

The European regulation of food supplements and food fortification

Intended normal use – the ultimate tool in organising level playing field markets and regulations, or how to break the fairy ring around ‘other substances’

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Introduction

A ‘fairy ring’ is an open space in a forest marked by a circle of mushrooms. Fairy rings can also be found in meadows. Technically, the circle indicates the periphery of perennial underground mycelial growth. In autumn, the mycelium forms mushrooms. According to folklore, the fairy ring is a dancing place for fairies. In some other languages, the fairy ring has the more ominous name of *hexenring* or *heksenkring*, meaning ‘witches’ ring’. When things are not clear or clearly defined, ‘fairy rings’ are easily formed, because it is all too human to fill in a knowledge vacuum with thoughts, ideas and superficial conclusions. For those who don’t know how mushrooms grow, a ring of mushrooms must be the magical result of what fairies and witches brew. Things become a bit more complex when those who are schooled in botanical and other sciences still present and interpret circles of mushrooms as fairy rings.

Mushrooms and other ‘other substances’ are on the plate of the European regulators who are making efforts to organise and harmonise markets and regulate the large variety of today’s food supplement products. Understandably, their efforts are made in the interest of public safety and the free movement of goods, two principles that are finely engraved in the minds of all EU regulators. In the case of ‘other substances’ (such as mushrooms), perceiving them as fairy rings obstructs and compromises the creation of a transparent and balanced legal framework that organises markets in an EU setting.

‘Other substances’ are substances or compounds other than vitamins and minerals with a nutritional or physiological effect. They are of particular interest because,

although these ingredients are entitled to free movement throughout the entire European ‘internal market’, they are at the same time subject to national obstacles, which hinder their free movement. In addition, ‘other substances’ are ingredients that play a role in different categories of food and food products, ie in food supplements and in fortified foods. As a result, ‘other substances’ will be subjected to the European Community’s tendency to set requirements and regulations for products in these two adjacent markets. ‘Other substances’ are at the crossroads of diverging and incompatible interests and ordering systems.

Supposedly, the European Community is a geographically determined economic, social and cultural level playing field that is taking shape as a result of the application of the legal principles of equality, non-discrimination, fair competition, freedom of movement of goods and persons, unobstructed access to EU-wide markets for suppliers of goods and services and the ensuing freedom for consumers to make choices in a competitive and free market. In that vast European common internal market many sub-markets exist. These sub-markets are defined by the product(s) brought to and exchanged on these particular markets.

It is standing international regulatory and legal practice to define products by their intended normal use. Applying this practice in the markets of foods and food supplements, the European Community has created a legal framework that defines, distinguishes, regulates and organises on an EU-wide scale the conventional foods market, the food supplements market, the fortified foods market and the market for so-called ‘novel foods’. In some Member States, outmoded nationally oriented systems of organising markets in accordance with the concomitant industrial and business interests show a tendency to persist, and resist alignment with the new overriding EU-wide regulations. Fundamentally, such conflicts are the result of the incompatibility between, on the one hand,

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organising level playing field markets on the basis of products' intended normal use and, on the other hand, the cartelising constraints-oriented 'command and control' approach.

Therefore, the question needs to be raised whether the current European legal framework suffices in relation to the functioning of EU-wide markets for the various categories of food products. Our contention is that existing regulation does indeed cover all grounds relevant to the marketing of such products. This we will show by means of analogy, both from the EU and the US, and by regulatory content in the relevant policy fields. Moreover, we will show that a recent regulatory proposal in this field is inconsistent with the principles underlying the current European regulatory framework, as the proposal's effect would work as an obstacle rather than an enhancement of the internal market. Overarchingly, we will show that *intended normal use* is the only way forward in markets noted for their diversity and innovation.

Intended normal use in the EU: the way forward

Intended normal use is a remarkably simple concept that, subject to its consistent and irrevocable execution and application, can serve to regulate products and to organise and harmonise relevant markets. We suggest that intended normal use is at the core of food supplements regulation. We will focus here on 'other substances' within the field of food supplements and we will elaborate on the concept of intended normal use within that field of food supplements as a means to ground future regulation in a transparent and consistent manner.

Intended use is not a new regulatory phenomenon. Far from it. The Construction Products Directive (CPD) for instance is an example in which intended use plays a central role in regulating and organising the construction products market. In Article 2, the CPD states:²

Member States shall take all necessary measures to ensure that the products referred to in Article 1, which are intended for use in works, may be placed on the market only if they are fit for this intended use, that is to say they have such characteristics that the works in which they are to be incorporated, assembled, applied or installed, can, if properly designed and built, satisfy the essential requirements referred to in Article 3 when and where such works are subject to regulations containing such requirements.

Moreover, Article 6 of the CPD states that 'Member States shall ensure that the use of such products, for the purpose for which they were intended, shall not be impeded by rules or conditions imposed by public bodies or private

bodies acting as a public undertaking or acting as a public body on the basis of a monopoly position'. Intended use, therefore, is put forward as the prime ordering principle in the CPD.

The products to which the CPD applies, ie construction products, are defined with Initial Type-Testing (ITT). This in fact is a product-description, which forms the basis for any producer wishing to enter the market. ITT of a construction product should be in conformity with the essential requirements as defined in Annex I of the CPD: (i) mechanical resistance and stability, (ii) safety in case of fire, (iii) hygiene, health and the environment, (iv) safety in use, (v) protection against noise, (vi) energy economy and heat retention.

