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legal and regulatory news

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New US Nutrition Label Introduced – Background

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It has been two decades since the US Food and Drug Administration ("FDA") updated the nutrition label format required on foods sold in the USA. Clearly, protecting the food supply from intentional acts of bioterrorism and unintended processing lapses with any potential to harm Americans has dominated the regulatory landscape for much of that time. However, the FDA finally removed the "Nutrition Facts" label from its rulemaking checklist.

In the first of two Federal Register documents, the FDA published final revisions to the conventional food and dietary supplement nutrition labeling regulations and changes to the daily values that were previously established for most nutrients and food components. 81 F.R. 33,742 (May 27, 2016). The second document covers changes to regulations covering serving sizes that can reasonably be consumed during one eating occasion, additions that will require dual-column labeling for certain packages that can be consumed in one eating occasion and modifications to several reference amounts customarily consumed. 81 F.R. 34,000 (May 27, 2016). These final agency actions complete parallel rulemaking processes which started over two years ago, inspired roughly 300,000 total comments, spawned several consumer studies and are chronicled in more than 450 pages of the Federal Register.

Technically, all the regulations take effect on July 26, 2016, but the FDA will not begin enforcement against domestic and imported food suppliers until July 26, 2018. Manufacturers with less than $10 million in annual food sales will have an additional year to update their labels. Plans to implement the changes on food labels should start soon to ensure that the transition is smooth and cost-efficient.

Regulations covering other food labeling components were neither proposed nor adopted. The FDA declined to initiate a rulemaking process to update the health claims regulations. It failed to revise food labeling regulations to finally implement the requirement, established by the American Technology Preeminence Act or 1991 (legislation signed into law by the elder President Bush), to declare the package's contents in the metric system in addition to the US Customary System. Finally, FDA missed the opportunity to develop regulations covering front of package nutrition labeling, leaving industry to rely on a morass of advisory materials that has not been updated in nearly five years. See, Front-of-Package Labeling Initiative.

Nutrition Facts Panel Changes

The FDA made a number of changes to the nutrition label in an effort to provide US consumers with access to more meaningful information presented in a way that attempts to highlight what is very important to the overall diet, specifically total calories and added sugars.

The new nutrition label format most prominently features the quantity per serving of calories, encouraging consumers to focus on information about the food that is most important to achieve and maintain the most desirable body weight. The decades old requirement to declare calories from fat has been removed, based upon recognition that the type of fat is more important in increasing the risk of chronic disease than the quantity of fat that is consumed.

FDA also decided to require declarations for the quantity and percent daily value of added sugars. This information must be declared as "Includes X g Added Sugars" and will be indented under the declaration of "Sugars", which itself has undergone a cosmetic change to "Total Sugars". The preamble to the final regulation gave a considerable amount of attention to justifying these changes.

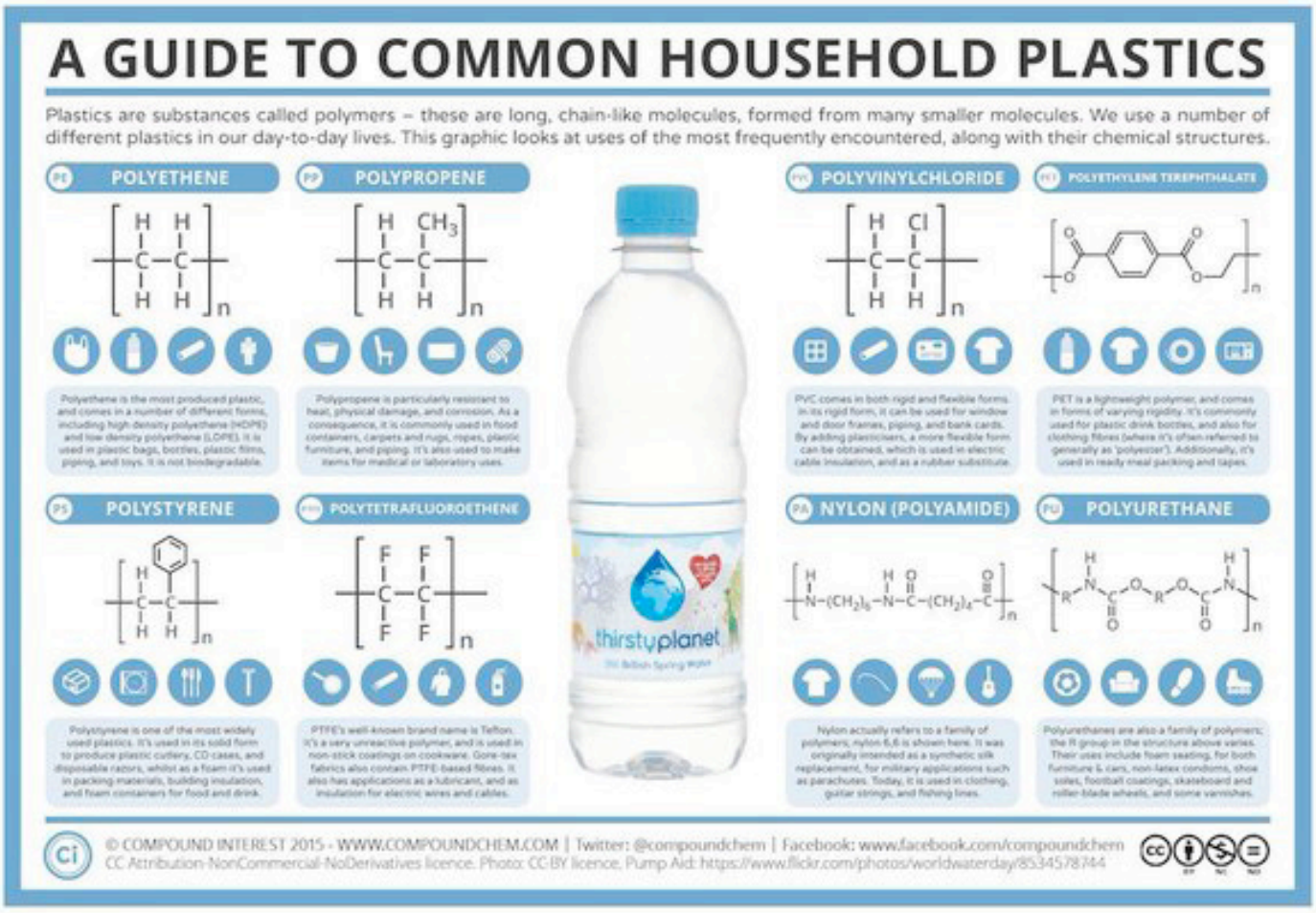
In addition to a number of graphic changes designed to make the label easier to understand, the new regulations will no longer require declarations for Vitamin A or Vitamin C, because deficiencies of these nutrients are no longer a problem in the US. In their place, declarations are mandated for Vitamin D, important for bone development, and potassium, a mineral important for regulating blood pressure. FDA determined that certain population groups do not consume adequate amounts of these nutrients. Samples of the old and new "Nutrition Facts" labeling panels are available at FDA's website by activating the following hyperlink: Graphic Showing Side-By-Side Comparison of the Original and New Nutrition Facts Labels.

