Fortification for Everyone?

The new Regulation (EC) No 1925/2006 on the Addition of Vitamins and Minerals and of certain other Substances to Foods

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Seemingly in the shade of the much debated Regulation on Claims[1] the European legislator presented food industry as well as consumers with the Regulation on the fortification of foods. The authors portray and analyse this new piece of legislation which is meant to additionally contribute to the harmonisation of European food law. Their main focus is on the essential provisions' impact on food manufacturing. Their examination of the relevant stipulations shows that – as with most recent Brussels law – the apparent quest for the smallest common denominator has left much to be desired; the regulation is somewhat ill conceived, slightly incoherent and clearly incomplete. Nevertheless, food business operators will have to find ways to cope with the binding provisions that apply from 1 July 2007. Hence the authors are highlighting the most important practical implications whilst suggesting solutions for some of the regulation's most problematic issues.

I. Introduction and current law

1. Introduction

The harmonisation of European food law has been growing ever more rapidly since 2002 when Regulation (EC) No 178/2002 laying down the general principles and requirements of food law[2] was published – the foundation of a newly conceived fully integrated, essentially science-based and purportedly coherent legal concept. The origins of this legislative approach go back to the Green Paper "General Principles of Food Law" of 1997[3] and the White Paper "On Food Safety" of 2000[4]. The latter proposed a "radically new concept" of food law and contained an Annex with an action plan of altogether 84 legislative measures. One of these measures was a Proposal for a Directive on fortified foods (Action No 61), the relevant Commission proposal was originally planned to be adopted by September 2000. Picking up the recent trend of European legislation to enact directly applicable Regulations rather than Directives requiring implementation into the laws of the Member States, the proposal of a Directive for which a first draft had been presented as early as June 2000 was changed into a proposal for a Regulation, namely for a Regulation on the addition of vitamins and minerals and certain other substances to foods, which was put forward on 10 November 2003[5]: Other than the Regulation on Claims which was extremely contested during the roughly three years of its conception, the parallel fortification draft did not stir up much noticeable criticism – allegedly because the original proposal had already been

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1 As to which cf. i.a. Loosen, ZLR 2006, 521 and Hagenmeyer, EffL 2006, 233.

2 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31/1.

3 Doc. COM (1997) 176, as to which cf. Streinz, ZLR 1998, 145.

4 Doc. COM (1999) 719, as to which cf. Horst/Mrohs, ZLR 2000, 125, 129 and Horst, ZLR 2000, 475.

5 COM(2003) 671, Proposal for a Regulation of the European Parliament and of the Council on the addition of vitamins, minerals and of certain other substances to foods..

much more of a compromise between the divergent approaches to the fortification of foods. Therefore legislators could easily slip it in after the publication of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods[6]. Two days before Bulgaria and Romania joined the European Union, precisely on 30 December 2006, Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and certain other substances to foods (hereinafter also called "Regulation on Fortification of Foods", "Regulation on Fortification" or the "Regulation") was published in the Official Journal[7]. Pursuant to its Art. 18 the Regulation entered into force already twenty days after its publication and it shall fully apply basically when this article is being published, namely from 1 July 2007.

2. Current law

Fortification was only partially harmonised in Europe before the entry into force of the new Regulation. Especially in the area of dietary foods one could observe a noteworthy codification of fortified/enriched foodstuffs. This legislative trend commenced with the so-called "Mother-Directive" 89/398/EEC on foodstuffs for particular nutritional uses[8] and its subsequently enacted "daughters" Directive 91/321/EEC on infant formulae and follow-on formulae (baby foods)[9], now replaced by Commission Directive 2006/141/EC[10], Directive 96/5/EC on processed cereal based foods and baby foods for infants and young children[11], Directive 96/8/EC on foods intended for use in energy-restricted diets for weight reduction[12] and Directive 1999/21/EC on dietary foods for special medical purposes[13], all of which contain more or less detailed provisions on the addition of vitamins and minerals to their respective food categories. The culmination point of this specific development of fortification so far was Directive 2001/15/EC on substances that may be added for specific nutritional purposes in foods for particular nutritional uses[14]. Shortly after, the legislator also paved the way for the harmonisation of food supplements by enacting Directive 2002/46/EC[15].

