "other substances", which it considered to be too vague and could well broaden the scope of the Directive.

The other delegations and the Commission could support the Presidency text for the sake of a compromise. The German, French, Netherlands and Portuguese delegations furthermore made clear that they would prefer this text not to be amended at all in future.

III. OTHER POINTS OUTSTANDING

Other remarks or reservations are detailed in the footnotes.

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The Council is asked to examine the proposal on the basis of the Presidency compromise with a view to reaching agreement and adopting a common position.

ANNEX

Amended proposal for a Directive of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,
Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,
Having regard to the proposal from the Commission *,
Having regard to the Opinion of the Economic and Social Committee **,
Acting in accordance with the procedure laid down in Article 251 of the Treaty,
Whereas:

(1) There is an increasing number of products marketed in the Community as foods containing concentrated sources of nutrients and presented for supplementing the intake of those nutrients from the normal diet.

(2) Those products are regulated in Member States by differing national rules that may impede their free movement, may create unequal conditions of competition, and thus have a direct impact on the functioning of the internal market. It is therefore necessary to adopt Community rules on those products marketed as foodstuffs.

(3) An adequate and varied diet could, under normal circumstances, provide all necessary nutrients for normal development and maintenance of a healthy life in quantities as those established and recommended by generally acceptable scientific data. However, surveys show that this ideal situation is not being achieved for all nutrients and by all groups of the population across the Community.

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* OJ C 311 E, 31.10.2000, p. 207 and C 180 E, 26.6.2001, p. 248.
** OJ C 14, 16.1.2001, p. 42.

(4) Consumers, because of their particular lifestyles or for other reasons, may choose to supplement their intake of some nutrients through food supplements.

(5) In order to ensure a high level of protection for consumers and facilitate their choice the products that will be put onto the market must be safe and bear adequate and appropriate labelling.

(6) There is a wide range of nutrients and other ingredients that might be present in food supplements including, but not limited to, vitamins, minerals, amino acids, essential fatty acids, fibre and various plant and herbal extracts. [1]

(7) As a first stage, this Directive should lay down specific rules for vitamins and minerals used as ingredients of food supplements. Food supplements containing vitamins or minerals as well as other their ingredients should also be in conformity with the specific rules on vitamins and minerals laid down in this Directive.

(8) Specific rules concerning other nutrients or other substances with a nutritional or physiological effect [2] used as ingredients of food supplements should be laid down at a later stage, provided that adequate and appropriate scientific data about them become available. Until the adoption of such specific Community rules and without prejudice to the provisions of the Treaty, national rules concerning nutrients or other substances with nutritional or physiological effect used as ingredients of food supplements, for which no Community specific rules have been adopted, may be applicable.

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[1] E maintained a reservation on this recital. It asked to add the word "essential" to "amino acids" (addition supported by EL) and to define the word "fibre". It also requested to delete the words "and various plant and herbal extracts" while EL was only in favour of the deletion of the word "herbal".
Some delegations, in particular DK, had reservations on this recital as well as on recitals 7 and 8, linked to their position on Article 2.

[2] See Presidency compromise on Article 2.

(9) Only vitamins and minerals normally found in and consumed as part of the diet should be allowed to be present in food supplements although this does not mean that their presence therein is necessary. Controversy as to the identity of those nutrients that could potentially arise should be avoided. Therefore it is appropriate to establish a positive list of those vitamins and minerals.

(10) There is a wide range of vitamin preparations and mineral substances used in the manufacture of food supplements currently marketed in some Member States that have not been evaluated by the Scientific Committee for Food and consequently are not included in the positive lists. These should be submitted to the Scientific Committee for Food for urgent evaluation, as soon as appropriate files are presented by the interested parties [3].

(11) The chemical substances used as sources of vitamins and minerals in the manufacture of food supplements should be safe and also be available to be used by the body. For this reason, a positive list of those substances should also be established. Such substances as have been approved by the Scientific Committee for Food, on the basis of the said criteria, for use in the manufacture of foods intended for infants and young children and other foods for particular nutritional uses can also be used in the manufacture of food supplements.

