



**K&L GATES**

**GLOBAL FOOD, DRUGS, MEDICAL  
DEVICES AND COSMETICS NEWSLETTER**

**3<sup>rd</sup> Edition – Fall 2014**

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

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## KEY CONTACTS

#### Sebastián Romero Melchor

+32 (0)2 336 1906

sebastian.romeromelchor@klgates.com

#### Suzan Onel

+1 (202) 778 9134

suzan.onel@klgates.com

## WELCOME

We are pleased to provide you with the Fall edition of the Global Food, Drugs, Medical Devices and Cosmetics newsletter. This newsletter provides updates on important issues and developments across these 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 that address important industry and regulatory trends and their correlation with the challenges faced by economic operators on a daily basis. This edition covers such diverse topics as regulatory developments in the fields of labelling, clinical trials and the use of nanomaterials in consumer products, and brand specific health claims on food products.

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, intellectual property, product liability and policy areas so can offer multidisciplinary support throughout the product life cycle. We hope you find this Fall 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*



## Draft Amendments to Food Safety Law Reached Law Maker

Following the unsuccessful efforts by the State Council<sup>[1]</sup> last December to put the proposed amendments to the Food Safety Law (“**Draft Amendments**”) on the Q1 2015 agenda of the standing committee of the National People’s Congress<sup>[2]</sup> (“**NPC**” or “**Law Maker**”), the Draft Amendments underwent additional discussions and revisions led by the China Food and Drug Administration (“**CFDA**”), the ministry for food regulations under the State Council.

On June 23, 2014, the State Council submitted the Draft Amendments to the Law Maker again. This time, the Law Maker docketed the draft. However, after its first review session, the Law Maker decided to put the Draft Amendments through a new round of public consultation<sup>[3]</sup>, beginning on July 1, 2014 and ending on July 31, 2014 (“**NPC Round**”). The previous round (“**State Council Round**”) was administered by the State Council, which took place between October 29, 2013 and November 29, 2013.

It is not unusual for a draft law to undergo two rounds of public consultations. However, it is quite unusual for the Law Maker to seek public comments *after* the State Council has already done the same. That could be a sign of unsettled significant issues in the Draft Amendments.

While the Law Maker has kept the reallocation of powers among the regulatory authorities proposed in the Draft Amendments circulated under the State Council Round, the NPC’s Draft Amendments have re-emphasized several key areas in line with PRC government’s goal to promulgate “the strictest food safety law” in the history of mankind. Those areas include a food safety risk monitoring and

assessment mechanism, more severe legal liabilities for violation, a whole-process supervision and traceability system and special regulations concerning function foods and online platforms. In particular, the Draft Amendments circulated under the NPC Round address those areas as follows:

1. Food safety risk monitoring and assessment mechanism (Articles 14-21)

The Draft Amendments circulated by NPC keep the National Health and Family Planning Commission (“**NHFPC**”) as the leading authority responsible for the food safety risk monitoring and assessment mechanism, but propose more specific monitoring measures and follow-up steps with the goal of establishing a more actionable system. In particular, the Draft Amendments further clarify that specialized technical institutions will be responsible for carrying out the monitoring and reporting their findings to NHFPC. Upon notification of any potential risks, NHFPC must give timely notices to CFDA, which will then conduct further investigations.

More noticeably, the Draft Amendments appear to have expanded the purpose of the food safety risk assessment into a more holistic and forward-looking one. Included in the proposed expanded purpose of the assessment are: to provide scientific evidence in support of the formulation of national food safety standards, to identify/develop critical monitoring areas/points within the existing system and to proactively identify/assess additional

risks beyond the existing system. In addition, NHFPC is also required to respond to requests for assessment from CFDA, the Administration of Quality Supervision, Inspection and Quarantine and the Ministry of Agriculture, etc.

2. More severe punishment on violation of food laws and regulations

Compared to the State Council’s Draft Amendments, the Draft Amendments circulated under the NPC Round have further increased the punishment for violations by emphasizing civil



## Draft Amendments to Food Safety Law Reached Law Maker

liabilities and punitive damages, raising the maximum fine amounts and broadening the application of criminal law. By way of example:

- › Civil liabilities and punitive damages (Article 138): Consumer may choose to go after either the food manufacturer or the retailer for damages. The food operator contacted first by consumer should fully compensate the consumer without any excuse. For those food products not in compliance with the national food safety standards, consumer is entitled to punitive damages in the amount of three times of the consumer's loss or 10 times of the sales price of the food products at issue.
- › Further increased fine amount (Articles 123-132): Under the Draft Amendments, production with recycled food/food ingredients will face a maximum fine up to 30 times of the sales value of non-complying food products. The NPC's Draft Amendments also increase the maximum fine amount to 20 times of the sales value of non-complying food products for use of food additives outside the permitted scope or production of infant formula food that fails to meet the prescribed nutrients requirement under the national food safety standards. Any person or entity providing venues or other assistance to illegal food manufacturers may also face a fine up to RMB 200,000.
- › Criminal liabilities (Article 140): The Draft Amendments provide a

catch-all clause to connect "severe violation" to the criminal law instead of specifying criminal liabilities in each violation. The generality and vagueness tend to give regulatory authorities a broadened and unchecked discretion to seek criminal liabilities. It is worth noting that the Draft Amendments also emphasize the potential criminal liabilities of the governmental officials to ensure the strict enforcement of the food safety laws and regulations.

### 3. Strict whole-process supervision and traceability system (Articles 46-48, 50, 53 and 93)

Under the Draft Amendments, a strict whole-process supervision system is introduced to ensure that the food operators comply with the food safety laws and regulations. This whole-process supervision system is aimed at consolidating the powers of different authorities into a centralized system under CFDA. The whole-process supervision connotes a traceability system that imposes stricter document retention requirements on the purchase of raw materials, manufacture and sale, wholesale operators and online sales of food products. All of the records must be kept for a period of time not less than 6 months after the expiry of the shelf-life of the relevant food products. When the shelf-life of certain food product is not clear, the records must be kept for at least two years.

### 4. More express regulatory guidance on function foods and operators of online

shopping platforms (Articles 65-68, 73 and 132)

NPC's Draft Amendments have further elaborated on the filing system of function food, which is designed to supplement the current approval/registration system. Under the proposed filing system, approval/registration will only be required when a function food contains new ingredients or is imported to China for the first time. For other function foods, only filing is required. That said, a function food manufacturer is required to observe good manufacturing practice, conduct regular self-inspection and routinely report to the CFDA. In addition, the formula and technical requirements of the function food must be filed with a provincial level office of CFDA in order to validate the filing. CFDA has also been given the authority to regulate the advertising of function foods.

Comparing with the State Council's Draft Amendments, NPC's Draft Amendments have removed the requirement that online shopping platform operators obtain food circulation permits as a prerequisite for allowing vendors to distribute food products on their platforms. However, the Draft Amendments do require that online shopping platform operators enhance their due diligence in reviewing applications of food vendors. For example, platform operators are required to obtain vendors' real names for vendor registration purposes and to verify vendors' licenses/permits for conducting food businesses.

Platform operators must also cease vendors' activities upon discovery of non-compliance. Similar to the State Council's Draft Amendments, NPC's version also provides that, in the event of any failure to fulfill the obligations above, the platform operators shall be jointly and severally liable for vendors' misconducts.

In summary, on its face, the NPC's Draft Amendments appear only attempting to flesh out the State Council's version. However, as stated in the beginning of this article, NPC's unusual second guessing of State Council's draft may suggest unsettlement on more significant fronts. Businesses are recommended to keep track of the Draft Amendments closely.

*By Max Gu and Aqua Huang*

### Citations

[1] 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.

[2] The National People's Congress is the supreme organ of state power and ultimate legislative body of the People's Republic of China.

[3] 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.



## New Sanctions on the Mislabeling of Products will be Introduced in Japan

### Background

In 2013, Japan saw an alarming increase of scandals involving mislabeled menus in restaurants and hotels. The Consumer Affairs Agency in Japan (“CAA”) stepped in and began conducting inspections and warning companies which tried to attract consumers with mislabeled menus.