Returning to fortified foods and food supplements, intended normal use in terms of eg consumption levels and safety, as unambiguously clarified and presented by the manufacturer on a product's packaging and accompanying information, should be the core regulatory and market ordering principle. Depending on the ingredient(s) used, manufacturers need to make certain indications concerning a product's conditions of use as either fortified foods or food supplements. This *de facto* state of affairs has been noted by the European Food Safety Authority (EFSA) as well, when they observe in their Discussion Paper on 'botanicals' that 'this heterogeneous group of commodities ..., mainly depending on their intended uses and presentations, fall under different Community regulatory frameworks'.³

In formulating a product's intended normal use, the role of science and the history of safety that has been established as a result of long-term widespread use (tacit knowledge)⁴ are different yet complementary and need to be internalised and/or explicated by the producer, whether through experimental scientific research, literature desk-top studies, or both. We envision products' quality, purity (when applicable), consistency and stability guaranteed through GMP (good manufacturing practice) and/or other industry standards that match today's safety requirements and concerns. This is an important aspect in the safety-guarantee producers need to assess, manage and communicate. This could be defined as the ITT for food supplements and/or fortified foods.

Moreover, contrary to conventional foods (the use of which needs no explanation), individuals consciously and voluntarily choose to purchase and consume food supplements and/or fortified foods. Therefore, consumers

2 Council Directive of 21 December 1988 (89/106/EEC) on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products [1989] OJ L0106/1–19.

3 'Discussion Paper on "Botanicals and Botanical Preparations widely used as food supplements and related products: Coherent and Comprehensive Risk Assessment and Consumer Information Approaches"' (2004) European Food safety Authority, Brussels (emphasis added).

4 *Tacit* knowledge, as opposed to *codified* (usually scientific) knowledge, is part and parcel of our daily lives and is transmitted through interpersonal contact, not through schoolbooks or scientific publications. Skills and traditions that have formed in laboratories, for instance, are utilised extensively, yet are not part of the codified output, such as journal publications and books. Therefore, even scientific knowledge in the public domain needs to be found, interpreted by specialists, and reprocessed for actual use.

consciously and voluntarily expose themselves to the ingredients contained in food supplements and/or fortified foods. For that reason, individuals expect those products to be safe, and rightly so.⁵ Food supplements and fortified foods that come to market must be safe, not only in terms of the safety of the ingredients used and the ways in which they are embodied in the relevant products, but also in terms of carrying clear, simple and product-specific indications for normal use, such as recommended daily intake. Even without the present regulatory context this is a crucial requirement that food business operators and other economic parties are obliged to take seriously in view of issues of trust, liability, product safety and consumer protection. Again, assessment, management and communication by the relevant economic parties of the recommended daily intake are vital prerequisites.

Additionally, conventional compounds with a long-standing widespread use – whether within or outside the EU⁶ – could in principle be generally regarded as safe (GRAS). Tea, as an example, has been consumed for thousands of years, and it is this long record of tea consumption that makes the potentially beneficial compounds present in tea an attractive target for research and marketing.⁷

In view of a number of papers published in the last few years, it seems that intended normal use *tout court* is difficult to embed into regulation. One of the reasons for this, we believe, is the idea that regulators, despite their prerogative *not* to regulate, inevitably will succumb to the compulsion to regulate, mostly for reasons of safety and security. Nobel laureate James M Buchanan and Gordon Tullock, the two founders of the Public Choice School in economics, showed that ‘command and control’ seemed to be favoured over such things as performance standards that allow producers to choose production technologies that induce cost effective control.⁸ As this is the mindset of numerous (government funded) research institutes as well, it is of great importance concisely to review the situation in the USA, to reiterate the current state of regulatory affairs in Europe concerning in particular food supplements and ‘other substances’, to take a closer look at the issue and definitions of botanicals, and critique a recent policy proposition in the field of botanicals.

Intended use and ‘substantial equivalence’ in the USA

Turning to the principle of intended use, the Food and Drug Administration (FDA) specifically explains: ‘An article is generally a food if it is used for food ... Whether an

article is a drug, medical device, or cosmetic under the Act turns on its “intended use” ... “Intended use” is created by claims made by or on behalf of a manufacturer or distributor of the article to prospective purchasers, such as advertising, labelling, or oral statements.’⁹ In the FDA’s Guidance on the CDRH Premarket Notification Review Program, ‘intended use’ is explained as instrumental and pivotal in differentiating closely related products that require the FDA’s evaluation to establish whether those products are ‘substantially equivalent’ or ‘substantially different’.¹⁰ In other words, substantial equivalence can be established or ‘broken up’ into ‘substantial difference’ by applying intended use. This is relevant eg in the field of medical devices, where new devices (which require the FDA’s a priori pre-market approval) must be distinguished from those already marketed. In these cases, the FDA looks at various essential aspects that establish intended use, such as ‘physiological purpose, condition or disease to be treated or diagnosed, professional or lay use, parts of the body or types of tissue involved, frequency of use etc’.

Of fundamental importance, however, are the labelling and promotional materials, referred to as ‘label indications’. When comparing new devices with marketed devices, such new and existing devices are regarded as substantially equivalent, when ‘descriptive or performance information demonstrate equivalence’, provided that no ‘new types of safety or effectiveness questions’ have arisen. According to the FDA, ‘Devices which do not have the same intended use cannot be substantially equivalent’. Safety and effectiveness are the key benchmarks in this evaluation process.

Substantial equivalence ‘is not intended to be so narrow as to refer only to devices that are identical to marketed devices nor so broad as to refer to devices which are intended to be used for the same purposes as marketed products. The committee believes that the term should be construed narrowly where necessary to assure the safety and effectiveness of a device but not narrowly where differences between a new device and a marketed device do not relate to safety and effectiveness’.¹¹

The reason behind formulating the definition of ‘substantial equivalence’ as narrowly as needed and required is to provide a level playing field for manufacturers in the public interest. According to the FDA, ‘If substantial equivalence were judged too narrowly, the marketing of devices that would benefit the public would be delayed; the device industry would be unnecessarily exposed to the greater burdens of pre-market approval; new devices would not be properly classified; and new manufacturers of pre-Amendments type devices would not have marketing equity. If substantial equivalence were judged too broadly, the statutory purpose may not be served, ie, devices with

5 C Starr ‘Social benefit versus technological risk’ (1969) 165 Science 1232–38.

6 Regulation (EC) 258/97 of the European Parliament and the Council of 27 January 1997 concerning novel foods and novel ingredients [1997] OJ L43/1–7.

