



Highlighting Issues and
Developments across the
Globe in the Food, Drugs,
Medical Devices and
Cosmetics Industries

Spring 2014

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Welcome

We are pleased to provide you with the Spring edition of the Global Food, Drugs, Medical Devices and Cosmetics newsletter. As stated in our inaugural issue, this newsletter provides updates on important issues and developments across the food, drug, medical device and cosmetic industries. Because our experience spans the United States, Europe, China, Australia and Asia, we are able to bring a unique, global perspective to these issues.

This edition of the newsletter focuses on a wide range of topics including GMO free labeling in the EU; EU regulation of nanomaterials in food, cosmetics and medical devices; differentiating beverages from liquid dietary supplements in the United States; China's implementation of its new food safety laws; Australia's prohibition on genetically modified foods; and Japan's recently enacted laws concerning medical devices, device software and regenerative medicine. In addition, our featured articles seek to provide a global perspective on the regulation of medical food.

Our experience on topics that matter most to the food, drug, medical device and cosmetic industries is both broad and deep. We invite you to become more familiar with the practice by visiting our [web page](#) where you will find a wealth of knowledge and experience.

K&L Gates' global platform allows our team to offer domestic, international and multinational companies 24/7 availability and a unique position from which to advise on research, approval, registration, import, export, and, recall matters globally. We are also closely integrated with our Life Sciences and Global Government Solutions practices and related practices in the corporate, antitrust, healthcare, IP, product liability, and, policy areas so can offer multidisciplinary support throughout the product life cycle.

We hope you find this Spring edition to be interesting and informative. If you have questions about any of the articles or wish to obtain further information, please contact the authors.

Sebastián Romero Melchor and Suzan Onel

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Thirst Quencher or Meal Supplement?

U.S. FDA Provides Guidance Distinguishing Conventional Beverages from Liquid Dietary Supplements

Introduction

For years, manufacturers and distributors have wrestled with categorizing their liquid products as dietary supplements or conventional beverages. Although in the United States under the Federal Food, Drug, and Cosmetic Act (“FDCA”), both dietary supplements and conventional beverages are considered “foods,” these products are defined and regulated in different ways. Whereas a “conventional beverage” is considered a conventional food under the FDCA, a “dietary supplement” is a product that is “intended to supplement the diet” and “is not represented for use as a conventional food or as a sole item of a meal or the diet.”^[1] Even after the U.S. Food and Drug Administration (“FDA”) issued its 2009 draft guidance document, “Factors that Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods,”

the regulatory line between a liquid dietary supplement and a conventional beverage has remained blurry. Designating a product as either a liquid dietary supplement or a conventional beverage has important regulatory ramifications that can result in FDA enforcement actions if the wrong regulatory requirements are followed. Significant differences exist between how these products are regulated, including:

- **Structure/Function Claims:** Structure/function claims are those claims about the product’s effects on the structure or function of the body. Such claims are typically restricted to drug products. However, both conventional foods and dietary supplements can make certain kinds of structure/function claims because foods affect the structure and function of the body by providing nutrition to sustain life and health. Under existing policy, conventional foods are limited to structure/function claims derived from the product’s taste, aroma, or nutritive value.^[2] In contrast, dietary supplements may utilize structure/function claims addressing the “role of a nutrient or dietary ingredient intended to affect the structure or function in humans or that characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, provided that such statements are not disease

claims.”^[3] Dietary supplements’ structure/function claims may also state benefits related to a classical nutrient deficiency disease.^[4] Making claims beyond these confines leave companies at risk of FDA regulating their products as drugs. In other words, if the products’ structure/function claims state or imply that the product is “useful in treating, mitigating, curing, or diagnosing a disease,” then the claim will “cause the product to be a drug.”^[5]

- **General Labeling Requirements:** Conventional beverages and dietary supplements possess different labeling requirements. The labeling of conventional beverages requires a “Nutrition Facts” panel with information such as the amounts of calories, total fat, cholesterol, and sodium.^[6] Conventional beverages must also declare all ingredients in the ingredient statement by their common and usual names and in descending order of predominance.^[7] On the other hand, the labeling of dietary supplements requires a “Supplement Facts” panel with information on quantities of ingredients that exceed standards or that are relevant to product claims.^[8] Only ingredients not listed in the Supplement Facts panel must be listed in the dietary supplement’s ingredient statement.^[9]

- **Adverse Event Reporting Requirements:** Dietary supplements have a mandatory requirement to report serious adverse events to FDA, whereas a voluntary adverse event reporting standard applies to conventional beverages.

In January 2014, FDA issued a final guidance document, “Distinguishing Liquid Dietary Supplements from Beverages,” to provide further clarity on this issue.

^[10] Responding to “an increase in the marketing of liquid products with a wide array of ingredients and intended uses,” the 2014 final guidance updates and replaces the 2009 draft guidance with greater information to assist in determining a liquid product’s proper classification.^[11]

Differentiating Conventional Beverages from Liquid Dietary Supplements

The 2014 guidance set forth that conventional beverages and liquid dietary supplements may be distinguished by certain key factors. In most circumstances, a single factor will not be determinative and, instead, a combination of factors is necessary to determine whether a product is a conventional beverage or a dietary supplement. FDA provided the following eight factors that it will consider—and that industry should consider—when categorizing a liquid product as either a conventional beverage or a liquid dietary supplement:

1. **Labeling and advertising:**^[12] When evaluating the intended use of a product and how it is represented, FDA reviews statements and graphics on product labels, labeling, and advertising, including websites and social media. For instance, given the intended purpose of a conventional beverage to quench thirst, a product advertising its intention to “refresh” or “rehydrate” represents the product as a conventional beverage. Graphics such as symbols, vignettes, and pictorial serving suggestions can also indicate that a product is a conventional food. For example, if a label includes a picture of a liquid product being poured on a green salad, such product would be considered a salad dressing and thus a conventional food.
2. **Product name:**^[13] A product name or brand name using conventional food terms represents the product as a conventional food. For example, use of the terms “beverage,” “drink,” “water,” or “soda,” or of typical beverage names such as “orange juice,” “apple cider,” “bottled water,” “iced tea,” and “coffee” would typically represent a liquid product as a conventional food. If the term is not “associated exclusively with conventional foods,” then the term must be evaluated in the broader context with other factors to determine if it is a conventional food or

not. Interestingly, FDA considers “tea” to be a term that must be evaluated in the broader context before concluding whether the “tea” product is a dietary supplement or a conventional food.

3. **Product packaging:**^[14] FDA will also look at a product’s packaging for similarity of the packaging to that used for common beverages. Packaging characteristics to consider include the size, shape, color, and design of the container or other packaging, the volume of liquid it holds, and whether it is reclosable or designed to be consumed in a single serving. FDA takes the position that single serving consumption implicitly represents the product as a conventional beverage.
4. **Serving size and recommended daily intake:**^[15] Where a liquid product suggests through its labeled serving size and/or recommended daily intake that it is intended to provide all or a significant part of the entire daily drinking fluid intake, then the product is effectively being represented as a conventional food. FDA estimates the average total daily drinking fluid intake per person to be about 1.2 liters (1200 ml).
5. **Recommendations and directions for use:**^[16] Recommendations and Directions for Use should be evaluated for similarity to the purpose of a conventional beverage versus the



Thirst Quencher or Meal Supplement? *cont.*

purpose of a dietary supplement. For example, because beverages are intended to be sources of fluids, a product recommended as a thirst quencher would be considered a beverage. Beverages are also intended to provide nutritive value (e.g., milk or orange juice) and provide taste and aroma (e.g., hot cocoa). Conversely, a dietary supplement is intended to “supplement the diet.” Therefore, if a product had directions such as “take one tablespoon three times a day,” such directions would be consistent with a dietary supplement.

6. **Marketing practices:**^[17] FDA identified certain marketing practices that may represent a product as a conventional beverage including labeling, advertising, or other promotional activities that (a) favorably compare the product to a category of beverages, (b) market the product as an accompaniment to a meal, (c) market the product based on typical beverage criteria like taste, refreshment, and thirst-quenching ability, or (d) paying for the product to be displayed in the beverage section of retail stores. FDA, however, cautioned that these marketing practices are not necessarily determinative; for instance, dietary supplements are often recommended to be taken with food, so simply recommending that the product accompany a meal will not solely dictate the product’s category.

7. **Composition:**^[18] Although significant overlap exists between dietary supplement ingredients and conventional food ingredients, there is a subset of ingredients that can be used only in dietary supplements and not in conventional foods. An ingredient may not be used in conventional foods where the ingredient’s use (a) does not conform with a food or color additive regulation, (b) is not generally recognized as safe (“GRAS”) for its intended use in food, or (c) does not qualify for one of the exceptions to the food additive definition. Furthermore, the addition of a dietary ingredient to what otherwise would be a conventional food does not transform it into a dietary supplement. For example, the addition of a botanical such as ginkgo to a Kool-Aid punch beverage would not automatically create a “ginkgo supplement.” FDA intends to consider composition with the other factors described above. To further highlight the differences between ingredients for conventional beverages and dietary supplements, FDA concurrently issued a separate guidance addressing this issue. Although the separate guidance does not provide any new requirements, it is a key document for industry to consider when evaluating its liquid products.