(12) In order to keep up with scientific and technological developments it is important to revise the lists promptly, when necessary. Such revisions would be implementing measures of a technical nature and their adoption should be entrusted to the Commission in order to simplify and expedite the procedure.

(13) For vitamins and minerals excessive intakes may result in adverse effects and therefore necessitate the setting of maximum safe levels for them in food supplements, as appropriate. Those levels must ensure that the normal use of the products under the instructions of use provided by the manufacturer will be safe for the consumer.

[3] Reservations entered on Article 4 apply also to this recital.

(14) When setting maximum levels, therefore, account should be taken of the upper safe levels of the vitamins and minerals, as established by scientific risk assessment based on generally acceptable scientific data, and of intakes of those nutrients from the normal diet. Due account should also be taken of reference intake amounts when setting maximum levels [4].

(15) Food supplements are purchased by consumers for supplementing intakes from the diet. In order to ensure that this aim is achieved, if vitamins and minerals are declared on the label of food supplements, they should be present in the product in a significant amount.

(16) The adoption of the specific values for maximum and minimum levels for vitamins and minerals present in food supplements, based on the criteria set out in this Directive and appropriate scientific advice, would be an implementing measure and should be entrusted to the Commission.

(17) General labelling provisions and definitions are contained in Directive 2000/13/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs [*], and do not need to be repeated. This Directive should therefore be confined to the necessary additional provisions.

(18) Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs [**] does not apply to food supplements. Information relating to nutrient content in food supplements is essential for allowing the consumer who purchases them to make an informed choice and use them properly and safely. That information should, in view of the nature of those products, be confined to the nutrients actually present and be compulsory.

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[4] Amendments suggested by the Presidency to align this recital on the text adopted for Article 5.

* OJ L 109, 6.5.2000, p. 29.

** OJ L 276, 6.10.1990, p. 40.

(19) Given the particular nature of food supplements, additional means to those usually available to monitoring bodies should be available in order to facilitate efficient monitoring of those products.

(20) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 * laying down the procedures for the exercise of implementing powers conferred on the Commission,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

- amended -

1. This Directive concerns food supplements marketed as foodstuffs and presented as such. These products shall be delivered to the ultimate consumer only in a pre-packaged form.

2. This Directive shall not apply to medicinal products as defined by Council Directives 65/65/EEC ** and 92/73/EEC ***.[5]

* OJ L 184, 17.7.1999, p. 23.
** OJ L 22, 9.2.1965, p. 369.
*** OJ L 297 of 13.10.1992, p. 8.
[5] DK and E maintained reservations on deletion of the reference to foods for particular nutritional uses as defined by Council Directive 89/398/EEC.

Article 2

- amended -

For the purposes of this Directive,

(a) "food supplements" means foodstuffs that are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, whose purpose is to supplement the normal diet;[6]

(b) "nutrients" means the following substances:

(i) vitamins,

(ii) minerals;[7]

(c) "dose form" means forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities.[8]

Article 3

- amended -

Member States shall ensure that food supplements may be marketed within the Community only if they comply with the rules laid down in this Directive.

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6 Compromise proposal by the Presidency (see Part II of the report).

7 E maintained a reservation on the deletion of the reference to the Annex, which the Commission proposal had contained.

8 DK was opposed to these modifications, which in its view did not cover the use of some products (such as, for instance, sprays…). F preferred "ingested" to "taken".

Article 4
- amended -

1. As regards vitamins and minerals, only those listed in Annex I, in the forms listed in Annex II, may be used for the manufacture of food supplements, subject to paragraph 6.

2. The purity criteria for substances listed in Annex II shall be adopted in accordance with the procedure referred to in Article 13(2), except where they apply pursuant to paragraph 3.