The FDA established an entirely new daily reference value (DRV) for Added Sugars, determined that this daily value should be 50 g (per day) and revised DRVs for several additional nutrients as follows: 1) Fat 78g (↑13g); 2) Total Carbohydrate 275g (↓25g); 3) Sodium 2300mg (↓100mg); and 4) Dietary Fiber (↑3g). A new Reference Daily Intake (RDI) of 550mg was created for Choline and RDIs were modified for an additional 23 vitamins and minerals[1].

1 Changes to the RDIs, with the amount of the change indicated in parentheses, are as follows: 1) Vitamin A converted to 900 RAE[2] (mcg); 2) Vitamin C 90mg (↑30mg); 3) Calcium 1300 (↑300mg); 4) Vitamin D changed to 20 mcg (from 400IU); 5) Vitamin E changed to 15 mg (from 30IU); 6) Vitamin K 120 mcg (↑40mcg); 7) Thiamin 1.2 mg (↓.3mg); 8) Riboflavin 1.3 mg (↓0.4mg); 9) Niacin 16 Niacin Equivalents (mg) (↓4mg); 10) Vitamin B6 1.7 mg (↓0.3mg); 11) Vitamin B6 1.7 mg (↓0.3mg); 12) Vitamin B12 2.4 mcg (↓3.6mcg); 13) Biotin 30 mcg (↓270 mcg); 14) Pantothenic acid 5mg (↓5mg); 15) Phosphorus 1250 mg (↑250mg); 16) Magnesium 420 mg (↑20mg); 17) Zinc 11 mg (↓4mg); 17) Selenium 55 mcg (↓15mg): 18) Copper 0.9 mg (↓1.1mg): 19) Manganese 2.3 mg (↑0.3mg): 20) Chromium 35 mcg (↓85mg): 21) Molybdenum 45 mcg (↓30mcg); 22) Chloride 2300 mg (↓1100mg); and 23) Potassium 4700 mg (↑1200mg).

The FDA took the long overdue step of eliminating the requirement for the confusing and often-disregarded footnote table listing the reference values for certain nutrients for 2000 and 2500 calorie-per-day diets. A revised footnote more clearly informs that the daily value indicates how much each nutrient contributes to a daily diet and that the intake of 2000 calories per day is used for general nutrition advice.

FDA used the nutrition labeling rulemaking process as another opportunity to expand the scope of its legal authority without the historically necessary Congressional authorization and to place additional responsibilities on the food industry. The new regulations include requirements for food manufacturers to create records, maintain those records for a period of two years and give FDA access to written records verifying Nutrition Facts label declarations for certain nutrition label declaration. The new record keeping, retention and access requirements apply to the following: the amount of non-digestible carbohydrate added that is not dietary fiber, soluble fiber or insoluble fiber; the amount of added sugars; the amounts of all *rac*-alpha-tocopherol added to the food and RRR-alpha-tocopherol in the finished food; the amounts of any added synthetic folate/folic acid and naturally occurring folate; and the amount of added sugars present after non-enzymatic browning and/or fermentation.



FDA justified expanding its inspection authority and imposing the additional obligations on the food industry using the rationale that obligatory recordkeeping and complete access to those records is needed to ensure that the accuracy of specific nutrition labeling declarations can be verified because there are no official methods of analysis to quantify those substances. The FDA previously decided to entirely circumvent Congressional authorization to expand its inspection authority to access production/batch records as a method to assess GMP compliance for dietary supplement good manufacturing practices (21 CFR § 101, Part 111, Subpart P). Until that time, only the applicable provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 ***et seq***., delineated the limits of the FDA's legal authority to access food production records and the corresponding, legal obligation of food manufacturers to allow access to such records.[2]

2 The scope of the FDA's general inspection authority over foods is set forth in 21 U.S.C. § 374. Inspectors who present appropriate credentials and written notice are authorized to enter at reasonable times and within reasonable limits and inspect the facility, pertinent equipment, finished and unfinished materials, containers and labeling. Congress more recently gave the FDA limited authority to access production records of foods to address credible threats of serious adverse health consequences or death. For instance, 21 U.S.C. § 350a provides the FDA with access to food production records only: 1) when there is a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death; or 2) when the FDA believes that there is a reasonable probability the food will cause serious adverse health consequences or death.

In the post-9/11 Terrorist Attack era, Americans appear to be less inclined to challenge expansions of regulatory authority and policing powers, particularly when health and safety are implicated (e.g., protecting the food supply, preventing harm in public places and during travel, etc.). Whether motivated by a sense of patriotism, fear of terrorism or general apprehension about the consequences of challenging government authority, individual and corporate citizens seem to find ways to rationalize the power grabs that continue to erode many of the basic rights and freedoms that were once enjoyed.

Redefining Single-Serving Containers, Requiring Dual-Column Nutrition Labeling and Other Changes

The second part of the FDA's nutrition labeling rulemaking initiative expands the definition of single serving containers, requires dual-column nutrition labeling for certain types of packages, modifies some reference amounts customarily consumed (RACCs) and makes other changes.

Citing a growing body of research suggesting that container sizes can influence the amount of food consumed at one time, the FDA recognized a corresponding need to expand the universe of food containers that must be labeled as one

serving. As a result, the FDA regulations will require that any product packaged and sold individually that contains less than 200% of the appropriate reference amount (i.e., the RACC) be labeled as containing only one serving. Thus, the previous exception from the one serving per package requirement that applied to foods with a RACC of 100 g, or 100 ml or larger (e.g., bagels, muffins, pies, pasta/ potato salad, etc.) in an individual container providing more than 150% but less than 200% of the RACC.

The FDA further amended its labeling regulations to require containers and units that contain at least 200% and up to and including 300% of the appropriate reference amount (the RACC) to be labeled with a column of nutrition information (including quantitative amounts and percent daily values) for the entire container in addition to the otherwise required column of nutrition information listing the amount and percent daily values for a serving size that is less than the whole container, specifically the serving size derived from the RACC.

Potentially, this change may have the most dramatic effect on packaging and labeling, especially for those smaller, lower-priced snack foods (e.g., chips, pretzels, popcorn, extruded snacks) and cookies/candy bars that are typically found in convenient stores and gas stations and in the impulse purchase areas near the checkout counters of grocery stores, etc. Manufactures with products subject to the new dual-column requirement may simply elect to increase the size of snack food containers and packages so that they provide 300% or more of the reference amount in order to circumvent this new requirement. This would, in turn, eliminate any need to include a second column of nutrition information which could potentially reveal shocking details about the excessive amounts of calories, sugars, fat and sodium in the whole package.

