



Highlighting Issues and
Developments Across the Globe
in the Food, Drug, Medical
Device and Cosmetic Industries

Fall 2013

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Welcome

It is with great pleasure that we launch the first edition of the Global Food, Drug and Medical Device newsletter.

This newsletter provides updates on important issues and developments across the food, drug, medical device and cosmetic industries. Among the topics covered in this first issue are changes to the regulatory framework in several countries, in the areas of food, cosmetic or medical devices. In addition, our featured articles seek to provide a global perspective on caffeinated energy drinks, new rules on medical devices in various jurisdictions, and their influence and impact on our clients' business.

The knowledge and insights of our experienced professionals can be a key resource for companies facing any challenges. The Global Food, Drug and Medical Device newsletter, prepared by members of the K&L Gates Global Food, Drug and Medical Device practice group, contains concise articles that seek to highlight key developments regarding a broad spectrum of topics.

K&L Gates' global platform allows our FDA 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 involving FDA-related issues on the East and West coasts of the United States, as well as throughout Canada, the European Union (EU), Australia, Japan and the Pacific Rim, Latin America, and other markets.

We hope you find this first edition of interest. 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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FTC Update - Juice Beverages

FTC Rules That “Randomized Clinical Trial” Evidence is Necessary to Support Advertising Claims for Juice Beverage and Related Products

I. Introduction

If you represent food and beverage manufacturers who advertise their products, you will want to be familiar with In the Matter of POM Wonderful LLC, a recent decision by the Federal Trade Commission (“FTC”) that is currently under review at the U.S. Court of Appeals for the District of Columbia. The FTC’s rather weighty decision (over 50 pages) contains a detailed look at the FTC’s current stance on the type of evidence an advertiser must possess in order to make claims about the health benefits of a food or beverage product. This article provides an overview of the advertising claims involved, a short explanation of the FTC’s decision, and some of the key take-aways that you and your clients may want to consider in assessing your food and beverage advertising campaigns.

II. The Challenged Ads

POM Wonderful manufactures and sells a family of pomegranate juice and related products under a variety of “POM”-branded names. POM Wonderful’s advertising campaign touted the health benefits

associated with its pomegranate juices and related products. While most of the POM Wonderful ads described study results as being “preliminary” and/or “promising,” the FTC took the position that many of them implicitly and sometimes expressly claimed that the POM products would “treat, prevent, or reduce the risk of” serious health ailments such as “heart disease, prostate cancer, and erectile dysfunction.”

The FTC also argued that many of the ads reinforced these claims by invoking “medical imagery” such as a blood pressure cuff encasing a POM bottle and “EKG” sensors, accompanied by taglines such as “[a]maze your cardiologist” and “[l]ucky I have super HEALTH POWERS.”

The FTC challenged these ads (and others like them) in 2010, ultimately claiming that a total of 43 violated Sections 5(a) and 12 of the FTC Act. The FTC also took the position that two double-blind randomized controlled clinical trials and FDA pre-approval should be required of POM before it could make any health-related statements in its advertisements. After a trial that spanned several months, the ALJ determined that 19 of the ads at issue contained implied claims that the products were effective at treating, preventing, or reducing the risk of these health conditions. While stopping short of requiring that POM Wonderful needed two full-blown randomized clinical trials as evidence to support these claims (which had been the FTC’s position throughout the litigation), as well as finding that FDA pre-approval of POM’s advertisements was not required, the ALJ nevertheless found these

ads deceptive. Accordingly, the ALJ issued an order that would prohibit POM Wonderful from making these advertising claims in the future unless they were based on “competent and reliable scientific evidence.”

Both the FTC and POM appealed the case to the full commission.

III. The FTC Decision and the Key Take-Aways

The FTC Commission reviewed the ALJ’s Initial Decision, revisiting each of the ads at issue, the messages conveyed therein, and the underlying substantiation for the advertising claims as introduced at trial. The FTC went further than the ALJ and found that 36 of the 43 ads were deceptive. Although an in-depth review of the FTC order with respect to the individual ads is beyond the scope of this alert, there are some key take-aways that are valuable for the industry to consider when developing marketing and ad campaigns.

First, the FTC found that most of POM’s challenged ads contained “establishment” claims in that they conveyed the message that POM products were “clinically proven” to treat, prevent, or reduce the risk of heart disease, prostate cancer, and erectile dysfunction. According to the FTC, when an advertiser claims, expressly or implicitly, that its food or beverage products treat, prevent, or reduce “serious diseases” such as the ones at issue, the advertiser must have “Randomized Clinical Trial” (“RCT”) evidence to support those advertising claims.

A properly structured RCT will select participants randomly, will be double-blind, and will have both a test group and a control group. While POM Wonderful produced expert testimony regarding the limitations of RCTs in connection with the study of the health benefits of foods, the value of in vitro, animal, and small-scale human studies, and the actual “health benefits” associated with pomegranates and pomegranate juice, the FTC found POM’s scientific substantiation did not provide sufficient support for its advertising claims and required that POM have RCTs for its claims. The final order requires “at least two [RCTs] of the covered product that are randomized, well controlled, based on valid end points, and conducted by persons qualified by training and experience to conduct such studies.” This represents a tougher standard than what the ALJ required, i.e., competent and reliable clinical evidence, but not necessarily RCTs. Notably, this new standard closely tracks the “gold standard” used by the FTC for drug claims and language appearing in recent consent decrees. Nevertheless, the FTC rejected the notion that requiring RCTs for food product health claims rises to the same level as the FDA’s standards for proof of drug claims. The Commission stated it was not holding POM Wonderful to a pharmaceutical standard because the FDA regulations for drugs require multiple phases of clinical trials producing different and greater substantiation than what the FTC required of POM Wonderful.

Thus, the key holding in the decision makes it clear that when an advertiser claims a food or beverage product provides any health-related benefits, it implicitly sends the message to consumers that the product treats, reduces, or prevents serious diseases, for which the FTC is going to expect robust substantiation in the form of RCTs. Second, consistent with prior FTC precedent, the decision underscores that when reviewing an ad for compliance with the FTC Act, it is necessary to consider the entire “gestalt” of the ad itself instead of considering individual elements. This principle was particularly important here because although some of the ads did not expressly rely on “scientific” evidence per se, the imagery and creative execution of those ads, particularly when combined with the text, could leave consumers with the impression that using the POM products at issue would be effective at treating, preventing, or reducing the risk of disease. For example, a POM bottle in the shape of an intravenous bag, the use of the caduceus (a well-recognized symbol of the medical profession), and stethoscope all reinforced the message that the products at issue were effective in treating or preventing the serious health conditions that were mentioned in the ads. The FTC’s treatment of the imagery is an important reminder that the visual effects of an ad simply cannot be divorced from the text. The unitary whole should always be considered.

Finally, the FTC decision also discusses the use of “qualifiers.” In several of the ads, the scientific evidence relied upon

was characterized as “preliminary,” “promising,” “encouraging,” or “hopeful.” POM Wonderful argued that because it qualified the nature of the clinical studies in this way, these particular ads were not making “establishment claims.” The FTC rejected the argument, finding that POM Wonderful’s “use of one or two adjectives does not alter the net impression that clinical studies prove their claims. This is especially true when the chosen adjectives - promising, encouraging, or hopeful - provide a positive spin on the studies rather than a substantive disclaimer.”

IV. Conclusion

In the Matter of POM Wonderful LLC is an important decision to keep in mind when considering the type of health and wellness claims that can be made when it comes to food and beverage products. The claim-substantiation standard appears to have been raised to a level that is closer to what is required of drug claims, but that is applied here across product lines to food and beverage products. If the advertising claims implicitly or expressly assert that the product helps treat, prevent, or reduce the risk of a serious health condition, then it will be necessary to support those claims with well-designed and well-executed RCTs. POM filed a petition for review of the FTC’s Order in the D.C. Circuit on March 8, 2013; the briefing schedule closes in October 2013, with a decision on the merits to be issued thereafter. ■

By J. Michael Keyes and Suzan Onel

EU Health Claims

New EU Guidance on Health Claims

Two developments of importance for the interpretation of the new list of permitted health claims in the Nutrition and Health Claims Regulation (Regulation 1924/2006 on nutrition and health claims made on foods, “the Regulation”) were adopted recently. The first one, on which only certain Member States have agreed, deals with how the so-called “flexibility” principle in the wording of health claims should be applied. The second one, on which all Member States have agreed and which entered into force today, sheds light on the scope of application of Article 10 of the Regulation (specific conditions for health claims).

General Principles on Flexibility of Wording for Health Claims

Recital 9 in the preamble to the Regulation envisages that, where the wording of a claim 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, that claim should be subject to the same conditions of use indicated for the permitted health claims.