### Major modifications

The scandals also led to the Government of Japan amending the Act against Unjustifiable Premiums and Misleading Representations (the “Act”), which currently prohibits improper advertising and labeling on products and containers or packaging in order to protect consumers and to assure fair competition. The following are the key points of the amendments (“Amendments”):

- Companies will be required to establish and maintain an internal system which can prevent improper labeling. This amendment aims to ensure that companies comply with the Act’s labeling requirements. The draft guidelines proposed by the CAA on August 8, 2014 provided further details of this internal system. According to the guidelines, companies need to take the following measures:
  1. Keep officers and employees informed of the regulations under the Act;
  2. Set out the company’s compliance policy and system;
  3. Verify the appropriate labeling;

4. Share the information regarding the appropriate labels among different departments involved in the products and their labels;
5. Have a person in charge of the administration of labeling;
6. Keep and maintain evidence of the labeling; and
7. Take prompt and proper measures when any mislabeling is found.

- There will be implementation of administrative monetary penalties for several types of violations of the Act. This amendment will become a significant threat to companies because the monetary penalty will likely be calculated based on the profits received by the company for the mislabeled product.

The summary draft of the amendment to the Act that was proposed by the CAA on August 26, 2014 provided further details of this administrative monetary penalty. According to the proposal:

1. The administrative monetary penalty will be 3 percent of the profits of the mislabeled products;
2. The administrative monetary penalty will be imposed based on the profits of the mislabeled products sold to consumers for a period up to the past 3 years;
3. The administrative monetary penalty will not be imposed if the profits of the mislabeled products are less than JPY 50 million;

4. A leniency policy will be implemented, which will offer companies involved in mislabeling a reduction of fines;
5. The 5 years statute of limitations will begin to run from the day when the violation of the Act has been corrected;
6. The administrative monetary penalty will not be imposed if a company proves that it has exercised due care in preventing the mislabeling; and
7. The administrative monetary penalty will not be imposed if a company takes the necessary steps and provides a refund to consumers after the mislabeling is found.

### Expected impact

The Amendments will become effective by the end of 2014, and the new law on the administrative monetary penalty will be proposed to the Diet in 2014 or 2015. Companies which label their products or outsource their labeling should be ready to review their internal systems and take any necessary steps to comply with the suggested guidelines to prevent any mislabeling which could result in enormous monetary exposure.

*By Junko Okawa and Ayuko Nemoto*



This amendment will become a significant threat to companies because the monetary penalty will likely be calculated based on the profits received by the company for the mislabeled product.

## New Rules for Foods (Including Food Supplements) Offered for Sale in Catalogs, Online Shops

*Regulation 1169/2011 on the provision of food information to consumers (the “FIC Regulation”) will be applicable as from December 13, 2014.*

Catalogs, leaflets, online shops and other “means of distance communication” offering foods, including food supplements, for sale in the EU countries, should, as of December 13, 2014, include all the mandatory information required by the FIC Regulation before the purchase is concluded.

As a consequence, any food supplied through distance selling must meet the same information requirements as food sold in regular shops.

So far, a few aspects of distance selling (e.g., information about the product’s price) are regulated at national level by electronic commerce and similar provisions. Therefore, distance selling regimes may vary across the EU.

### Mandatory particulars

“Mandatory food information” means the particulars that are required to be provided to the final consumer by union provisions (and not only by FIC). The particulars that must be available before the purchase is concluded are:

1. The name of the food;
2. The list of ingredients;
3. Any ingredient or processing aid causing allergies or intolerances;
4. The quantity of certain ingredients or categories of ingredients;

5. The net quantity of the food;
6. Any special storage conditions and/or conditions of use;
7. The name or business name and address of the food business operator responsible for the food information;
8. The country of origin or place of provenance; and
9. Instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions.

In addition, other specific mandatory information should be made available at the moment of delivery – for instance, warnings regarding caffeine consumption or a statement on sweetener content.

### Method of presentation of information

The FIC Regulation also indicates how the mandatory information should be presented for distance selling purposes. As a general rule, mandatory information must appear on the material supporting the distance selling or be provided through other appropriate means clearly identified by the food business operator. Furthermore, mandatory food information must be provided without any supplementary costs.

### Who is responsible

Where foods are offered for sale by means of distance selling, the responsibility for providing mandatory food information before the purchase is concluded lies with the owner of the website.

### Timeframe


The FIC Regulation entered into force on December 13, 2011 and will apply from December 13, 2014. For nutrition information, the transition period is two years longer (i.e., December 13, 2016). Even so, it is possible to include nutrition information together with any other mandatory particulars required from December 13, 2014 or even now.

### Challenges

It is crucial that the information provided in the labeling of the product be consistent with the information given to the consumer before the purchase is concluded. In practice, this means only seven and a half months remain to adjust the means of distance communication to the new requirements.

Any change in the labeling of a product will have to be reflected in the information made available for the distance selling. For instance, any promotional packaging containing increased quantities of the product means that the net weight will have to be reflected in the information on the relevant website or in the catalogue, etc.

*By Izabela Tanska and Sebastián Romero Melchor*



...[t]he responsibility for providing mandatory food information before the purchase is concluded lies with the owner of the website.

## How the Food Information for Consumers Regulation (“FIC”) will Change Food Supplements Labeling

*Regulation 1169/2011 on the provision of food information to consumers (the “FIC Regulation”) will be applicable as from December 13, 2014.*

Food supplements are classified by EU law as foodstuffs. As such, the legal provisions that apply to regular food generally apply to food supplements too. This article looks at FIC rules that particularly impact food supplements labels.

### Presentation of food supplements’ mandatory particulars

FIC defines mandatory food information as particulars that EU provisions require to be provided to the final consumer. Such information must be marked in a conspicuous place in such a way as to be easily visible, clearly legible and, where appropriate, indelible. The minimum font size (1.2 mm) set out in FIC is new. The presentation of warnings and statements that are mandatory in the label of food supplements (e.g. “Do not exceed recommended daily dose” or “Keep out of reach of young children”) must also follow these new provisions.

The names of any allergens on the list of ingredients must be emphasized through a typeset that clearly distinguishes it from the rest of the ingredients – for example, by means of font, style or background color. The most common solution is to bold the name (or the part of the name) of the ingredient.

Food additives must be designated by the name of that category, followed by their specific name or, if appropriate, E number (e.g., glazing agent – hydroxypropyl methyl

cellulose or glazing agent – E 464). The name of the food additive category should always appear first. The decision whether to use the name or E number is quite important, for instance when the product contains aspartame. If this sweetener is designated in the list of ingredients only by reference to the E number, the additional labeling particular is “contains aspartame (a source of phenylalanine).” Otherwise, if the designation is by the specific name, the additional labeling particular is “contains a source of phenylalanine.”

Food supplements placed on the market after December 12, 2014 to which caffeine is added with a physiological purpose should bear in the same field of vision as the name (food supplement) the warning: “Contains caffeine. Not recommended for children or pregnant women.” The caffeine content should be expressed per portion as recommended for daily consumption on the labeling.

Mandatory particulars, such as the instructions for use, must be indicated with words and numbers, pictograms or symbols being only an additional means to express such particulars. Food supplements in powder or in other forms which require mixing of the product with water or other liquids should therefore include written instructions and not only depictions.

### Nutrition declaration

Food supplements are exempted from the mandatory nutrition declaration. Nevertheless, if provided voluntarily, such information must comply with FIC. This applies to all seven mandatory nutrients: energy, fat, saturates carbohydrate,

sugars, protein, and salt. Pursuant to Food Supplements Directive 2002/46/EC, the amount of the nutrients or substances with a nutritional or physiological effect present in the product have to be declared on the labeling. For consistency, the European Commission advises using the same terminology for food supplements as for other foods. Thus, “Reference Intakes” should replace “Recommended Daily Allowance.” As a general rule the nutrition declaration is required for the food as sold, but where appropriate, it can instead also relate to the food as prepared. Most of food supplements bear nutrition and health claims that should refer to the food ready for consumption. Therefore, when it comes to food supplements that bear nutrition and health claims and need preparing before consumption, nutrition labeling relating to the food as prepared might be more convenient for both consumer and producer. On the other hand, where there are various preparation options – such as with water, milk or juice, such obligation may force a choice of only one option.

For nutrition declaration purposes as well as the declaration of the vitamins and minerals present in food supplements, the names listed in Annex XIII of FIC should be used. For instance, “Thiamin” cannot be replaced with B1 or “Folic acid” with B9.