The last mentioned two Directives merit a brief closer look, because they can be called the "god-parents" of the Regulation on the fortification of foods. The Food Supplements Directive 2002/46/EC currently confines the scope of its authorisation to vitamins and minerals, albeit without laying down minimum or maximum levels for these nutrients, and merely envisages the inclusion of "other substances" on the list of authorised substances at a later stage. In this context Recital 6 of Directive 2002/46/EC mentions that "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 plants and herbal extracts". The Directive, however, does not make any stipulations on these ingredients, apparently because the legislators could not agree in this respect. Furthermore, Directive 2001/15/EC on the fortification of dietary foods does not only specifically allow the addition of four more categories of substances over and above vitamins and minerals, namely amino acids, carnitine and taurine, nucleotides and choline and inositol. It also contains an interesting opening clause in its Art. 1 para. 2 according to which "other" substances not covered by any of the six categories of the Directive's annex may be added to dietary foodstuffs. Since European law takes precedence over the national laws of Community Member States, these rules are applicable even where they have not been properly implemented, e.g. in Germany. Finally, the principle of free movement of goods within the Community, as entrenched in Art. 28 of the EC-Treaty, of course demands the mutual recognition of fortified foodstuffs from other Member States in areas of food law which have not yet been harmonised, provided such products do not raise any health issues[16].

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6 OJ L 404/9 of 30.12.2006, fully replaced by the corrected version in OJ L12/3 of 18.1.2007.

7 OJ L 404/26 of 30.12.2006.

8 OJ L 186/27, last amended by Regulation (EC) 1882/2003, OJ L 284/1.

9 OJ L 175/35, last amended by Directive 1999/50/EC, OJ L 139/29.

10 OJ L 401/33.

11 OJ L 49/17, last amended by Directive 2003/23/EC, OJ L 41/33.

12 OJ L 55/22, last amended by Directive 2007/29/EC, OJ L 139/22.

13 OJ L 91/29.

14 OJ L 52/19.

15 OJ L 183/52, last amended by Commission Directive 2006/37/EC, OJ L 94/32.

16 On this issue cf. Klaus, EffL 2006, 17.

II. The Regulation

1. Recitals ("Whereas")

As has become usual in recent times, Regulation (EC) No 1925/2006 is introduced by more non-binding Recitals than it comprises proper stipulations. The altogether 23 Recitals set out the legislators' motives and deliberations whilst also showing their occasional insecurity and partial inability to compromise. The most important of these Recitals shall be mentioned here: Recital 1 of the Regulation contains a hidden quotation of the above mentioned Recital 6 of Directive 2002/46/EC in the statement that "there is a wide range of nutrients and other ingredients that might be used in food manufacturing, including, but not limited to, vitamins, minerals including trace elements, amino acids, essential fatty acids, fibre as well as various plant and herbal extracts". The Regulation's most important aim is set out in its Recital 2: to regulate the addition of vitamins and minerals and the use of certain other substances which are being used, eventually resulting in "the ingestion of amounts 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". It is therefore food safety the Regulation is primarily concerned with and whether or not a substance can safely be added is the essential question and criterion for the admissibility of the addition of nutrients and other substances to foods according to the Regulation. Recital 7 admits a truth which some politicians are reluctant to concede, but which has already been mentioned once before in Recital 3 of Directive 2002/46/EC; it is the realisation that the "ideal situation" of an "adequate and varied diet" "is being achieved neither for all vitamins and minerals nor by all groups of the population across the Community" and that "foods to which vitamins and minerals have been added appear to make an appreciable contribution to the intake of these nutrients and as such may be considered to make a positive contribution to overall intakes". Additionally Recital 8 acknowledges that "some nutrient deficiencies… exist at present in the Community", that socio-economic as well as life-style changes "have led to different nutritional requirements and to changing dietary habits" and that "progress in scientific knowledge indicates that intakes of some nutrients for maintaining optimal health and well-being could be higher than those currently recommended". These insights cannot be over-emphasized when interpreting the Regulation's binding Articles! The further Recitals essentially deal with food safety aspects of fortification and the ensuing demands on consumer protection.