In December 2012, 17 Member States’ experts agreed on a series of general principles on flexibility of wording for health claims (“General Principles”). The Member

States are Austria, Belgium, Denmark, Estonia, Finland, France, Germany, Hungary, Ireland, Lithuania, Luxembourg, Netherlands, Norway, Poland, Portugal, Sweden and United Kingdom.

The General Principles set out the main rules to be respected when authorised health claims are used but the wording is not exactly as authorised. Helpful examples of acceptable and unacceptable variations are given. The Principles are summarised below:

- The adapted wording must have the same meaning for the consumer as the authorised wording. In particular, it must not be stronger, or a medicinal claim, or misleading;
- The word “normal” in authorised health claims in the English version of the Regulation should not be replaced or removed (e.g. “Beta-glucans contribute to the maintenance of normal blood cholesterol levels”);
- The claim must not state or imply that there is a link between the claimed effect and anything other than the nutrient, substance, food or food category which is directly responsible (e.g. “Product X contributes to the maintenance of normal blood levels”);
- Although mandatory statements on food supplements are exempt from the Claims Regulation, that Regulation may apply if the context and overall presentation of a claim go beyond a simple mention of the nutrient or

substance (e.g. “Food supplement with gut-protecting probiotic bacteria”);

- Where reference is made to general, non-specific benefits of a nutrient or food or for overall good health or health-related well-being, it must be accompanied by a specific, authorised health claim. This applies also where the general claim is a trade mark, brand name or fancy name; and
- Extreme care should be exercised if using sentences or words from an EFSA opinion to adapt the wording of an authorised health claim, since this may change the meaning of the claim.

Guidelines for the Implementation of Specific Conditions for Health Claims

The Commission adopted guidelines for the implementation of specific conditions for health claims (“Guidelines”). These Guidelines are to be taken into account by the national control authorities and food business operators.

The Guidelines are summarised below:

1. Health claims which are not authorised and health claims which have been authorised but whose use does not comply with the Regulation are prohibited;
2. Article 10(2) of the Regulation requires that authorised health claims include certain mandatory information in the labelling or in the presentation and advertising if there is no labelling.

3. The guidelines clarify as follows:

- › An example of a situation where there is no labelling (so that the information would need to be included in the presentation or advertising) would be where a health claim is used in generic advertising for a food, e.g. olive oil;
- › In cases of distance selling (e.g. internet orders), access to labelling is restricted and the information must be included in the presentation and advertising of the food;
- › Article 1(2) of the Regulation provides that the mandatory information listed in Article 10(2) (a) (a statement indicating the importance of a varied and balanced diet and healthy lifestyle) and (b) (the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect) does not have to be provided in the case of non-prepackaged foodstuffs put up for sale to the final consumer or to mass caterers and foodstuffs packed at the point of sale at the request of the purchaser or pre-packed with a view to an immediate sale. In contrast, the Guidelines state that the information required under Article 10(2)(c) (where appropriate, a statement addressed to persons who should avoid using the food) and (d) (an appropriate warning for products that are likely

to present a health risk if consumed to excess) is always required;

- › Further guidance is given regarding the information listed in Article 10(2). In particular, the Guidelines note that Food Business Operators (FBOs) should assume their responsibilities under general food law and comply with the fundamental and overriding requirement to market food which is safe and not harmful to health.
4. Article 10(3) of the Regulation permits reference to general, non-specific benefits for overall good health or health-related well-being provided that a specific, authorised health claim is also provided.
 - › The Guidelines state that the accompanying specific health claim should be made next to or following the general statement and should bear some relevance to the general reference;
 - › Moreover FBOs have the responsibility to demonstrate the link between the general reference and the accompanying health claim;
 - › Finally, the Guidelines clarify that a general or non-specific claim that is on the list of non-authorised claims may still be lawfully used in accordance with Article 10(3) provided that they are accompanied by a specific, authorised claim.

The General Principles and the Guidelines provide timely and useful guidance for the interpretation of the list of permitted health claims. Whilst the documents are “soft law” instruments and do not have legal value, they represent a safe harbour for companies willing to adjust to the interpretation of the national authorities. However, a different interpretation may still be lawful. ■

by Sebastián Romero Melchor and Vanessa C. Edwards



Blanket Ban on Animal Testing on Cosmetics Enters into Force

The European Union (EU), through a Commission Communication, has decided to implement a total marketing ban on cosmetic products and ingredients tested on animals as from March 11, 2013. This ban will be enforced despite the fact that alternative non-animal tests have not yet been developed for repeated-dose toxicity, reproductive toxicity and toxicokinetics tests.

The total marketing ban will impact the marketing in the EU of cosmetics tested on animals in non-EU countries, such as China, as these tests cannot be relied upon in order to prove the safety of the product in the EU.

Consequences

In practice, a cosmetics company wanting to use a new ingredient that cannot be tested via proven alternative methods to animal testing will not be able to rely on animal testing data for the purpose of complying with the safety requirements of Regulation 1223/2009 on cosmetic products.

Companies will be able to rely only on proven alternative methods to animal testing for the purpose of assessing an ingredient's safety. In the absence

of such methods, there will be no possibility of using the ingredient. The Commission has acknowledged that this will negatively impact innovation; but believes this decision reflects the EU's political choices with respect to animal testing, which seek to promote animal welfare over other considerations.

Exceptions

Animal testing may be necessary to ensure compliance with certain non-cosmetics related EU legislative frameworks (such as pharmaceuticals, detergents, food or REACH). Testing conducted according to those regulations shall not trigger the marketing ban, and can be relied on in the cosmetics safety assessment.

In contrast, if animal testing has been carried out for the purpose of complying with cosmetics requirements in third countries, this data cannot be relied on in the EU to prove the cosmetic product is safe. This approach seeks to prevent cosmetic providers from conducting animal tests outside the EU, in order to then commercialise their products safely in the EU.

Background

EU laws on cosmetics established a prohibition to test finished cosmetic products and cosmetic ingredients on animals (testing ban), and a prohibition to market in the European Community, finished cosmetic products and ingredients

included in cosmetic products which were tested on animals (marketing ban).

A testing ban on finished cosmetic products applies since September 11, 2004. In addition, a testing ban on cosmetic ingredients applies since March 11, 2009.

The marketing ban applies since March 11, 2009 for all tests on animals with the exception of repeated-dose toxicity, reproductive toxicity and toxicokinetics. For these specific tests the Commission could have postponed the ban or provided for derogations, but it has decided that, as from March 11, 2013, repeated-dose toxicity, reproductive toxicity and toxicokinetics tests may no longer be performed.

In any case, and regardless of the EU's current position, the ultimate interpretation of the meaning of the marketing ban on animal testing will correspond to the Court of Justice of the European Union. ■

by Sebastián Romero Melchor and Sara Aparicio Hill



New Food Regulator in China

The China Food Drug Administration

On March 14, the 12th NPC [FN1] of China approved a plan to create a consolidated and revamped food and drug safety agency. The plan elevates the State Food and Drug Administration (SFDA) to a ministerial-level China Food Drug Administration (CFDA) and consolidates responsibilities previously shared by several other governmental agencies. CFDA came into force as of March 22, 2013.

Under the previous system, as many as 13 ministerial level government agencies oversaw food safety related regulations and enforcement. This inevitably resulted in overlapping responsibilities, as well as “blind spots” in the food safety regulation. As early as 2003, the State Council [FN2] attempted to resolve this issue by forming the SFDA and granting it greater regulatory power (at the ministerial or deputy ministerial level). However, the agency was later downgraded to be supervised by the Ministry of Health (“MOH”), following a series of corruption scandals involving several SFDA officials in 2008. SFDA was primarily responsible for policies and programs on the administration of drugs, health food, medical devices and cosmetics, but had limited jurisdiction

for food safety enforcement (i.e. hygiene conditions of restaurants, etc.).

In February 2010, the State Council made yet another effort to streamline the somewhat discrete disciplines of the various agencies by forming a high-profile food safety commission (“Commission”). However, lacking in transparency and over-the-board cooperation, the Commission achieved little, if much at all, to crack down food safety issues. By way of example, the legacy MOH, which has the primary responsibility of drafting and interpreting food safety related standards, often found itself in a constant out-of-breath race with the Administration of Industry and Commerce (“AIC”), which has been the most powerful and aggressive enforcement agency against food safety issues. AIC was believed to have thousands of field enforcement offices nationwide, which were not hesitant to interpret the legacy MOH standards differently, partially because of the less than thought-through way those legacy MOH standards were drafted at the first place. In other instances, industry standards issued by other agencies (such as the Ministry of Commerce and the Administration of Quality Supervision, Inspection and Quarantine) that were meant for voluntary adoption sometimes got inadvertently incorporated by the

legacy MOH into its mandatory food safety standards, which essentially converted the voluntary standards into mandatory ones without inter-ministerial coordination.