### COOL

The indication of the country of origin or of the place of provenance (“COOL”) is mandatory for certain foodstuffs (e.g., beef, honey, olive oil). It also should be provided whenever its absence is likely to mislead consumers as to the true country of origin

or place of provenance of that product. In some cases, producers indicate the origin of a food on a voluntary basis to draw consumers’ attention to the qualities of their product (e.g. “Product of USA,” “Produced in EU”). Such indications should also comply with harmonized criteria. Moreover, where the country of origin or the place of provenance of a food is given and where it is not the same as that of its primary ingredient (i.e., ingredient that represents more than 50 percent or which is usually associated with the name of the food) COOL of the primary ingredient must be indicated as different to that of the food. With regard to food supplements, the origin of plant extract or even of the capsule may have impact on the correct labeling.

### Responsibilities

FIC applies to food business operators (“FBO”) at all stages of the food chain, where their activities concern the provision of food information to consumers. The operator under whose name the food is marketed is responsible for the food information. For imported food where FBO does not operate in the EU, the importer may be responsible for the food information. It is mandatory to indicate on the label the name or business name and address of the food business operator responsible for food information. Although it will be still possible to mention more than one FBO on the label (e.g., “produced by... for ...”), there should be clear indication which FBO is responsible for food information. Some companies have already been using the statement: “food business operator responsible for the food information: ...”

### Labeling, advertising, presentation

It is worth bearing in mind that not only labels are affected by FIC but also information concerning a food and made available to the final consumer by means of another label accompanying material, or any other means including modern technology tools or verbal communication. This includes also advertising and presentation.

\*\*\*\*\*

Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers changes the EU’s legal regime on food labeling, advertising and promotion, replacing two EU directives.

As with all regulations, FIC is binding in its entirety and directly applicable in all Member States. This should mean that food information provisions are the same in all EU countries. Member States will continue to be responsible for enforcement of food law, as well as monitoring and verifying the compliance of food business operators.

*By Izabela Tanska and Sebastián Romero Melchor*



## New EU Clinical Trials Regulation

On May 27, 2014, EU Regulation 536/2014 on clinical trials on medicinal products for human use (hereinafter the “**Regulation**”), which will replace and repeal the current EU Clinical Trials Directive 2001/20/EC (hereinafter “**current rules**”), was published in the Official Journal of the European Union. The Regulation will enter into force on June 16, 2014; however, it will not apply until six months after the IT infrastructure that supports the Regulation (i.e., EU portal and database) has become fully operational, and, in any event, not earlier than May 28, 2016. Until then, the current rules will still apply. The main objective of the Regulation is to make the EU more attractive for clinical research by introducing a single harmonized regime for all clinical trials carried out in the EU while maintaining high standards of patient safety.

### Main changes introduced by the Regulation

- **In contrast to a directive**, a regulation is immediately enforceable and does not need transposition into national legislations; therefore, the fact that the rules are now incorporated in a Regulation means that all EU Member States will have identical rather than similar rules in force.
- **The scope of the Regulation:** The Regulation will apply to all clinical trials of medicinal products within the EU except non-interventional studies.
- **The concept of “clinical trial” has been clarified** by introducing a broader concept of “clinical study” that comprises the clinical trial as a category. This approach takes into account international guidelines and is in line with EU law governing

medicinal products, thus achieving a dichotomy of “clinical trial” and “non-interventional studies.”

- **The “low-intervention clinical trial”** concept has been introduced.

This is defined as a trial that (i) is conducted with authorized (instead of investigational) medicinal products and (ii) does not pose more than minimal additional risk compared to normal clinical practice. These low-intervention trials will be subject to less stringent rules, particularly with regard to monitoring and reporting obligations and traceability of investigational medicinal products.

- **An “auxiliary medicinal product” is a new category of medicinal products**

defined to refer to products used for the needs of a clinical trial that are not part of the investigation (they are not “investigational products”). These products may or may not have a marketing authorization (in the first case they will enter into the “authorized auxiliary medicinal products” sub-category).

- **It is no longer mandatory for non-EU sponsors to have a legal representative.**

Thus, national rules will decide whether a legal representative is needed but, at the least, an EU contact person for non-EU sponsors will be required. In addition, the Regulation states that co-sponsorship will be possible.

- **Authorization procedure:** The new regime provides a harmonized procedure for the assessment and approval of clinical trial authorization

application and applications for substantial modifications.

- **Streamline the submission and communication process through a single EU portal:**

The sponsor will have to submit a single application dossier through an EU portal to all the Concerned Member States (“**CMS**”) at the same time. All further information, communication and data about a particular clinical trial will be performed using the single EU portal.

- **Centralized assessment by a “Reporting Member State”**

(hereinafter “**RMS**”): The assessment of the application dossier is divided into two parts:

- › **For all the aspects covered in Part I**, the CMS will jointly assess the scientific aspects of the trial and, therefore, the sponsor proposes one of the CMS to act as the RMS (if only one Member State is involved in the trial, that Member State is the RMS). Once the RMS has confirmed, it will have to (i) coordinate the validation of the clinical trial application within 10 to 25 days, (ii) assess the application for the Part I aspects and (iii) issue the Part I assessment report (whether the trial is: acceptable; acceptable subject to conditions; or not acceptable) within 45 calendar days.

This assessment report is valid for the entire EU. Therefore, all CMS must adopt the conclusion of the assessment report, unless they opt out and communicate their reasons through the EU Portal.

- › **All aspects covered in Part II** (i.e., assessment of site details, ethics, etc.) are assessed within 45 days

by the other CMS, remaining at national level and under the Ethics Committees’ responsibility.

- **Shorter timeframes for authorities to approve:**

Following the assessment, a decision must be given within five days, hence the overall timings may be between 60 and 106 calendar days.

- **Notification of trial events through the EU portal:**

The sponsor must notify all the CMS via the portal within 15 calendar days of the following stages:

- › The start of the clinical trial;
- › The first visit of the first subject;
- › The end of trial subject recruitment;
- › Any temporary cessation of the trial and when it has been recommenced;
- › The end or early termination of the clinical trial in each Member State or in all the CMS;
- › The end of the clinical trial in all the CMS and in all third countries where the trial has been conducted.

- **Simplified adverse reaction reporting:**

The sponsor obliged to report all suspected serious unexpected adverse reactions within seven days will be able to do so via the recent EU electronic database for safety reporting.

- **Public disclosure of clinical data**

(increased transparency on clinical trial results). The European Medicine Agency, in collaboration with CMS and the EU Commission, will set up an EU database, which will contain all the data and information submitted in accordance with the Regulation.

The EU database will identify each trial by a unique EU trial number and all the contained information will be publicly accessible, except: (i) personal data; (ii)

commercial confidential information; (iii) confidential communication between Member States related to the assessment report; and (iv) information that needs disclosure to ensure effective supervision of a clinical trial by Member States.

- Other changes include:

- › **The Commission will have the possibility to conduct controls** in the EU and third countries to ensure that the rules are being properly supervised and enforced.

- › **Compensation for damages:** The CMS must ensure systems (in the form of insurance, guarantee or similar) for compensation for any damage suffered by a subject as a result of participating in a clinical trial.