The FDA also changed the RACCs for a number of specific food product categories. For example, the FDA increased the serving size of ice cream (from ½ cup to ⅔cup) and included it in a new category along with frozen yogurt, sherbet, sweetened ice pops and all types of bulk novelties (bars, cones, sandwiches). It also raised by 50% the RACC for carbonated beverages (from 240 ml/8 fl. oz. to 360 ml/12 fl. oz.) to more accurately reflect the amount ordinarily consumed. This new carbonated beverage RACC is identical to the volume of carbonated beverages that typically are sold in aluminum cans throughout the US.

Other RAAC changes and technical amendments also are covered by this rulemaking.

Conclusion

While the dust continues to settle around the voluminous documents that FDA delivered to the food industry which mandate changes to the manner in which foods must bear nutrition labeling in the near future, the industry must appreciate that the compliance dates by which changes must be made will arrive soon. Responsible food manufacturers need to educate their development, compliance and marketing staffs about the changes, evaluate each product label and package to determine how the new regulations will impact them, initiate steps necessary to implement changes in advance of the compliance date and complete the process. Of course, consulting with expert legal counsel throughout the process will help ensure that the undertaking is done promptly, efficiently and correctly.

Applicability of the German Regulation on Dietetic Foods with respect to Regulation (EU) 609/2013 and delegated acts

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On 20 July 2016, Regulation (EU) Nr. 609/2013 of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control (OJ L 181, 29.6.2013, pp. 35–56) will enter into force (Article 22). Nevertheless, the German Regulation on Dietetic Foods (Diätverordnung, *DiätV*) will not become obsolete.

Although the European legislative authority intends to abolish "the concept of 'foodstuffs for particular nutritional uses'" (recital 13, Regulation 609/2013), the German DiätV will remain effective even after 20 July 2016 and may only be overruled in part by certain delegated acts (so-called "Regulations on Food for Specific Groups", or FSG Regulations) with regard to

- infant formula and follow-on formula,
- processed cereal-based foods and other complementary foods,
- foods for special medical purposes, and
- total diet replacement for weight control.

Applicability of Regulation 609/2013 and delegated acts

The scope of Regulation 609/2013, like Directive 2009/39/EC on foodstuffs intended for particular nutritional uses (OJ L 124/21, 20.5.2009), includes only a scaffold of conditions for certain foodstuff categories and an authorization to enact further regulations in these categories in the form of so-called "delegated acts" (Regulation 609/2013, Article 11). Regulation 609/2013 itself includes only a small number of directly implemented, enforceable rules, such as

- Article 3, Interpretation decisions
- Article 10, Additional requirements for infant formula and follow-on formula
- Article 15, Union list.

The Dietary Framework Directive 2009/39/EC will be nullified with the entry into force of the new law on 20 July 2016 (Regulation 609/2013, Article 20).

However, the German DiätV will remain in effect (not only, but especially) with regard to the current European regulations that were enacted on the basis of the Dietary Framework Directive 2009/39/EC, whose implementation was carried out in German law in the form of the DiätV.

The Regulations enacted on the basis of the Dietary Framework Directive 2009/39/EC, including **Regulation (EC) Nr. 953/2009 and Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC**, will remain in effect until the delegated acts enter into force (Regulation 609/2013, Article 20, paragraph 4). This is the case, for example, for the following delegated acts and categories:

- Delegated Regulation (EU) 2016/127 for infant formula and follow-on formula,
- Delegated Regulation (EU) 2016/128 for food for special medical purposes (FSMP), and
- A delegated regulation on total diet replacement for weight control (draft version from 19 May 2016 available).

Prof. Dr. Alfred Hagen Meyer

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The focus of his legal work lies on all facets of food law and the law on food contact materials and commodity items, e.g. product development, labelling and health claims, risk assessment and crisis management as well as lobbying at the national and European levels.

An honorary professor at the TU Munich, Prof. Meyer has lectured on food law at the Institute for Food Chemistry, TU Munich, since 1995/1996.

Prof. Dr. Meyer's academic achievements are evidenced by over 300 publications.

Prof. Dr. Meyer is chairman of the committee on legal affairs of the German Association on Food for Specific Groups (Diätverband), Managing Director of the Research Centre for German and European Food Law in Bayreuth and chairman of the administrative board of the German Nutrition Society (DGE).

Delegated Regulation 2016/127 enters into force as of 22 February 2020, but not for infant and follow-on formula that is produced from protein hydrolysates, for which the law is first applicable as of 22 February 2021. Regulation 2016/128 for food for special medical purposes is effective as of 22 February 2019, but not for food for special medical purposes developed to satisfy the nutritional requirements of infants, for which the law enters into force as of 22 February 2020.

Note that foods regulated under Delegated Regulation (EU) 2016/127 and Delegated Regulation (EU) 2016/128 may be marketed according to the new standard before their respective dates of entry into force; however, it would not be permissible to market foods that partially adhere to the previous legal standards and partially to the standards in the new delegated acts.

The rules regarding **complementary food** remain unsettled after the European Parliament rejected a proposed draft on 20 January 2016; according to an EFSA announcement, the EU Commission will present a new draft soon.

In the case of foods offered as a replacement for one or more daily meals for weight control, **Directive 96/8/EC** will not apply after 20 July 2016 (Regulation 609/2013, Article 20, paragraph 3); rather, this legal subject matter will be regulated henceforth in the context of health claims (relevant EU Commission draft published as DG SANTE/12273/2015 (POOL/E4/2015/12273-EN.doc) D043783/01).

Priority application and barrier effect of EU law

Apart from the areas of law governed by Regulation 609/2013 and the delegated acts passed in association with it, the German DiätV remains unaffected and further applicable.

However, the principle of (primary and secondary) EU law requiring a higher priority of application of the EU law over national law triggers a barrier effect regarding the national law and limits the political autonomy of the Member States. Moreover, to the extent that a secondary law exists, it not only triggers a barrier effect, but also opens Member States to measures that further confine their legislative authority and are not part of the European legal framework.

German authority

Even if European legislators intend to put an end to "the concept of 'foodstuffs for particular nutritional uses'", doing so would thereby limit their own legislative scope, i.e., grow the barrier effect of European law with regard to national law singularly with respect in the categories of

- infant formula and follow-on formula,
- processed cereal-based foods and other complementary foods,
- foods for special medical purposes, and
- total diet replacement for weight control.