With several responsibilities consolidated under the new CFDA, China is seeking to resolve the issue of overlapping or unclear jurisdictions and weak enforcement. The new agency has the power to regulate most food safety related issues ranging from the production, distribution and consumption of food. CFDA's roles and responsibilities will include:

- Production and quality control (formerly under the State Administration of Quality Supervision, Inspection and Quarantine)
- Distribution of food product (formerly under State Administration for Industry and Commerce)
- Ensuring food safety in the restaurant industry (formerly under SFDA)

However, two other governmental agencies are responsible for certain food safety-related issues, namely:

- Health and Family Planning Commission, which is the resulting agency of the combination the legacy MOH and the legacy Commission of Population and Family Planning –

assessment of food safety risks and establishing food safety standards

- Ministry of Agriculture – quality regulation of farm products and regulation of swine slaughter

The roll-out and streamlining will likely take months, and the new administration seems to know that. CFDA has announced on March 22 that the old regulations will still be in place until it comes up with new sets of rules and regulations. Some scholars predict that the agency may take up to the end of 2013 to just “settle down,” considering the current pace of changes.

But CFDA seems up for the challenge – the agency has already submitted a proposal for amending the existing Food Safety Law of China, which is believed to be included in the State Council's list of legislations for consideration in 2013. CFDA will also have consolidated local agencies that will enable regulation and enforcement at the grassroots levels, as the State Council's Guiding Opinions on Reforming and Improving Food and Drug Supervision and Regulation Regime at Local Levels (issued in April 2013), calls for the regional regulatory agencies to be consolidated in accordance with the central authorities.

While the 13-in-1 effort is certainly not a breezy one, the agency may just be the

only hope in the current state of affairs, where 96% of the people surveyed by People's Daily expressed concerns regarding the safety of food products. The market players are advised to keep a close eye on the progress and changes, particularly on the local levels where they have business. ■

[FN1] “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 elected for a term of five years. NPC meets in session once a year.

[FN2] 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. The State Council is composed of a premier, vice premiers, State councilors, ministers in charge of ministries and commissions, the auditor general and the secretary general. In the State Council, a single term of each office is five years, and incumbents cannot be reappointed after two successive terms.

by Max Gu



Privacy Update: Australia

Amendments to Australian Privacy Laws – Important changes for Organisations

Changes to Privacy Legislation

The Federal government of Australia has introduced changes to privacy laws which will have far-reaching consequences for organisations in relation to the collection, use and disclosure of personal information, including in relation to the disclosure of such information outside Australia.

The Privacy Amendment (Enhancing Privacy Protection) Act 2012 (the Amending Act) contains substantial amendments to the Privacy Act 1988 (Privacy Act). Amendments include introducing a new set of Australian Privacy Principles (APPs), replacing current credit reporting provisions, and strengthening the investigative and regulatory powers of the Australian Information Commissioner. Of particular relevance is APP 8, which governs disclosure of personal information to overseas recipients.

Entities that collect or hold information in Australia will need to change their practices to comply with the Amending

Act before its commencement on 12 March 2014. Organisations affected by the changes will need to act promptly in amending their systems and procedures to meet this deadline.

Important Changes to the Collection and Handling of Personal Information

The new APPs replace the existing National Privacy Principles and Information Privacy Principles (existing Principles), governing the collection, use, disclosure and maintenance of personal information by both public and private sector organisations. Among the important changes from the existing Principles are:

- APP 1 – Open and transparent management of personal information

APP 1 contains new obligations regarding data transparency, and specifies the information that must be included by organisations in their privacy policies. Organisations will need to specify how an individual can make a complaint about a breach of their privacy, whether the organisation is likely to disclose information overseas, and (if practicable) the locations in which personal information is likely to be held or disclosed. Organisations will also need to ensure that their privacy policy

is permanently available to the public (typically by posting it to their website).

- APP 4 – Dealing with unsolicited information

APP 4 regulates the receipt of information by organisations, requiring organisations to determine whether the information they receive from a third party could have been collected by them under APP 3. Information that does not meet these standards will generally need to be destroyed or de-identified.

- APP 5 – Notification of the collection of personal information

Existing notification requirements to individuals upon collection of their personal information will be expanded, with organisations required to disclose the circumstances in which they collected the information if not directly from the individual, whether they are likely to disclose the information overseas, and (if practicable) the location of any likely overseas disclosure.

- APP 8 – Cross-border disclosure of personal information

Under APP 8, before organisations may disclose personal information overseas, they must take reasonable steps to ensure that the recipient of the information does

not breach the APPs. Importantly, although organisations that meet this requirement will be permitted to disclose information lawfully, they may still be held liable for any breach of the APPs by the recipient and be penalised. This includes situations where they have received a contractual assurance from the recipient that they will treat the information in accordance with the APPs. Organisations can escape liability for the acts of recipients if:

- the organisation reasonably believes that the recipient is subject to laws in its country that protect the information in a substantially similar way to the APPs, and that an individual affected by a breach is able to access that justice system (this may be a difficult threshold to meet)
- the organisation expressly informs the individual that their information will be disclosed overseas, and the individual consents to that disclosure in the knowledge that the organisation will not be held liable for any breaches
- the disclosure is required by law, or a “permitted general situation” applies.

These changes are significant for organisations that currently rely on the

exceptions in the Privacy Act permitting overseas disclosures that are subject to a contract – organisations will still be permitted to disclose information in this situation, but may find themselves held liable for breaches outside their control. They also raise the standard of consent required from individuals, meaning that organisations that have relied on individuals’ consent may need to review and re-write their consent clauses and options to be protected from sanction under the Privacy Act.

Important Changes to Powers of the Australian Privacy Commissioner

The amendments also vest additional powers in the Australian Privacy Commissioner. The most important of these is the power to apply to the Federal Magistrates Court or Federal Court of Australia for a penalty of up to A\$1.7 million in respect of a corporation where the Australian Privacy Commissioner alleges that the corporation has breached a civil penalty provision. This includes engaging in an act or practice that is a “serious” or repeated interference with an individual’s privacy, or breach of credit reporting provisions. The Australian Privacy

Commissioner is also empowered to accept written undertakings from entities, and to apply to a Court to enforce these or to order that compensation be paid.

The Australian Privacy Commissioner’s powers of investigation have also been strengthened, with the Australian Privacy Commissioner now empowered to conduct own motion investigations regarding a possible breach of any of the APPs ie without a complaint having been made. ■

by Paris Petranis and Vanessa Baic

Unification of Japan's Food Labeling Laws

On June 21, 2013, the National Diet of Japan approved of a new food labeling bill, which will unify Japanese food labeling regulations under one set of laws by 2015.

Currently, food labeling requirements are determined primarily by the *Food Sanitation Act*, but are also regulated by the *Act Standardization and Proper Quality Labeling of Agricultural and Forestry Products* (the "JAS Act") and the *Health Promotion Act*. As a result, labeling regulations overlap, and, depending on the product, some labels may require compliance with two or more different Acts.

For example, dried fruits are classified as "fresh food" under the *Food Sanitation Act* but as "processed food" under the JAS Act. Therefore, companies which sell dried fruits have to review the regulations for fresh food under the *Food Sanitation Act* and also refer to the regulations for processed food under the JAS Act.

The new *Food Labeling Act* will unify the current regulations under the three Acts and have a single comprehensive

framework for food labeling. This unification should make it easier for companies to determine whether their labels comply with the relevant regulations and provide one government agency (the Consumer Affairs Agency) to address any labeling issues.

Although the new Act will not substantially change the scope of the food labeling requirements, one key difference is that it may have stricter administrative orders and sanctions for not complying with an administrative order issued by the Consumer Affairs Agency. For example, mislabeling of expiration dates may lead to more serious administrative orders such as broad recalls and/or business suspensions. Further, if the company does not comply with an administrative order, the company may be liable for a fine up to JPY 300 million (which is currently JPY 100 million) and an individual fine and/or imprisonment for the person in charge of the labeling.

Since the detailed regulations under the new Act will be drafted before the enforcement of the new Act, continuous monitoring of this new Act will be necessary. ■

By Junko Okawa and Yuki Sako



Caffeinated Energy Drinks - a Global Perspective

U.S. Regulation

Introduction

In the United States, there is no statutory or regulatory definition for “energy drinks.” The U.S. Food and Drug Administration (“FDA”) – the government agency with jurisdiction over regulating energy drinks – has informally stated that an “energy drink” as “a class of products in liquid form that typically contains caffeine, with or without other added ingredients.”^[1] Although varying in caffeine content and concentration, energy drinks are often characterized as containing high levels of caffeine and may be combined with other stimulants and specialty ingredients.