7 See eg D S Wheeler et al ‘The Medicinal Chemistry of Tea’ (2004) 61 Drug Dev Res 45–65.

8 J M Buchanan and G Tullock *The Calculus of Consent* (University of Michigan Press Ann Arbor 1962).

9 ‘Guidance for Industry. Botanical Drug Products’ (2004) US Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER).

10 See <http://www.fda.gov/cdrh/k863.html> (last accessed on 11 April 2007).

11 *ibid*.

new uses or those presenting new or different risks would be marketed without adequate regulatory control' (emphasis added).

Thus, by correctly applying 'intended use' to establish 'substantial equivalence' and/or 'substantial difference' products and markets can be appropriately regulated without upsetting the level playing field, ie providing equal opportunities and conditions to market entrants, such as in the interest of the public and explicitly heeding the principles of safety and efficiency.

European food law: state-of-the-art

In the European Community, food law is taking shape not only in generally but also to a large degree in a specific way. By the enactment of specific rules, which provide specific requirements for specific types of food products, the EC is defining relevant markets. The core regulation in EU food law is Regulation 178/2002/EC.¹² According to this regulation, 'food' (or 'foodstuff') means: 'any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans'. The scope of Regulation 178/2002/EC concerns 'all stages of the production, processing and distribution of food ...' and its general objective is to provide 'a high level of protection of human life and health and the protection of consumers' interests ...'. This Regulation thus sets, in the broadest of terms, general rules for all products that are brought to the food market. To that effect, the general requirements of the regulation deal with food safety, presentation, traceability and the related responsibilities of food business operators.

Directive 2002/46/EC (Food Supplements Directive – FSD), which was enacted on 10 June 2002, defines and regulates food supplements and so defines the food supplement market.¹³ According to the FSD, food supplements are defined as 'foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely 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'.

Although the FSD does not address all aspects of food supplements, it does set general legal requirements for all food supplements in Articles 6 to 9. These general requirements, focusing on the labelling and presentation of food supplements, apply to all food supplements, ie also to those supplements for which no 'specific rules'

have yet been established. The effect of setting general requirements for all food supplements is that the relevant market has been defined. The FSD notably provides:

- a positive list of vitamins and minerals which may be used for the manufacture of food supplements and a positive list of their forms (Article 4);
- a provision calling for a report from the Commission not later than 12 July 2007 '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 those referred to in paragraph 1 (*vitamins and minerals*), accompanied by any proposals for amendment to (the Directive) which the Commission deems necessary' (Article 4, paragraph 8).

Regulation 1925/2006/EC (Food Fortification Regulation – FFR), enacted on 20 December 2006,¹⁴ sets requirements for 'the addition of vitamins and minerals and of certain other substances to foods'. The subject matter and scope of the FFR are defined as harmonising '... the provisions laid down by law, regulation or administrative action in Member States which relate to the addition of vitamins and minerals and of certain other substances to foods, with the purpose of ensuring the effective functioning of the internal market, whilst providing a high level of consumer protection'.

Although the FFR does not specify a product or product category (in fact it regulates a *process*, namely adding substances to foods), its subject matter and scope make it unequivocally clear that it aims at regulating 'fortified foods'. As a result, one may in any case conclude that the FFR defines and organises the 'fortified foods market'. It notably provides:

- a positive list of vitamins and minerals which may be added to foods and a positive list of their forms (Article 3)
- certain restrictions (Article 4) and requirements (Article 6) on the addition of vitamins and minerals to foods
- restrictions applicable to the addition of substances other than vitamins and minerals (or an ingredient containing a substance other than vitamins and minerals) or its use in the manufacture of foods (Article 8).

The content of the FFR is twofold, certain provisions being specific to the addition of vitamins and minerals (Chapter II), while certain other provisions are specific to the addition of 'other substances' (Chapter III). Recital (5) of the FFR states that 'Given that detailed rules on food supplements containing vitamins and minerals have been adopted by Directive 2002/46/EC, ... provisions of this Regulation

¹² Regulation (EC) 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 [2002] OJ L31/1–24.

¹³ Directive 2002/46/EC 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 [2002] OJ L183/51–57.

¹⁴ Regulation (EC) 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods [2006] OJ L404/26–38.

regarding vitamins and minerals should not apply to food supplements'. The intent expressed in this recital is later reflected in Article 1, paragraph 2, which states that 'The provisions of this Regulation regarding vitamins and minerals shall not apply to food supplements covered by Directive 2002/46/EC'.

Prospective concerns: intersecting policies and obstructing Member States

Arguably, and as the *first* topic of this paragraph, the way the FFR was drafted could lead to the interpretation that the FFR's provisions regarding 'other substances' apply to the FSD as well. Thus, 'other substances' could become the bone of contention in a possible legal overlap between the FFR and the FSD, as these are excluded from the overlap restriction of the FFR with the FSD. This would have the effect that, since the enactment of the FFR, 'other substances' used in the food supplements market would now be subject to the same quantitative requirements that have been formulated for the use of 'other substances' in the adjacent fortified foods market. This would be no trivial matter for national authorities and food business operators but, within the framework of this article, we must necessarily restrict ourselves to only a few comments.

Prima facie, because of its stated general purpose, the FFR should not apply to situations where there cannot be any 'addition' *per se*, such as in the manufacturing of food supplements. For that reason the reach of the FFR into the sphere of the FSD could probably be challenged for the lack of a proper legal basis. Indeed, the FFR, being based on Article 95 of the Treaty establishing the European Community (harmonisation of national provisions),¹⁵ the argument could be raised that the harmonisation should be restricted, as outlined in its Recital 1, to harmonising national provisions relating to the addition of vitamins and minerals and of certain other substances to foods, recognising that the matter of the approximation of the laws of the Member States relating to food supplements has already been taken care of (albeit with its own limitations) by the FSD.

