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CODE OF PRACTICE ON VITAMIN A & D FORTIFICATION OF MARGARINES AND FAT SPREADS

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Preface

Margarines and fat spreads have been fortified with vitamins A and D within the European Community for over 70 years. Indeed many Member States currently require the mandatory addition of vitamin A and D to margarine and fat spreads for reasons of public health.

The recent EU (draft) Regulation on the addition of nutrients to food¹, however, only concerns the voluntary fortification to foods but excludes those products or group of products, that already have mandatory rules at a local level. Additionally Member States can in some circumstances ban the importation and marketing of foodstuffs in order to protect public health or even ask for high levels of certain vitamins on the grounds of public health. However these differing national rules on fortification with vitamin A and D and levels of fortification within the Community presents the industry with complexity. It impedes the free movement of products, creates unequal conditions of competition, and thus has a direct impact on the functioning of the internal market.

To overcome these differences IMACE has developed a Code of Practice on fortification of margarine and fat spreads with vitamins A and D, which is based on scientific risk assessment as its basic principle as outlined in the draft Regulation on addition of nutrients to foods. The Code demonstrates that fortified margarines and fat spreads can be consumed at similar intake levels within a diversified diet and will even help improve the public health situation within the European Community.

Additionally there is a general recognition within the EU Commission Green Paper on Food Law that Codes of Practice are an acceptable alternative to the traditional directives and regulations that are no longer able to satisfy the growing needs of the Single Market. Not only has the industry agreed to adhere to the principles laid down in the Code but they also will maintain industry adherence to the code through self-regulation.

Anthonie Stal
President IMACE

¹ Draft Proposal for a Regulation of the European Parliament and of the Council on the Addition of Vitamins and Minerals and of certain other substances to Foods (COM 2003 424 Final)

1. HISTORY OF FORTIFICATION OF MARGARINE AND SPREADS WITH VITAMINS A AND D

Voluntary fortification of margarine with vitamins has been practiced by manufacturers since 1925, but in 1940 with the advent of the war, certain Governments' took action to safeguard the nutritional status of the nation by making the addition of vitamin A and D compulsory. This mandatory fortification was justified in the view that margarine was being used to replace butter in the diet.

Indeed if margarine had not been fortified there was evidence that a large proportion of the population, particularly children, were at risk of deficiencies. Vitamin A and D were added at that time to equate to the levels found in butter.

Most countries in the EU no longer produce only margarine but also produce lower fat spreads as an alternative to margarine and butter. Annex 1 gives an overview of the current legislation and practices in the different Member States.

The nutritional need for fortification of margarines and fat spreads has been reviewed by a number of countries (ref UK, Finland, Netherlands²). In UK (margarine only), Belgium and Sweden mandatory fortification is still seen as crucial whereas in the UK (fat spreads) and in the Netherlands fortification is now on a voluntary basis. In the latter country, the margarine industry and retailers have signed an agreement with the government to ensure the addition of vitamin A and D to margarine and fat spreads.

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UNITED KINGDOM Department of Health (1998) Nutrition and Bone Health: with particular reference to calcium and vitamin D. Report of the Subgroup on Bone Health - Working Group on the Nutritional Status of the Population of the Committee on Medical Aspects of Food and Nutrition Policy, HMSO London. Recommendation 8

The statutory requirement to fortify margarine with vitamin D should be maintained; reduced fat spreads should also be fortified with vitamin D but providing the majority of manufacturers continue to do this on a voluntary basis there is no need for this to be a statutory requirement.

FINLAND National Nutrition Council Proposal (21.1.2001) to the Ministry of Trade and Industry concerning the vitamin D fortification of certain foodstuffs.

NETHERLANDS Health Council Opinion (12.10.1995)

2. NUTRITION REASONS FOR FORTIFICATION

As detailed in the scientific background paper

- Replacement for butter, details about limited sources of food that contain these vitamins
- Need for public health particularly vitamin D but also for vitamin A (include details on requirement, intake and status).
- Ideal carrier for fat soluble vitamins
- There is a low deviation of average intake throughout Europe
- No issues on safety since the carrier is self-limitative (no risk of over-consumption from this source)

3. APPROPRIATE LEVELS OF FORTIFICATION

This Code of Practice follows the EU Scientific Committee on Food (SCF) guidelines on the basic principles for evaluation of the adverse effects of micro-nutrients in humans and for establishing upper levels of intake of micro-nutrients which are unlikely to result in adverse effects in the general population³.

The SCF has issued opinions⁴ on the tolerable upper intake levels for vitamin A and D which have been set respectively at 3000 μg RE per day and 50 μg per day. A recent review by the SCF on reference intake levels has led to the confirmation of reference values of 800 μg vitamin A and 5 μg vitamin D⁵.

As shown in the scientific background paper 800 μg vitamin A per 100 gram end product and 7.5-10 μg vitamin D per 100 gram end product can be safely incorporated whilst being nutritionally relevant.

4. PRINCIPLES THROUGH WHICH WE WILL OPERATE

The members of IMACE will undertake to make every effort to have their national authorities recognize the Code of Practice.

³ Guidelines of the Scientific Committee on Food for the development of tolerable upper intake levels for vitamins and minerals, adopted 19 October 2000, *SCF/CS/NUT/UPPLEV/11 Final*

⁴ Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Preformed Vitamin A (retinol and retinyl esters), expressed on 26 September 2002, *SCF/CS/NU/UPPLEV/24 Final* and Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Vitamin D, expressed on 4 December 2002, *SCF/CS/NUT/UPPLEV/38 Final*

⁵ Opinion of the Scientific Committee on Food on the revision of reference values for nutrition labeling, expressed on 5 March 2003, *SCF/CS/NUT/GEN/18 Final*

Similarly, IMACE undertakes to take all the necessary measures to have the Code recognized by the EU authorities.