Since their introduction to the U.S. market, the popularity of energy drinks has grown rapidly with an industry projected to reach \$19.7 billion in sales this year and a large portion of sales attributed to adolescents and young adults.^[2] Since early 2012, U.S. congressional leaders have petitioned FDA to address health concerns associated with caffeine levels in energy drinks. After FDA disclosed adverse events (including deaths) potentially associated with four energy drinks,^[3] congressional leaders issued a detailed report highlighting concerns from all sectors regarding the regulation and marketing of these caffeinated energy drinks.^[4] In May 2013, FDA announced that, in response to a trend in which caffeine is being added to a growing number of products, the agency

will investigate the safety of caffeine in food products, particularly its effects on children and adolescents.^[5] If science warrants it, FDA is prepared to establish “clear boundaries and conditions on caffeine use” through the regulatory process and also consider enforcement actions against individual products as appropriate. In September 2013, FDA identified the development of policy and regulatory options for energy drinks as a priority for 2013-2014. This article will examine current U.S. regulations and marketing of caffeine in energy drinks and potential future developments.

Regulation of Caffeine

In the 1950s, FDA determined that 200 parts per million (ppm) (approximately 71 mg per 12 fluid ounce serving) in cola type beverages was “generally recognized as safe” (GRAS) and has not challenged the use of caffeine in other beverages at levels comparable to 200 ppm since then. In comparison, energy drinks reportedly contain caffeine levels of 160 to 500 mg per serving. With the emergence of energy drinks, FDA examined caffeine consumption in the U.S. population. In addition to finding that most caffeine consumed was naturally present in coffee and tea as opposed to other products, FDA estimated that “healthy adults” can have a caffeine intake of up to 400 mg per day without associated detrimental health effects, such as general toxicity and

cardiovascular problems. The “healthy adult” standard may not be applicable to young consumers who are likely to be significantly smaller than adults and may have different metabolic reactions to high caffeine levels.

In a March 2013 letter to FDA, a group of scientists and public health professionals concluded that “there is neither sufficient evidence of safety nor a consensus of scientific opinion to conclude that the high levels of added caffeine in energy drinks are safe under the conditions of their intended use”; in other words, caffeine levels in energy drinks did not meet the GRAS standards for food additives.^[6] They further found that “the best available scientific evidence demonstrates a robust correlation between the caffeine levels in energy drinks and adverse health and safety consequences, particularly among children, adolescents, and young adults.”

Although FDA has not responded directly to this letter, FDA acknowledged that “the environment has changed” and children and adolescents may be exposed to caffeine “beyond anything FDA envisioned when it made the determination regarding caffeine in cola.”^[7] In May 2013, FDA announced its plan to respond to the “disturbing” “proliferation of [caffeinated] products in the marketplace,” by first developing a better understanding of caffeine consumption and use patterns to determine a safe level for total consumption of caffeine, particularly for children and

adolescents. FDA emphasized its concern about “caffeine appearing in a range of new products, including ones that may be attractive and readily available to children and adolescents, without careful consideration of their cumulative impact.” FDA has met with companies who manufacture caffeinated products and plans to engage trade associations such as the American Beverage Association (“ABA”) and Grocery Manufacturers Association. FDA has further recognized that energy drinks, as a “relatively new class of products,” may pose significant risks when consumed in excess or by vulnerable groups such as young people.^[8] FDA is working to strengthen its understanding of the nature of energy drinks and any causal risks to health, including investigating reported deaths and other serious adverse events potentially associated with energy drink consumption.

Regulation of Energy Drinks

Current Regulations

In the United States, energy drink manufacturers decide whether to market an energy drink as a conventional food (i.e., a beverage) or a dietary supplement. However, FDA can, and has, challenged the product category chosen for some energy drinks. Categorizing an energy drink as a dietary supplement or a beverage can be difficult even with FDA’s December 2009 draft guidance (which has not been finalized) providing factors

distinguishing liquid dietary supplements from beverages.^[9] Whether a product is a dietary supplement or a beverage results in significantly different regulatory standards, including: (1) mandatory requirement for dietary supplements to report serious adverse events to FDA versus the voluntary adverse event reporting standard for beverages; (2) labeling requirements for dietary supplements to include a “Supplement Facts” panel with information on quantities of ingredients that exceed standards or that are relevant to product claims versus labeling requirement for beverages to include a “Nutrition Facts” panel with information such as the amounts of calories, total fat, cholesterol, and sodium; (3) a disclaimer on the label of dietary supplements that “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.” and (4) dietary supplement structure/function claims must be scientifically substantiated and notice of use must be submitted to the FDA within 30 days of first use. Importantly, neither dietary supplements nor beverages are required to disclose caffeine content under federal law.^[10]

The majority of energy drink companies now classifies and markets its products as beverages. In the past year, three major energy drink companies – Monster Beverage Corporation, Rockstar Inc., and AMP Energy – re-designated their

energy drinks from dietary supplements to conventional beverages and will disclose caffeine content on their labels.

Proposed Changes

In the past year, congressional leaders, trade organizations, and public health professionals, have proposed more transparent guidelines in order to protect energy drink consumers, specifically children and adolescents, including:

- **Uniform and Transparent Disclosure of Caffeine Concentrations on Product Labeling:** All groups urged energy drink companies to clearly disclose caffeine content on the products’ labels.^[11] After conducting an investigation into the practices of commonly sold energy drink brands, legislators found that energy drink manufacturers confused consumers by representing caffeine content differently in nearly identical energy drinks and that only about half of these products disclosed caffeine concentrations on their labels at all. Given that energy drinks come in different sizes with varying amounts of caffeine, these legislators proposed that concentrations of caffeine per entire container should be uniformly represented on the products’ labels instead of (1) based on a recommended serving size, (2) in comparison to other products, or (3) not at all.



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- **Prominently Displaying Precautionary Statements on Labeling:** Because of the high caffeine content in energy drinks and the risk of caffeine toxicity,^[12] groups proposed that energy drink labels state that the products are not intended or recommended for individuals under 18, pregnant or nursing women, or for those sensitive to caffeine and that such persons should consult a healthcare professional before consuming the product.
- **Reporting All Serious Adverse Events Associated with Energy Drink Use:** Groups recommended that adverse events should be reported for all energy drinks, regardless of whether they are dietary supplements or conventional beverages.

Promotion and Advertising of Energy Drinks

FDA and the Federal Trade Commission (“FTC”) share jurisdiction over health and nutrient claims made regarding energy drinks and work closely to police the marketplace for deceptive and unsubstantiated claims that present safety concerns. FDA oversees the labeling and the prevention of misbranding, whereas the FTC has primary jurisdiction over advertising. The FTC traditionally defers to FDA to address issues relating to food product content and ingredient safety.

Energy drink manufacturers use “structure/function”^[13] claims – including promises

of increased endurance, high performance energy, and focus – to market their products, which groups have viewed as directed specifically at children and young adults.^[14] Energy drink marketing also has included sponsoring: (1) young athletes as promoters of the brands, (2) music events targeted to young audiences, (3) high school sport events, and (4) awards to outstanding high school student athletes. Because of concern over increased risk of caffeine toxicity in young people who consume energy drinks, groups are urging for stricter regulation by FDA and the FTC over these promotional activities. FDA recently expressed concern that energy drinks are being aggressively marketed, including to young people, and questioned whether it is “appropriate to use foods that may be inherently attractive and accessible to children as the vehicles to deliver” caffeine. Organizations, such as the National Collegiate Athletic Association and the National Federation of State High School Associations, have issued position papers warning student-athletes of the negative effects of energy drinks. Likewise, the American Beverage Association prohibits energy drinks from being marketed to children generally and from being sold and marketed in schools from kindergarten through 12th grade.

Conclusion

This past year’s significant commentary, recommendations, and guidelines targeted at energy drinks promise further

developments regarding the regulation and marketing of these products in the near future. FDA is actively examining caffeine and energy drink issues, including (1) studying caffeine consumption, use patterns, and potential consequences and health effects of caffeine products in the food supply, (2) determining safe levels for total consumption of caffeine for adults and children, (3) addressing the types of products that are appropriate for the addition of caffeine, (4) determining whether FDA should place limits on the amount of caffeine in certain products, (5) issuing a final guidance on designating energy drinks as conventional beverages or dietary supplements, (6) investigating deaths and adverse events potentially associated with energy drink consumption, (7) engaging specialized expertise outside FDA such as the Institute of Medicine, advisory committees, public meetings, trade associations, and companies, and (8) if necessary, establishing clear boundaries and conditions on caffeine use through regulatory and enforcement actions. FDA urges the food and beverage industry to utilize “voluntary restraint” regarding adding caffeine to products while FDA sets regulatory boundaries and conditions. Additionally, trade associations have indicated that they will publish their own energy drink guidances and policies to help guide the energy drink industry. The decisions of Monster Energy and Rockstar to disclose caffeine content on their products will likely lead to

similar changes by other energy drink manufacturers. Further, state and federal legislators are contemplating energy drink legislation and lawsuits against energy drink manufacturers.