Additionally, applying the procedures of the FFR's Article 8 indistinctively to both fortified foods and food supplements could probably be challenged for breach of the principle of equality and non-discrimination, a general principle of EU law which prescribes that like things should be treated alike and unlike things should be treated differently. Food supplements are defined through their very specific purpose (to supplement a normal diet), composition (concentrated sources of certain substances, alone or in combination) and marketing conditions (dose form, measured small unit quantities). These criteria determine in the most precise manner what is the normal intended use of food supplements.

Obviously, fortified foods are a different product category. Fortified foods form part of the diet, and

therefore their normal intended use is not to supplement the diet but to be consumed as part of a fortified diet. However, because the FFR does not describe or define a product (category) and the relevant market, but certain activities (the addition to and use of ingredients as foods), the FFR creates uncertainty as to which specific market it applies to. This could work as an extra argument to challenge the FFR on grounds of lack of legal certainty. This example shows the importance of constructing regulations on the basis of products, intended normal use and markets. As soon as these are left out of the equation, legal certainty rapidly evaporates.

Secondly, European food law has set specific rules for products containing vitamins and minerals ('nutrients') by way of *positively listing* certain groups of nutrients and the specific forms of these nutrients that may be used as food supplements in addition to foods, leaving the unlisted ones out of the equation. In terms of markets, this means that vitamins and minerals added to and/or used as foods have become subject to a high and strict degree of regulation (access or exclusion, quality, quantity) in the respective fortified foods and food supplement markets. This is how EU regulators have been capable of, on the one hand, respecting and acknowledging the realities of these existing and developing markets while, on the other hand, limiting access of these essential ingredients to the relevant markets and retaining the options to modulate the permitted ones in terms of the minimum and maximum levels that may be present in fortified foods and food supplements.

Botanicals, phytonutrients, enzymes, essential fatty acids, and all other substances or compounds *not* being vitamins or minerals, are regarded as 'other substances' as far as EU food law is concerned. Products containing 'other substances' alone or in combination, which are in conformity with the definition of food supplements as provided in Articles 1 and 2 of the FSD, and which furthermore comply with the labelling and other requirements set out in that directive, are entitled to free movement within the entire European Community, in accordance with Article 11 (1) of the FSD, which provides for the free movement of food supplements in Europe.

However, invoking Article 11 (2) of the FSD, and subject to the developments and interpretations regarding the application of Article 8 of the FFR, Member States have the discretion to regulate food supplements for their territory and for any aspect that is not specifically regulated by the FSD (eg setting a positive (or negative) list of other substances, maximum levels for vitamins, minerals or other substances, subjecting marketing of products containing 'other substances' alone or in combination to a specific authorisation procedure etc).

These national measures, however, are subject to the principle of 'mutual recognition'. Such national restrictive measures can only be opposed to products that are legitimately marketed in the Member State of export under the conditions laid down in Article 30 of the Treaty establishing the European Community ('... public morality, public policy or public security; the protection of health

¹⁵ See http://europa.eu.int/eur-lex/en/treaties/dat/C_2002325EN.003301.html (last accessed on 11 April 2007).

and life of humans, animals or plants; ...').¹⁶ In simple terms, the restricting Member State must demonstrate that the product poses a serious danger to public health. In case such a prohibitive decision would give rise to a conflict, the European Court of Justice (ECJ) is the competent body that will make a decision. Under EU case law, the burden of proof is on the Member State and such decisions will always be made on a case-by-case basis. Member States may only take action against individual, single finished products, not against groups of products or ingredients.

In a judgment that concerned a situation in which Germany had refused entry of certain food supplements, the ECJ condemned the practice and explicitly stated:¹⁷

... 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 36 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 to public health.

In view of the fact that most nutrients and 'other substances' are harmless at the intended normal use levels, the chances that a Member State could successfully exercise its discretion based on the concept of risks to public health are indeed small. Obviously, as discussed above, the precautionary principle ('risks cannot be excluded') can always be invoked in these matters, by which market obstacles can be instituted.¹⁸ We shall not discuss the matter further here.

Defining markets: products are made by manufacturers

From the above it would appear that regulation and jurisprudence creates markets. Nothing is further from the truth. It seems therefore critical to reiterate the obvious: manufacturers make products and thereby create markets.

However, it is worth stipulating the obvious, because users sometimes overlook or discard the manufacturer's original intention and the ensuing use he had in mind when he conceived, developed, tested, manufactured and brought his product to market. In our view, the manufacturer's intention, as expressed in the *intended normal use* of his product, is fundamental in classifying a product. The manufacturer's viewpoint, *not* the user's or for that matter the regulator's viewpoint, must be, indeed cannot be, the guiding principle in classifying a product.

In the European Community, the defining of markets by product is a prerequisite in matters of antitrust and establishing competitiveness. According to the Commission:

In a preliminary analysis, the Commission attempts to define the product market by investigating whether product A and product B belong to the same market. It also tries to determine the geographic market by producing an overview of the breakdown of the market shares held by the parties in question and by their competitors, the prices charged and any price differentials.¹⁹

Once the product market and the geographic market have been defined, the Commission carries out a more detailed analysis based on the concept of substitutability. Firms subject to a competitive system must respect two major constraints: demand substitution and supply substitution. A market is competitive if 'customers can choose between a range of products with similar characteristics and if the supplier does not face obstacles to supplying products or services on a given market'. In our opinion, interference with the free movement of goods constitutes the creation of an *obstacle* in a market that would otherwise be competitive. On the formation of a single market, the European Commission poignantly asserts the following:²⁰

21st century Europe is indivisible from the world economy. Its prosperity has and will continue to flow from dismantling barriers and creating open markets. This openness has been made possible and facilitated by a strong regulatory framework. The single market principles remain sound. The challenge of the 21st century is to adapt the application of these principles: to secure the right regulatory framework, to ensure that markets function properly, to promote competitiveness and to respond to the dynamism and change that flows directly from Europe's engagement with the world economy. The goal of the 21st century single market is to make markets work better for the benefit of European citizens, consumers and

¹⁶ *ibid.*

¹⁷ *Commission v Germany* (2004) Case C-387/99. See <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:61999J0387:EN:HTML> (last accessed on the 11 April 2007).