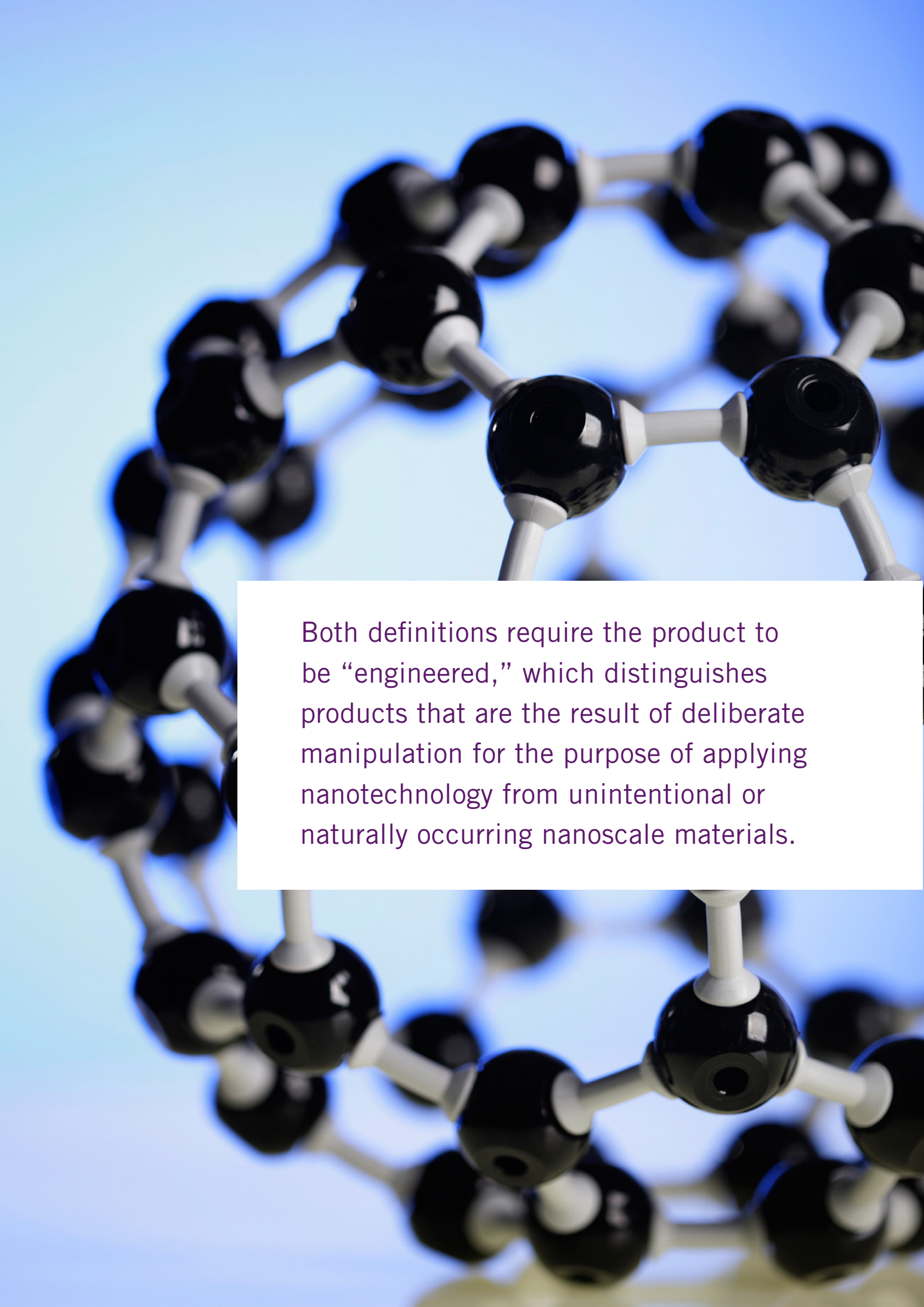
- › **Extended protection of vulnerable population and informed consent:** The Regulation introduces new rules for the specific situation of urgency where it is not possible to obtain free and informed consent from the participants in the trial or from their legal representatives.

### Conclusion

To sum up, the Regulation represents progress in the harmonization of clinical trials as well as a clear attempt to speed up the authorization of new clinical trials. The transparency required by the Regulation will help researchers, doctors and patients to verify the effectiveness of the medicines as they will have access to the results of all clinical trials. In view of the above and taking into account the simplification of the rules, it will lead to an increase in the number of multinational trials in the EU, reversing the significant decline under the directive.

*By Vanessa Edwards*





Both definitions require the product to be “engineered,” which distinguishes products that are the result of deliberate manipulation for the purpose of applying nanotechnology from unintentional or naturally occurring nanoscale materials.

## Nanomaterials: Invisible to the Human Eye but Potential for Significant Impact—U.S. FDA Issues Four Guidance Documents on Regulation of Nanotechnology in Products

### Introduction

As an emerging technology, the use of nanotechnology in a growing range of products is of great interest to many sectors of industry. The list of products containing nanomaterials is seemingly endless and includes sunscreen, chocolate syrups, sports drinks and a variety of drug products. Manufacturers use nanomaterials because they convey a benefit due to their size, but concerns have been expressed that the resulting altered properties need to be assessed more thoroughly.<sup>[1]</sup>

On June 24, 2014, the United States Food and Drug Administration (“**FDA**” or the “**Agency**”) issued three final guidance documents and one draft guidance document related to the use of nanotechnology in FDA-regulated products.

<sup>[2]</sup> Pursuant to these guidance documents, FDA’s regulatory approach to products involving nanotechnology remains largely unchanged. Under its product-focused, science-based regulatory policy, FDA will continue to regulate products containing nanomaterials under the existing statutory authorities specific to each product category (i.e., drugs, cosmetics, food, etc.).

This article will discuss the following concepts presented in the guidance documents issued in June:

1. FDA’s current definition of nanotechnology, including how to determine whether a product involves the application of nanotechnology;<sup>[3]</sup>
2. FDA’s stance on the impact of manufacturing process changes, including nanotechnology, on the safety and regulatory status of food ingredients;<sup>[4]</sup>

3. FDA’s perspective on the cosmetic industry’s use of nanotechnology in cosmetic products;<sup>[5]</sup> and

4. FDA’s current position on using nanotechnology in animal food.<sup>[6]</sup>

As will be described in greater detail below, all four documents carry forward the consistent theme that FDA will continue to regulate products derived through nanotechnology under existing statutes and regulations. In other words, FDA currently does not plan to issue any nanotechnology-specific regulatory definitions. However, FDA remains interested in products “deliberately manipulated” by the application of nanotechnology and describes situations where traditional safety tests and assessments may not be suitable.

### Guidance for Industry: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology

In the Nanotechnology Guidance, FDA provides an overarching framework across product areas for its approach to nanotechnology products and further defines its current thinking on nanotechnology.<sup>[7]</sup> The Agency clarifies that it is not establishing a final definition of nanotechnology or nanomaterials.<sup>[8]</sup> To determine whether a product applies nanotechnology, FDA provides two “Points to Consider”:

1. Whether a material or end product is engineered to have at least one external dimension, or an internal or surface structure, in the nanoscale range (approximately 1 nm to 100 nm); or

2. Whether a material or end product is engineered to exhibit properties or phenomena, including physical or chemical properties or biological effects, that are attributable to its dimension(s), even if these dimensions fall outside the nanoscale range, up to one micrometer (1,000 nm).<sup>[9]</sup>

The “Points to Consider” serves as an initial screening tool to be broadly applied to all FDA-regulated products (e.g., food, drug, cosmetic, biologic, devices) and focuses not on just the size of the particle, but also the particle’s properties. If either point applies to a product, the industry should pay particular attention to whether the premarket evaluations of “safety, effectiveness, public health impact, or regulatory status of that product [ ] identifi[y] and adequately address[ ] any unique properties or behaviors of the product.”<sup>[10]</sup> The Agency emphasizes that it does not categorically assess products applying nanotechnology as harmful or harmless, and that it would continue to treat food and drug products on a case-by-case basis.<sup>[11]</sup>

Within the “Points to Consider,” certain terms require additional explanation. The inclusion of “material or end product” means that the guidance applies to both final products and materials used in the manufacturing of finished products. Both definitions require the product to be “engineered,” which distinguishes products that are the result of deliberate manipulation for the purpose of applying nanotechnology from unintentional or naturally occurring nanoscale materials. FDA selected the nanomaterial size range in accordance with working definitions in the scientific and regulatory communities.



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The second point includes a broader scale because the upper size limit for nanotechnology is not yet established and may need to be modified in the future; one micrometer presents an appropriate range that is consistent with current scientific definitions.

### Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients

The Manufacturing Process Change Guidance outlines for food ingredients and food contact substance manufacturers and end users factors to consider when determining whether manufacturing processes that make a significant change in a food product will require additional registration with FDA. Such factors include whether the change affects the identity of the food substance, negatively impacts the ability to safely use the food substance or affects the regulatory status of the food substance.<sup>[12]</sup> The Agency offers examples of manufacturing process changes that may be considered significant, such as switching to a more effective catalyst, selecting a more cost-efficient solvent, adding a process to reduce contaminants like lead or incorporating emerging technologies such as materials on the nanometer scale.<sup>[13]</sup> As such, the use of nanotechnology in food manufacturing can result in a “significant manufacturing change” that could require a new submission to FDA.

The Manufacturing Process Change Guidance recommends a four-step

approach to determining whether the manufacturing process change is significant: (1) determine whether there is a change to the food product’s identity,<sup>[14]</sup> (2) conduct a safety assessment for the use of the food substance, (3) consider whether the food substance falls under the prior regulatory category and (4) consult with FDA officials if unclear. The four-step approach is applied to food substances (1) that are the subject of a food additive or color additive regulation, (2) for which there is an effective Food Contact Notification, (3) that are affirmed or identified as Generally Recognized as Safe (“GRAS”) or (4) for which there is an existing determination that a use of a food substance is GRAS. Manufacturers should be aware that products that were previously categorized as GRAS, required a prior food or color additive petition, or a food contact notification may require an additional regulatory submission if either; (1) the identity, manufacturing process, or conditions of use do not comply with a regulation or are significantly different or; (2) impurities introduced within the food substance during the manufacturing process results in the food being an inappropriate food grade.