The question remains how quickly developments will occur and who will lead the changes – the industry or FDA. It is estimated that a full transition of Rockstar’s energy drinks from dietary supplement to conventional beverage will take one year. Trade associations such as the Council for Responsible Nutrition urges compliance with its new recommendations by April 1, 2014, AHPA requires members to comply with the new Code of Ethics by September 6, 2013, and NPA anticipates presenting its energy drinks guidance to its board in September 2013. We will continue to monitor developments regarding energy drinks and the regulation of caffeine.

Citations

- [1] 8/10/12 Letter from FDA Assistant Commissioner Jeanne Ireland to Senator Richard Durbin at 1, available at <http://www.shb.com/newsletters/FBLU/Etc/RichardDurbin-Letter-Aug2012.pdf>
- [2] A 2010 study commissioned by FDA noted that 65% of energy drink consumers were 13- to 35- year olds. See Somogyi LP. *Caffeine intake by the US population*. Silver Spring, MD: Food and Drug Administration; 2010. More recent reports show that 30 to 50% of adolescents and young adults

consume energy drinks.

- [3] See FDA Voluntary and Mandatory Reports on 5-Hour Energy, Monster Energy, and Rockstar Energy Drink, available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/CFSANFOIAElectronicReadingRoom/UCM328270.pdf>; FDA Voluntary Reports on Red Bull Energy Drink, available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/CFSANFOIAElectronicReadingRoom/UCM328525.pdf>

- [4] Report by Staffs of Congressman Edward J. Markey, Senator Richard J. Durbin, & Senator Richard Blumenthal, *What’s all the buzz about? A Survey of Popular Energy Drinks Finds Inconsistent Labeling, Questionable Ingredients and Targeted Marketing to Adolescents* (“Buzz Report”), Apr. 10, 2013, available at http://markey.house.gov/sites/markey.house.gov/files/documents/2013-04-10_EnergyDrink_Report_0.pdf

- [5] FDA Consumer Update, *FDA to Investigate Added Caffeine* (FDA May 3, 2013), available at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm350570.htm>

- [6] See 3/19/13 Letter from A. Arria *et al.* to FDA Commissioner Margaret Hamburg. The City Attorney for San Francisco Dennis Herrera joined these eighteen public health professionals in their letter to FDA.

- [7] Statement of FDA Deputy Commissioner Michael R. Taylor (FDA Apr. 29, 2013), available at <http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm094210.htm>

- [8] 11/21/12 Letter from FDA Acting Associate Commissioner Michele Mital to Senators Richard Durbin and Richard Blumenthal at 1, available at <http://www.durbin.senate.gov>.

- [9] See Draft Guidance for Industry: Factors that Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods (FDA Dec. 2009), available at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm196903.htm>

- [10] Some states have enacted laws regarding disclosure of caffeine content.

- [11] See, e.g., ABA Guidance for the Responsible Labeling and Marketing of Energy Drinks at 1, available at [www.ameribev.org/files/339_Energy%20Drink%20Guidelines%20\(final\).pdf](http://www.ameribev.org/files/339_Energy%20Drink%20Guidelines%20(final).pdf) (recommending voluntary label statement identifying quantity of caffeine from all sources contained in beverage separate from ingredient statement and Nutrition Facts Panel, for example, “caffeine content: xx mg / 8 fl. oz.”); American Herbal Products Association (“AHPA”), Code of Ethics & Business Conduct (March 2013) at 7, available at www.ahpa.org/Portals/0/



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[pdfs/13_0319_AHPA_CodeofEthics.pdf](#) (setting mandatory requirements for its members to disclose caffeine presence for dietary supplements and foods containing total caffeine of more than 5 mg per serving and specific labeling for products containing 25 mg or more of caffeine per recommended serving); Council for Responsible Nutrition (“CRN”), *Recommended Guidelines: Caffeine-Containing Dietary Supplements* at 1, available at <http://www.crnusa.org/caffeine/> CRN-RecommendedGuideline sCaffeine0312.pdf (providing voluntary recommendation that dietary supplements containing added caffeine or more than 25 mg per serving of naturally occurring caffeine should disclose caffeine content from all types of caffeine in mg per serving in Supplement Facts Box or in separate statement on label).

[12] In March 2013, public health professionals explained that younger individuals are particularly vulnerable when consuming caffeine given their greater sensitivity to a serving of caffeine as compared to adults because of lower body mass and less likelihood for having developed a pharmacological tolerance from regular caffeine consumption.

[13] “Structure/function” claims describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans. See FDA Structure/Function Claims, available at <http://www.fda.gov/Food/Ingredients>

[PackagingLabeling/LabelingNutrition/LabelClaims/StructureFunctionClaims/default.htm](#). FDA’s regulation of “structure/function” claims in conventional foods and dietary supplements has its own host of issues. Although manufacturers are responsible for ensuring the accuracy and truthfulness of these claims, they are only required to submit a notification to FDA about the structure/function claims for dietary supplements and not for conventional foods. Similarly, dietary supplement manufacturers are required to include a disclaimer on their products’ labels that FDA has not evaluated the structure/function claim; no similar disclaimer requirement exists for conventional food manufacturers.

[14] In the investigation completed by Congressman Markey, Senator Durbin, and Senator Blumenthal, all of the companies surveyed indicated that their products were not directed at children. See Buzz Report at 15-16. ■

by Jacqueline Chan and Carol Pratt, Ph.D.



Caffeinated Energy Drinks - Australia

The Australian Perspective

Background

Australia has recently seen an increase in media reports relating to the consumption of caffeinated drinks and their associated side effects, particularly for young children. A number of reports have identified caffeine toxicity resulting from overconsumption of caffeinated drinks. Furthermore, the growing trend of alcoholic caffeinated drinks has become a concern for many health interest groups and possible changes to the existing regulatory regime are being considered by the relevant policymakers.

Australian Regulatory Regime

From an Australian regulatory perspective, caffeinated drinks can be categorised as follows:

- non-alcoholic “kola-type soft” drinks containing caffeine as an additive (Kola Drinks);
- non-alcoholic “energy” drinks with a higher level of caffeine content for the purpose of enhancing mental performance (Energy Drinks);
- packaged ready-to-drink products combining alcohol with caffeine (RTDs); and
- Energy Drinks that are mixed with alcohol and served to patrons in licensed premises (Post-Mixers).

Non-alcoholic caffeinated drinks

The sale of Kola Drinks and Energy Drinks is regulated in Australia (and New Zealand) by a bi-national code of food standards, referred to as the Australian New Zealand Food Standards Code (ANZ Code). Food legislation in each Australian State and Territory adopts the ANZ Code and proscribe breaching the ANZ Code. The ANZ Code was created pursuant to an agreement between the Australian and New Zealand Governments.

Under the ANZ Code, there are effectively 2 types of non-alcoholic caffeinated drinks:

Type	Permissible caffeine content
Kola Drinks	No more than 145 mg/kg
Energy Drinks	Between 145 mg/L and 320 mg/L

Kola Drinks which contain caffeine as an additive require “caffeine” to be included in the ingredient list and the package labels to contain an additional advisory statement to the effect that the product contains caffeine.

Energy Drinks are defined as a “non-alcoholic water-based flavoured beverage which contains caffeine [from whatever source] and may contain carbohydrates, amino acids, vitamins and other substances, including other foods, for the purpose of enhancing mental performance”.

Some of the regulatory requirements specific to Energy Drinks include:

- maximum permitted levels of other substances being present in an Energy Drink as follows:

Substance	Maximum amount per one-day quantity
Thiamin	40 mg
Riboflavin	20 mg
Niacin	40 mg
Vitamin B6	10 mg
Vitamin B12	10 µg
Pantothenic acid	10 mg
Taurine	2,000 mg
Glucuronolactone	1,200 mg
Inositol	100 mg

(Other Substances); and

- cautionary statements on package labels;
- where an Energy Drink contains one or more of the Other Substances, of the prescribed daily consumption limit of the Energy Drink; and
- to the effect that Energy Drinks are not recommended for children, pregnant or lactating women and individuals sensitive to caffeine.

Alcoholic Caffeinated Drinks

RTDs are not affected by the ANZ Code requirements specific to Energy Drinks and are regulated in as much the same way as alcoholic drinks without caffeine.

The State of Victoria has expressed concern about RTDs from a consumer safety perspective. To this end, on 17 May 2008,



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the Victorian Minister for Consumer Affairs issued a public warning statement on RTDs, cautioning that these products may pose particular risks to consumers' health and wellbeing.

Apart from the State of Western Australia (WA), Post-Mixers are largely unregulated (other than, of course, the regulations applying to Energy Drinks that are, in the first instance, mixed in these drinks). In April 2011, WA's liquor licensing authority effectively banned licensed venues in Perth from supplying Post-Mixers after midnight.