8. **Other Representations:**^[20] FDA will consider other representations made by the manufacturer or distributor about the product, including those made in publicly available documents and filings with government agencies. For example, if the product is described as a type of “bottled water” or “coffee drink” in such documents, FDA would weigh that conventional beverage representation against the other above factors.

Conclusion

Industry should carefully consider the above factors when evaluating whether to describe their liquid products as dietary supplements or conventional beverages. FDA will certainly point to this guidance as it reviews liquid products being marketed in the U.S. In particular, the conventional beverage versus dietary supplement debate will be key to FDA’s increased investigation and potential regulation of caffeinated products, such as energy drinks. Failure to properly categorize a product as a conventional beverage or a liquid dietary supplement—and therefore failure to apply the correct regulatory regime—can lead to FDA enforcement actions, including import detentions and warning letters. Industry should be prepared to support their decisions. ■

By Suzan Onel and Jacqueline Chan

Citations

[1] FDCA 201(ff).

[2] Guidance for Industry: Distinguishing Liquid Dietary Supplements from Beverages (FDA Jan. 2014) (“Distinguishing LDS from Beverages Guidance”) at 8, [available here](#).

[3] 21 C.F.R. § 101.93(f).

[4] Distinguishing LDS from Beverages Guidance at 9. See also FDCA 403(r) (6) (requirements for dietary supplement classical nutrient deficiency disease claims).

[5] Distinguishing LDS from Beverages Guidance at 8.

[6] See 21 C.F.R. § 101.9.

[7] See 21 C.F.R. § 101.4.

[8] See 21 C.F.R. § 101.36.

[9] *Id.*

[10] Distinguishing LDS from Beverages Guidance. FDA’s guidance documents represent FDA’s current thinking on particular topics. Although FDA specifies that guidance documents “do[] not create or confer any rights for or on any person and do[] not operate to bind FDA or the public,” in practice, FDA largely follows its guidance documents and expects regulated entities to do so as well.

[11] *Id.* at 2.

[12] *Id.* at 2-3.

[13] *Id.* at 3.

[14] *Id.*

[15] *Id.*

[16] *Id.* at 4.

[17] *Id.*

[18] *Id.* at 4-5.

[19] See Guidance for Industry: Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements (FDA Jan. 2014), [available here](#). FDA’s purpose for issuing this guidance was to remind manufacturers and distributors of both conventional foods and dietary supplements of the applicable requirements to adding substances to their products. *Id.* at 3. FDA indicated its concerns that (1) novel substances are being added to conventional foods, potentially causing the foods to be adulterated because the substances are not GRAS for their intended use and are not being used as required in a food additive regulation and (2) some substances are being used in levels exceeding their traditional use levels or in new types of conventional foods. *Id.* at 5. The guidance laid out long-standing requirements regarding GRAS substances and food additives, and how these requirements apply to conventional foods versus dietary supplements.

[20] Distinguishing LDS from Beverages Guidance at 5.

GMO-Free Labeling of Food

The EU Moves Towards Harmonized GMO-Free Labeling of Food

The widely publicized debate around many aspects of genetically modified organisms (“GMO”) has resulted in consumers’ interest in knowing whether the foods they consume actually contain these organisms. In the absence of legislation at the EU level establishing what food products can claim to be absent from GMO, EU member states are increasingly developing national provisions regarding “GMO-free” labeling.

Given the proliferation of such national schemes across the EU, the European Commission is considering whether it is necessary to tackle this issue by developing a harmonized, single EU-wide scheme for GMO-free labeling. The purpose of EU harmonization would be to ensure equal protection for EU consumers, as well as to prevent any barriers to trade.

Compulsory GMO Labeling: “Contains GMO”

The EU enacted legislation in 2003 setting forth that foods produced from GMO must be labelled as such. This mandatory labeling obligation is meant to cover food and feed which contains, consists of or is “produced from” GMO. “Produced from” GMO is defined to mean “derived in whole or in part, from GMOs, but not containing or consisting of GMOs”. This also applies

to products derived from GMO but no longer containing GMO if there is still DNA or protein resulting from the genetic modification present in the final product.

However, the above labeling obligation does not apply to food and feed produced with a GMO. This would exclude the mandatory labeling of products from animals fed from GMO, or products manufactured with the help of GMO processing aids and carriers. In addition, any foods comprising levels below 0.9% of materials which contain, consist of, or are produced from GMO, and whose presence is adventitious or technically unavoidable (the proof of this falls on the food business operator) are also excluded from the mandatory labeling obligation.

The result of the described labeling system is somewhat paradoxical: products produced from GMOs are subject to labeling requirements, even when they do not contain any genetically modified DNA, while other products actually containing GMO material may be exempted from the rules.

Voluntary GMO Labeling: “GMO Free”

As opposed to the mandatory regime concerning what foods must be labelled as containing GMO, there are no rules at the EU level setting forth what products can claim to be free from GMO, beyond the general prohibition not to mislead consumers. EU member states have made

the most of the lack of provisions on GMO-free labeling, in order to enact their own legislation. This results in various national labeling schemes, that range from total prohibitions against labeling foods as GMO-free (Sweden, Belgium), to establishing detailed conditions (Germany, Austria, France, Netherlands, Greece, Luxembourg, Hungary, Czech Republic, South Tyrol (Austria) and Finland).

These national schemes vary in terms of the criteria that must be met in order to make GMO-free claims. For instance, in Germany and France, products of animal origin may not come from an animal fed with GMO during an established number of months before slaughter, whereas in Austria they cannot be fed with GMO from birth; Germany and France have established a threshold of 0.1% for the presence of GMO in food, whereas Austria sets this threshold at 0.9%; a logo must be borne in Germany though not in France nor in Austria; and other details differ in various jurisdictions.

The Road Ahead

The current diversification of national legislation on GMO free labeling creates an obstacle to the free market and leads to increased costs for food business operators, since a product validly labelled as GMO-free in one member state might contravene the national provisions on GMO-free labeling in another (for example, a GMO-free product containing 0.7% GMO

could be GMO-free labelled according to Austrian scheme, but not according to the German or French scheme.

Even if the possibility of a harmonized EU-wide approach appears to be gaining speed, the EU is constantly being challenged by its own member states, who believe they should have the freedom to address specific national or local aspects raised by GMO. Whether a consensus can be reached in this field in the future, will remain to be a hot topic in the EU during 2014. ■

By Sebastián Romero Melchor, Sara Aparicio Hill and Lara Skoblikov

Nutrition

Typical Values

Energy Value

per 100

180 kcal

ories

40 kcal

in

0.5 g

hydrate

9.0 g

h Sugars*

9.0 g

0.1 g

Ti



Nutrient Values on Labels

New EU Commission Guidance on Tolerances for Nutrient Values on Labels

On January 1, 2014, the EU Commission guidance document on tolerances for nutrient values declared on label (hereinafter, the “Guidance”) has entered into force. It aims at providing directions to the authorities of the member states competent for the enforcement of food law, as well as to food business operators.

The Guidance applies to most of nutrition labeling rules, including the ones relating to foodstuffs, food supplements, and to the addition of vitamins and minerals to food^[1], as well as to nutrients for which a health or nutrition claim is made. Tolerances are defined as “the acceptable differences between the nutrient values declared on the label and those established in the course of official controls.”

It should be stated at the outset that, as a general principle, the difference between the actual values for a product and the ones stated on its label should not deviate substantially, because of the risk of misleading consumers. However, the Guidance acknowledges that it is not possible for foods to always contain the exact levels of energy and nutrients mentioned on the label, due to factors such as the source of the values, the effects of processing, the storage conditions and storage time, or the stability of the nutrient.

In addition to setting forth general principles for calculation and tolerance levels, the Guidance establishes numerical tolerances for controlling the compliance of a measured value with the amounts declared on the label.

General Principles for Calculation and Tolerance Levels

The average value as a reference

The Guidance clarifies that the energy and nutrient content has to be labelled as the “average value” under the relevant legislation, based on (i) the analysis of the food carried out by the manufacturer, (ii) a calculation from the average values of the ingredients, and (iii) a calculation from generally established and accepted data.

In addition, business operators must act in good faith and ensure a high degree of accuracy. Therefore, declared values should approximate average values across multiple batches of food, and not be set at either extreme of a defined tolerance range, in order to have more attractive figures on the label.

Food safety

The Guidance takes into account situations where food safety is an issue. In those cases, the maximum amount set in the legislation (if any) takes precedence over the tolerance range. This is the case of tolerances for added vitamins and minerals to food (including food supplements); should the tolerance range around a

declared value extend above the legally maximum amount, the tolerance will only operate until that maximum level.^[2]

Compliance over shelf life

According to the Guidance, the measured values should be within the tolerance range around the declared value during the entire shelf life. Therefore, while the change in the values due to storage conditions and storage time can be tolerated, this can only be within the set tolerance range.