Furthermore, for GRAS products, FDA notes that the burden remains on the manufacturer to demonstrate that the ingredient used in the initial petition is the same after the manufacturing process.

<sup>[15]</sup> Additionally, the Agency specifies that a food substance manufactured for the purpose of creating very small particle sizes with new functional properties likely would not be covered by an existing GRAS determination for a related food substance. FDA explains that, for nanotechnology

applications in food substances, questions exist related to the technical evidence of safety and general recognition of that safety; as such, they are likely to warrant formal premarket review and approval by FDA.<sup>[16]</sup>

### Guidance for Industry: Safety of Nanomaterials in Cosmetic Products

FDA issued the Cosmetic Guidance in response to the July 2007 FDA



Nanotechnology Task Force Report, in which the Task Force recommended that the Agency issue guidance describing safety issues manufacturers should consider to ensure that cosmetic products made with nanomaterials are safe.

As background, cosmetic products are not subject to premarket regulation by FDA and the industry generally has broad discretion to determine what ingredients may be used in cosmetics without regulation, as long as the ingredient is not prohibited by regulation, is not a color additive or

does not adulterate the cosmetic.<sup>[17]</sup> As is consistent with prior regulations, manufacturers and distributors are responsible for substantiating the product’s safety, which can be done based on available toxicological data or through additional testing for new products.<sup>[18]</sup> For cosmetics containing nanomaterials, FDA emphasizes that the unique properties of nanomaterials may require an evaluation of data needs and testing methods. For instance, FDA notes that because of the potential for nanotechnology to alter the materials’ distribution and bioavailability, additional

testing methods within the existing FDA framework may be required for cosmetic products applying nanotechnology.<sup>[19]</sup>

Like other cosmetic ingredients, nanomaterials used in cosmetics must be fully described including: nanomaterial name, Chemical Abstracts Service number, structural formula and the elemental and molecular composition (including noting the degree of purity and any known impurities).<sup>[20]</sup> The Agency also provides a list of physical and chemical properties to consider with regards to the safety of the nanotechnology,

such as: measurement of the particle size, distribution, aggregation and agglomeration characteristics, surface chemistry, morphology, solubility, density and porosity.<sup>[21]</sup>

FDA puts the responsibility on the manufacturer and/or distributor to select the appropriate assessment methods, including toxicological testing, based on the ingredient’s properties to fully characterize the nanomaterial. Additionally, the industry must look at the long- and short-term toxicity and possible ingredient interactions with other ingredients or packaging.<sup>[22]</sup> For example, FDA cites the property of solubility as impacting the appropriate testing methods because certain *in vivo* methods are suitable for soluble nanomaterials but *in vitro* methods may be required (or adjusted) for insoluble materials.<sup>[23]</sup>

Additional areas for consideration in the use of nanotechnology in cosmetic products are the routes of exposure, uptake and absorption. For instance, the Agency notes that some cosmetic products are sprays with a possibility of inhalation or oral exposure. FDA cautions that manufacturers and distributors should consider primary and secondary exposure organs in selecting the appropriate testing. Additionally, the Cosmetic Guidance emphasizes the need for the assessment to consider the movement of the materials through an increase in “uptake, absorption, transport into cells, and transport across barriers or altered bioavailability or biological half-life.”<sup>[24]</sup> Consistent with industry standards from the Cosmetic, Toiletry and Fragrance Association (now known as the Personal Care Products Council), FDA recommends that at a minimum toxicity testing include: “testing for acute toxicity, skin irritation, ocular irritation, dermal photoirritation, skin sensitization, mutagenicity/genotoxicity,

repeated dose (21-28 days) toxicity, and subchronic (90 days) toxicity.”<sup>[25]</sup>

### Draft Guidance for Industry: Use of Nanomaterials in Food for Animals

On the same day that FDA published the three final guidance documents, the Agency also published the Animal Food Draft Guidance,<sup>[26]</sup> explaining FDA’s thinking on the use and application of nanotechnology in animal food products. The draft guidance explains that nanomaterials may impact the physicochemical properties of the ingredients, citing an example of tea polyphenols as anti-oxidants in bulk form but pro-oxidants in nanoscale form.<sup>[27]</sup> Because of such differences, companies should use specific data and separate assessment to support the safe use of nanomaterials in already-approved ingredients or GRAS. Similar to the Manufacturing Process Change Guidance document, FDA recognizes that there are no known GRAS nanomaterials for use in animal food.<sup>[28]</sup>

Additionally, the nanomaterial may warrant a resubmission or initial submission of a food additive petition (“FAP”) to FDA. A FAP submission should consider the following qualities of the ingredient: the identity (including, among other things, the name and relevant physical, chemical and biological properties); manufacturing methods and controls (such as the stability of the nanomaterial, byproducts and impurities); intended use, use level and labeling; analytical methods (to determine the chemical composition, amount of nanomaterial within the product, and purity, quality and strength); safety evaluation and proposed tolerances for the food additive; proposed regulation (identification information); and environmental assessment.

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FDA recommends that manufacturers contact the Agency in the early stages of product development if considering the application of nanotechnology to animal food products.

### Conclusion

Overall, FDA largely maintains the same approach to regulating products containing nanomaterials as it did prior to the issuance of the guidance documents. It continues to regulate the products based on the statutory and regulatory legal standards that apply to the product category, i.e., drugs, medical devices, foods and so forth, because it believes the current safety assessment framework is “sufficiently robust and flexible” to apply to nanomaterials. The new guidance documents provide greater detail for this framework and should be considered when nanomaterials are involved. Particular attention should be placed on products where the material or end product is “deliberately manipulated” by the application of nanotechnology as opposed to when nanomaterials may occur naturally in the product.

As noted in its guidance documents, FDA intends to provide further guidance to the industry as needed to address the application of nanotechnology to specific FDA-regulated classes of products and also encourages manufacturers to contact the Agency at the early stages of product or process development. To further enhance its scientific capabilities, FDA is investing in a nanotechnology regulatory science program that will help to develop the data and tools to identify nanomaterials’ properties and impact. As its understanding of the science evolves,

the Agency has stated that it may revise its approach, including developing regulatory definitions relevant to nanotechnology. We will continue to monitor developments in this area.

By *Suzan Onel, Jacqueline J. Chan and Elizabeth M. Johnson*

### Citations

[1] Guidance for Industry: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology at 3 (FDA June 2014), available at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM401695.pdf> (“Nanotechnology Guidance”).

The Nanotechnology Guidance finalizes FDA’s draft guidance entitled “Draft Guidance for Industry: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology” issued in June 2011.

[2] An FDA guidance document is intended as industry recommendations but is not binding unless it cites to principles outlined in specific regulations or statutes. Furthermore, the Agency notes that alternative approaches to the guidance, within the bounds of existing regulations and statutes, are acceptable.

[3] Nanotechnology Guidance.

[4] Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives (FDA June 2014), available at <http://www.fda.gov/downloads/Cosmetics/GuidanceRegulation/GuidanceDocuments/UCM300927.pdf> (“Manufacturing Process Change Guidance”).

[5] Guidance for Industry: Safety of Nanomaterials in Cosmetic Products (FDA June 2014), available at <http://www.fda.gov/downloads/Cosmetics/GuidanceRegulation/>

[GuidanceDocuments/UCM300932.pdf](#) (“Cosmetic Nanotechnology Guidance”).

[6] Draft Guidance for Industry: Use of Nanomaterials in Food for Animals (FDA June 2014), available at <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM401508.pdf> (“Animal Food Draft Guidance”).

[7] Nanotechnology Guidance at 4.

[8] *Id.* at 5.

[9] *Id.* at 6-7.

[10] *Id.* at 5-6.

[11] *Id.* at 4.

[12] Manufacturing Process Change Guidance.

[13] *Id.* at 4.

[14] The Manufacturing Process Change Guidance provides several examples of what constitutes a product’s identity: the product’s name, identification number, chemical formula, source, quantitative composition, impurities and contaminants and physical and chemical properties.

[15] *Id.* at 19.

[16] *Id.* at 20.

[17] *Id.* at 5.

[18] *Id.* (citing 40 Fed. Reg. 8912, 8916 (Mar. 3, 1975)).

[19] *Id.* at 6.

[20] *Id.* at 7.