Additionally, in light of this legal framework, national laws may be enacted or continue to apply. This applies in particular to

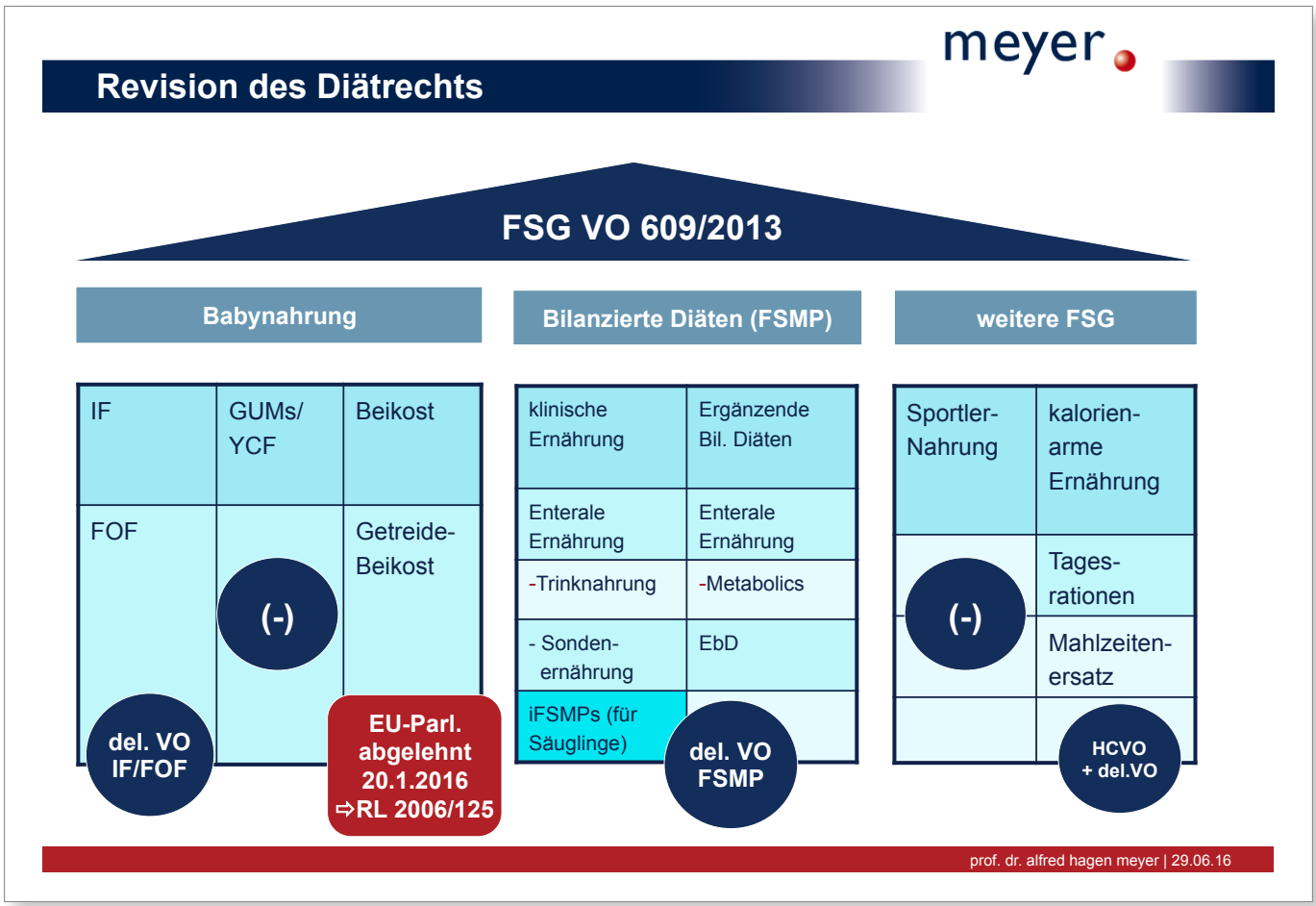
- Children's tea
- Foodstuffs for pregnant women,
- Salt substitutes,

but also

- sportsfood, and
- growing-up milk (acronym "GUM"/YCF),

because the Commission was granted authority to regulate the final two items (Regulation 609/2013, Article 12 and 13); however, as long as the Commission does not exercise this authority, it remains within the purview of national legislative bodies to do so (subsidiarity principle).

Therefore, the established practice for child formulae pertaining to notification procedures under the German Federal Ministry for Consumer Protection and Food Safety (BVL) may continue. Because of the application of Regulation 609/2013 beginning on 20 July 2016, foods previously considered to be



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diatetic will not be allowed to receive exceptional approval or "general rulings" under German law for use of individual ingredients.

Reference is given to the jurisdiction of the either obsolete or, on account of its exceptions, very narrowly construed section 2, paragraph 3 of the German Food Act (LFGB): Bundesgerichtshof I ZR 99/09, 15. Juli 2010 (German Federal Court of Justice), „Gelenknahrung II" / "Joint Nutrition II", Bundesverwaltungsgericht 3 C 15.11, 1. März 2012 (German Federal Administrative Court) concerning glucosamine; Administrative Court of Braunschweig, Order for Reference to the European Court of Justice, 5 A 67/13, 27. Mai 2015 concerning amino acids.

The latest **Report of the European Commission on young child formulae** from 31.3.2016 does not oppose this approach (the same applies to Commission Report on food intended for sportspeople, COM(2016) 402 final). The Commission claimed that it would not likely attempt to include this food group in the FSG Regulation framework. The Commission also refers to the fact that the existing applicable law suffices, including the Regulation (EC) 1925/2006 on fortification of foods and Regulation (EC) 1924/2006 on health claims. However, the Commission invokes the false impression that the legal status of child formulae will change completely after the 20 July 2016. This is not the case. Although the FSG Regulation 609/2013 may enter into force on the 20 July 2016, the delegated acts nevertheless enter into force in 2018 and later; otherwise the Commission is not actually exercising its legislative authority from Regulation 609/2013, Article 12. The same rules should apply in this timeframe as otherwise, namely, that Member States may create regulations for legal areas where none yet exist in European Union law. As such, the path is clear for a German regulatory scheme for child formulae; France is currently doing the same with a regulation issued in 1978 (which the European Commission quotes in footnote 27 of its report from 31.3.2016). The Commission expressed clearly that it wishes to examine such regulations and draft regulations (sections 6 and 8 of the report), a competency that stems from the Technical Regulation Information System or TRIS Regulation (Directive 83/189/EEC of 28.3.1983, OJ L 109/9; with Directive 88/182/EEC of 22.3.1988, OJ L 81/75, applied to food regulations), although the European Commission's examination authority in this sense is limited to the compatiblity of doing so with primary EU law principles (rules of the free movement of goods, etc., so that the structure of national authority is limited, particularly with regard to the marketability of foods).

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Disclaimer: The author is Chairman of the Legal Committee of the German Association for Dietetic Foods.

TURKEY – Turkish Food Codex and Recent Developments

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A. Relevant Legislation

Turkish Food Codex Regulation (the "**Food Codex Regulation**"), which entered into force on 29 December 2011, harmonizes the related legislation and enables many other specialized regulations and communiqués to be adopted in accordance with it (collectively the "**Food Codex**").