Considerations when measured value is outside tolerance levels

Finally, the Guidance lists the aspects which need to be taken into account, should the measured value be outside the tolerance range. The consequences might entail sanctions (warnings, enforcement notice, and fines) and depend on several factors. These include (i) the nutrient in question and its features, (ii) the extent and the nature of the deviation, (iii) the features of the product, (iv) the validity of the manufacturer’s process for establishing the declared value; (v) the self-monitoring system of the company, and (vi) the existence of any previous problems with a particular food business operator. It should be noted that manufacturers may be asked to provide input in order to justify the deviation from the tolerances.

Enforceability of the Guidance

Despite the undeniable practical relevance of the Guidance, it has no formal legal status. This means that the interpretation

of the law contained therein is not official and should a dispute arise, it will be for the European Courts to establish the correct interpretation of EU labeling legislation. Furthermore, the Commission recommends that member states adopt a “pragmatic and proportionate approach” towards the new guidance, and accepts that they provide for a smooth transition in carrying out the controls (until December 13, 2014, the date from which Regulation 1169/2011 on food information to consumers will apply).

The Guidance will be updated in the future; taking into account the experience acquired at national level and other information gathered during its application.

Citations

[1] The Guidance does not apply to tolerances around declared values for (i) vitamins and minerals added to foods when the addition is mandatory under national rules and (ii) foodstuffs intended for particular nutritional uses.

[2] Regulation (EC) No 1925/2006 of the European Parliament and of the Council of December 20, 2006 on the addition of vitamins and minerals and of certain other substances to foods and Directive 2002/46/EC of the European Parliament and of the Council of June 10, 2002 on the approximation of the laws of the Member States relating to food supplements. ■

By Sebastián Romero Melchor and
Alessandro Di Mario

Regulations on Nutrition Labeling in Japan

In June 2013, the Food Labeling Act of Japan (“New Act”) was promulgated and will become effective by June 2015. Some changes to the regulations on nutrition labeling is expected to be made under the regulations to be enacted under the New Act accordingly.

Under the current laws in Japan,

- If a company intends to put a label on food products to state a special use of the products, such as: (i) Food for Sick People, (ii) Milk Powder for Nursing Mothers, (iii) Formula Milk for Infants, and (iv) Food for People with Swallowing Problems; the company must obtain approval from the Japanese government under the Health Promotion Act of Japan.
- If a company intends to put a label on food products to state a health claim, the company must undergo certain tests which examine the scientific basis on the effectiveness and safety of the products and determine the physiological and other certain health functions and must obtain approval from the Consumer Affairs Agency.
- If a company intends to put a label on food products to state a certain function of nutrient components, the company must comply with the Nutrient Label Standard of Japan (“Standard”) and display such function and warnings provided in the Standard, but does not need to file or obtain approval or license from the government.
- A company does not need to put a nutrient declaration on food products unless the food products have a description of nutrition or health claims.

Under the regulations which will implement the New Act, it is expected that the fourth bullet point above will change and that nutrient declarations will be mandatory for all prepackaged foods (with only a few exceptions). There will also be a grace period of up to five years to prepare for such changes.

Some other amendments will be made by through implementing regulations of the New Act. These changes will unify Japanese food labeling regulations and harmonize the regulations in Japan with the regulations in other countries. Also, some changes may relax the labeling regulations on food products in Japan. Through these changes, Japan aims to revitalize the food industry in Japan.

by Max Gu



Nanomaterials and EU Regulation

Recent Developments

There have been a number of significant recent developments in EU legislation concerning the regulation of nanomaterials in food, cosmetics, and medical devices. These include the adoption of new draft legislation and guidance and the consideration by various EU public health committees of nanomaterial regulation.

Food Labeling Regulation's Definition of "Engineered Nanomaterials"

Regulation (EU) 1169/2011 ("the Food Labeling Regulation") defines "engineered nanomaterial" as:

"any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale."

Properties that are characteristic of the nanoscale include:

1. those related to the large specific surface area of the materials considered; and/or
2. specific physico-chemical properties that are different from those of the non-nanoform of the same material.

Article 18(3) of the Food Labeling Regulation requires that all ingredients present in the form of engineered nanomaterials must be clearly indicated in the list of ingredients, followed by the word "nano" in brackets.

Article 18(5) requires the European Commission (the "Commission") to adapt the definition of engineered nanomaterials according to technical and scientific progress or to definitions agreed at international level. The Commission may adopt such amending legislation itself provided that there has been no objection by the European Parliament (the "Parliament") or the Council of the EU (the "Council"), the two arms of the EU legislature.

In October 2011, the Commission adopted a non-binding Recommendation on the definition of nanomaterial, which set out a new definition taking into account the Commission Joint Research Centre's Reference Report "Considerations on a Definition of Nanomaterial for Regulatory purposes," the opinion of the Scientific Committee on Emerging and Newly Identified Health Risks ("SCENIHR") concerning the "Scientific basis for the definition of the term 'Nanomaterial'" and the definition of "nanomaterial" developed by the International Organization for Standardization.

The Recommendation defines "nanomaterial" as "a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate

or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm," with the proviso that "In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50% may be replaced by a threshold between 1 and 50%."

The Recommendation also provides that fullerenes, graphene flakes, and single-wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.

In October 2012 the Commission expressed its intent to apply the above definition of nanomaterial to EU legislation.

In December 2013 the Commission accordingly proposed a regulation amending the Food Labeling Regulation (the "Amending Regulation")¹¹ by replacing the definition of engineered nanomaterials with the following:

"any intentionally manufactured material, containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm to 100 nm."

In accordance with the Recommendation, the Amending Regulation also considered fullerenes, graphene flakes, and single-wall carbon nanotubes with one or more

external dimensions below 1 nm to be engineered nanomaterials.

However, the proposed new definition in the Food Labeling Regulation added a derogation not provided for in the Recommendation, in accordance with which food additives covered by the new definition of "engineered nanomaterials" would not be considered to be engineered nanomaterials for the purpose of the Food Labeling Regulation (and hence, would not be required to be shown on the label) if they had been included in the EU lists of permitted food additives. The Commission explains in the recitals to the Amending Regulation that indicating such food additives in the list of ingredients followed by the word "nano" in brackets may confuse consumers as it may suggest that those additives are new while in reality they have been used in foods in that form for decades. The Commission considers instead that nano-related labeling requirements relating to such additives should be addressed separately and if necessary by amending the conditions of their use in the EU lists.

In February 2014, the Parliament objected to the delegated Regulation and requested that the Commission submit a new delegated act. The Parliament considered that to exclude additives in the EU lists from the definition of engineered nanomaterials contradicted the aim of the legislation, which is to ensure that consumers are able to make informed

choices by requiring all ingredients in the form of engineered nanomaterials to be labelled, and that the Amending Regulation confuses safety issues surrounding nanomaterials with general labeling requirements for the purpose of informing consumers. The Parliament added that the Amending Regulation set a threshold for what constitutes an "engineered nanomaterial" at 50% of particles, whereas the European Food Safety Authority ("EFSA") had previously suggested the threshold should be set at 10% for food-related applications. The Parliament concluded that by setting such threshold at 50% the Commission had violated the basic aim of the legislation: to pursue a high level of protection of consumer health.

The Amending Regulation cannot enter into force now that the Parliament has objected to it. The Commission will have to submit a new proposal taking into account the Parliament's position.

Novel Food Regulation

Under EU law, "novel food" is currently defined as food and food ingredients which have not been used for human consumption to a significant degree within the EU before May 15, 1997 (i) which have a new or intentionally modified primary molecular structure; (ii) which consist of or are isolated from microorganisms, fungi, algae, or plants; (iii) which are isolated from animals, except those obtained by traditional propagating or breeding

practices and with a history of safe food use; or (iv) to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.

Such foods have been regulated since 1997 by Regulation 258/97 concerning novel foods and novel food ingredients ("the Novel Food Regulation"). To market a novel food or ingredient, companies must apply to an EU member state authority for authorization, presenting the scientific information and safety assessment report. Authorization covers conditions of use, designation of novel food or novel food ingredient, and specification and labeling requirements.

On December 18, 2013, the Commission published a proposal for a new Regulation on Novel Foods. The proposal provides for:

- a simpler, clearer and more efficient authorisation procedure for novel food that would be centralised at EU level;
- a more balanced approach to food that has not been marketed in the EU but has a history of safe use in non-EU countries; and
- protection of innovation that is supported by new scientific developments, which offers the innovator submitting an application five years exclusively before the novel food can be produced by others.