The core of the Regulation is made up of 18 Articles, the first two containing definitions, the next five restricting the addition of vitamins and minerals which are listed in Annexes I and II of the Regulation, and only one containing the rules on the addition of other substances to foods, however not in the form of a positive listing as for vitamins and minerals, but through restrictions and prohibitions with regard to substances still to be listed in Annex III of the Regulation. The last ten Articles then set out formal and technical matters including transitional measures. This is what the new law regulates in some detail:

2. Subject matter, scope and definitions (Art. 1 and 2)

The most interesting feature of Art. 1 is its para. 2, which limits the scope of application: "The provisions of this Regulation regarding vitamins and minerals shall not apply to food supplements". This does make sense, because – as will become clear later on – the new Regulation authorises essentially the same minerals and vitamins as Directive 2002/46/EC. Consequently a duplication of stipulations in two different legal instruments had to be avoided. However, the negative demarcation at the same time implies that the provisions of the Regulation regarding other substances, i.e. its Art. 8, is applicable to food supplements. Furthermore Art. 1 para. 3 makes it clear that subsisting European law on foods for particular nutritional uses shall not be prejudiced by the Regulation especially with respect to their "compositional requirements". The same holds true for specific Community legislation on novel foods and novel food ingredients, genetically modified food, food additives and flavourings and, last but not least, authorised oenological practices and processes.

Art. 2 defines the term "other substance" as "a substance other than a vitamin or a mineral that has a nutritional or physiological effect". This definition largely corresponds with that of Art. 2 of

Directive 2002/46/EC on food supplements as well as with that of Art. 2 paras. 2 and 3 of the Claims Regulation (EC) No 1924/2006. It serves practical purposes in drawing a line between substances the legislators could agree on (nutrients) and other substances they included but did not regulate – as in the case of food supplements. Interestingly enough, what could be left for later decision and agreement here, namely the decision on safety and admissibility of other substances will surface soon in the context of the Regulation on Claims, where before 31 January 2010 a Community list of accepted health claims is to be agreed. It remains to be seen how that issue is going to be solved, whether an agreement can be achieved or whether a stepwise approach may become necessary in the context of fortification as well. As the Claims Regulation has that positive list approach for all nutrients and/or other substances, an agreement on claims valid for other substances normally is a must and could (and arguably would have to) come before any agreement on the substances in the context of the Food Supplements Directive or the Regulation on Fortification.

3. Addition of vitamins and minerals (Art. 3 to 7)

The core of the Regulation can be found in its Arts. 3, 4 and 6 which contain the essential rules on requirements for, restrictions on and conditions for the fortification of foods with vitamins and minerals. Art. 3 para. 1 confines the list of authorised vitamins and minerals to those "listed in Annex I in the forms listed in Annex II". This rule re-codifies well-chartered territory, it corresponds exactly with Art. 4 and the respective annexes of the Food Supplements Directive. Lawful fortification comprises the same vitamins and minerals that are currently allowed for the manufacture of food supplements with the exception of calcium-L-methylfolate, recently authorised pursuant to the new Directive 2006/37/EC[17]. Why this type of folate was not also included in the new Regulation is inconceivable. Over and above the vitamin forms permitted for the use in food supplements Annex II of the new Regulation merely lists one substance, namely pyridoxine dipalmitate, a Vitamin B6 compound that can also be found on the Annex of Directive 2001/15/EC. As in the case of food supplements and additives, subsisting European purity criteria apply to the nutrients in question pursuant to Art. 5 of the Regulation.

Art. 3 para. 2 then establishes additional requirements for the addition of vitamins and minerals to foods, namely

– "a deficiency of one or more vitamins and/or minerals in the population or specific population groups",
– "the potential to improve the nutritional status of the population or specific population groups and/or correct possible deficiencies in dietary intakes of vitamins and minerals due to changes in dietary habits" and
– "evolving generally accepted knowledge on the role of vitamins and minerals in nutrition and consequent effects on health".