3. Purity criteria for substances listed in Annex II, specified by Community legislation for their use in the manufacture of foodstuffs for purposes other than those covered by this Directive, shall apply [9].

4. For those substances listed in Annex II for which purity criteria are not specified by Community legislation, and until the adoption of such specifications, generally acceptable purity criteria recommended by international bodies shall be applicable and national rules setting stricter purity criteria may be maintained.

5. Modifications to the lists referred to in paragraph 1 shall be adopted in accordance with the procedure referred to in Article 13(2).

6. [10] By way of derogation from paragraph 1 and for seven years from the date of entry into force of this Directive, Member States may allow in their territory the use of vitamins and minerals not listed in Annex I, or in forms not listed in Annex II, provided that:

   (a) the substance in question is used in one or more food supplements marketed in the Community on the date of entry into force of this Directive,

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[9] E would like a reference to the European Pharmacopoeia, which would also apply to paragraph 4.

[10] E maintained a specific reservation on paragraphs 6 and 7.

(b) the Scientific Committee for Food has not given an unfavourable opinion in respect of the use of that substance, or its use in that form, in the manufacture of food supplements, on the basis of a dossier supporting use of the substance in question to be submitted to the Commission by the Member State not later than 18 months after the date of entry into force of this Directive.

7. Notwithstanding paragraph 6, Member States may, in compliance with the rules of the Treaty, continue to apply existing national restrictions or bans on trade in food supplements containing vitamins and minerals not included in the list in Annex I or in the forms not listed in Annex II.

8. Within five years [11] of the date of entry into force of this Directive, 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 [12] other than those referred to in the first paragraph of this Article, accompanied by any proposals for amendment to this Directive which the Commission deems necessary.

Article 5

- amended -

1. Maximum amounts of vitamins and minerals present in food supplements per daily portion of consumption as recommended by the manufacturer shall be set taking the following into account:

(a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different consumer groups;

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[11] Presidency proposal to take account of the deadline for transposing the Directive (one year) and to meet the Commission's wishes in the matter (F would prefer four years).

[12] See Presidency compromise proposal on Article 2.

(b) intakes of vitamins and minerals from other dietary sources.

2. When setting the maximum levels referred to in paragraph 1, due account should also be taken of reference intakes of vitamins and minerals for the population [13].

3. To ensure that significant amounts of vitamins and minerals are present in food supplements, minimum amounts per daily portion of consumption as recommended by the manufacturer shall be set, as appropriate [14].

3. The maximum and minimum amounts of vitamins and minerals referred to in paragraphs 1 and 2 shall be adopted in accordance with the procedure referred to in Article 13(2).

Article 6

- amended -

1. For the purposes of Article 5(1) of Directive 2000/13/EC, the name under which products covered by this Directive are sold shall be "food supplement".

2. The labelling, presentation and advertising must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties.

3. Without prejudice to the requirements of Directive 2000/13/EC, the labelling shall bear the following mandatory particulars:

(a) the names of the categories of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances;

(b) the portion of the product recommended for daily consumption;

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[13] Presidency compromise proposal (see part II of the report).

[14] DK and E felt that minimum levels should be fixed in all cases, and requested the deletion of "as appropriate".

(c) a warning not to exceed the stated recommended daily dose;

(d) a statement to the effect that food supplements should not be used as a substitute for a diversified diet;

(e) a statement to the effect that the products should be stored out of the reach of young children.

[15]

Article 7

- amended -

The labelling, presentation and advertising of food supplements shall not include any mention stating or implying that a balanced and diversified diet cannot provide appropriate quantities of nutrients in general.

Rules for implementing this Article may be specified in accordance with the procedure referred to in Article 13(2).

Article 8

- amended -

1. The amount of the nutrients or substances with a nutritional or physiological effect [16] present in the product shall be declared on the labelling in numerical form. The units to be used for vitamins and minerals shall be those specified in Annex I.

   Rules for implementing this paragraph may be specified in accordance with the procedure referred to in Article 13(2).