Nanomaterials and EU Regulation *cont.*

The definition of “novel food” in the Proposal includes “food containing or consisting of ‘engineered nanomaterials’ as defined by” the Food Labeling Regulation (see previous article). If this definition is included in the legislation as adopted by the Parliament and the Council (as is likely), food containing or consisting of such nanomaterials will be explicitly covered by EU novel food legislation for the first time.

If adopted, the new Regulation would be expected to enter into force in 2016.

Cosmetics Regulation Guidelines and Memorandum on Nanomaterials in Cosmetics

Regulation 1223/2009 on cosmetic products (the “Cosmetics Regulation”), which came into force on July 11, 2013, defines “nanomaterial” as “an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm”. The Cosmetics Regulation provides a mechanism for notification, labeling, and safety evaluation of cosmetic products containing nanomaterials and requires the Commission to make available a catalogue of all nanomaterials used in cosmetic products.

The Commission released guidelines on the Cosmetics Regulation in November 2013. These guidelines aim to facilitate the understanding of Annex I to the

Cosmetics Regulation, which sets out the requirements for the cosmetic product safety report which must be compiled for each cosmetic product made available on the EU market.

The guidelines explain that the particle size and distribution curve of nano-substances should be included in the section of the report headed “Physical/chemical characteristics and stability of the cosmetic product.”

Subsequently in December 2013 the Commission’s Scientific Committee on Consumer Safety (“SCCS”) released a memorandum on the main considerations in evaluating nanomaterials, entitled “Relevance, Adequacy and Quality of Data in Safety Dossiers on Nanomaterials.” The memorandum concluded that the data in a dossier in support of nanomaterial safety must be relevant to the type of nanomaterials under evaluation, sufficiently complete and of appropriate standards for adequate risk assessment of nanomaterials in cosmetic products. The SCCS referred to its previous guidance on the safety assessment of nanomaterials in cosmetic products, within which it elaborates further on the essential elements that must form part of a nanomaterial safety assessment under the Cosmetics Regulation.

The SCCS memorandum invited comments by February 17, 2014. Comments will be discussed at the SCCS’s next plenary meeting on March 27, 2014 with a view to publishing an adopted opinion.

Public Health Call on Silica (nano)

The Commission has received 172 notifications under the Cosmetics Regulation of cosmetic products (leave-on and rinse-off cosmetic products, including hair, skin, lip, face, and nail products) containing silica in nano-structured form.

The Commission has concerns on the use of silica in nano form because of the potential high exposure in many types of products and because of the potential for nanoparticles of silica to break out of the agglomerates and enter cells.

The Commission has, therefore, requested the SCCS to give its opinion on the safety of silica (nano), hydrated silica (nano), silica silylate (nano) and silica dimethyl silylate (nano) in the abovementioned categories of products, taking into account the reasonably foreseeable exposure conditions.

On February 11, 2014, the SCCS put out a public health call that will run until May 31, 2014, requesting interested parties to submit relevant information on the safety of silica in nano-structured form. This includes information on:

- cosmetic products using such ingredients and their concentration;
- differences in solubility, including for surface coated materials;
- protocols of applications;
- adverse health effects;

- results from toxicological tests with such products or ingredients contained within—including inhalation toxicity, genotoxicity/carcinogenicity/toxicokinetic studies, photocatalytic activity and phototoxic effect, or any other scientific data/publications considered relevant to assess the safety of such products.

Nanosilver in Medical Care and Cosmetic Products

In December 2013, the SCENIHR committee has the mandate of advising the Commission on emerging risks; newly identified risks; broad, complex, or multidisciplinary issues requiring comprehensive assessment; and issues not covered by other bodies (including on nanotechnologies) approved its preliminary opinion on the safety, health, and environmental effects and role in antimicrobial resistance of nanosilver. The opinion aimed to assess in particular whether nanosilver used in medical care and cosmetic products could result in additional risks and whether nanosilver used to control bacterial growth could cause resistance of micro-organisms.

SCENIHR concluded that consumers and the environment are being exposed to new sources of silver because of the widespread use of products containing silver but that more data are required to properly understand nanosilver’s risks. In particular, the bacterial response of certain other nanoparticles has been

to substantially increase the horizontal gene transfer between bacteria which is relevant for developing resistance. Therefore, nanosilver may have a similar bacterial response.

The Commission launched a public consultation on SCENIHR’s opinion, which closed on February 2, 2014. SCENIHR is expected to consider the public consultation’s results during its plenary meeting on February 26, 2014 and will decide which comments to include in its final opinion.

Nanomaterials in Food/Feed

In 2010, EFSA established the Scientific Network of Risk Assessment of Nanotechnologies in Food and Feed (the “Network”) under its strategy for cooperation between member states in relation to the regulation of nanomaterials. During its 2013 annual meeting, the Network focussed on research results from toxicological studies relevant for oral exposure to nanomaterials that occur in the food/feed chain. The Network agreed on recommendations for genotoxicity tests, the adequacy of in vitro test methods for food and feed (oral exposure) and the relevance of developing gastro-intestinal tract tests for in vitro digestibility. The Network also finalised a list of national laboratories with the equipment and know-how for analysing certain nanomaterials.

Nanomaterials Register

In February 2014, Germany’s environment agency, the Umweltbundesamt, released in English a document previously released in December 2012, which supports the creation of an EU nanomaterials register to avoid overlaps and differing obligations for persons placing nanomaterials on the market in various member states. It is suggested that such a register would be integrated with EU Regulation 1272/2008 on classification, labeling, and packaging of substances and mixtures; Regulation 1907/2006 on the registration, evaluation, authorisation and restriction of chemicals (REACH); the Novel Food Regulation; and the Cosmetics Regulation, and provide an overview of products used by consumers and in the environment that contain nanomaterials.

However, France introduced a national nanomaterials register in December 2013 and Belgium has approved a law implementing a national nanomaterials register from January 2016. Denmark also notified the Commission in November 2013 of its intention to set up a national nanomaterials register.

The Commission is currently undertaking an impact assessment on an EU nanomaterials register and is expected to decide whether to propose such a register by early 2015.



Nanomaterials and EU Regulation *cont.*

NGO Report

The non-governmental organisation Health Care Without Harm (“HCWH”) published a report entitled “Nanomedicine: new solutions or new problems?” in December 2013 on the use of nanomaterials in healthcare, including in particular nanomaterials used as dispersives in disinfectants. HCWH highlights evidence suggesting that the EU regulatory framework does not offer enough protection to human health and the environment from nanotechnology in health care because nanomaterials are new and largely untested chemicals and there is, therefore, little knowledge of how their toxicity, persistence, and bioaccumulation could affect the human body.

HCWH’s report recommends the following in relation to nanomaterials in healthcare:

- a precautionary principle should be applied to prohibit nanomaterials from being placed on the market because their benefits have not yet been fully proven;
- the current nanomaterial definition under REACH should not restrict the size threshold of nanomaterials and should require data for nanomaterials;
- nanomedicines that combine both pharmacological and mechanical functions should be regulated strictly, recognizing the risks of both intentional and unintentional releases;

- waste management legislation and guidance should be reviewed in light of the need for safe waste disposal of nanomaterials;
- the entire lifecycle of nanomedicines, including manufacture, disposal, and possible environmental impacts, must be considered; and
- patients, workers, and communities need full access to information so that they can be included in decision-making processes regarding nanomaterials regulation. This would include an EU register listing the production, import, and use of nanomaterials; compulsory labeling of all nanomedicine products; and public participation in decisions relating to the exposure of patients, workers, and communities to nanomaterials. ■

by *Vanessa Edwards and David Naidu*

Citations

[1] Amending Regulation (EU) 1363/2013 was published in error in the Official Journal on December 12, 2013, before the Parliament and Council could confirm that they had no objections. Its publication was stated to be null and void in a Corrigendum published in the Official Journal on December 19, 2013.



New Food Regulation in China

Good Momentum, Old Habits

The Emerging New Food Regulation System in China

In March 2013, the 12th NPC^[1] made a decision to create a consolidated and revamped food and drug safety agency—the China Food and Drug Administration or CFDA.

A year has passed. The past year has seen encouraging progresses in the formulation of the country’s new food regulation system, in terms of the country’s visible achievement in consolidating multiple food regulation functions into the CFDA at both national and local levels. Unsurprisingly, however, the infant CFDA has not been successful with alienating itself from the many institutional “old habits,” such as (i) propagandas in legislative documents, and (ii) lack of coordination among the regulatory authorities.

The following two featured legislative movements in 2013 offer a glimpse of how those stubborn old habits could get in the way as the country is formulating its new food regulation system:

- Proposed amendments to the current 2009 Food Safety Law led by the CFDA
- Promulgation of the long-awaited General Rules on Formula Foods for Special Medical Purposes (“FSMP Rules”) on December 26, 2013 by the National Health and Family Planning Commission (“NHFPC”), which is

being replaced by the CFDA as the country’s leading regulatory authority for the food industry.

Proposed Amendments to the 2009 Food Safety Law led by the CFDA

The public consultation^[2] on the proposed amendments to the current 2009 Food Safety Law (the “Proposed Amendments”) began on October 29, 2013 and ended on November 29, 2013.