The first requirement may well present an issue with respect to foodstuffs for particular nutritional purposes which have to be formulated in a different manner than other food, including fortified products, pursuant to Art. 1 para. 2 of Directive 89/398/EEC. A dietary supplement for pregnant women may thus arguably no longer amount to a food for particular nutritional uses, because the necessary difference can no longer be maintained by the mere addition of certain vitamins and minerals; such a product would thus have to be marketed as a food supplement in the future unless there is a marked difference in the formulation. The second criterion is the most straightforward and probably easiest to establish. A potential to improve the nutritional status through the intake of nutrients should be possible in most cases imaginable. The same would seem to be the case with regard to the correction of possible deficiencies in dietary intakes of vitamins and minerals due to changes in dietary habits. The last requirement, however, appears to be open to wide ranges of interpretation. As is well known, science is continuously evolving, but at the same time it remains unclear when scientific findings begin to be "generally" accepted; this lack of clarity may lead to a considerable amount of disputes. That vitamins an minerals need to be added in a form which is bio-available to the human body may go without saying, Art. 2 para. 2 mentions it nonetheless. Finally, whilst in the original Commission proposal Art. 3 para. 2 stipulated that "vita-

17 OJ L 94/32.

mins and minerals may be added to foods only for the purpose of restoration, nutritional equivalence of substitute foods or fortification and enrichment, Art. 3 para. 2 of the Regulation finally adopted refers "in particular" to the requirements just mentioned above, that in the original proposal were elements of the definition of fortification/enrichment. It seems clear therefore that the addition of vitamins and minerals to foods may well be justified "taking into account" other purposes and requirements, inter alia but not exclusively those mentioned in the Commission proposal, namely restoration and nutritional equivalence of substitute foods. This opening underlines that the sole purpose of the Regulation is to assure food safety and consumer protection. The "purpose" of fortification is therefore merely illustrated by, certainly not limited to the requirements according to Art. 3 para. 2, even though the potential to improve the nutritional status (as mentioned in Art. 3 para. 2 (b)), will be relevant in most cases. Art. 3 para. 3 then goes on to stipulate that modifications to the lists of vitamins and minerals in Annexes I and II shall be adopted by Comitology procedure on the basis of stakeholder consultations. The first amendment to the Regulation still under way at the time this article is published will replace the regulatory procedure now foreseen with the new regulatory procedure with scrutiny, therefore the European Parliament will be involved in the deliberations.

Art. 4 a) prohibits the fortification of unprocessed foodstuffs with vitamins and minerals, fruit, vegetables, meat, poultry and fish are mentioned in way of example. The term unprocessed should be interpreted as in Art. 2 para. 3 of Directive 95/2/EC and Art. 2 para. 11 of Directive 94/36/EC, meaning "not having undergone any treatment resulting in a substantial change in the original state of the foodstuffs". Art. 4 para. b) likewise generally bans the addition of such nutrients to alcoholic beverages (beverages containing more than 1,2 % by volume of alcohol), albeit with the exception of certain wines. This is in full harmony with Art. 4 para. 3 of the Claims Regulation which makes claims on intoxicating drinks illegal, too. Although the legislators most probably also consume such liquids, they do not wish to see them fortified or advertised towards other consumers in any health related way.