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[15] Some delegations continued to request the addition of other mandatory labelling particulars:
– "not to be given to children under 10 years" and "has not been tested as a medicinal product" and " misuse of these products may imply negative consequences to the consumer's health" (E)
– "may be taken by pregnant women or infants under 12 months old only after consultating a doctor or health visitor" (DK supported by E).

[16] See Presidency compromise on Article 2.

2. The amounts of the nutrients or other substances declared shall be those per portion of the product as recommended for daily consumption on the labelling.

3. Information on vitamins and minerals shall also be expressed as a percentage of the reference values mentioned, as the case may be, in the Annex to Directive 90/496/EEC.

Article 9 [17]

- amended -

1. The declared values mentioned in Article 8(1) and (2) shall be average values based on the manufacturer's analysis of the product.

   Further rules for implementing this paragraph with regard in particular to the differences between the declared values and those established in the course of official checks shall be decided upon in accordance with the procedure referred to in Article 13(2).

2. The percentage of the reference values for vitamins and minerals mentioned in Article 8(3) may also be given in graphical form.

   Rules for implementing this paragraph may be adopted in accordance with the procedure referred to in Article 13(2).

Article 10

- amended -

To facilitate efficient monitoring of food supplements, Member States may require the manufacturer or the person placing the product on the market in their territory to notify the competent authority of that placing on the market by forwarding it a model of the label used for the product.

[17] EL maintained a reservation as it considered good manufacturing practices are necessary and should be mentioned.

Article 11

- amended -

1. Without prejudice to Article 4(7), Member States shall not, for reasons related to their composition, manufacturing specifications, presentation or labelling, prohibit or restrict trade in products referred to in Article 1 which comply with this Directive and, where appropriate, with Community acts adopted in implementation of this Directive.

2. Without prejudice to the relevant provisions of the EC Treaty, in particular Articles 28 and 30 thereof, paragraph 1 shall not affect national provisions which are applicable in the absence of Community acts adopted in implementation of this Directive.

Article 12

1. Where a Member State, as a result of new information or of a reassessment of existing information made since this Directive or one of the implementing Community acts was adopted, has detailed grounds for establishing that a product referred to in Article 1 endangers human health though it complies with those provisions, that Member State may temporarily suspend or restrict application of the provisions in question within its territory. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision.

2. The Commission shall examine as soon as possible the grounds adduced by the Member State concerned and shall consult the Member States within the Standing Committee for Foodstuffs, and shall then deliver its opinion without delay and take appropriate measures.

1. If the Commission considers that amendments to this Directive or to the implementing Community acts are necessary in order to remedy the difficulties mentioned in paragraph 1 and to ensure the protection of human health, it shall initiate the procedure referred to in Article 13(2) with a view to adopting those amendments. The Member State that has adopted safeguard measures may in that event retain them until the amendments have been adopted.

Article 13

- amended -

1. The Commission shall be assisted by the Standing Committee for Foodstuffs instituted by Decision 69/414/EEC * (hereinafter referred to as "the Committee").

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

   The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

3. The Committee shall adopt its rules of procedure.

Article 14

Provisions that may have an effect upon public health shall be adopted after consultation with the Scientific Committee for Food.

* OJ L 291, 19.11.1969, p. 9.

Article 15

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 May 2002. They shall forthwith inform the Commission thereof.

Those laws, regulations and administrative provisions shall be applied in such a way as to:

(a) permit trade in products complying with this Directive, from 1 June 2002 at the latest;

(b) prohibit trade in products which do not comply with the Directive, from 1 June 2004 at the latest.