CFDA was not expecting the public consultation to bring in substantive comments and had in fact planned to submit the Proposed Amendments through the State Council^[3] to the NPC’s standing committee (which approved the current 2009 Food Safety Law) by the end of 2013 for final review followed by promulgation in June 2014.

The Proposed Amendments did not reach the NPC by the end of 2013, however. Surprisingly, the public consultation brought in a large number of comments from different stakeholders, which require addressing before the Proposed Amendments are ready for the NPC.

The surprise was expected. Apparently, the CFDA might have been too aggressive with its first major project since its debut, and what makes it worse is that the new regulator has not done an impressive job writing its new (and good) ideas into the Proposed Amendments.

It was widely perceived that the Chinese central government was not expecting

the amendments to the current 4-year-old Food Safety Law to be surgical. This round of amendments is supposed to focus on (i) the establishment of CFDA’s leading role in the regulations of the food industry per earlier decisions by NPC and State Council, and (ii) more severe sanctions on violations. The Proposed Amendments have addressed these two aspects as follows:

Reallocation of power among the regulatory authorities

- Under the current Food Safety Law, the NHFPC (which is the legacy Ministry of Health) assumes the role of “overall coordination” regarding the regulation of the food industry. Under the Proposed Amendments, the CFDA is taking over this role. Further, the current law empowers the General Administration of Quality Supervision, Inspection and Quarantine (“AQSIQ”) to regulate the manufacture of food products and empowers the Administration of Industry and Commerce to regulate food safety issues when the food products enter into the marketplace. The Proposed Amendments are reallocating those powers to the CFDA. In addition, the Proposed Amendments specifically lists the Public Security Bureau, i.e., the police department, as a food regulator to echo the newly added or explicitly stated criminal liabilities in the Proposed Amendments.



New Food Regulation in China *cont.*

Pending the approval of the Proposed Amendments, this power reallocation is already taking place nationwide, irreversibly.

More severe punishment on violation of food laws and regulations

- The Proposed Amendments aggravate the sanctions on violations by explicitly linking certain violations to criminal liabilities, increasing the maximum fine amount, clarifying liabilities for easier regulatory enforcement, and potentially giving additional discretionary powers to the regulatory authorities. By way of example:
 - › *Criminal liability:* The Proposed Amendments explicitly state that defects in the labeling of food products could result in criminal liability when the current law is vague on that.
 - › *Increased fine:* Under the current Food Safety Law, the maximum fine amount is 10 times of the value of the non-complying food products. The Proposed Amendments increase this number to 30 times.
 - › *Clarifications on liabilities for easier regulatory enforcement:* The Proposed Amendments prohibit the use of food additive outside of the permitted scope and punish the violation with a fine up to five times of the value of the non-complying products. The current Food Safety Law is vague on the fine amount for this violation.

- › *Additional discretionary powers for the regulatory authorities:* The Proposed Amendments contain a catchall clause which is designed to punish conducts violating “all other” food safety standards or requirements by a fine up to five times of the value of the non-complying food products. Without the “all other” being qualified, this catch-all clause gives the regulators tremendous amount of discretion in the enforcement of the law.

If the Proposed Amendments had addressed only the above two aspects (reallocation of power and severe sanction), they probably would have made to the NPC in the end of 2013. But, the CFDA did way more than that in the Proposed Amendments. The Proposed Amendments also: (i) propose innovative measures, which appear more propagandistic than legally logic; and (ii) contains provisions which could potentially contradict existing regulations.

CFDA's innovations

- Before commencing with the preparation of the Proposed Amendments, the CFDA reviewed a large quantity of literature concerning food regulations and policies of other countries and jurisdictions. The CFDA has made the attempt incorporating certain good practices of such other countries and jurisdictions into the Proposed Amendments. Many of those good practices would be

evolutionary for China, but the CFDA did not appear having done an impressive job writing them into the Proposed Amendments.

The vague and propagandistic way of drafting those new measures makes them inspirational, somewhat persuasive but not feasible. Examples include:

- › *A new licensing model:* Under the current Food Safety Law, a separate license is required for each of the food manufacture, distribution, and catering service. The Proposed Amendments try to introduce a “food production and operation license” to cover all aspects of the food business. This indeed is a good effort to streamline the overly burdensome licensing requirements for businesses to start operating. Nevertheless, the Proposed Amendments went completely silent on the documentation requirements and steps to follow in order to obtain such food production and operation license.
- › *A self-regulation system:* The Proposed Amendments require food business operators to establish and reinforce their internal process in the following areas: (i) a food traceability system, (ii) dedicated food safety management personnel with specific qualifications, (iii) a training system for food business personnel, and

(iv) a self-inspection system of food safety. However, the Proposed Amendments do not provide much guidance on how to establish the system. For some aspects of the self-regulation system, the CFDA appears relying on the State Council to provide detailed guidance. (Then, the time-table becomes a moot point.) For the other aspects, the Proposed Amendments went completely silent on where business operators may find guidance to establish the system.

- › *Enhanced regulations over operators of online shopping platforms:* The Proposed Amendments, for the first time, require operators of online shopping platforms to obtain the food production and operation license as long as food products are sold on the platforms. The Proposed Amendments also hold operators of the platforms severally and jointly liable for food business operators' violations should the operators of the platforms fail to comply with the requirements under the laws and regulations. There are at least two moot points with these provisions. First, it might not even be possible for some online platform operators to obtain such food production and operation license because their business models do require them to maintain facilities for warehousing or handling food products, which are usually required for food-related

licenses. Second, it is not clear as to how far the platform operators should go to monitor the sales of foods on the platforms in order to comply with the requirements under the laws and regulations.

Potentially contradicting provisions

- *Food recall:* Under the current law, the area of food recall is regulated by the AQCIQ and the NHFPC. In fairly recent years, several important regulations in this area were promulgated by these two authorities, which are still in full effect. For example, the Provisions on Food Recall Administration promulgated by the AQSIQ on August 27, 2007 and the Provisions on the Administration of Food-safety Risk Assessment (Trial Version) promulgated by the Ministry of Health (now the NHFPC) on January 21, 2010. The Proposed Amendments shift this power to the CFDA. Before the AQSIQ and NHFPC regulations are repealed and replaced by the CFDA regulations, there are going to be competing provisions in this area of food recall in the different regulations.
- *Good manufacturing practices:* The Proposed Amendments provide that GMP of foods will be prepared by the CFDA. However, the NHFPC just issued the GMP of FSMP on December 26, 2013.
- *Advertisements of food products:* The Proposed Amendments keep the same language in the current law that

advertisements of food products shall not suggest disease prevention and medical efficacy. However, with the promulgation of the FSMP Rules on December 26, 2013 by the NHFPC, exceptions probably should be carved out from this general prohibition. Certain types of FSMP, by definition, are specific to certain diseases and medical conditions, as discussed further below. In addition, the FSMP Rules explicitly require the label of any FSMP to conspicuously display: “use under the directions of doctors or clinical nutritionists.” As such, in order to accurately describe the FSMP on the labels (which could constitute a form of advertisement), the suggestion of medical efficacy would probably be inevitable.

The FSMP Rules

On December 26, 2013, the long-awaited FSMP Rules were issued by the NHFPC, with the effective date of July 1, 2014.

The promulgation of the FSMP Rules symbolizes the country's official recognition of the new category of foods, foods for special medical purposes or FSMP, and the foreseeable establishment of a substantial new sub-sector in the country's food industry.

But, the Proposed Amendments went silent on FSMP, which indicates the lack of coordination between the CFDA and the NHFPC and probably also accounts partially for the Proposed Amendments' failure to reach the NPC in the end of 2013.



New Food Regulation in China *cont.*

Not only that this new category of foods appears significant enough to deserve mentioning in the Proposed Amendments, but more compellingly, the FSMP Rules by itself would be a mere scrap of paper.

The FSMP Rules consist primarily of technical requirements and parameters. These requirements and parameters do not provide guidance on dossier items and procedure required to register a food as FSMP. The FSMP Rules are even silent on the authority with which the registration of FSMP should take place, although most likely, the CFDA would be such authority for the registration of FSMP. Hopefully, between now and the effective date of the FSMP Rules (i.e., July 1, 2014), the CFDA will come up with additional guidance on the registration of FSMP.

Above said, the FSMP Rules have provided some useful definitions, classifications and general requirements.

According to the FSMP Rules, FSMP is defined as formula dietary foods made for the special dietary needs of certain groups of people (at the age of 1-year old or above) with feeding difficulties, disorder of digestion and absorption, metabolic disturbance and other specific diseases. The FSMP must be used under the directions of doctors and clinical nutritionists.

FSMP is divided into three sub-categories:

- Complete Nutrition Formula Dietary Foods, used as the sole nutrition source to satisfy the nutritional needs of certain targeted groups of people.