According to the General Directorate of Food and Control (the "**Directorate**") under the Ministry of Food, Agriculture, and Livestock, there are currently 95 pieces of legislation that comprise the Turkish Food Codex, including

- the Turkish Food Codex Communiqué on Turkish delight,
- the Turkish Food Codex Communiqué on ice cream,
- the Turkish Food Codex Communiqué on table olives,
- the Turkish Food Codex Communiqué on cheese etc.

There are also some new pieces of draft legislation, which have been announced in order to receive comments and queries from interested parties. For instance,

- the Turkish Food Codex Communiqué on Plants and Plant Products that Can Be Used in Food,
- the Turkish Food Codex Regulation on Nutrition and Health Statements, and
- the Turkish Food Codex on Distilled Alcoholic Beverages

are all available in draft form, and they have already received comments and queries.

The Food Codex determines the necessary minimum technical and hygienic criteria related to food, and the materials and articles that come into contact with food, including pesticides and veterinary medicinal residue, additives, contaminants. The Food Codex also regulates the principles for sampling, packaging, labeling, transport, storage, and the methods of analysis.

B. Developments in Turkish Food Legislation

Individual pieces of the Food Codex are also being amended and new legislation is being drafted to comply with the requirements of the European Union (the "**EU**").

Turkey has faced difficulties and sometimes public backlash while adopting certain legislation that impacts Turkish food traditions and Turkish taste. For example, a law was passed in 2008 that prohibited the use of real uncooked meat in steak tartar a la turca (çiğköfte) in compliance requirements of the EU. In 2013, meatless steak tartar a la turca was also included in the Turkish Food Codex, which prohibited the use of any kind of additive.

Notwithstanding the pushback on steak tartar a la turca regulation, the public appreciated some recent amendments to the Food Codex. For example, the Honey Communiqué prohibited the sale of honey without a barcode in order to keep fake honey off of the market because it can cause death to people with diabetes. This new requirement entered into force in 2015 and it coincides with a decrease the number of consumer complaints.

Some legislation received both positive and negative reactions from the public. For instance, the Turkish Food Codex Communiqué on Cheese prohibits the sale of cheese without vacuum packing. Some consumers criticize this rule as they want to taste the cheese before deciding to buy it and also because the vacuum packing of the cheese will be reflected in the price of the cheese, but some consumers prefer this requirement because they find it healthier.

C. Use of GMOs under Turkish Legislation

According to legislation relating to food products containing Genetically Modified Organisms ("**GMOs**") in Turkey, it could be possible to consider GMOs to be "contaminants." However, if they made up less than 0.9% of a product, and if these GMO contaminants were approved by the Biosafety Board, then producers would be free to use them. That said, the Biosafety Board has not yet approved any GMOs for food purposes and it has only approved GMOs to be used for animal feed. In accordance with the recent explanations provided by the Biosafety Board Deputy Chairman, even if a product contains GMOs of less than or equal to 0.9%, and even if that GMO has been approved by the Biosafety Board, it can still only be used for animal feed, and not for human consumption.

The Turkish GMO regulatory approval system holds the unique distinction of being the only system in the world that does not approve GMOs for food use; even the EU operates a GMO regulatory regime that has approved GMOs for use in both food and animal feed.

D. Recent Turkish Food legislation News

It was reported on 23 June 2016 that a famous US based food and beverage chain put aside plans for opening its first branch in Istanbul, Turkey. The famous brand uses GMO ingredients in some of its recipes and these GMOs are prohibited under Turkish legislation. It would seem that the brand had actually decreased the total number of ingredients containing GMOs to seven, in order to satisfy Turkish regulations, but unlike regulations in the United States, the EU, and many other countries, Turkey prohibits the use and production of any food that includes GMOs (even the use of one GMO ingredient is prohibited for food products) therefore, the efforts of the brand to come into compliance were in vain.

E. Consequences for a Breach of Laws under the Food Codex

A breach of the requirements set forth in the Turkish Food Codex may result in monetary fines and special cases imprisonment that are specified in each specialized piece of legislation.

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Hergüner Bilgen Özeke

Hergüner Bilgen Özeke Attorney Partnership ("Hergüner") is Turkey's leading independent business law firm. Since its establishment in 1989, the firm provides legal guidance to its clients on all aspects of international business law and is known as the firm which brought the 'full-service law firm' concept to Turkey. Hergüner represent major multinational corporations, international financial institutions, agencies and other notable clientele in Corporate, Dispute Resolution & Commercial, and Finance & Projects areas.

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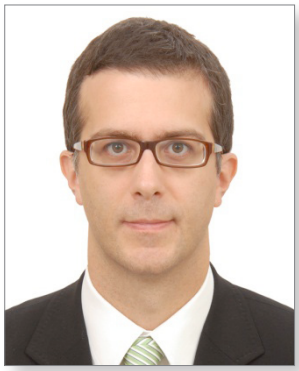

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Chlorpyrifos –
abgesenkte ARfD, niedrigere MRLs

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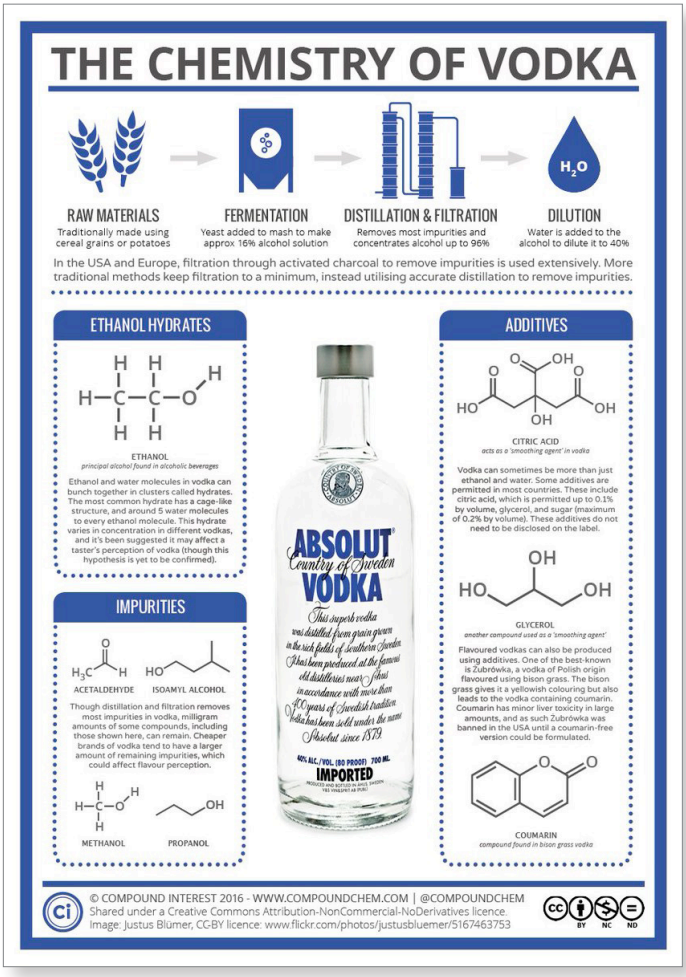
EFSA senkt Akute Referenzdosis (ARfD) - sind Lebensmittel trotz Einhaltung der rechtlich vorgegebenen Rückstandshöchstmengen noch verkehrsfähig? Sind im vorauseilenden Gehorsam Maßnahmen notwendig? Können Unternehmen auf Übergangsfristen setzen?