¹⁸ J C Hanekamp 'The precautionary principle: a critique in the context of the EU Food Supplements Directive' (2006) 2 *Env. Liability* 43-51; J C Hanekamp and A. Bast 'Food supplements and fortified foods: the EC's patriarchal precautionary perspective on public health' (2006) 5 *Env. Liability* 181-91.

¹⁹ See <http://europa.eu/scadplus/leg/en/lvb/l26073.htm> (last accessed 11 April 2007; emphasis added).

²⁰ Commission of the European Communities (2007) 'Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions: A Single Market for Citizens' Brussels.

businesses, and to promote a more competitive and sustainable Europe. The EU has to ensure that the opening of markets and increasing competition results in fair commercial practices, so as to maximise consumers' welfare and continues to contribute to economic growth and jobs. ...

In antitrust cases, the Commission's analyses must take place on a case-by-case basis, and they must incorporate '... both the product and the geographical dimensions of the relevant market', so that they 'can be used to determine whether there are actual competitors which are capable of constraining the behaviour of the firms in question and to assess the degree of real competition on the market'. As the Commission has stated, 'The substitutability criterion enables research to be targeted on any substitute products, thus making it possible to define the relevant product market and geographic market with a greater degree of certainty'.

In the field of conventional, novel and fortified foods, and food supplements and medicines, applying the same principles to define and distinguish products and markets are of equal importance, because these products, and especially food supplements, are being used not only in their intended nutritional setting, but also in therapeutic and/or experimental ones. When a nutritionally oriented medical doctor advises a patient to take a food supplement to effectuate an improvement of that patient's physical or mental condition, that does not change the basic intended normal use given to that food supplement by its manufacturer. Equally, when in scientific research a food supplement is applied in dosages that far exceed those recommended for the product's intended normal use, these scientific activities cannot alter the basic intended normal use designed for and explicitly mentioned on the packaging of that product by its manufacturer. Abnormal use should not alter or replace intended normal use.

'Other substances': of mushrooms and botanicals

Regulators who are in the process of organising and harmonising European markets by imposing regulations are confronted by numerous different 'fairy rings': markets that are the result of different cultural, industrial, economic, religious, philosophical, intellectual and social backgrounds, traditions and origins. Markets are the result of the economic exchange of products and thus, in order to regulate and organise markets, it is necessary to define the products that are being exchanged on that market. This practice is not new. Numerous marketplaces in European towns and villages still carry the names of the products that were physically exchanged: Fish Market, Cattle Market, Wheat Market, and the like.

Fundamentally, it should be possible to classify products by looking at (i) what they *are* (type of product; content), (ii) what they *do* (working activity and/or function) and (iii) what they effectuate or accomplish (health, pleasure, hallucinations etc). However, in a legal framework (such as EU food law) that addresses products

that are in terms of content analogous to a large extent, yet require regulatory differentiation from the perspective of what they *do* and *effectuate*, it is essential that the same classification and definition systems are used. Otherwise, serious problems will arise, because products may end up in different legal settings, and thus will give rise to conflicts and uncertainties for and between business operators.

In this respect, by analogy with mushrooms and fairy rings, the problem is that things that *are* identical or very similar (mushrooms) can nevertheless be perceived as 'different' when looking at their effects, which are, in most cases, directly related to and following from their *intended use*. When growing in a circle, mushrooms, in folklore, seem to be intended to be used by fairies as a demarcation of their nightly playground. Those same mushrooms, when placed in baskets in the grocery section of a supermarket are obviously intended to be used as food. A mushroom in a plastic bag sold in a 'Magic Mushroom' shop is intended to be used to produce hallucinations and similar sorts of 'pleasure'. In all cases, we're dealing with mushrooms, but as products they are different because their *intended use* and effect is different. As products, they create different markets.

This might appear to be a trivial example. Indeed, a mycologist would point out that the mushrooms in the last two examples are different species of mushrooms not easily confused. However, such a remark misses the point of the example entirely. The consumer entering a supermarket in search of mushrooms to accompany his steak is in search of the well-known button mushroom *Agaricus bisporus*. He is most likely unaware of this, because the designated supermarket engenders a setting (market) for the purchase of such a mushroom. The consumer entering the 'Magic Mushroom' shop is probably considering the purchase of *Psilocybe*, because of its hallucinogenic properties. So *intended use* – food, drug – defines the type of mushroom (species) to be sold and the setting (market) in which the species can be purchased.

Things take a different turn when ingredients are embodied in product-forms that can be used for different purposes. A tablet or capsule may contain a mushroom extract, but *prima facie* it is unclear what the intended use of such a tablet is. On the one hand, the form of the product simplifies things, as it often provides a clue for the product's intended use, but when the form does not unequivocally give away the product's intended use, we are confronted with a multi-purpose problem. Not only is the intended use of the product's active ingredient unclear but the intended use of the product's form as such remains ambiguous. Even if the precise content of the capsule is clear, ie the quantity and quality of the dried or extracted mushroom of a certain species, guidance would still be required from the tablet's manufacturer regarding its intended use. How does one classify such products?

In what is taking shape as EU food law, mushrooms can end up in several sections of the legal construct. First of all, mushrooms fall within the general, overarching food law. They are foodstuffs. Secondly, mushrooms may end up in the special rules set for food supplements. In this case,

mushrooms are classified as 'other substances', meaning substances with a nutritional or physiological effect other than vitamins and minerals. Thirdly, mushrooms may end up as substances that may be added to foods. In that case, they are also referred to as 'other substances'. To complicate matters further, mushrooms may also end up in EU medicines law, as ingredients presented for medicinal purposes. The various definitions and therefore markets are therefore in the 'eye of the beholder'. This example makes clear that intended use is the defining criterion in terms of products and markets, and the concomitant policies to which the products need to conform.