- Specific Nutrition Formula Dietary Foods, used as the sole nutrition source to satisfy the nutritional needs of certain targeted groups of people during specific disease or medical conditions.
- Partial Nutrition Formula Dietary Foods, used to satisfy partial nutritional needs of certain targeted groups of people.

The FSMP Rules also list 13 Specific Nutrition Formula Dietary Foods suitable for the groups of people with the following diseases and medical conditions:

- Diabetes
- Disease of respiratory system
- Nephropathy
- Tumour
- Hepatopathy
- Sarcopenia
- Medical conditions involving trauma, infection, surgery and stress state
- Inflammatory bowel disease
- Food protein allergy
- Intractable epilepsy
- Gastrointestinal disorder of absorption and pancreatitis
- Fatty acid metabolism anomaly
- Obesity and liposuction surgery

The FSMP Rules also require that any formula of the FSMP undergo medical and/or nutrition researches. Further, the safety and clinical application/effect of the

FSMP must be scientifically verified, which suggests that clinical trials may be required for all FSMP.

The year of 2014 will see dust continuing to settle down amongst active legislative movements. It will take a while for everything to be there, but the good momentum is there and a clearer outlook will be available in a matter of months. Businesses should monitor the development of the food regulation system closely and keep track of the pace of consolidation of food regulators in their cities of residence. It should also be expected that severe sanctions on violation are on the way.

by *Max Gu*

Citations

[1] “NPC” refers to the National People’s Congress, which is the supreme organ of state power and the ultimate legislative body of the People’s Republic of China. Each NPC is selected for a term of five years. NPC meets in session once a year.

[2] The public consultation is a process administered by the Chinese government, by which the general public, interested groups, and stakeholders are invited to submit comments on proposed new laws or proposed amendments to the existing laws.

[3] The State Council of the People’s Republic of China is also known as the Central People’s Government, which is the highest executive organ of the state power.



Australia and New Zealand Update

Revision to the Food Standards Code

The Australia and New Zealand Food Standards Code (“Code”) is a collection of standards relating to labeling, processing requirements, individual food product standards, and primary production standards.

The Code is given force of law by the Australian States and Territories and New Zealand federal law. It provides an effective operational guide for the food industry and is written in plain English. However, many of the standards in the Code were last reviewed over a decade ago and recently there has been criticism of the Code, and a push for reform. Food Standards Australia New Zealand (FSANZ) has prepared “Proposal 1025” to review the Code.

The first round of submissions on the Code review was completed in September 2013. FSANZ’s next step is to prepare a draft food regulatory measure which will be the subject of a second round of submissions in the second quarter of 2014.

GM Foods

The prohibition on GM foods is topical. The Australian and New Zealand approach to Genetically Modified Foods (“GM Foods”) is to prohibit their use entirely unless they are expressly permitted. The relevant standard under the Code is Standard 1.5.2–Food produced using Gene Technology (Standard). Division 1 of the Standard sets out the permission and conditions for the sale and use of GM Foods, and Division 2 specifies the labeling requirements.

Definition

GM Foods are defined under the Standard as food that is, or contains as an ingredient, a food produced using gene technology. “A food produced using gene technology” means a food derived or developed from an organism which has been modified by gene technology. To be classified as a GM Food, the food must also:

1. have one of the “altered characteristics” that are specifically listed in the Code; or
2. contain DNA or a protein which, as a result of the use of gene technology, is chemically different from the DNA or protein present in a similar food which has not been produced using gene technology.

An example of a GM Food is food derived from corn which has been genetically modified to be herbicide tolerant.

The definition of a GM Food does not include a food derived from an animal which has been fed GM Food. If a cow is fed GM Food, the milk it produces will not be a GM Food.

General Prohibition

A GM Food must not be sold or used as an ingredient of a food unless:

1. it is specifically listed in the schedule to the Standard; or
2. it is already regulated as a food additive or processing aid.

To be listed in the schedule the GM Food must be approved by the FSANZ. The FSANZ assesses new GM Foods on a case-by-case basis and prepares a Risk Assessment Report. In considering whether to approve a new GM Food, The Australia New Zealand

Food Authority (“ANZFA”) will look at factors such as general safety, toxicological and nutritional issues.

Labeling Requirements

If a food is a permitted GM Food, the label on the GM Food’s package must include the statement “genetically modified.”

However, the following foods are exempt from GM Food labeling requirements:

1. highly refined food where the effect of the refining process is to remove novel DNA or novel protein;
2. a processing aid or food additive, except where novel DNA or novel protein from the processing aid or additive remains in the food to which it is added;
3. flavouring present in the food in a concentration of no more than 1g per kilogram; or
4. a food, ingredient, or processing aid in which genetically modified food is unintentionally present in a quantity of no more than 10 grams per kilogram.

The current system for regulating GM Foods is not the target of review by Proposal 1025, and the FSANZ is yet to identify any safety concerns with the GM Foods it has assessed. As for the drafting concerns contained elsewhere in the Code, it is a case of “watch this space” for Australia and New Zealand food law. Hopefully, a new and improved Code will emerge in late 2014. ■

by *Murray Landis and Richard Gunningham*

Pharmaceutical Law Amendments in Japan

New Framework on Medical Device and Online Sales of OTC Drugs

In 2013, the bills to revise the current Pharmaceutical Affairs Law of Japan were approved by the Diet and will come into effect in 2014. These amendments (i) update its framework for the regulations on medical devices and software used for medical treatment, so as to speed up the approval process and to stimulate the medical device industry and, (ii) generally allow online sales of over-the-counter (OTC) drugs directly to consumers with some exceptions. For further details, please see our client alert [Japan Enacts Regenerative Medicine Law and Revisions to Pharmaceutical Affairs Law](#), issued in December 2013 and our [Global Food, Drug and Medical Device Newsletter](#), issued in Fall 2013.

Registration toward Regenerative Medicine

Japan recently introduced registration toward regenerative medicine to expedite the use of such regenerative medicine for medical purposes. First, the new Act regarding Ensuring of Safety of Regenerative Medicine Law enacted in 2013 sets out the definitions of regenerative medicine and criteria for (i) organizations that provide regenerative medicine, (ii) manufacturers of specific cell products, and (iii) cell culture processing facilities. Second, the amendment to the Pharmaceutical Affairs Law enacted in 2013 would allow faster approval on the regenerative medical products and require tighter safety measures on regenerative medicine. For further details, please see our client alert [Japan Enacts Regenerative Medicine Law and Revisions to Pharmaceutical Affairs Law](#), issued in December 2013. In addition, the new Act regarding Promotion of Proper Provision of Hematopoietic Stem Cell used for Transplantation, came into effect this January 2014. Under the new Act, an entity which intends to do arrangement service business providing hematopoietic stem cell used for transplantation is required to meet criteria set out in the Act, to get a business license and to take necessary measures to secure the safety. More details will be provided in new regulations and guidelines accordingly.

by Naoki Watanabe and Ayuko Nemoto



A photograph of several laboratory glassware items, including graduated cylinders and beakers, with orange caps, set against a red background. The glassware is slightly out of focus, showing measurement markings.

Medical Foods in the U.S.

Regulation of Medical Foods in the U.S.

In the United States, “medical foods” are a subset of foods that are regulated differently from conventional foods, dietary supplements, and drug products. The U.S. Federal Food, Drug, and Cosmetic Act (“FDCA”) defines “medical food” as “a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.”^[11] This definition was further refined by the U.S. Food and Drug Administration (“FDA”) in its nutrition labeling regulations. According to the regulations, a medical food must meet the following five criteria:

1. It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube;
2. It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or

certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone;

3. It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation;
4. It is intended to be used under medical supervision; and
5. It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.^[12]

Historically, FDA has taken the position that the statutory definition of medical foods “narrowly constrain[s]” the types of products that fit in this food category.^[13] However, this position is controversial and, over the past two decades, the product category has grown as industry has explored the opportunities and legal boundaries of the statutory and regulatory definitions. Part of the allure of the product category is that medical foods are allowed to make disease-related claims (which are prohibited for dietary supplements) and there is no premarket submission or approval requirement.

This, of course, creates regulatory tension in terms of distinguishing medical food from drug products and what diseases or conditions are appropriate for medical foods to manage.^[14]

Over the years since medical foods were first defined in 1988, FDA has provided relatively little guidance on its definition and regulation of medical food.^[15] However, in August 2013, FDA issued a draft guidance entitled, “Frequently Asked Questions About Medical Foods; Second Edition” (hereinafter “Medical Foods Revised Draft Guidance”), that potentially reflects a renewed regulatory focus on this product category.^[16] While this draft guidance largely reiterates information provided in the earlier 2007 version, it also, for the first time, provides specific examples of diseases or conditions that may or may not be appropriate for management by medical food. As such, the Medical Foods Revised Draft Guidance raises significant legal and scientific questions for both FDA and industry. In this article, we will address some of the most significant aspects of the August 2013 draft guidance, industry’s response, recent enforcement activity, and the current status of the draft guidance.