The "conditions" set out in Art. 6 are actually maximum amounts. As in the case of food supplements the European legislators have not yet agreed on such amounts, however, a first proposal or discussion paper is expected in 2007. Art. 6 para. 1 envisages proposals of maximum levels by the Commission until 19 January 2009, i.e. two years after the entry into force of the Regulation. The amounts to be laid down shall take into account two essential criteria according to Art. 6 para. 3 which are clearly copied from Art. 5 para. 1 the Food Supplements Directive: (a) upper safe levels of vitamins and minerals as established by science and (b) intakes of these nutrients from other dietary sources. Especially the latter criterion correlates with the threshold-definition in Art. 6 para. 1: maximum levels shall apply accordingly to "the total amount of vitamin or mineral present…in the food as sold", i.e. including such nutrients from other sources, e.g. vitamin C naturally present in an ingredient, or substances with nutritive capacities used as additives, e.g. alpha tocopherol (E 307) or calcium phosphate (E 341). This concept makes sense, because the consumer's body of course cannot distinguish between substances present in a foodstuff as a result of intentional fortification or for other reasons. As a consequence any manufacturer adding vitamins or minerals to a foodstuff will have to obtain an analysis of the finished product in order to assess whether the statutory maximum amounts have been observed – once these levels have been decreed.

Furthermore Art. 6 para. 4 demands – as does Art. 5 para. 2 of the Food Supplements Directive – that reference intakes of the population shall be taken into account when setting maximum amounts. And, linking the Regulation to the Claims Regulation, Art. 6 para. 5 prescribes that not only the contribution of individual products to the overall diet of the population in general or of subgroups of the population shall be taken into account, but also the nutrient profile of a product that may eventually be established until 19 January 2009 according to Art. 4 para. 1 of the Claims Regulation, only, however, when maximum amounts have been set for vitamins and minerals whose reference intakes for the population are close to the upper safe levels. Therefore, nutrient profiles will have no bearing on the addition of all those vitamins and minerals for which no maximum levels are being set in the first place, which will be the case for many vitamins and minerals where there is simply no safety issue. For the other nutrients impact and relevance of nutrient profiles remain to be seen. This may

especially concern Vitamins A and D which are known to have potential negative effects if consumed excessively, because they are not water-solvable and thus can accumulate in the human body.

Art. 7 contains additional labelling, presentation and advertising rules. There is a specific provision in Art. 7 para. 1 banning misleading claims which imply "that a balanced and varied diet cannot provide appropriate quantities of nutrients" with the possibility of a derogation by law and via Comitology. Although this rule appears almost identical to he advertising ban codified in Art. 7 of the Food Supplements Directive, the words "in general" at the very end of the sentence are missing. It is unclear whether or why fortified foodstuffs should be subject to stricter rules than supplements in this respect and it is therefore suggested that this omission is irrelevant. Art. 7 para. 1 is once again a link to the Claims Regulation that in Art. 3 d) stipulates exactly the same prohibition and, in addition, in Art. 10 para. 2 a) foresees that all foods bearing claims need to also bear "a statement indicating the importance of a varied and balanced diet and a healthy lifestyle". Certainly those reiterations would not have been necessary. Art. 7 para. 3 makes nutrition labelling compulsory for products to which vitamins and minerals have been added. This provision also appears somewhat superfluous, since it can be expected with some certainty that added vitamins and minerals will be mentioned or even "claimed" in the labelling of the product and the mentioning of added nutrients has always triggered off the compulsory nutrition information pursuant to Art. 2 para. 2 of Directive 90/496/EEC and its respective national implementations. However, the big difference Art. 7 para. 3 brings on in relation to the approach taken in the Nutrition Labelling Directive is that regardless of the nutrition claim "Big 8" nutrition labelling in accordance with Art. 4 para. 1 group 2 is mandatory when vitamins and minerals are added. That makes life easier in so far as with regard to fortified foods there will be no more question of whether 4 or 8 nutrients have to be indicated as a start, it is always 8. Certainly this is one big difference in relation to the hitherto existing situation. Finally, Art. 7 para. 4 contains yet another reference to the Claims Regulation in allowing the labelling of fortified products to "bear a statement indicating such addition under the conditions laid down in Regulation (EC) No 1924/2006". Another cross-reference that seems all but superfluous, it is at least beyond the authors' imagination what original relevance that reference may have over and above the simple message that claims may be made, however only when their conditions set out in the Claims Regulation are met. Why should this be different for fortified foods?