The merits of consistently applying the system of intended normal use become obvious against the backdrop of the various definitions that exist in the field of plants, herbals, botanicals and the like. The American Heritage Dictionary (3rd edn) defines a 'botanical' as 'a drug, medicinal preparation or similar substance obtained from a plant or plants'. According to Integrative Medicine Resources (National Center for Complementary and Alternative Medicine, National Institutes of Health, USA) 'botanical' is a synonym for 'herb'. 'Herb' is defined as: 'A plant or plant part that is used for its flavour, scent, and/or therapeutic properties'. The Dietary Supplement Education Alliance (USA) defines 'botanical' as: 'Plant or plant-derived (includes herbs)'. Subsequently, a 'herb' is defined as 'plant or part of a plant used for medicinal, taste or aromatic purposes'. The European Food Safety Authority (EFSA) defines 'botanical materials' as: 'eg whole, fragmented or cut plants, algae, fungi, lichens'. According to the EFSA, 'botanical preparations are obtained from botanical materials by various processes (eg extraction, distillation, purification, concentration and fermentation)'.²¹

Comparing these definitions, it becomes apparent that formulating a definition of 'botanical' from the strict viewpoint of what a 'botanical' *is*, is relatively simple but at the same time meaningless; it then becomes a catch-all phrase. Indeed, practically every substance or compound that is or has been derived from a plant could, in principle, be classified as a 'botanical'. Definitions of the term 'botanical' do become meaningful when they clarify the word in terms of products and, consequently, markets. The definition of the term 'botanical' provided by the FDA in the glossary clarifies many points: 'a finished, labelled product that contains vegetable matter, which may include plant materials (a plant or plant part (eg bark, wood, leaves, stems, roots, flowers, fruits, seeds, or parts thereof) as well as exudates thereof), algae, macroscopic fungi, or combinations of these. Depending in part on its intended use, a botanical product may be a food, drug, medical device, or cosmetic'.²²

Conversely, the FDA makes clear that highly purified or chemically modified substances from botanical sources should not be regarded as botanicals. Such compounds

are usually referred to as phytonutrients.²³ However, the differentiation between botanicals and phytonutrients is not as straightforward as it looks. Carotenoids and bioflavonoids, for instance, come in many different forms, meaning that phytonutrients are not necessarily pure, single chemicals. Such pure substances should be defined as 'phytochemicals'. No matter how interesting all these definitions may be, they do not provide clues *unless* one knows the intended use of 'botanicals' and 'phytonutrients'.

Recapitulation

It seems then that EU regulators have consistently and systematically opted for regulating products and organising markets by using intended normal use as their preferred and predominant guiding principle. The EFSA has also noted this state of affairs.²⁴ We have discussed this in our articles in *Environmental Liability*²⁵ and our recent scientific review article expands on this.²⁶ Policies such as those defined in the CPD, albeit outside the field of food and food products, underline this conclusion.

Within the field of foods and food supplements, three policies determine the boundary of food supplements. We have discussed the main characteristics of these policies and summarise the main points here:

- Regulation 178/2002/EC sets out, in the broadest of terms, general rules for all products that are brought to the foods market. To that effect, the general requirements of this regulation deal with food safety, presentation, traceability and the related responsibilities of food business operators
- Directive 2002/46/EC (FSD) deals with the general requirements for all food supplements (including those supplements for which no 'specific rules' have been established yet), focusing on the labelling and presentation of food supplements
- Regulation 1925/2006/EC (FFR) sets requirements for the addition of vitamins and minerals and of certain other substances to foods.

In the US, as stated by the FDA, whether an article is a food, a drug, medical device or cosmetic turns on its intended use. The distinction is created by claims such as advertising, labelling or oral statements made by a manufacturer or distributor of the article to prospective purchasers.

Despite the consistency of 'intended use' and its level playing field-generating characteristics within and outside the EU markets, we have located a number of legal tacks

21 See n 3.

22 See note 9, emphasis added.

23 See <http://www.ars.usda.gov/Aboutus/docs.htm?docid=4142> (last accessed on 11 April 2007).

24 See n 3.

25 See n 18.

26 J C Hanekamp and A Bast 'Food Supplements and European Regulation within a Precautionary Context: A Critique and Implications for Nutritional, Toxicological and Regulatory Consistency' (2007) 47 *Crit Rev Food Sci Nutr* 267–85.

that might upset the level playing field of intended use. The precautionary principle is one such legal approach we have discussed elsewhere.²⁷ Furthermore, we have mentioned that the ambiguity of the FFR could, when considering the fact that the FFR sets specific quantitative requirements for the addition of substances to foods (Article 8), disrupt the European market for food supplements, which is regulated through the FSD. Moreover, invoking Article 11 (2) of the FSD, and subject to the developments and interpretations of Article 8 of the FFR, Member States have the discretion to regulate food supplements for their territory and for any aspect that is not specifically regulated by the FSD with reference to Article 30 of the Treaty establishing the European Community.²⁸

In the remainder of this article, we will address and comment on other obstacles which influence and upset the internal food supplement market. We will show that intended normal use is the only way out of this confusion, again, within the bounds of product safety.

Upsetting markets: of jurisprudence ...

Impeding the free movement of food supplements and/or fortified foods brought to markets in the European Community is a serious infraction not only of the principle of free movement but also of the principles of antitrust, as the Member State which raises the obstacle in an EU-wide market seriously limits the choices of customers residing in its territory.