Anfang 2016 wurde die Verordnung (EU) 2016/60 veröffentlicht, wonach die Anhänge II und III der Verordnung (EG) Nr. 396/2005 hinsichtlich der Rückstandshöchstgehalte von Chlorpyrifos geändert werden. Damit ist eine zum Teil drastische Absenkung zahlreicher MRLs verbunden, wie die für Äpfel, Pfirsiche, Tafeltrauben und Birnen. Die Verordnung (EU) 2016/60 gilt ab dem 10. August 2016. Die neu festgesetzten Rückstandshöchstgehalte (Maximum Residue Levels – MRL) gelten dann uneingeschränkt; Übergangsregelungen für Ware, die bis dahin nach „altem Recht" hergestellt wurde, gibt es nicht.



Dem neuen Recht ging ein Assessment voraus. Im Rahmen der im Jahr 2005 durchgeführten EU-Bewertung von Chlorpyrifos wurde auf Basis akuter und verzögerter Neurotoxizitätsstudien bei Ratten unter Berücksichtigung eines Sicherheitsfaktors von 100 noch eine ARfD von 0,1 mg/kg Körpergewicht (KG) abgeleitet. Seit der Bewertung des Wirkstoffes im Jahr 2005 sind allerdings neue Studien zu bestimmten toxikologischen Wirkungen von Chlorpyrifos veröffentlicht worden; so publizierte die US Environmental Protection Agency (EPA) im Jahr 2011 eine vorläufige Bewertung des aus dem Acetylcholinesterase (AChE)-hemmenden Potentials von Chlorpyrifos resultierenden Risikos für die menschliche Gesundheit. Das BfR sichtete die Bewertung der US EPA und kam zu dem Schluss, dass auch in der EU eine Überprüfung der gesundheitlichen Referenzwerte von Chlorpyrifos erfolgen sollte (BfR Stn. 026/2012).

Im April 2013 erteilte die EU Kommission der EFSA das Mandat, die im Jahr 2005 etablierten toxikologischen Referenzwerte zu überprüfen und auch insbesondere die BfR-Stellungnahme, die EPA-Bewertung und weitere neue Studien zu berücksichtigen. Die EFSA publizierte ihre Stellungnahme hierzu am 22.4.2014. In dieser leitete die EFSA auf Grundlage der neuen toxikologischen Daten eine niedrigere ARfD in Höhe von 0,005 mg/kg KG ab; dies unter Berücksichtigung eines Sicherheitsfaktors von 100 auf den NOAEL (no observed adverse effect level) von 0,5 mg/kg KG/Tag bezüglich der Cholinesterase-Hemmung in roten Blutkörperchen (EFSA Journal 2014;12(4):3640).

Die VO 2016/60 kam insofern nicht überraschend, gar etwas spät. Unternehmen mit Risiko basierter QS - unabdingbar heute - konnten sich hierauf einstellen, zumal angesichts einer Latenzzeit seit 2012 (BfR), spätestens 2014 (EFSA). Angesichts der neuen Erkenntnisse zu Chlorpyrifos ist eine halbjährige Frist zwischen Inkrafttreten und Geltung übrigens ein weites Entgegenkommen gegenüber den Lebensmittelunternehmen. Ein Lamentieren hierüber stünde der Wirtschaft nicht gut an.

Portionspackungen – wie viel muss drauf?

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Es läuft derzeit seit Mai 2015 ein Vorabentscheidungsverfahren (EuGH C-113/15) über die Rechtsfrage, ob Portionspackungen, die in Sammelpackungen an Anbieter von Gemeinschaftsverpflegung verkauft werden, der vollständigen Kennzeichnungspflicht der LMIV 1169/2011 unterliegen.

Ob Portionspackungen sämtliche Pflichtkennzeichnungsmerkmale enthalten müssen, richtet sich danach, ob es sich um „vorverpackte Lebensmittel" gem. Art. 2 Abs. 2 Buchstabe e) LMIV 1169/2011 handelt.

Ein „**vorverpacktes Lebensmittel**" ist nach Art. 2 Abs. 2 Buchstabe e) LMIV 1169/2011 *„jede Verkaufseinheit, die als solche an den Endverbraucher und an Anbieter von Gemeinschaftsverpflegung abgegeben werden soll und die aus einem Lebensmittel und der Verpackung besteht, in die das Lebensmittel vor dem Feilbieten verpackt worden ist, gleichviel, ob die Verpackung es ganz oder teilweise umschließt, jedoch auf solche Weise, dass der Inhalt nicht verändert werden kann, ohne dass die Verpackung geöffnet werden muss oder eine Veränderung erfährt"*.

Anbieter von Gemeinschaftsverpflegungen sind gem. Art. 2 Abs. 2 Buchstabe d LMIV wiederum Einrichtungen, […] *in denen Lebensmittel für den unmittelbaren Verzehr durch den Endverbraucher zubereitet werden*.

Portionseinheiten (z.B. Marmelade, Honig, Senf oder Tee), die den Kunden von Anbietern von Gemeinschaftsverpflegung als Teil der Mahlzeit zum unmittelbaren Verzehr angeboten werden, wären danach nur dann als vorverpackte Lebensmittel einzustufen, wenn sie **Verkaufseinheiten** darstellen würden. Die „Verkaufseinheit" ist in der LMIV nicht weiter definiert, aber als die Einheit zu verstehen, die bestimmungsgemäß zum Kauf an Endverbraucher oder Anbieter von Gemeinschaftsverpflegungen feilgeboten wird. Entscheidend ist nach *Zipfel/Rathke*, ob die betreffende Verkaufseinheit dazu **bestimmt** ist, an Verbraucher und Anbieter von Gemeinschaftsverpflegungen abgegeben zu werden, was für Portionsverpackungen nicht der Fall sei (*Zipfel/Rathke*, Kommentar zur LMIV C 162, Art. 2 Rn. 64; so auch *Voit/Grube*, Kommentar zur LMIV, Art. 8, Rn. 61). Auch die Europäische Kommission verneint in ihrem Dokument „Fragen und Antworten zur Anwendung der Verordnung (EU) Nr. 1169/2011 betreffend die Information der Verbraucher über Lebensmittel" überzeugend die Einordnung von Portionsverpackungen als Verkaufseinheiten.