Should any members of IMACE wish to modify the Code of Practice they must first seek the approval of IMACE through the Council of Experts. The final approval would have to be agreed by the IMACE General Meeting.

Without prejudice to the rules laid down in the labelling directive 2000/13⁶ and Regulation 2991/94 on fat spreads⁷, members of IMACE will always apply nutrition labelling, with or without a nutrition claim. Members will follow the rules of Council Directive 90/496 on nutrition labelling for foodstuffs⁸.

Article 1 (Scope)

This Code concerns the addition of vitamin A and D to margarines and fat spreads which will be delivered as such to the ultimate consumer.

Additionally this Code will apply to substitute products as defined in article 2. Liquid cooking products and industrial products are not covered by this Code. However if and when vitamin A and D are added to liquid cooking products or industrial products this Code of Practice shall be applied.

Article 2 (Definitions)

For the purpose of this code:

- a) Margarine and fat spreads are those referred to in Council Regulation (EC) No 2991/94 including the sales descriptions defined in the Annex of this Regulation.
- b) A "substitute food" is a food which is designed to resemble a common food in appearance, texture, flavour and odour and is intended to be used as a complete or partial replacement for the food it resembles.

Article 3 (Sources)

Annex 2 of the EU Commission draft Proposal for a Regulation of the European Parliament and of the Council on the Addition of Vitamins and Minerals and of certain other substances to Foods determines the chemical substances which can be used as a source of vitamin A and D. Their form and composition will be safe and also biologically active and/or available.

⁶ Directive 2000/13/EC of the European Parliament and of the Council relating to the labelling, presentation and advertising of foodstuffs, *OJ L 109 p.29 of 6.5.2000*.

⁷ Council Regulation 2991/94/EC laying down standards for spreadable fats, *OJ L 316 p.2 of 9.12.1994*

⁸ Council Directive 90/496/EEC on nutrition labelling of foodstuffs, *OJ L 276 p.40 of 6.10.1990*

Vitamin A

Retinyl-acetate

Retinyl- palmitate

Retinol

Beta-carotene or mixed carotenes with pro-vitamin A activity

Vitamin D

Vitamin D2 (ergocalciferol)

Vitamin D3 (cholecalciferol)

Article 4 (Levels of addition)

Members of IMACE will add vitamin A and D to the products defined in Article 1 using only the sources mentioned in Article 3 to the following levels.

- Vitamin A will be added to a content of 800 μg per 100 gram end product.
- Vitamin D will be added to a content of either 7.5 or 10 μg per 100 gram end product.

Article 5 (Food labelling)

Margarines and spreads will be labelled in accordance with the general provisions of the General Labelling Directive and the specific rules laid down in Regulation 2991/94.

Article 6 (Nutrition labelling and tolerances)

Members of IMACE will ensure that the vitamins A and D content will be labelled on margarines and fat spreads as part of the nutrition panel in order to contribute to the consumer making an appropriate choice. Members will ensure that the amount present on average will not deviate more than below 80% and/or above 150% at the best before date from the amount declared.

Article 7 (Modifications to the Code)

Any modifications to this Code of Practice shall require approval by the members of IMACE in the General Meeting.

The Code will be reviewed every three years.

Article 8 (Entry into force)

From 1 January 2005 onwards members of IMACE will apply the Code.

ANNEX 1

NATIONAL LEGISLATION ON WHICH FORTIFICATION IS BASED

- Austria** Generally permitted according to the principles of the Austrian Foodstuff Law (23.1.1975) as far as the amount of the vitamins is not health damaging.
- Belgium** Arrêté royal (2.10.1980) relatif à la fabrication et à la mise dans le commerce de la margarine et des graisses comestibles. Mandatory fortification.
- Finland** Decree No.917/2002 of the Ministry of Trade (30.10.2002) on the addition of vitamins and certain other substances to foodstuffs.
- France** Decree concerning dietetic products that require a specific lipid content, Chapter IV, art. 23 (20.7.1977)
- Germany** Verordnung über vitaminisierte Lebensmittel (1.9.1942)
Diätverordnung (Verordnung über diätetische Lebensmittel)
- Hungary** Joint amended decree No. 43/2002, §12, 5 (14.5.2002) to the Hungarian Food Law
- Italy** D.L.G. (27.01.1992) No.111 on dietetic products (no specific rules on margarine fortification)
- Netherlands** Decree No.428 on fat spreads (22.9.1999). Voluntary agreement between administration and margarine industry (30.11.1999). Decree on vit.D for "senior" margarines/fat spreads (1.5.2003)
- Poland** Regulation of the Ministry of Health on nutrients added to foodstuffs and conditions of their use (Dz.U. 27, 237/2003)
- Portugal** Portaria No. 947/98 (3.11.98). Voluntary fortification.

- Sweden** National Food Administration's Regulation on enrichment of foods (SLV 1983:2 H35). Mandatory fortification of margarines/fat spreads.
- UK** Statutory Instrument 1999 No.2457 Spreadable Fats (Marketing Standards). Mandatory fortification for margarine and voluntary fortification for fat spreads.
- Turkey** Directive of the Ministry of Agriculture & Rural Affairs, No. 58/2002 (based on EU labelling legislation)