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

Article 16

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

Article 17

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament *For the Council*

The President *The President*

ANNEX I

Vitamins and minerals which may be used in the manufacture of food supplements

1. Vitamins

Vitamin A (µg RE)
Vitamin D (µg)
Vitamin E (mg α-TE)
Vitamin K (µg)
Vitamin B1 (mg)
Vitamin B2 (mg)
Niacin (mg NE)
Pantothenic acid (mg)
Vitamin B6 (mg)
Folic acid (µg)
Vitamin B12 (µg)
Biotin (µg)
Vitamin C (mg)

2. Minerals

Calcium (mg)
Magnesium (mg)
Iron (mg)
Copper (µg)
Iodine (µg)
Zinc (mg)
Manganese (mg)
Sodium (mg)
Potassium (mg)
Selenium (µg)
Chromium (µg)
Molybdenum (µg)
Fluoride (mg)
Chloride (mg)
Phosphorus (mg)

ANNEX II

Vitamin and mineral substances which may be used in the manufacture of food supplements

1. Vitamins

VITAMIN A

– retinol

– retinyl acetate

– retinyl palmitate

– beta-carotene

VITAMIN D

– cholecalciferol

– ergocalciferol

VITAMIN E

– D-alpha-tocopherol

– DL-alpha-tocopherol

– D-alpha-tocopheryl acetate

– DL-alpha-tocopheryl acetate

– D-alpha-tocopheryl acid succinate

VITAMIN K

– phylloquinone (phytomenadione)

VITAMIN B1

– thiamin hydrochloride

– thiamin mononitrate

VITAMIN B2

– riboflavin

– riboflavin 5'-phosphate, sodium

NIACIN

– nicotinic acid

– nicotinamide

PANTOTHENIC ACID

– D-pantothenate, calcium

– D-pantothenate, sodium

– dexpanthenol

VITAMIN B6

– pyridoxine hydrochloride

– pyridoxine 5'-phosphate

FOLIC ACID

– pteroylmonoglutamic acid

VITAMIN B12

– cyanocobalamin

– hydroxocobalamin

BIOTIN

– D-biotin

VITAMIN C

– L-ascorbic acid

– sodium-L-ascorbate

– calcium-L-ascorbate

– potassium-L-ascorbate

– L-ascorbyl 6-palmitate

2. Minerals

calcium carbonate

calcium chloride

calcium salts of citric acid

calcium gluconate

calcium glycerophosphate

calcium lactate

calcium salts of orthophosphoric acid

calcium hydroxide

calcium oxide

magnesium acetate

magnesium carbonate

magnesium chloride

magnesium salts of citric acid

magnesium gluconate

magnesium glycerophosphate

magnesium salts of orthophosphoric acid

magnesium lactate

magnesium hydroxide

magnesium oxide

magnesium sulphate

ferrous carbonate

ferrous citrate

ferric ammonium citrate

ferrous gluconate

ferrous fumarate

ferric sodium diphosphate

ferrous lactate

ferrous sulphate

ferric diphosphate (ferric pyrophosphate)

ferric saccharate

elemental iron (carbonyl+electrolytic+hydrogen reduced)

cupric carbonate

cupric citrate

cupric gluconate

cupric sulphate

copper lysine complex

sodium iodide

sodium iodate

potassium iodide

potassium iodate

zinc acetate

zinc chloride

zinc citrate

zinc gluconate

zinc lactate

zinc oxide

zinc carbonate

zinc sulphate

manganese carbonate

manganese chloride

manganese citrate

manganese gluconate

manganese glycerophosphate

manganese sulphate

sodium bicarbonate

sodium carbonate

sodium chloride

sodium citrate

sodium gluconate

sodium lactate

sodium hydroxide

sodium salts of orthophosphoric acid

potassium bicarbonate

potassium carbonate

potassium chloride

potassium citrate

potassium gluconate

potassium glycerophosphate

potassium lactate

potassium hydroxide

potassium salts of orthophosphoric acid

sodium selenate

sodium hydrogen selenite

sodium selenite

chromium (III) chloride

chromium (III) sulphate

ammonium molybdate (molybdenum (VI))

potassium molybdate (molybdenum (VI))

potassium fluoride

sodium fluoride