Dass nun die Generalanwältin Eleanor Sharpston in ihrer Stellungnahme vom 5. April 2016 Portionspackungen, die in Umverpackungen an Einrichtungen der Gemeinschaftsverpflegung veräußert und von diesen im Rahmen einer Mahlzeit an den Endverbraucher zum unmittelbaren Verzehr abgegeben werden, unter den Begriff eines „vorverpackten Lebensmittels" fallen lassen möchte, überrascht vor diesem rechtlichen Hintergrund sowie der klar von der Europäischen Kommission bezogenen Position doch sehr. Zu diesem Ergebnis kommt die Generalanwältin, da sie bei Portionspackungen – selbst wenn sie als Teil einer verkauften Mahlzeit an den Endverbraucher abgegeben werden – das Vorliegen einer Verkaufseinheit entgegen der Kommission und der Literaturstimmen bejaht.

Die Verkaufseinheit, die der Anbieter von Gemeinschaftsverpflegungen erwirbt, ist jedoch nur die **Sammelpackung**. Die darin enthaltenen Einzelpackungen des (zäh-)flüssigen Honigs dienen lediglich der einfacheren Portionierung desselben. Gibt z.B. ein Krankenhaus als Mahlzeit zwei Scheiben Brot mit einer Scheibe Käse und einer Portion Honig an den Patienten ab, sind das Brot und der Käse ebenfalls nicht zu kennzeichnen und können portioniert werden, indem sie lediglich auf den Teller gelegt werden. Der Honig kann jedoch nicht abgegeben werden, ohne ihn zunächst zu portionieren. Diesen aufgrund der andersartigen Konsistenz anders zu behandeln, als die Brot- und Käsescheiben, erscheint wenig sinnvoll und ist so sicher nicht von dem Gesetzgeber gewollt.

Natalie Hartmann

Rechtsanwältin Hartmann ist seit Juni 2012 bei meyer.rechtsanwälte. Dort ist sie schwerpunktmäßig im Bereich des Lebensmittelrechts tätig. Sie betreut internationale und nationale Mandanten im Rahmen der allgemeinen Beratung insbesondere in Fragen der stofflichen Verkehrsfähigkeit im Rahmen innovativer Produktentwicklungen, Kennzeichnung und Bewerbung von Lebensmitteln sowie in Auseinandersetzungen mit Wettbewerbern und Behörden. Ein weiterer Schwerpunkt von Rechtsanwältin Hartmann liegt im Risk Assessment und Krisenmanagement, insbesondere im Rahmen von Rückrufen von Produkten sowie Warnungen hierüber.

Auch für den unmittelbaren Verkauf an Endverbraucher bestimmte Sammelpackungen, die einzeln verpackte Verzehreinheiten (z.B. die klassische Bonbons-Tüte) enthalten, werden die einzeln verpackten Bonbons nicht als Verkaufseinheit angesehen und stellen damit keine Vorverpackung i.S.d. Art. 2 Abs. 2 Buchstabe e LMIV dar. Nur die äußere Sammelpackung ist dabei vollständig zu kennzeichnen.

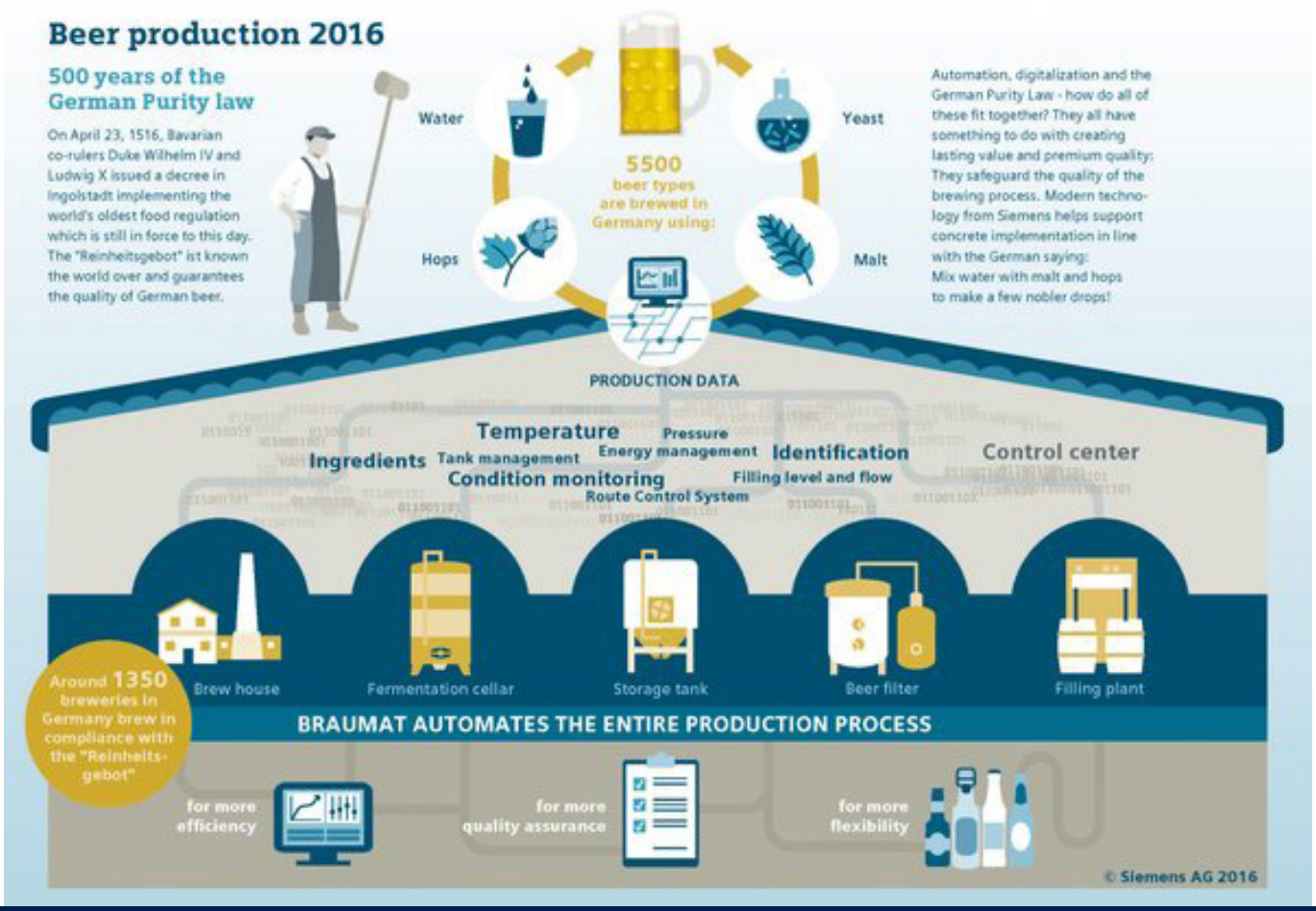
Hinzu kommt, dass sich der Endverbraucher bei Abgabe von Portionspackungen durch Gemeinschaftsverpflegungen jederzeit vor Ort über die Pflichtkennzeichnungselemente, die nicht auf der Portionspackung vorhanden sind, bei dem Anbieter der Gemeinschaftsverpflegung erkundigen kann. Die Situation ist dort also ähnlich wie bei loser Ware, für welche eine Kennzeichnungspflicht (abgesehen von Allergenen) ebenfalls nicht gegeben ist.