Current Issues

RTDs and Post-Mixers have attracted considerable interest in Australia. The death of a 16-year-old schoolgirl in June 2011 has been suspected of being linked to the consumption of RTDs. This has led to calls by a number of health-related organisations, including the Australian Medical Association and the Victorian Health Promotion Foundation (a Victorian-based statutory authority mandated to promote public good health), for a nationwide ban on RTDs and/or Post-Mixers.

In May 2011, the Legislature and Governance Forum on Food Regulation (Forum) agreed to a full review of its policy guideline on the addition of caffeine to foods (Policy Guideline) due to global developments in regulatory approaches to caffeinated products (Review). (The regulation of Kola Drinks and Energy Drinks under the ANZ Code is guided by this Policy Guideline.) In

early September 2013, the Food Regulation Standing Committee (FRSC) released the Food Regulation Policy Options Paper (Consultation Paper) for the purpose of the Review. The Consultation Paper sets out, amongst other things, problems identified by the FRSC that are associated with the Policy Guideline (and the ANZ Code), such as a lack of clarity regarding the addition of caffeine to formulated supplementary sports foods/electrolyte drinks and the absence (with exceptions) of restrictions on the addition of ingredients that naturally contain caffeine (eg guarana, tea, coffee) to any food. The Consultation Paper recommends amending the Policy Guideline to include specific principles to assist in the undertaking of any review of standards relating to caffeine, with special focus on managing risks to vulnerable populations. Public submissions on the Consultation Paper are being sought, which will end on 18 October 2013. Once the Review is complete, the Forum will decide on whether to refer to Food Standard Australia and New Zealand for further regulatory changes to the ANZ Code regarding Kola Drinks and/or Energy Drinks.

The issue of RTDs and Post-Mixers has been identified as a drug-specific priority by the Ministerial Council on Drug Strategy (MCDS). The MCDS is the peak Australian policy and decision-making body in relation to licit and illicit drugs, which is represented by the Federal and various State and Territory Ministers

of Health and Law Enforcement. It is possible that regulations will be developed and promulgated to address perceived concerns with the consumption of RTDs and Post-Mixers.

Another reported issue is that some Energy Drinks containing caffeine levels above the ANZ Code-limit had been listed as therapeutic goods under the Australian therapeutic goods legislation. By being classified as therapeutic goods, these Energy Drinks were statutorily excluded from the purview of the ANZ Code and the relevant food authority could not take any enforcement action until the Australian therapeutic goods authority (the Therapeutic Goods Administration) had declassified them as "therapeutic goods".

Future Considerations

Australia will quite possibly experience changes to the existing regulatory regimes (both at the Federal and State/Territory levels) on caffeinated drinks, especially for RTDs and Post-Mixers. The extent of the changes will depend on the outcomes of:

- the Review of the Policy Guideline, following public feedback in response to the Consultation Paper;
- the MCDS intergovernmental committee's report on RTDs and Post-Mixers. ■

by Paris Petranis and Jeremy Lee



Caffeinated Energy Drinks - Europe

EU Developments

There is no agreed definition at EU level of "energy drink". A recent report commissioned by the European Food Safety Authority (EFSA)^[1] treated the category as comprising "a variety of non-alcoholic beverages containing caffeine, taurine and vitamins (often in combination with other ingredients) marketed for their actual or perceived effects as stimulants, energisers and performance enhancers."

Legislation Specific to Caffeine

In the EU, the labelling of foods containing caffeine is currently governed by Directive 2002/67. This requires beverages (other than those sold under a name including "coffee" or "tea") containing more than 150 mg per litre of caffeine to show "High caffeine content" on the label in the same field of vision as the name under which the product is sold, followed by the caffeine content expressed in mg per 100 millilitre.

Directive 2002/67 will be repealed by Regulation 1169/2011 as from 13 December 2014. Regulation 1169/2011 will strengthen the labelling requirements described above: the label must also include a warning "Not recommended for children or pregnant or breast-feeding women". Similar labelling must also be used on foods other than beverages where caffeine is added with a physiological purpose.

The above legislation also requires caffeine used as a flavouring to be mentioned by name in the list of ingredients.

Nutrition and Health Claims Regulation

Regulation 1924/2006 on nutrition and health claims made on foods provides a legal framework for the control of such claims. It sets out general principles (e.g., the claim must not be false, ambiguous or misleading) and conditions (e.g., the substance for which the claim is made is in a form that is available to be used by the body) applicable to both types of claim and then lays down a specific regime for each type.

The Regulation defines a health claim as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health". It lays down a number of specific conditions for permitted health claims (e.g., the labelling must include an indication of the importance of a varied and balanced diet and healthy lifestyle) and prohibits certain health claims (e.g., claims which suggest that health could be affected by not consuming the food). It then sets out the procedure for permitted or authorised claims.

Health claims describing or referring to (inter alia) the role of a substance in the functions of the body may be made if they are indicated in the EU register of permitted claims to be adopted by the Commission, provided that they are based on generally accepted scientific evidence and well understood by the average consumer.

After the Regulation was adopted in December 2006, EU countries provided

national lists of approximately 44,000 health claims to the Commission. These were consolidated into a list of some 4600 claims and sent to EFSA for evaluation. In its assessment, EFSA considers whether:

- the subject of the claimed effect (food, substance) was sufficiently characterised for a scientific assessment;
- the scientific evidence assessed established a cause and effect relationship between the food and the claimed effect;
- the scientific evidence assessed established that the claimed effect was beneficial for health.

Failure to satisfy any of these requirements meant that the claim was rejected. The EU Register lists authorised and rejected health claims, with conditions of use or reasons for rejection respectively.

The Register was established by EU Regulation 432/2012 and has been applicable from 14 December 2012. The approved list includes 222 health claims which (subject to specified conditions) may be used on food products, representing nearly 500 entries from the consolidated list.

With effect from 14 June 2013, rejected claims may no longer be used. The rules on prohibited health claims are directly applicable to all food business operators in the EU and it is the responsibility of the national authorities to enforce them.



Caffeinated Energy Drinks - Europe

Application of the Nutrition and Health Claims Regulation to Caffeine

Ten health claims for caffeine were rejected before the Register was adopted. These were mainly concerned with weight loss, but also included claims to enhance or improve physical performance, provide a performance edge, delay the onset of fatigue and increase exercise intensity/work rate. All were rejected on the ground that, on the basis of the scientific evidence assessed, the claimed effect had not been substantiated.

Five further claims had originally been accepted by EFSA for inclusion in the EU Register. These are that caffeine:

- Helps to improve concentration
- Helps to increase alertness
- Contributes to a reduction in the rated perceived exertion/effort during endurance exercise
- Contributes to an increase in endurance performance
- Contributes to an increase in endurance performance capacity

In April 2011 EFSA gave positive opinions about these claims. However Member States voiced concerns about their possible use, particular in products such as energy drinks that are popular with children and teenagers. They were accordingly dropped from the draft positive list in March 2012 and put on an “on hold” list pending

further consideration. It was reported in November 2012 that a Commission working group had found growing support to authorise the claims provided that they contained strict conditions of use statements. It was therefore planned to include the claims in a proposed update of the list of permitted claims. However, at a February 2013 meeting of the relevant standing committee involved in the process of authorising claims, Member States again expressed concerns. Accordingly the Commission agreed to refer the matter back to EFSA for advice before those claims are authorised. It has since submitted a request to EFSA for further scientific advice in relation to the safety of caffeine intake within different target groups of the population. The Commission has asked EFSA to assess in particular:

- The safe maximum level of caffeine intake from all sources
- The risk of interaction of caffeine with alcohol and other ingredients of energy drinks
- The validity and appropriateness of the maximum daily intake proposed in conditions for use of caffeine of 300 mg/day
- The levels of consumption that do not represent a risk for the following population groups: population in general, adults performing physical activities of various intensities, pregnant women, lactating women, children and adolescents.

In several EU Member States there is an increased focus on the amount of caffeine used in energy drinks and beverages, in particular the use of such drinks in combination with alcohol.

It is settled case-law that a national prohibition on marketing energy drinks containing caffeine in excess of a certain limit will be lawful only if it is shown to be proportionate. This means that the prohibition must be necessary to achieve a legitimate aim (such as the protection of human health or consumers) and that the same aim could not be achieved by a measure that was less restrictive of trade. Unless both these conditions are satisfied, such a prohibition will infringe the free movement of goods guaranteed by the Treaty on the Functioning of the EU and will be unlawful.