[21] *Id.* at 8.

[22] *Id.* at 9.

[23] *Id.*

[24] *Id.* at 10.

[25] *Id.* at 11.

[26] Animal Food Draft Guidance.

[27] *Id.* at 6.

[28] *Id.* at 7.





While the Flexibility Guidance is non-binding, its impact should not be underestimated, as it is applied by the national competent authorities responsible for enforcement of the Claims Regulation.

## INFLEXIBILITY GUIDANCE?: The Case against Brand-Specific Claims

*“Fair words are as a honeycomb: sweetness to the soul, and health to the bones.” - Proverbs 16:24*

*In a regime of harmonized permitted health claims under Regulation 1924/2006<sup>[1]</sup> (the “**Claims Regulation**”), differentiating commercial communications from others has become a challenge in the food industry. The Flexibility Principle, laid down in Recital (9) of Regulation 432/2012<sup>[2] [3]</sup>, plays a key role here, allowing for the use of a wording different from that expressly authorized. The use of health claims referring directly to the brand name of a product (“**Brand-Specific Claims**”), instead of the specific nutrient or other substance subject of the authorized claim, is expressly prohibited in the recommendations on general principles on flexibility of wording for health claims<sup>[4]</sup> (“**Flexibility Guidance**”). This article examines the legality of such outright prohibition in the light of EU law.*

### Introduction

The so-called Flexibility Guidance, which was adopted in December 2012 by 17 Member States stresses the importance of a link between the claimed effect and the nutrient, substance, food or food category responsible for the effect. According to the Member States, a claim such as “*Product Y contributes to the normal function of the immune system,*” even if accompanied by the claim “*Product Y contains substance X*” does not make a clear link between substance X and the claimed effect and would therefore not be allowed. The same reasoning is reflected in the terms and conditions of the online EU Register of nutrition and health claims, which state that “[h]ealth claims should only be made for the nutrient, substance, food or

*food category for which they have been authorized, and **not** for the food product that contains them.”<sup>[5]</sup> While the Flexibility Guidance is non-binding, its impact should not be underestimated, as it is applied by the national competent authorities responsible for enforcement of the Claims Regulation.<sup>[6]</sup>*

Brand-Specific claims should be distinguished from brand names that by themselves can be construed as health claims, which may be used pursuant to Article 1(3) of the Claims Regulation, provided that they are accompanied by a related, authorized health claim. They should further be distinguished from general, non-specific health claims as referred to in Article 10(3) of the Claims Regulation.

According to the Flexibility Guidance, the reason for the prohibition of Brand-Specific Claims is that “*the authorized claim describes the particular health relationship that EFSA said is substantiated by scientific evidence.*” This reasoning is flawed, since the use of an authorized health claim on a product automatically implies a relationship between that product and the health benefit for which the claim is made. A Brand-Specific Claim accompanied by the full wording of the authorized health claim or by a reference to the ingredient responsible for the effect would provide the necessary information for consumers to understand the true health relationship.

Besides the reason provided in the Flexibility Guidance, the prohibition of Brand-Specific Claims relies on a presumption that Brand-Specific Claims would, *per se*, infringe Article 2(a)(iii) of Directive 2000/13<sup>[7]</sup> and Article 7(1)(c)

of Regulation 1169/2011,<sup>[8]</sup> according to which “*the labeling and methods used must not be such as could mislead the purchaser to a material degree, particularly by suggesting that the foodstuff possesses special characteristics **when in fact all similar foodstuffs possess such characteristics.***”<sup>[9]</sup>

Indeed, it is conceivable that the claim “*Brand X contributes to the normal function of the immune system*” could, under certain circumstances, raise the impression that only Brand X is good for the immune system, whereas other similar foods deliver the same benefit. However, the question is whether this would justify the absolute nature of the recommendation in the Flexibility Guidance.

This article will first of all assess whether a general prohibition on Brand-Specific Claims in the labeling, presentation and advertising of a foodstuff could be justified in the light of EU law. Subsequently, it will assess to which extent an average consumer is likely to be misled by Brand-Specific Claims in the light of the case-law of the Court of Justice of the European Union (“**CJEU**”).

### 1. Legality of a general ban on Brand-Specific Claims

It should be stated at the outset that the Claims Regulation does not expressly prohibit the use of Brand-specific Claims.<sup>[10]</sup> According to settled caselaw of the CJEU, the risk of misleading consumers by means of labeling or advertising statements or descriptions cannot override the requirements of the free movement of goods and so justify barriers to trade arising from blanket bans on the use of such statements unless that risk is “*sufficiently*

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*serious or obvious.*<sup>[11]</sup> There are numerous examples of total bans on statements or descriptions in the labeling and advertising arising from national provisions that have been invalidated by the CJEU on grounds of their lack of proportionality.

In *Pall*, the Court dismissed the argument of the German authorities that banning the marketing of all products bearing the symbol “®” next to the trademark was justified since it misleads consumers if the trademark is not registered in the country where the goods are marketed on the ground that “even assuming that consumers, or some of them, might be misled on that point, such a risk cannot justify so considerable an obstacle to the free movement of goods, since consumers are more interested in the qualities of a product than in the place of registration of the trademark.”<sup>[12]</sup>

In *Douwe Egberts*, the Court maintained that “[a]n absolute prohibition on particulars appearing on the labeling of certain foodstuffs relating to slimming or medical recommendations without an examination on a case-by-case basis of whether they are in fact apt to mislead the buyer would mean that foodstuffs bearing those indications would not be able to be freely marketed in Belgium even where those statements are not fraudulent.” As such a measure would exceed what is necessary in order to attain the objective pursued, it is incompatible with EU law.<sup>[13]</sup>

In *Commission v. Austria*, the Court found that a general prohibition, subject to prior authorization, for health-related information in the labeling of foodstuffs infringed EU law since it “has the consequence in practice that foodstuffs bearing health-

related information may not be marketed freely in Austria, even if the information is not liable to mislead the consumer.”<sup>[14]</sup>

In *SARPP*, the Court held that the prohibition on statements referring to the word “sugar” or the physical, chemical or nutritional properties of sugar in the labeling and advertising of artificial sweeteners is “manifestly disproportionate” to the objective of protection against unfair competition as “not every statement in the labeling of artificial sweeteners alluding to the word ‘sugar’ or to its properties necessarily has the effect of denigrating sugar.”<sup>[15]</sup>

In *Unilever*, a case relating to toothpastes claimed to prevent the formation of tartar or parodontosis, the Court held that the general prohibition on the advertising of substances not listed in the Austrian legislation on cosmetic products (*Kosmetikverordnung*) unless an authorization is sought constituted a “wholly unjustified obstacle to the free movement of the product in question” in so far as those rules do not list all active substances that may prevent the formation of tartar or parodontosis.<sup>[16]</sup>

In *Linhart*, the CJEU ruled that national provisions prohibiting references to expert medical opinions on the marketing of cosmetic products – in particular, the use of the statement “clinically tested” or “dermatologically tested” – unless non-misleading information on the physiological or pharmacological effects of the product concerned had been authorized – went beyond the aim of consumer protection laid down in the EU rules on cosmetic products.<sup>[17]</sup>

It can be concluded from the aforementioned caselaw that a general prohibition on Brand-Specific Claims is contrary to EU law since it deprives food business operators from making the said claims without an examination, on a case-by-case basis, of whether they are, in fact, apt to mislead consumers, thereby exceeding what is necessary to attain the objective of consumer protection laid down by the Claims Regulation.



### 2. Risk of misleading the consumer: The need of a case-by-case approach

Notwithstanding this, Brand-Specific Claims may still be prohibited on a case-by-case basis<sup>[18]</sup> and, in particular, if a “sufficiently serious” risk exists that they mislead consumers, for example, by suggesting that only that particular brand could have the generic health benefit claimed, whereas other foods would deliver the same benefit as long as they comply with the conditions of use.

In effect, according to settled caselaw, in order to determine whether an appellation, brand name, advertising statement or labeling particular is misleading, the national courts must take into account the presumed expectations that it evokes to an average consumer who is reasonably well informed and reasonably observant and circumspect.<sup>[19]</sup> The concept of an average consumer refers (i) to the final consumer of a product (who may or not coincide with the buyer); (ii) who receives the necessary information he wishes to obtain on the product he is purchasing and the

conditions of its marketing (the latter must not be limited to the point of sale or the time of purchase); (iii) who has sufficient experience and abilities to process that information; and (iv) who does not have a merely passive attitude but a prudently active behavior without conducting thorough investigations.<sup>[20]</sup>

In other words, the average consumer is not one who buys irrespective of the characteristics of the products but takes in all the information that is made available to him.