FDA’s Revised Draft Guidance Regarding Medical Foods

FDA’s 2013 Medical Foods Revised Draft Guidance is a revision to its May 2007 guidance titled “Guidance for Industry: Frequently Asked Questions About

Medical Foods.” In releasing the 2013 draft guidance, FDA stated that it intends the guidance to “provide industry with a convenient place to find answers to frequently asked questions (FAQs) about medical foods” that address “the definition of and regulations for medical foods.”^[17]

According to the revised draft guidance, FDA generally considers inborn errors of metabolism (“IEMs”) to be diseases or conditions that medical foods could be used to manage. FDA defines IEMs to include “inherited biochemical disorders in which a specific enzyme defect interferes with the normal metabolism of protein, fat, or carbohydrate. As a result of diminished or absent enzyme activity in these disorders, certain compounds accumulate in the body to toxic levels and levels of others that the body normally makes may become deficient.”^[18] As provided by FDA, specific examples of IEMs manageable by medical foods include those that require significant restriction of particular amino acids and/or total protein such as phenylketonuria, ornithine transcarbamylase deficiency, and methylmalonic acidemia, or significant modification of fatty acids/total fat such as in very long-chain acyl-CoA dehydrogenase deficiency.^[19]

In contrast, FDA indicates that pregnancy, type 1 and 2 diabetes, and diseases resulting from essential nutrient deficiencies^[10] are diseases or conditions

that generally do not meet the regulatory criteria for a medical food.^[11] FDA states that because modification of a regular diet alone can meet the needs of an individual affected by these diseases or conditions, the agency generally would not consider a product labeled and marketed for these diseases or conditions to be medical food.

The revised draft guidance also indicates that FDA considers the use of National Drug Code numbers and the “Rx only” symbol or statement on medical food to misbrand the product. In support of this position, FDA states that these terms uniquely apply to drug products. Furthermore, although a medical food must be consumed or administered enterally under the supervision of a physician, a written or oral prescription is not required for a medical food. As a result, if “Rx only” is used on a medical food, such statements would be false or misleading as applied to the product.^[12]

Lastly, the revised draft guidance reiterates that medical food, as food products, must comply with the current good manufacturing practices for foods, allergen labeling requirements, certain registration requirements, and FDA’s compliance program guidance manual. Additionally, any ingredient used in a medical food must be either an approved food additive or a GRAS ingredient.

Subsequent Industry Response

The Medical Foods Revised Draft Guidance has generated significant discussion. Various industry groups—including physicians, trade associations, law firms, and medical food manufacturers—submitted comments on the draft guidance. Many commenters disagreed with FDA’s interpretation of the diseases or conditions that may be managed by medical foods, particularly the agency’s exclusion of diabetes and other disease conditions which could be managed through the modification of normal diet. Industry response on this issue largely falls within two categories: (1) legal arguments and (2) public health arguments.

Legal arguments

From a legal standpoint, many posited that FDA’s definition of medical food in the revised draft guidance is significantly different from the plain language of the FDCA statute. Some took the position that FDA lacks the authority to alter the statutory definition of medical food by adding a requirement not found in the statute. They argued that the U.S. Congress broadly defined “medical foods” in the statute and FDA must give effect to that intent and cannot substitute its own criterion or policy.

Many commenters also asserted that FDA’s definition of medical food is inconsistent with the FDCA’s fundamental principle that regulatory product categories are based

Medical Foods in the U.S. *cont'*

on the “intended use” of the product. The “intended use” of a medical food is “for the specific dietary management of a disease or condition for which distinctive nutritional requirements . . . are established by medical evaluation.” As such, under the “intended use” principle, so long as a product is consumed or administered enterally under the supervision of a physician *and* meets this intended use, then it should be regulated as a medical food even if nonmedical food products could manage the disease or condition at issue. Industry contended that as described in the revised draft guidance, the regulatory determination for a potential medical food product turns on whether a given disease or condition can be managed by a nonmedical food product instead of on the intended use of the product.

Lastly, arguments were raised as to the constitutionality of FDA’s definition of medical food under the First Amendment (as an unlawful restriction of commercial speech) and the Fifth Amendment (because the lack of clarity in the medical food definition may subject manufacturers to civil and criminal actions without fair notice).

Public health arguments

From a public health standpoint, many commenters emphasized the importance of patient access to medical foods. Specifically, they noted that as the science of nutrition evolves, diseases

and conditions have become increasingly treatable with not just drugs, but also with medical foods. An increased use of medical foods can potentially lead to more cost-effective healthcare for patients. Some diseases and conditions require complicated dietary changes that could be better addressed with medical foods. Likewise, some diseases and conditions may require lifelong dietary restrictions for which medical foods used as meal replacements can lead to increased dietary adherence.

Finally, questions were raised as to whether the concept of dietary modification can be uniformly applied across a patient population. Although certain conditions or diseases may traditionally be treated through diet management, dietary management may not be a successful approach for all individuals. The availability of the medical food option may be crucial to some patients’ adherence to certain treatment regimens.

FDA’s Recent Enforcement Actions

Historically there has been relatively little FDA enforcement activity related to medical food products. However, between 2003–2007, FDA showed an increased interest in the category, largely due to the growth of this industry as an alternative to dietary supplements. Over the past 10 years, FDA enforcement activity against companies

marketing products as medical food has trended at one–two a year. The typical reasons FDA has asserted for finding a product characterized as a medical food to be misbranded and/or adulterated have been: (1) the disease or condition does not have distinct nutritional requirements and/or (2) the disease or condition could be managed by modification of the diet alone.

Since the issuance of the Medical Foods Revised Draft Guidance, the number of warning letters and enforcement actions appears to be increasing. When viewed in conjunction with FDA’s statements in the 2013 draft guidance, it seems FDA is preparing to draw a line in the sand. We summarize overleaf the diseases or conditions FDA questioned in the warning letters issued since August 2013 and indicate FDA’s stated reason(s) for taking the position that these products do not qualify as medical food. *See table overleaf.*

Notably, the two most–recent warning letters from December 2013 appear to pose an additional requirement; i.e., that medical foods must be “for a patient who is seriously ill or who requires use of the product as a major component of a disease or condition’s specific dietary management.” As with other aspects of FDA’s recent activity relating to medical food, the addition of this language to warning letters is highly controversial and being watched closely.

Table showing diseases or conditions FDA questioned in the warning letters

Condition/Disease	No Distinctive Nutritional Requirement	Patients Do Not Have Limited or Impaired Capacity to Ingest, Digest, Absorb, or Metabolize Specific Nutrients	Nutritional Needs Can Be Met Through Dietary Modification Alone
Alzheimer’s Disease (Mild to Moderate)	X	X	
Atopic Disorders (Eczema, Rhinitis, and Allergy-Responsive Asthma)	X		
Bariatric Patients (Pre- and Post-Operatively)			X
Cardiovascular Disease			X
Chronic Fatigue Syndrome	X	X	
Fibromyalgia	X	X	
Inflammatory Bowel Conditions or Disease	X		
Leaky Gut Syndrome	X	X	
Metabolic Syndrome			X
Peripheral Artery Disease	X		
Polycystic Ovary Syndrome	X	X	
Type 2 Diabetes			X

Conclusion

With the comment period to the draft guidance now closed, FDA must decide whether to finalize the proposed language as is or to take a step back and reconsider its position vis–a–vis the legal and public health issues raised in the comments. In the meantime, the primary challenge posed by the draft guidance for industry is determining whether to pursue the marketing of certain products as medical food when they are intended to be used for diseases or conditions specifically discussed in the Medical Foods Revised Draft Guidance.

Industry should continue to monitor developments closely, including reviewing FDA enforcement activity in this area. While the potential regulatory risk for entering the medical food space may have increased for certain types of products with the issuance of the draft guidance, there remains great opportunities for those companies that can defend the categorization based on a thorough analysis of the relevant statutory, regulatory, and scientific considerations. We will continue to monitor developments and will issue future alerts and articles which may be of interest. ■

by Suzan Onel and Jacqueline Chan

Citations

- [1] 21 U.S.C. § 360ee(b)(3).
- [2] 21 C.F.R. § 101.9(j)(8).
- [3] 56 Fed. Reg. 60366 at 60377 (Nov. 27, 1991).
- [4] On April 4, 2013, K&L Gates FDA lawyers Suzan Onel, Sebastián Romero Melchor, and Max Gu conducted a webinar entitled, “The Regulation of Medical Food and Nutritionals in the European Union, China, and the United States.” A recording of this webinar, which



Medical Foods in the U.S. *cont'*

includes an overview of the regulatory and compliance requirements in the U.S. as well as presentation materials and an Alert providing further information on recent U.S. developments, may be accessed [here](#).

[5] In 1996, FDA attempted to provide more guidance in an Advance Notice of Proposed Rulemaking, but it was subsequently withdrawn in 2004. While FDA issued a Compliance Program Guidance Manual section describing the medical foods program and a 2007 Frequently Asked Questions, neither offered significant clarification of ambiguous terms.