Despite this settled case-law, several Member States have recently initiated administrative practices consisting in applying maximum limits of caffeine in beverages and food supplements. In Belgium, according to Belgian Royal Decree of 1st March 1998 on additives in foodstuffs, the current limit for caffeine is 320 mg/l. Early last year the Belgian Health Council passed a recommendation to limit the daily intake in food supplements to 80 mg^[2]. The Belgian health Authority is already applying the recommendation of 80 mg/day, even though a new law has not yet been adopted. They rely on the so-called precautionary principle for these purposes.

Although the Italian authorities have not set a maximum limit of caffeine, the National Committee for Food Safety issued an Opinion in 2012^[3] recommending dissemination of the information contained in the said Opinion in order to prevent the risks involved in the use of alcohol in conjunction with energizing substances. Health authorities of other Member States are also closely monitoring the issue.

Conclusion

For the moment, energy drinks can carry health claims related to caffeine, if they are “on hold” claims. These are claims for which EFSA has yet to complete a scientific evaluation (e.g. the so-called “botanical claims”), or whose consideration by the European Commission has not yet been completed. “On-hold” claims may continue to be used^[4] provided that they (i) are scientifically substantiated, and (ii) comply with existing national provisions applicable to them. Until EFSA has reported back in response to the Commission’s request, it is not possible to predict whether the “on hold” claims in connection with caffeine will be authorized by the Commission or not. ■

Citations

[1] “Gathering consumption data on specific consumer groups of energy drinks”; <http://www.efsa.europa.eu/en/supporting/pub/394e.htm>

[2] http://www.health.fgov.be/internet2Prd/groups/public/@public/@shc/documents/ie2divers/19076526_en.pdf

[3] http://www.salute.gov.it/imgs/c_17_pubblicazioni_1790_allegato.pdf

[4] Recitals 10 and 11 of Regulation 432/2012.

[5] On the basis of Article 28(5) and (6) of Regulation 1924/2006, according to which: “Health claims as referred to in Article 13(1) (a) may be made from the date of entry into force of this Regulation until the adoption of the list referred to in Article 13(3), under the responsibility of food business operators provided that they comply with this Regulation and with existing national provisions applicable to them, and without prejudice to the adoption of safeguard measures as referred to in Article 24”.

by Vanessa C. Edwards
and Sebastián Romero Melchor

Webinar recording

Regulation of Medical Food and Nutritionals in the European Union, China, and the United States

Sebastián Romero Melchor, Max Gu, and Suzan Onel hosted an informative webinar covering the regulation of medical food and nutritionals in the European Union, China, and the United States on 4th April. During this session, topics such as the current overhaul of the PARNUTS legislation in the EU, the Chinese Ministry of Health’s standards on medical foods and the continuing medical food categorisation in the US were discussed.

To listen to a recording of this webinar please contact Victoria Patterson at victoria.patterson@klgates.com



Medical Devices in the U.S.

Medical Devices in the U.S.

In the US, companies that market medical devices subject to the 510(k) premarket notification requirement have always been required to review post-market changes to their cleared devices to assess whether a change or modification could “significantly affect the safety or effectiveness of the device.” In order to assist companies with this assessment, the Food and Drug Administration (“FDA”) issued a guidance document in 1997 entitled, “Deciding When to Submit a 510(k) for a Change to an Existing Device.” This guidance provided explanatory text and flow charts to help guide companies in determining whether a change requires the submission of a new 510(k) premarket notification or if a letter to file would be sufficient. An incorrect assessment could lead FDA to conclude that a device is misbranded and/or adulterated because it is being marketed without appropriate clearance or approval. In 2011 FDA issued a revised draft version of the 1997 guidance that removed the

flow charts and largely guided industry to consider most changes as requiring a new 510(k) submission. The revised draft guidance received a significant amount of criticism across industry and multiple other sectors. While FDA announced plans to re-issue the revised draft guidance in light of the comments, the Food and Drug Administration Safety and Innovation Act (“FDASIA”) of 2012 included a provision which required FDA to withdraw the 2011 draft guidance and within 18 months report directly to Congress on the approach that should be taken as to when a device modification will require new clearance. The statutory provision also specifically states that FDA may not issue any new guidance on the subject until at least 12 months after the report has been submitted to Congress. In the meantime, the 1997 guidance remains in effect.

In preparation for this report and any future guidance that may be issued, FDA recently announced that it will be holding a public meeting on June 13, 2013 to solicit input on its regulations concerning when a new 510(k) is required for a change to a 510(k) cleared device. FDA is accepting written comments to Docket No. FDA-

2013-N-0430 from interested parties through July 13, 2013. FDA is specifically seeking comments on the following:

- Potential use of risk management in 510(k) device modification decisions;
- Potential reliance on design control activities;
- Potential use of critical specifications;
- Potential risk-based stratification of medical devices for 510(k) modification purposes;
- Potential periodic reporting;
- Potential other solutions;
- Examples of device changes that companies believe should not trigger the requirement for a new 510(k) submission.

More details concerning the upcoming public meeting and potential topics for discussion can be found at 78 Federal Register 26786 (May 8, 2013). ■

by *Suzan Onel*



Medical Devices in the EU

Revision of the Framework for Medical Devices in the European Union

The European Commission has proposed to update the more than 20 years old framework for medical devices. The proposal consists of a Regulation on medical devices (to replace Directive 90/385/EEC regarding active implantable medical devices and Directive 93/42/EEC regarding medical devices) and a Regulation on *in vitro* diagnostic medical devices (to replace Directive 98/79/EC regarding *in vitro* diagnostic medical devices). The new rules will apply to all devices manufactured in and imported into the European Union (EU).

The proposed Regulations are currently being discussed by the two arms of the EU legislature, the European Parliament and the European Council. The Commission is hopeful that the Regulations will be adopted in 2014 and the new rules will come into force gradually from 2015 to 2019. While the final text as adopted by the EU legislators may differ from the Commission proposal, the changes will apply directly in all EU Member States without the need for implementing legislation at the national level and will have a significant impact to all stakeholders in the medical devices market from manufacturers to providers of diagnostic services and internet sales. Some of these

changes that are common to the both Regulations are briefly summarised below.

One of the aims of the proposal is to clarify rights and responsibilities for manufacturers. For instance, manufacturers will be required to appoint a ‘qualified person’ responsible for regulatory compliance (a similar requirement can be found in EU legislation on medical products). The Commission has also increased requirements for clinical evidence and set stricter requirements for trials carried out for regulatory purposes.

In an attempt to improve the access to information on medical devices marketed in the EU, non-confidential information held in Eudamed (the European database on medical devices) will be made available to the public. Manufacturers of devices that fall within the high-risk classification will be obliged to publish a summary of key safety and performance clinical data.

To achieve better traceability throughout the supply chain, manufacturers will have to fit their devices with a unique device identifier, thus allowing an effective response to safety problems. This requirement will be implemented gradually, depending on the risk class of the device. Additionally, it is proposed to create an EU portal where all serious adverse events will be reported by manufactures. Having a transparent system will make it possible to react promptly and effectively to safety issues.

While the Regulations will be directly applicable in all Member States, the practical implementation and enforcement

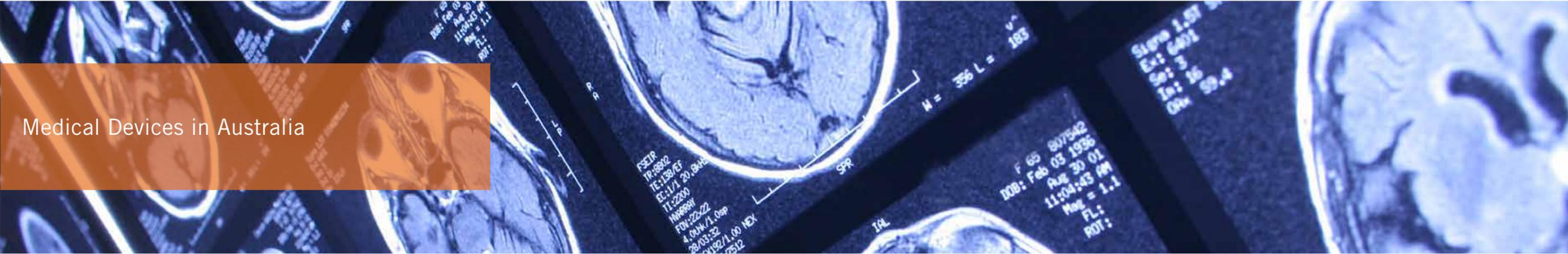
will be carried out at the national level. Some of the changes with regards to enforcement consist of more powers to the notified bodies to ensure thorough testing and regular checks, including unannounced factory inspections and the conducting of more sample tests. At the same time, the national competent authorities will be given wider and more detailed responsibilities with regard to the designation and monitoring of the notified bodies.