Importantly, it needs to be taken into account that consumers whose purchasing decisions depend on the composition of the products in question will first read the list of ingredients, the display of which is required by Article 6 of Directive 2000/13 and Article 9 of Regulation 1169/2011. For example, consumers could not be misled by the term “naturally pure” used on the label of a jam simply because it contains an additive whose presence is duly indicated on the list of ingredients.<sup>[21]</sup> For the same reason, consumers could not be misled by the intense yellow of biscuits and pastry products due to the presence of additive “E 160 F” or béarnaise sauce and hollandaise sauce made with vegetable fats, although this is contrary to the traditional German recipe.<sup>[22]</sup>

In view of this legal framework, the risk to mislead an average consumer by linking the beneficial effect of a health claim directly to a brand name should not be considered “sufficiently serious,” as required by the CJEU in order to prohibit such claims. Several rulings by the CJEU confirm this view. For example, in *Mars*, in response to the attempt of the German court to ascertain whether the marking “+10%” in the wrapping of ice-cream bars lawfully marketed in France was misleading, the Court held that “[r]easonably circumspect consumers may be deemed to know that there is not necessarily a link between the size of publicity markings relating to an increase in a product’s quantity and the size of that increase.”<sup>[23]</sup> In *Estée Lauder*, the Court maintained that “the clinical or medical connotations of the word ‘Clinique’ are not sufficient to make that word so misleading as to justify the prohibition of its use on [cosmetic] products.”<sup>[24]</sup> In *Darbo*, the Court stated that circumspect consumers

may be deemed to know that even where a food is promoted as “naturally pure,” it is not free of any residues and pesticides, since it is common ground that lead and cadmium are present in the natural environment and that the use of pesticides, even by private individuals is one of the most usual means of combating the presence of harmful organisms on vegetables and agricultural products.<sup>[25]</sup> Finally, in *Estée Lauder (II)*, the Court stated that “the average consumer – reasonably well informed and reasonably observant and circumspect – ought not to expect a cream whose name incorporates the term ‘lifting’ to produce enduring effects.”<sup>[26]</sup>

In addition to the legal construction of the average consumer, whose attentiveness and active attitude towards labeling and advertising would prevent him from being misled by a Brand-Specific Claim, there are several legal arguments which reinforce the aforesaid conclusion.

First of all, Article 1(3) of the Claims Regulation generally allows for trademarks, brand names or fancy names that may be construed as health claims in themselves. It follows that the EU legislature itself presumes that the average consumer would not be misled by names claiming a health benefit *per se* without referring to a generic food constituent. In other words, there is a presumption that the average consumer is able to disconnect the property of the name from the alleged benefit, e.g., any averagely informed and circumspect consumer understands that *Weight Watchers* does not have a monopoly on the slimming products market.

Secondly, the Court has stated that the length of time for which a name has been used is an objective factor that may

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affect the expectations of the reasonable consumer.<sup>[27]</sup> Since it can be presumed that health-related references connecting a beneficial effect directly to the brand name of a product have been in use on the EU market for a long time prior to the entry into force of the Claims Regulation, the risk that consumers would be misled by such practice after the establishment of the list of permitted health claims is reduced.

Thirdly, Article 5 of Directive 2000/13 and Article 17 of Regulation 1169/2011, which could be applied by analogy, offer the possibility to use the fancy name of a food as long as it is accompanied by the sales name or a description of the product (it is only prohibited to substitute the sales name by a fancy name or trademark).

<sup>[28]</sup> Moreover, the CJEU has held that a prohibition to include a fancy name or a trade name in the labeling of a food “would restrict information to consumers on the characteristics of the products (...) and would be contrary to one of the objectives set out in the sixth recital in the preamble to Directive 2000/13,” i.e., the need to inform consumers.<sup>[29]</sup> For that reason, a well-known trademark could increase the ability of consumers to understand a health claim, in compliance with Article 5(2) of the Claims Regulation, according to which “the use of nutrition and health claims shall only be permitted if the average consumer can be expected to understand the beneficial effects as expressed in the claim.”<sup>[30]</sup>

Finally, it is worth noting that the legal framework for medicinal products (more stringent than the food legal framework) not only allows the use of trademarks in the advertising of “over the counter medicines” but, in some cases, it allows the advertisers

to include only the trademark of the medicine and not its active substance.<sup>[31]</sup>

### Conclusions

We can conclude that a general prohibition on Brand-Specific Claims such as that proposed in the Flexibility Guidance is contrary to EU law since it deprives food business operators from making the said claims without an examination, on a case-by-case basis, of whether they are, in fact, apt to mislead consumers, thereby exceeding what is necessary to attain the objective of consumer protection laid down by the Claims Regulation. We can also conclude that, while there is a risk that Brand-Specific Claims mislead consumers by suggesting that only that particular brand could have the generic health benefit claimed, whereas other foods would deliver the same benefit, the case law of the CJEU on the definition of an “average consumer” suggests that this risk is not “sufficiently serious and obvious” in order to prohibit such claims.

Therefore, instead of an *a priori* ban, there should be an assessment, taking into account all the elements in the labeling, presentation and advertising and the overall impression in an average consumer.

The risk of misleading the consumer when making use of Brand-Specific Claims in the labeling, advertising or presentation of foodstuffs can be reduced or even avoided by accompanying the Brand-Specific Claim by the full wording of the authorized claim or by a reference to the ingredient responsible for the health benefit (preferably in the same field of vision and with the same font size), so as to ensure that the labeling, advertising

or presentation “tells the whole truth,” i.e., ultimately, consumers should be informed of the nutrient or other substance responsible for the beneficial effect. Brand-Specific Claims of an excluding tone (e.g., “the only one to lower cholesterol”) should be avoided, as well as any suggestions that could mislead consumers into believing that a product is the only one to have the alleged beneficial effect. Finally, it may be useful to carry out surveys and opinion polls to test the consumers’ understanding of the Brand-Specific Claims intended to be used, in order to clarify whether or not they are misleading.

By Sebastián Romero Melchor and Lara Skoblikov

### Citations

[1] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404/9 of 30.12.2006), as last modified by Commission Regulation No 116/2010 of 9 February 2010 (OJ L 37/16 of 10.2.2010).

[2] Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children’s development and health (OJ L 136, 25.5.2012, p. 1–40).

[3] According to Recital (9) of Regulation 432/2012, “where the wording of claims has the same meaning for consumers as that of a permitted health claim, because it demonstrates the same relationship that exists between a food category, a food or one of its constituents and health, the claims should be subject to the same conditions of use indicated for the permitted health claims.”

[4] General principles on flexibility of wording for health claims, available at: [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/217005/health-claims-flexibility-of-wording-principles-UK-19-Dec-2012.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/217005/health-claims-flexibility-of-wording-principles-UK-19-Dec-2012.pdf).

[5] This position of the European Commission and Member States was already made clear at the meeting of December 18, 2008 of the STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH, where it was stated that “the beneficial effect referred to in a health claim (...) should refer to a nutrient or a substance present in the food. A reference only to the trademark or product name would not be acceptable.” STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH (hereinafter, “SCOFCAH”), Section on General Food Law, Summary Record of Meeting of 18 December 2008, paragraph 7, p. 4.

[6] For example, a € 110.000 fine was recently imposed on a food business operator by the Italian Competition Authority, who took the Flexibility Guidance into account. AUTORITÀ GARANTE DELLA CONCORRENZA E DEL MERCATO, provvedimento n. 24938, May 20, 2014, paragraph 49.

[7] Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labeling, presentation and advertising of foodstuffs (OJ L 109, 6.5.2000, p. 29–42).

[8] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18–63).

[9] At the meeting of COMMISSION WORKING GROUP ON HEALTH AND NUTRITION CLAIMS of January 12, 2009, several Member States suggested to develop guidance to help enforcement authorities establish the limits of flexibility “particularly where certain wording while appearing to represent the listed claim might actually mislead consumers, for example by suggesting that only the food bearing the claim could have the health benefit whereas other foods would deliver the same benefit.” (Cf. UK FOOD STANDARD AGENCY meeting summary of January 12, 2009). A project guidance prepared by the European Commission to help enforcement authorities performing the “admissibility check” of applications was subsequently circulated at the meeting of April 20, 2009, reflecting the stance expressed by the SCOFCAH: “[t]he beneficial effect referred to in a health claim, shall refer to

a food category or a food as denomination, or a nutrient or a substance, sufficiently characterised, and present in the food. A reference only to the trademark or product name is not acceptable. To illustrate the distinction; a product that contains plant sterols or plant stanol esters may refer to: ‘Plant sterols have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease,’ Whereas it may not refer to: ‘Trademark X has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease.’” Vid. European Commission Working Paper (Agenda Item 5) – Guidance in carrying out the admissibility check).