4. Addition of certain other substances (Art. 8)

Chapter III of the Regulation that consists of the one provision of Art. 8 foresees procedures according to which the use of substances other than vitamins and minerals, hence other substances, can be prohibited or restricted. Its scope is confined – as already envisaged by Recital 2 – by its para. 1 to additions of those other substances potentially resulting "in the ingestion of amounts . . . 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". It is not clear from this provision what type of risk this is meant to comprise or what amounts of a substance are supposed to be normally contained in a balanced and varied diet. However, in view of the Regulation's goals already mentioned in Recital 2, it has to be assumed that food safety risks is what it is all about. That view seems to be supported in the provision itself where reference is made the amounts of a substance greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet. First, this will have to include a wide range of different possibilities, since clearly consumers all over Europe feed themselves rather differently – be it for cultural or for socio-economic reasons. Secondly, and particularly for the use of the word "greatly" it is clear that only excessive fortifications, i.e. especially high concentrations of certain substances, could justify prohibitions or restrictions.

The essential mechanism of Art. 8 is codified in its para. 2. It empowers the Commission, again via Comitology and the new regulatory procedure with scrutiny, to include substances in Annex III of the Regulation. As the Commission has not had an opportunity to deal with this issue yet, Annex III is currently still empty. At a later stage it is meant to contain three lists, namely "Part A – Prohibited substances", "Part B – Restricted substances" and

"Part C – Substances under Community scrutiny". The inclusion of a substance into either Part A or Part B requires that "a harmful effect on health has been identified". Apparently depending on the degree of that harmful effect or subject to conditions to mitigate the potential harm, substances may be listed as prohibited or as restricted. In the former case their use in the manufacture of foodstuffs is completely banned, in the latter case it shall remain "allowed under the conditions specified" in Annex III – which may probably mean maximum amounts in the first place. Where the possibility of harmful effects remains scientifically uncertain, a substance shall be placed in Part C. The safety of such substances may be evidenced by any interested party pursuant to Art. 8 para. 4 by way of submitting scientific data to the European Food Safety Authority (EFSA). Implementing Rules to this Article shall be established also via Comitology. In any event the fate of such a substance under Community scrutiny must be decided within four years from its listing on Part C according to Art. 8 para. 5. It can then either be generally allowed to be used for fortification purposes or shifted to Parts A or B of the annex. Examples of substances likely to be listed in Annex III are Kava-Kava (probably in Part A) and St. John's Wort (probably in Part B).

5. General and final provisions (Art. 9-18)

Art. 9 para. 1 obliges the Commission to "establish and maintain a Community Register", similar to the one to be drawn up pursuant to Art. 20 of the Claims Regulation. This Register, which "shall be made available to the public" pursuant to Art. 9 para. 2, will comprise all essential details on fortification. According to Art. 9 para. 2 it shall list inter alia

- the vitamins and minerals from Annex I,
- their permitted formulations as mentioned in Annex II,
- maximum and minimum amounts of these nutrients "and any associated conditions" to be set down pursuant to Art. 6,
- existing national provisions on the mandatory addition of vitamins and minerals which have been notified by the relevant Member States to the Commission until 19 July 2007 in accordance with Art. 11,
- further restrictions on nutrients pursuant to Art. 4 and
- information about the substances listed in Annex III, particularly its Part C.

Clearly the Register, once complete, will be a useful practical instrument for food manufacturers wishing to fortify their products.

In the event that a Member State has "serious grounds for considering that a product endangers human health despite complying with this Regulation" it is permitted to "temporarily suspend or restrict the application of the provision in question within its territory" in accordance to Art. 13. Whilst such a stipulation may have been desirable for the protection of national consumer health, it is clearly contravening the principle of free movement of goods, endorsed not least by Art. 1 and particularly Art. 10. It can be assumed that some Member States nonetheless insisted on the inclusion of this rule and the legislators finally compromised in order not to jeopardise their Regulation as a whole.