Further, a Medical Devices Coordination Group (MDCG) will be established, to consist of experts appointed by the Member States and to be chaired by the Commission. In general, the MDCG will provide advice to the Commission and assist the Commission and the Member States in ensuring a harmonized implementation of both Regulations. The MDCG will be notified of all notifications through the Commission and will be involved in the conformity assessment process of high risk devices.

The adoption of the proposed Regulations is still at an early stage: currently it is indicated that the vote in the European Parliament plenary session will take place on 19 November 2013. It should be noted that the adoption process does not end there. Therefore there is still scope for interested parties to engage in the process.

View the full [Regulation on medical devices](#) and [Regulation on *in vitro* diagnostic medical devices](#). ■

by *Vanessa C. Edwards*



Medical Devices in Australia

Reforms to Australia's Regulation of Medical Devices

In December 2011, the Therapeutic Goods Administration (**TGA**) announced that it was implementing a package of reforms to the Australian regulatory framework of therapeutic goods, part of which proposed to reform the regulation of medical devices in the following areas:

- reclassification of joint (ie hip, knee and shoulder) replacement implants as a higher risk type of medical device;
- the use of third party assessment bodies by Australian medical device manufacturers;
- increasing the premarket scrutiny for implants; and
- increasing the level of available information relating to medical devices to improve transparency for consumers and health professionals.^[1]

Reclassification of Hip, Knee and Shoulder Joint Replacement Implants

Since 1 July 2012, the inclusion of hip, knee and shoulder joint implants (total and partial) in the Australian Register of Therapeutic Goods (**ARTG**) has been reclassified from Class IIb (medium-high risk) to Class III (high risk), which has increased the level of regulatory oversight for such devices. In addition, such a

reclassification means that these devices must be included in the ARTG as specific individual devices, rather than pertaining to a “kind of devices” whereby a single entry can cover a number of specific devices. This change is expected to be in line with the current regulation of replacement joint implants in the European Union. Existing sponsors have a 2-year transition period until 30 June 2014 to apply for reclassification of those hip, knee and shoulder joint implants that are already included in the ARTG as Class III medical devices. The TGA has stated that it will take action to remove any non-conforming entries in the ARTG.^[2]

Premarket Assessment of Medical Devices

On 14 January 2013, the TGA released a public consultation paper which proposed changes to the premarket assessment requirements for implantable medical devices. The public consultation process closed on 15 March 2013.^[3] Having reviewed the response submissions, the TGA released an exposure draft of a Regulation Impact Statement (**RIS**) for further consultation with relevant stakeholders. Interested parties were required to respond by 3 June 2013.^[4] On 26 June 2013, the TGA released the finalised version of the RIS.^[5] On 1 August 2013, the Australian Government announced its decision to proceed with the regulatory changes as recommended in the RIS.^[6]

The proposed changes are as follows:

- increasing scrutiny of conformity assessment as part of mandatory application audits prior to ARTG inclusion;
- publishing medical device regulatory decisions; and
- abolishing the requirement for TGA conformity assessment for Australian manufacturers of all medical devices except for Class 4 in vitro diagnostic medical devices (**IVDs**).

Increasing Scrutiny of Conformity Assessment

This proposal includes:

- increasing the number of products targeted for mandatory audits of an application to include certain Class IIb implantable and long term surgically invasive medical devices (to be specified by way of legislative instrument); and
- introducing a new “Level 3” audit for active implantable medical devices and Class III implantable and surgically invasive medical devices to more closely review existing conformity assessment information relating to the device (together with a fee commensurate to the additional analysis required).

Grouping of applications for related medical devices may occur, in order to

reduce costs, if the devices contain the same following attributes: classification, manufacturer, level of audit and Global Medical Device Nomenclature code.

Publication of Medical Device Regulatory Decisions

This proposal involves publishing information on positive and negative regulatory decisions made by the TGA about ARTG inclusions and conformity assessment applications for medical devices and IVDs. Negative decisions will only be published where the reason for rejection relates to the safety and/or efficacy of the medical device. The format for publishing all medical devices decisions is expected to be similar to the Australian Public Assessment Reports for prescription medicines (**AusPAR**). (An AusPAR is compiled by the TGA after a decision is made relating to the submission for new prescription medicines and major changes to existing prescription medicines. It contains information on quality, safety, efficacy, pharmacovigilance and risks and benefits.) The final format is to be developed after further consultation with stakeholders.

Removal of Requirement for TGA Conformity Assessment

Under this proposal, it is expected that an Australian manufacturer of a medical device (other than a Class 4 IVD) can choose to have their conformity assessment

certificates issued by a European notified body rather than being limited to using the TGA. This provides for the TGA to more closely align the level of assessment to the risk of the device.

Class 4 IVDs are to be excluded from this proposal until the European reforms to adopt the Global Harmonisation Task Force model for IVD regulation come into force. At this stage, the regulatory and evidentiary requirements for IVDs classified as Class 4 are higher in Australia than for the same devices in Europe.

Expected Timeline

Implementation of the above changes is expected to commence between 1 July 2015 and 1 July 2017. The RIS states that the TGA is currently developing an implementation plan for these reforms, which includes the following:

- implementation for decisions on conformity assessment and ARTG inclusion are to be staggered as these are separate application types with different legislative frameworks and processes;
- a 2-year transition period is proposed for the publication of information relating to TGA decisions;
- all aspects of the proposal to change premarket assessment for medical devices are to be implemented by 1 July 2017;

- from 1 July 2015, it is expected that Australian manufacturers can choose whether or not to submit conformity assessment applications with the TGA for all medical devices other than Class 4 IVDs; and
- from 1 July 2015, applications selected for mandatory audit will be charged a fee commensurate with the level of assessment being conducted under the audit. ■

Citations

[1] <http://www.tga.gov.au/industry/devices-reforms.htm>

[2] <http://www.tga.gov.au/industry/devices-reforms-joint-implants-2012.htm>; <http://www.tga.gov.au/industry/devices-reforms-joint-implants-2012-keyissues.htm>

[3] <http://www.tga.gov.au/newsroom/consult-medical-devices-premarket-assessment-130114.htm>

[4] <http://www.tga.gov.au/newsroom/consult-ris-medical-devices-premarket-assessment-130510.htm>

[5] <http://www.tga.gov.au/industry/devices-reforms-premarket-scrutiny-ris-130626.htm>

[6] <http://www.tga.gov.au/industry/devices-reforms-premarket-scrutiny-130515.htm>

by Paris Petranis and Jeremy Lee

Medical Devices in Japan

The Japanese government has proposed to update its framework for the regulations on medical devices to speed up the approval process and to stimulate the medical device industry. Amendments to the current Pharmaceutical Affairs Act of Japan, which includes regulations on medical devices, were proposed in May 2013 and submitted to the Japanese Diet to discuss. The amendments include significant changes to the Act, including the addition of “Medical Devices” to the title of the Act and the separation of the regulations on medical devices from those on medicine. Additional important changes are briefly summarized below.

License Requirements for Medical Device Manufacturers

Under the current law, a company that aims to start manufacturing medical devices in business in Japan must apply for government approval and obtain a license. To encourage new entries into the medical devices business, the amendment to the Act will relax this requirement and will only require registration of such a business.

Expansion of Authority of Registered Private Independent Organization

Currently, medical devices that present the higher potential risks to patients must be approved by the Pharmaceuticals

and Medical Devices Agency of Japan (PMDA). The proposed amendment will allow registered private independent organizations to approve certain higher risk medical devices than those currently approved by such organizations. This delegation will enable PMDA to focus on higher-risk, new developed medical devices and to shorten the “device lag” further that may still exist in Japan compared to other countries in terms of the speed of the approval process.

Software as Medical Devices

Unlike in the US or the EU, software used for medical treatment as a part of a medical device is not categorized as a “medical device” in Japan under the current Act. For example, diagnostic imaging software cannot be approved as a medical device by itself but must be approved as a part of diagnostic imaging unit. It has been a burden for companies to obtain approval for a complete medical device every time the software is upgraded. The amendment will categorize such software as independent “medical devices,” which enables companies to get approval for software alone, so that they will not need to get approval for the complete medical device if only the software has been upgraded. This change will harmonize Japanese standards with standards in other countries and reduce the burden on medical device companies.

Quality Management System

The proposed amendment also makes a number of changes intended to expedite the Quality Management System (QMS) examination process. For instance, changes will enable reviewers to examine a group of related products at the same time to avoid duplicated examination, whereas under the current Act each product must be examined individually. These changes will likely reduce the time and cost of QMS review.

Approval Process for Tissue-engineered Medical Products

The proposal also aims to speed up the approval process for the manufacturing and distribution of tissue-engineered medical products. According to the proposal, in certain circumstances where effectiveness of a product is presumed and the safety of the product is proved, companies will be allowed to manufacture and distribute such products, subject to certain limitations.

The amendments to the Pharmaceutical Affairs Act of Japan are expected to take effect in 2014 or 2015. ■

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