[10] Contrary to, for example, the use of health claims on alcoholic beverages, which have been considered misleading as such by the EU legislature. Judgment of the CJEU of 6 September 2012, *Deutsches Weintor eG contre Land Rheinland-Pfalz.*, Case C-544/10, not yet published, paragraph 52.

[11] Judgment of the CJEU of 26 November 1996, *F.lli Graffione SNC v Ditta Fransa*, Case C-313/94, ECR [1996] p. I-06039, paragraph 24. See also the opinion of the Advocate General Léger delivered on January 20, 2000 in Case C-465/98, paragraph 58.

[12] Judgment of the CJEU of 13 December 1990, *Pall Corp. v P. J. Dahlhausen & Co*, Case C-238/89, ECR [1990] p. I-04827, paragraph 19.



## INFLEXIBILITY GUIDANCE?: The Case against Brand-Specific Claims

[13] Judgment of the CJEU of 15 July 2004, *Douwe Egberts NV v Westrom Pharma NV and Christophe Souranis*, Case C-239/02, ECR [2004] p. I-07007, paragraph 43.

[14] Judgment of the CJEU of 23 January 2003, *Commission of the European Communities v Republic of Austria*, Case C-221/00, ECR [2003] p. I-01007, paragraph 51. See also judgment of 23 January 2003, *Renate Sterbenz and Paul Dieter Haug*, Joined Cases C-421/00, C-426/00 and C-16/01, [2003] ECR I-1065, paragraph 40.

[15] Judgment of the CJEU of 12 December 1990, SARPP - *Société d'application et de recherches en pharmacologie et phytothérapie SARL v Chambre syndicale des raffineurs et conditionneurs de sucre de France and others*, Case C-241/89, ECR [1990] p. I-04695, paragraph 21.

[16] Judgment of the CJEU of 28 January 1999, *Österreichische Unilever GmbH v Smithkline Beecham Markenartikel GmbH*, Case C-77/97, ECR [1999], p. I-00431, paragraph 34.

[17] Judgment of the CJEU of 24 October 2002, *Criminal proceedings against Gottfried Linhart and Hans Biffel*, Case C-99/01, ECR [2002] p. I-09375, paragraph 46.

[18] The CJEU has emphasized that only an absolute prohibition of claims, without an examination on a case-by-case, would be incompatible with EU law. Judgment of the CJEU of 30 April 2014, *Moritz Hagenmeyer and Andreas Hahn v European Commission*, T-17/12, not published yet, paragraph 97.

[19] Judgment of the CJEU of 16 July 1998, *Springenheide*, Case C- 210/96, ECR [1988] p. I-4657, paragraph 37. See also, inter alia, judgment of 28 January 1999, *Verbraucherschutzverein eV v Sektellerei G.C. Kessler GmbH and Co*, Case C-303/97, ECR [1999] p. I-00513, paragraph 36; and *Renate Sterbenz and Paul Dieter Haug*, cited *supra* in note 15, paragraph 43.

[20] See GONZÁLEZ VAQUÉ L, "La noción de consumidor normalmente informado en la

*jurisprudencia del Tribunal de Justicia de las Comunidades Europeas: la Sentencia Gut Springenheide*," *Derecho de los Negocios*, n° 103 (April 1999). *Vid.* from the same author "La noción de consumidor normalmente informado en la jurisprudencia del Tribunal de Justicia de las Comunidades europeas," *Revista de Derecho Comunitario Europeo*, año 8, n°17, (January-April 2004) and "El Derecho del Consumo en la Unión Europea: la problemática planteada por la armonización mínima en las normativas comunitarias relativas a la protección de los consumidores", *Gaceta Jurídica de la UE* n°233 September-October 2004, p. 38-41.

[21] Judgment of the CJEU of 4 April 2000, *Verein gegen Unwesen in Handel und Gewerbe Köln eV v Adolf Darbo AG*, Case C-465/98, ECR [2000] p. I-02297, paragraph 22. When describing the concept of consumer provided for in Directive 2000/13, the Advocate General Cosmas stated: "[t]he fact that the directive focuses on the average consumer does not mean that this is an ill-informed consumer or one who is unable to articulate his preferences or requirements (...) the consumer does not buy and must not be encouraged to buy a product irrespective of its characteristics or because that product has been the subject of more widespread publicity," *Vid.* Opinion of Mr Advocate General Cosmas delivered on 19 February 1998, *Criminal proceedings against Hermann Josef Goerres*, Case C-385/96, ECR [1998] p. I-04431.

[22] Judgment of the CJEU of 26 October 1995, *Commission of the European Communities v Federal Republic of Germany*, Case C-51/94, ECR [1995] p. I-03599, paragraph 34.

[23] Judgment of the CJEU of 6 July 1995, *Verein gegen Unwesen in Handel und Gewerbe Köln e.V. v Mars GmbH*, Case C-470/93, ECR [1995] p. I-01923, paragraph 24.

[24] Judgment of the CJEU of 2 February 1994, *Verband Sozialer Wettbewerb eV v Clinique Laboratoires SNC et Estée Lauder Cosmetics*

*GmbH*, Case C-315/92, ECR [1994] p. I-00317, paragraph 23.

[25] *Vid.*, *Adolf Darbo AG*, cited *supra* in note 22, paragraphs 26-29.

[26] Judgment of the CJEU of 13 January 2000, *Estée Lauder Cosmetics GmbH & Co. OHG v Lancaster Group GmbH*, Case C-220/98, ECR [2000] p. I-00117, paragraph 30. The Court went on to say that "it nevertheless remains for the national court to determine, in the light of all the relevant factors, whether that is the position in this case." See, along the same lines, judgment of of the CJEU of 6 November 2003, *Commission of the European Communities v Kingdom of Spain*, Case C-358/01, ECR [2003] p. I-13145.

[27] Judgment of the CJEU of 10 September 2009, *Alberto Severi v Regione Emilia Romagna*, Case C-446/07, ECR [2009] p. I-08041, paragraph 62.

[28] Also, Article 6(2)(c) Directive 2000/13 and Article 19(e)(ii) of Regulation 1169/2011 provide that products comprising a single ingredient do not need to label the ingredient in the case where the name of the food enables the nature of the ingredient to be clearly identified. Along the same lines, if a compound ingredient is well known by consumers, there is no need to label the ingredients. Otherwise, they need to be labelled next to the compound ingredient.

[28] Judgments of the CJEU of 15 July 2004, *Douwe Egberts NV v Westrom Pharma NV*, Case C-239/02, ECR [2004] I-07007, paragraph 28.

[29] *Id.*

[30] Cf. Art. 88(2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67-128). According to Article 89(2), Member States may decide that the advertising of a medicinal product to the general public may include only the trademark in some cases.

[31] Opinion of Advocate General Sharpston delivered on May 7, 2009 in Case C-446/07, ECR [2009] p. I-08041, paragraph 66.



For further information please contact:

Editors:

Sebastián Romero Melchor	sebastian.romeromelchor@klgates.com	T: +32 (0)2 336 1906	Brussels
Suzan Onel	suzan.onel@klgates.com	T: +1 (202) 778 9134	Washington, D.C.

Authors:

Jacqueline Chan	jacqueline.chan@klgates.com	T: +1 (202) 778 9291	Washington, D.C.
Vanessa Edwards	vanessa.edwards@klgates.com	T: +44 (0)20 7360 8293	London/Brussels
Max Gu	max.gu@klgates.com	T: +86 21 2211 2084	Shanghai
Aqua Huang	aqua.huang@klgates.com	T: +86 21 2211 2089	Shanghai
Ayuko Nemoto	ayuko.nemoto@klgates.com	T: +81 3 6205 3618	Tokyo
Junko Okawa	junko.okawa@klgates.com	T: +81 3 6205 3619	Tokyo
Lara Skoblikov	lara.skoblikov@klgates.com	T: +32 (0)2 336 1900	Brussels
Izabela Tanska	izabela.tanska@klgates.com	T: +32 (0)2 336 1948	Brussels

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