Tactically, a Member State may try to prohibit the free movement of a food supplement and/or a fortified food in another way rather than contesting its safety. A Member State may instead claim that a product that is manufactured and presented in the country of export for the purpose of supplementing or fortifying the diet *is* in fact a medicine. This move would bring that product under the pre-market-entrance-authorisation regime of pharmaceutical registration in the prohibiting Member State. Lacking such pre-market-entrance-authorisation, such a food supplement would be deprived of its entitlement to free movement within the prohibiting Member State. In such a case, the prohibiting Member State is raising a geographical obstacle in a market that is defined as EU-wide in the relevant FSD and FFR.

Nutrients and 'other substances' such as 'botanicals' can be marketed as food, food supplements and medicines, according to the different intended normal uses designed for the products containing these ingredients. Redefining a product's intended normal *nutritional* use by claiming that it is a medicine upsets the principle of defining products and relevant markets on the basis of the products' intended normal use as designed for that product by its manufacturer. A Member State which raises an obstacle to free movement by trying to redefine a product's intended normal use as explicitly presented on the packaging of that product is in fact raising a claim that the

intended normal use designed for that product by the original manufacturer in the country of export was *abnormal* and contrary to the intended use perceived or known as *normal* in the prohibiting Member State. Such a claimant deprives food business operators, who are operating within the European legal framework set for the manufacturing and EU-wide marketing (distribution; promotion, advertising and labelling indicating intended use permissible within the legal framework) of fortified foods and food supplements, of their fundamental statutory right to do so under conditions set in EU food law.

Attempts to raise such trade barriers on the basis of arguing that normal nutritional use in the country of export is abnormal use in the prohibiting Member State have been dealt with by the ECJ. The criteria for making a distinction between food (supplements) and medicines are given in the case *Commission v Germany* (page 24). It dealt with the problem that a certain Member State prohibited the free movement of food supplements, in this case certain 'vitamin preparations', by classifying them as medicines (products subject to a priori authorisation). The prohibition was based on the argument that these products (vitamin preparations) surpassed the 3xRDA (Recommended Daily Allowance) criterion.

The ECJ rejected these practices. With regard to distinguishing food (supplements) from medicines, the court stated that:

The national authorities, acting under the control of the court, must work on a case-by-case basis, having regard to *all of their (the products, authors) characteristics*, in particular their composition, their pharmacological properties –to the extent to which they can be established in the present state of scientific knowledge– the manner in which they are used, the extent of their distribution, their familiarity to consumers and the risks which their use may entail ...²⁹

It is noteworthy that in these judicial attempts to distinguish products the ECJ does address these products' *intended normal use*, albeit in passing: 'the manner in which it [the product] is used'. Since EU food law abounds with labelling requirements and instructions correctly to inform consumers about the products' purpose and the manner in which they must be and should not be used, it must be assumed that the average consumer is capable of using products in 'the manner' that fits the intended normal use.

Another example of upsetting the European market is the Belgian pre-EU-regulation Koninklijk Besluit (Royal Decree) of 29 August 1997.³⁰ Belgium organises its

29 See n 17 (emphasis added). Similar wording can be found in the ECJ's judgment of 9 June 2005 in Joined Cases C-211/03, C-299/03 and C-316 to C-318/03. See <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62003J0211:EN:HTML> (last accessed on 11 April 2007).

30 See https://portal.health.fgov.be/pls/portal/docs/PAGE/INTERNET_PG/HOME_PAGE_MENU/VOEDSELVEILIGHEID1_MENU/VOEDINGSMIDDELEN1_MENU/SUPPLEMENTEN1_MENU/SUPPLEMENTEN1_DOCS/KB_29_08_97_PLANTEN.PDF (last accessed 11 April 2007).

27 See n 18.

28 See n 15.

'botanicals' markets by applying the criterion of dosage, separating 'botanicals' presented as medicines from 'botanicals' presented as food supplements. Some 'botanicals' may not be sold as food supplements in dosages higher than 80 per cent of the dosages found in medicines containing those same 'botanicals'. In spite of the fact that this practice is inconsistent with current EU law and case law, no one has ever challenged this Belgian system.

... science ... and beyond

Ten years after the enactment of the Belgian Koninklijk Besluit, this pre-EU-regulation system unexpectedly emerged in a scientific article with the title 'Use of Botanicals in Food Supplements'.³¹ In this article, the authors propose a model to make a science-based distinction between 'botanicals' when used for medicinal purposes and the very same 'botanicals' when used for health-promoting (nutritional) purposes. They also explore the scientific basis for the use of 'botanicals' in food supplements and for guidance on claims substantiation for botanical health products.

This approach by Coppens *et al* presupposes a problem. Apparently, the authors are of the opinion that the current and/or evolving EU regulatory framework and the ways in which this provides openings and opportunities for market-participants does not provide sufficiently adequate ways and means for industry and trade to make, at the consumer level, the differentiation between foods and medicines.

Heeding their own recognition of the impossibility to classify 'botanicals' *per se* on an *a priori* basis, the authors begin with classifying 'botanicals' in accordance with the intended normal use principle. Doing so, the article subsequently presents the entire EU legal framework in which 'other substances' such as 'botanicals' have already found their various places on the basis of their intended use. However, although the authors accurately place intended normal use at the highest level, ie at the top of the proposed decision tree, they abandon and discard this principle by introducing at a lower level the conflicting and incompatible selection criterion: that of dosage or 'therapeutic dosage'. The decision tree thus contains two squarely conflicting systems to regulate and organise markets. As such, this is a typical example of not applying the principle of intended normal use, which, when correctly applied, leaves no room for 'exit points', 'cut-off points', 'maximum and/or minimum levels' and other obstacles that concern something other than safety.

The authors devote considerable attention to the fact that intended use provides good guidance in the organisation of products and markets. However, in the final analysis, they opt for the use of the 'dosage criterion' as the key instrument to organise the 'botanicals' markets. For reasons unexplained, they favour and propose to

introduce an obsolete 'command and control' approach in EU-wide markets that meanwhile have been defined by the EU Council, Parliament and Commission by applying the principle of intended normal use. In our opinion, in a system that organises competitive European markets, the 'therapeutic dosage' criterion is a 'command and control' regulation that enforces a particular constraint in one market (foods) while allowing the adjacent market (medicines) to operate without that very same constraint.