Transitional measures are laid down in Art 17. para. 1. This provision allows Member States to prolong national rules on the fortification with vitamins and minerals not listed in Annex I or in forms not listed in Annex II until 19 January 2014 under certain conditions. Such measures are only available to substances in use for fortification purposes within the Community "on 19 January 2007", the day the Regulation entered into force", which presumably means prior to or until that time because a use on that particular date can hardly be evidenced in every perceivable case, and on the condition that there is no "unfavourable opinion" by EFSA on the substance in question on a basis of a dossier to be submitted not later than 19 January 2010. National bans of vitamins and minerals relating to nutrients of forms thereof – and again – not listed in Annexes I or II may be continued also until 19 January 2014 pursuant to para. 2. Furthermore, according to para. 3 "existing national provisions on maximum and minimum amounts of vitamins and minerals listed in Annex I added to foods and on the conditions applicable to this addition" may remain in force until the Commission adopts uniform levels in accordance with Art. 6. This may take at least until 19 January 2009 when the Commission has to submit its proposals according to Art. 6 para. 1 and eventually even longer. This provision is relevant with regard to all Member States in which such provisions on minimum and

maximum amounts exist, for example on vitamins A and D in Germany. It is however restricted to already existing provisions on minimum or maximum levels and additional conditions to fortification and does not empower Member States to enact new restrictions or conditions. An interesting question will be, whether Art. 17 para. 3 also justifies outright bans of fortification, maximum levels of zero that equal to outright bans or any other form of general restrictions, and be it in the form of a general prohibition with the option of authorisation of fortification on appeal that are not based on a case by case evaluation of the nutrient or other substance and the conditions of its addition to foods. The case-law of the ECJ in many comparable instances indicates that such general prohibitive approaches cannot be justified and would be not in "compliance with the Treaty", another prerequisite for the application of Art. 17 para. 3. Thus, specific restrictions in the form of minimum or maximum levels or restrictions of the addition of certain nutrients or other substances would seem to be covered by Art. 17 para. 3, not, however, general prohibitions that go against the spirit and approach of the Regulation that foresees restrictions only on food safety grounds and with regard to specific nutrients or other substances. This may become particularly relevant in Germany, where the relevant Federal Authorities will possibly try to insist on demanding individual applications for exemptions, and in France where fortification has traditionally been restricted to a limited scope of foodstuffs and purposes.

III. Conclusion and outlook

1. Conclusion

The Regulation on the addition of vitamins and minerals and of certain other substances to foods is the next step towards full harmonisation of European food law. As the Claims Regulation it was urgently needed as Member States' laws and practices on fortification of foodstuffs differed so much that a single market for fortified foods was all but an illusion. The Regulation is a good start, especially with regard to vitamins and minerals that are now fully harmonised as far as Annexes I and II of the Regulation go. The next big step will concern the agreement on minimum and especially maximum levels on Community level that will then eventually make the provisions of the Regulation concerning vitamins and minerals complete and equally so the harmonisation of the law in all Member States in that respect. Much more needs to be done with regard to other substances, where Annex III needs to be filled in order to equally overcome Member States' conflicting traditions. The approach to other substances, foreseeing a negative list of prohibited and/or restricted substances rather than a positive list of all other substances is both: a compromise that needed to be agreed to get the Regulation adopted, and a necessity, as it would have surely proved impossible to agree on a list of other substances that is only close to complete and concise.

2. Outlook

Much depends now on whether Commission, Member States and the European Parliament that will be involved via Comitology are willing and able to agree minimum and maximum amounts quickly, because only then will "full" harmonisation become effective, at least with regard to vitamins and minerals. Much will also depend on how Member States execute the rights and obligations conferred by Art. 17, especially para. 3, in the meantime.

The next big challenge with at least indirect effect on the Regulation and food business operators' ability to add other substances to foods will be the deliberations on the list of health claims according to Art. 13 of the Claims Regulation, as in that context all those other substances that did not need to be assessed now will have to be assessed with regard to their effectiveness for justifying health claims. Some expect that in this context much of the debate which could now be avoided will be had. The Regulation on the addition of vitamins and minerals and of other substances to foods should be referred to in that context in so far as questions concerning the safety of the substances should be transferred for scrutiny under the Regulation and not, indirectly, become a matter in the debate on the justification and acceptability of claims.