[6] Draft Guidance for Industry: Frequently Asked Questions About Medical Foods; Second Edition (FDA Aug. 2013), [available here](#). FDA's draft guidance documents when finalized represent FDA's current thinking on particular topics. Although FDA specifies that guidance documents "do[] not create or confer any rights for or on any person and do[] not operate to bind FDA or the public," in practice, FDA largely follows its guidance documents.

[7] *Id.* at 3.

[8] *Id.* at 10.

[9] *Id.* at 10-11.

[10] FDA explained that classical nutrient deficiency diseases, such as scurvy or pellagra, that result from essential nutrient deficiencies are "typically caused by inadequate intake (e.g., famine, significant

calorie restriction, eating disorders, alcoholism, diet practices/fad diets)." *Id.* at 12.

[11] *Id.* at 11-12.

[12] FDA however would not object to use of language such as "must be used under the supervision of a physician." *See id.* at 8-9.



Medical Foods in the EU

For Things to Remain The Same, Everything Must Change

The category commonly known as "medical foods" in other jurisdictions is legally defined in the EU as food for special medical purposes ("FSMP") and is regulated by a specific piece of legislation since 1999 (Directive 1999/21). Because FSMP are disease-oriented, their commercialization in the EU is subject to several restrictions and special characteristics, some of which are not present in other categories of foods.

FSMP are a subcategory of "foods for particular nutritional uses" (PARNUTS or dietetic foods) and therefore, they are subject to the general rules applicable to this type of foodstuffs; i.e., the PARNUTS Directive 2009/39, and to the general food laws.

Directive 2009/39 deals with products specially designed to meet the particular nutritional requirements of the persons for whom they are mainly intended. Basically, it contains a common definition for PARNUT and general labeling requirements. This general framework is complemented by specific directives applicable to specific categories of foods (food intended for infants and young children, food for special medical purposes, total diet replacement for weight control, people intolerant to gluten, etc.).

Importantly, a general labeling requirement for all PARNUTS is an indication of their suitability for the nutritional purposes being claimed. This "indication of suitability" is mandatory and, as such, it is not subject to restrictions arising from the strict legal regime of health and nutrition claims (in particular, Regulation 1924/2006) in the EU.

Precisely because of this feature, industry has been accused of abusing the PARNUTS category by marketing as such regular foodstuffs or food supplements with the view of circumventing the application of the health claims rules. In its report of 2008, the European Commission indicated that an increasing number of foodstuffs were currently marketed and labelled as PARNUTS, due to the broad definition laid down in Directive 2009/39. The study report also pointed out that food regulated under that Directive differed significantly between member states, and thus, similar food could at the same time be marketed in different EU countries as food for particular nutritional uses and/or as food for normal consumption, including food supplements, addressed to the population in general or to certain subgroups thereof, such as pregnant women, postmenopausal women, older adults, growing children, adolescents, variably active individuals, and others.

The Commission noticed that this undermined the functioning of the internal market and created legal uncertainty, "while the risks of marketing abuse and distortion of competition cannot be ruled out."

As a result, a new piece of legislation was adopted last year and will apply as from 2016 [Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control]. The new rules will repeal Directive 2009/39/EC and abolish the current concept of PARNUTS or dietetic foods. However, the rules for medical foods remain largely the same as in Directive 1999/21, inter alia:

- in order to fall under the FSMP category, a product has to be "specially processed or formulated and intended for the dietary management of patients;"
- it has to be "used under medical supervision;"
- its formulation has to be based on "sound medical and nutritional principles" and comply with the compositional criteria specified in the annex to Directive 2009/39 until the Commission adopts specific compositional (and labeling) rules;
- it has to be "safe and beneficial and effective in meeting the particular



Medical Foods in the EU *cont'*

nutritional requirements of the persons for whom they are intended as demonstrated by generally accepted scientific data;”

- FSMP are generally subject to a notification procedure before the health authorities of the member states. For successfully completing this process, the manufacturer (or the importer) may need to produce the scientific work and the data establishing that the product complies with the conditions laid down in Directive 1999/21. This will typically take place where the national authorities harbor doubts as to the legal classification of the product as a FSMP or the scientific substantiation supporting its indication of use;
- In some member states, advertisement of FSMP to the “general population” is strictly forbidden. However, as a category of PARNUT, dissemination of any useful information or recommendations exclusively intended for “persons having qualifications in medicine, nutrition or pharmacy is allowed;”
- restrictions surrounding retail channels (e.g., distribution in pharmacies or hospitals only) may apply;
- in some member states, FSMP are reimbursable by their respective social security systems.

Specific Regime for Medical Food Intended to Infants and Pre-Terms

Directive 1999/21 requires that certain compositional requirements for infant formula and for follow-on formula as set out in their specific legislation (Directive 2006/141) apply to FSMP intended for infants, depending on their age. However, certain provisions, including those relating to labeling, presentation, advertising, and promotional and commercial practices set out in Directive 2006/141 currently do not apply to such food.

This legal loophole has been addressed in Regulation 609/2013, which refers to “developments in the market accompanied by a significant increase of such food” to highlight the need to review requirements for formulae intended for infants such as requirements on the labeling, presentation, advertising, and promotional and commercial practices. Those rules will also apply, as appropriate, to FSMPs developed to satisfy the nutritional requirements of infants.

Further, the rules will also apply to pre-term and low-birth-weight infants, on a case-by-case basis. Indeed, whilst according to the recommendations of the World Health Organization, low-birth-weight infants should be fed mother’s milk, Regulation 609/2013 acknowledges that low birth

weight infants and pre-term infants “may have special nutritional requirements which cannot be met by mother’s milk or standard infant formula.”

Dependent on factors such as the infant’s weight in comparison with that of an infant in good health, and on the number of weeks the infant is premature, it will be decided on a case-by-case basis whether the infant’s condition requires the consumption, under medical supervision, of a FSMP developed to satisfy the nutritional requirements of infants (formula) and adapted for the dietary management of that infant’s specific condition. ■

by Sebastián Romero Melchor



Medical Foods in China

China’s First Set of Rules on Formula Foods for Special Medical Purposes

The long-awaited General Rules on Formula Foods for Special Medical Purposes (“FSMP Rules”) on December 26, 2013 by the National Health and Family Planning Commission (“NHFPC”), which will take effect on July 1, 2014.

The promulgation of the FSMP Rules symbolizes the country’s official recognition of this new category of foods, FSMP, and the foreseeable establishment of a substantial new sub-sector in the country’s food industry. It is perceived by some market players that this new category of foods will take up a big portion of the idle production capacity of function foods in China.

However, FSMP does not appear on the top of the agenda of CFDA, which has taken the place of NHFPC as the leading regulator of the food industry. In the recent CFDA-led proposed amendments to China’s Food Safety Law, the term FSMP bears no mention at all.

Further, the “Table of Contents of Items Requiring Administrative Approval” (“Table of Contents”) issued by the CFDA on February 17, 2014 also went completely silent on FSMP.

The FSMP Rules would be a mere scrap of paper without further implementation regulations because these rules consist primarily of technical requirements and parameters. These requirements and parameters do not provide guidance on dossier items and procedure required to register a food as FSMP. The FSMP Rules are also silent on the authority with which the registration of FSMP should be made.

That said, the FSMP Rules have provided some useful definitions, classifications, and general requirements.

According to the FSMP Rules, FSMP is defined as formula dietary foods made for the special dietary needs of certain groups of people (at the age of one year old or above) with feeding difficulties, disorder of digestion and absorption, metabolic disturbance, and other specific diseases. The FSMP must be used under the directions of doctors and clinical nutritionists.

FSMP is divided into three sub-categories:

- Complete Nutrition Formula Dietary Foods, used as the sole nutrition source to satisfy the nutritional needs of certain targeted groups of people.
- Specific Nutrition Formula Dietary Foods, used as the sole nutrition source to satisfy the nutritional needs of certain targeted groups of people during specific disease or medical conditions.
- Partial Nutrition Formula Dietary Foods, used to satisfy partial

nutritional needs of certain targeted groups of people.

The FSMP Rules also list 13 Specific Nutrition Formula Dietary Foods suitable for the groups of people with the following diseases and medical conditions:

- Diabetes
- Disease of respiratory system
- Nephropathy
- Tumor
- Hepatopathy
- Sarcopenia
- Medical conditions involving trauma, infection, surgery, and stress state
- Inflammatory bowel disease
- Food protein allergy
- Intractable epilepsy
- Gastrointestinal disorder of absorption and pancreatitis
- Fatty acid metabolism anomaly
- Obesity and liposuction surgery

The FSMP Rules also require that any formula of the FSMP undergo medical and/or nutrition research. Further, the safety and clinical application and/or effect of the FSMP must be scientifically verified, which suggests that clinical trials may be required for all FSMP. ■

by Junko Okawa and Ayuko Nemoto

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