By way of the FSD, the EU Council and Parliament have defined food supplements and the relevant market. *In this market, no products may be sold as having a therapeutic effect.* Likewise, fortified foods may not be sold as having a therapeutic effect. The 'therapeutic dosage' criterion, which applies exclusively to medicines, is therefore extraneous to the food supplement and fortified foods markets, and, when applied as a constraint, restricts expansions and entry. While industry and business that are on the 'free side' of this equation, ie in the market where the specific businesses are required to set 'therapeutic dosages' for medicines, welcome and favour this form of cartelisation, food business operators, who do work in conformity and harmony with the regulations set for the EU-wide food supplement market, all of a sudden find their legitimate products constrained by a criterion which does not and, legally speaking, cannot concern their products.

Even if it is accepted that the therapeutic dosage criterion should take precedence over intended normal use, it is still necessary to define the term 'therapeutic dosage'. After all, as the authors state and recognise, when it is impossible *a priori* to classify a specific botanical as such, the criterion that should remedy this problem should be clear and unambiguous. Unfortunately, the authors do not provide such an unequivocal definition. In fact, the authors note that for the term 'therapeutic' or 'pharmacological dosage': '... no precise definition is given in legislation. And even if there were such definitions they would not provide much further clarity from a scientific point of view'.³² Indeed, as the definition as such is meaningless, any dosage deserving the label 'therapeutic' specifically requires a disease/pathological condition at which the dosage is targeted. Defining therapeutic dosage *in vacuo* creates a non-entity. Moreover, by tagging the word 'therapeutic' to the word 'dosage', the authors self-fulfillingly yet paradoxically obfuscate the fact that in the case of substances that cannot be classified as such ('botanicals'), 'therapeutic dosage' is by definition the result of intended normal use. 'Botanicals' become food (supplements) or medicines *as a result of* an intended use decision that *preceded* dosage. *Dosage always follows intended use, not the other way around.*

31 P Coppens et al 'Use of Botanicals in Food Supplements. Regulatory Scope, Scientific Risk Assessment and Claim Substantiation' (2006) 50 *Annals of Nutr & Metab* 538–54.

32 See Coppens et al (n 31) at 540. Coppens specifically refers to the ETAF (European Training and Assessment Foundation) publication of 2002 in which pharmacological dosage (not therapeutic dosage) is a key element in the decision tree. However, in view of the intended use approach suggested in the current paper, pharmacological dosage is consistently secondary to intended use. A Bast et al 'Botanical health products, positioning and requirements for effective and safe use' (2002) 12(4) *Env Tox Pharm* 195–211.

Here, we find the perfect match between intended normal use and the claims that a manufacturer makes for its product(s), as claims help organise and *confirm* markets. Indeed, by way of Regulation 1924/2006/EC (the Health Claims Regulation – HCR),³³ the EU Council and Parliament have provided a framework that opens the possibility for food business operators to make nutritional and health claims for food supplements as well as for conventional, novel and fortified foods. Even more so, the HCR clearly marks the periphery between medicines and foods, as ‘the use of information that would ... attribute medicinal properties to food’ is prohibited. (However, ‘reduction of disease risk’ can be part of claims of certain food products, according to the HCR.) The HCR therefore is a very interesting and positive development, because, in the entire EU food law construct, it forms another important regulatory instrument in which organising markets by their products’ ‘intended normal use’ is incorporated, and because it so segregates the foods from the medicines market.

Concluding remarks

Much has been discussed in this article. We have shown that in European food markets the intended normal use approach taken by the EU Council, Parliament and the Commission to regulate and organise these markets is still under constant threat from the old ‘command and control’ perspective, in which the precautionary principle has its part to play. Buchanan and Tullock demonstrated convincingly that ‘vested interests’ of established industry has something to gain from federally-mandated (‘Public Choice’) output restrictions and other constraints. Through ‘therapeutic dosage’, a criterion that by definition belongs in the medicines market, the food market can be restricted where it could potentially compete with the medicines market, as it enforces a particular constraint in one market (foods) while allowing the adjacent market

(medicines) to operate without that very same constraint. This constraining effect is amplified when accompanied by demands for regulatory control under the flag of eg a high level of consumer protection with the aid of the precautionary principle. ‘Command and control’ regulation sets an output constraint and actually mandates methods and standards for individual economic parties to meet the constraint; this approach restricts expansions and entry.³⁴ The ‘command and control’ approach will result in cartelised, stagnant markets in which consumers are deprived of information and must consequently make uninformed choices.

We showed that the various directives and regulations dealing with food (supplements) and those dealing with medicines form, *per se*, the very distinction between foods and medicines in the sense that they define and regulate the products brought to and sold on the relevant distinct markets. As a consequence, there is no further need to set criteria for market distinction in the documents, because the documents constitute that very distinction *per se*. As a consequence, a food business operator does not require ‘decision trees’ or other templates to consider before market entry. Determining the intended normal use for a product immediately and unconditionally defines that product’s market and the concomitant legal framework.

We brought arguments to show that the intended normal use system will produce open, innovative and competitive markets in which consumers can make informed choices. We have also shown that European regulations and policies render the intended normal use approach we have set out above viable for product and market regulation in which safety for consumers can be guaranteed effectively. Separated by intended use, ‘other substances’ may well cross paths in adjacent markets, but manufacturers are sufficiently bound to subject those ‘other substances’ to the disparate requirements set out in food law on the one hand and medicine law on the other.

³³ Regulation (EC) 1924/2006 of the European Parliament and the Council of 20 December 2006 on nutrition and health claims made on foods [2006] OJ L404/9–25.

³⁴ B Yandle ‘Public Choice at the Intersection of Environmental Law and Economics’ (1999) 8 Eur J Law Econ 5–27.