Anders wäre lediglich der Fall zu beurteilen, dass Anbieter einer Gemeinschaftsverpflegung Portionspackungen nicht zum unmittelbaren Verzehr abgeben, sondern als separate Einheiten verkaufen, da sie damit Portionspackungen zu Verkaufseinheiten machen würden. Dann wäre die Situation für den Endverbraucher dieselbe, als wenn er die Portionseinheit im Einzelhandel erworben hätte. Die Kennzeichnungspflicht kann in diesem Fall nur dann den Hersteller des Produktes treffen, wenn die einzelnen Portionspackungen nicht ausdrücklich von der separaten Abgabe ausgenommen sind (z.B. durch den Hinweis „nicht zum Einzelverkauf bestimmt"). Die Anbringung dieser Klarstellung ist daher jedem Hersteller zu empfehlen, der nicht ausschließen kann, dass seine Portionspackungen durch Kantinen o.ä. als separate Einheiten an den Endverbraucher verkauft werden, diese also zur „Verkaufseinheit zum nicht sofortigen Verzehr" werden können.

Sollte sich der EuGH der Auffassung der Generalanwältin anschließen (was jedoch offen ist) und das Vorliegen von vorverpackten Lebensmitteln bei Portionspackungen bejahen, hätte dies erhebliche Auswirkungen für alle betroffenen Lebensmittelhersteller. Insbesondere bei Sammelpackungen, die mehrsprachig gekennzeichnet sind, würde dies bedeuten, dass auf den kleinen Portionspackungen sämtliche Kennzeichnungselemente (inkl. platzeinnehmender Nährwertdeklaration) in allen Sprachen aufgebracht werden müssten.

Insofern bleibt den Herstellerunternehmen nur zu hoffen, dass der EuGH sich der klar in dem „Fragen und Antworten-Dokument" geäußerten Ansicht der Kommission anschließen wird und die Definition der Verkaufseinheit nicht durch die Rechtsprechung weiter gefasst wird, als durch den Gesetzgeber vorgegeben.

conflict of interests: meyer.rechtsanwälte vertraten das Unternehmen im hier angesprochenen EuGH-Verfahren in den ersten beiden Instanzen



New Law – in headwords & details

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Below the latest European regulations and directives in 2016. The table shows the matching No., under which the legal norm can be found in the (German) Textbook C.H.Beck, Meyer Lebensmittelrecht, the particular legal norm (2nd column) and in the 3rd column the current amendment. Via hyperlink the new legal norms can be recalled online.

Meyer Textbook C.H.Beck		
Nr.	**Legal Norm**	**Amendment**
Reg. 178/2002		
20	Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013)	- Corrigendum to Regulation (EU) No 1308/2013 (OJ L 130, 19.5.2016, p. 9–12)
Food Additives, Enzymes		
600	Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008)	- Commission Regulation (EU) 2016/56 of 19 January 2016 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of extracts of rosemary (E 392) in spreadable fats (OJ. L 13, 20.1.2016, p. 46–48) - Commission Regulation (EU) 2016/263 of 25 February 2016 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the title of the food category 12.3 Vinegars (OJ. L 50, 26.2.2016, p. 25–26) - Commission Regulation (EU) 2016/324 of 7 March 2016 amending and correcting Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of certain food additives permitted in all categories of foods (OJ L 61, 8.3.2016, p. 1–4) - Commission Regulation (EU) 2016/441 of 23 March 2016 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of Steviol glycosides (E 960) as a sweetener in mustard (OJ L 78, 24.3.2016, p. 47–48) - Commission Regulation (EU) 2016/479 of 1 April 2016 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of steviol glycosides (E 960) as a sweetener in certain energy-reduced or with no added sugars beverages (OJ L 87, 2.4.2016, p. 1–3)

600	Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008)	- Commission Regulation (EU) 2016/683 of 2 May 2016 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of propionic acid — propionates (E 280-283) in tortillas (OJ 117, 3.5.2016, p. 28–29) - Commission Regulation (EU) 2016/691 of 4 May 2016 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of food additives in edible caseinates (OJ L 120, 5.5.2016, p. 4–6)
800	Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods (OJ L 354, 31.12.2008, p. 34–50)	- Commission Regulation (EU) 2016/54 of 19 January 2016 amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards inclusion of gamma-glutamyl-valyl-glycine in the Union list of flavouring substances (OJ L 13, 20.1.2016, p. 40–42) - Commission Regulation (EU) 2016/55 of 19 January 2016 amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards certain flavouring substances (OJ L 13, 20.1.2016, p. 43–45) - Commission Regulation (EU) 2016/178 of 10 February 2016 amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards removal from the Union list of certain flavouring substances (OJ L 35, 11.2.2016, p. 6–8) - Commission Regulation (EU) 2016/637 of 22 April 2016 amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards removal from the Union list of certain flavouring substances (OJ. L 108, 23.4.2016, p. 24–27) - Commission Regulation (EU) 2016/692 of 4 May 2016 amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards certain flavouring substances (OJ L 120, 5.5.2016, p. 7–9)

Hygiene, Radiation

910	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (Official Journal L 139/55, 30.4.2004)	- Commission Regulation (EU) 2016/355 of 11 March 2016 amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards the specific requirements for gelatine, collagen and highly refined products of animal origin intended for human consumption (OJ L 67, 12.3.2016, p. 22–28)

Contaminants, Residues

1205	Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (Official Journal 364/5, 20.12.2006)	- Commission Regulation (EU) 2016/239 of 19 February 2016 amending Regulation (EC) No 1881/2006 as regards maximum levels of tropane alkaloids in certain cereal-based foods for infants and young children (OJ L 45, 20.2.2016, p. 3–5)

1220 Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC **(Official Journal L 70/1, 16.3.2005)**

- Commission Regulation (EU) 2016/1 of 3 December 2015 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenazate, boscalid, cyazofamid, cyromazine, dazomet, dithiocarbamates, fluazifop-P, mepanipyrim, metrafenone, picloram, propamocarb, pyridaben, pyriofenone, sulfoxaflor, tebuconazole, tebufenpyrad and thiram in or on certain products (OJ L 2, 5.1.2016, p. 1–62)

- Commission Regulation (EU) 2016/46 of 18 January 2016 amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for oxadixyl and spinetoram in or on certain products (OJ L 12, 19.1.2016, p. 28–41)

- Commission Regulation (EU) 2016/53 of 19 January 2016 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for diethofencarb, mesotrione, metosulam and pirimiphos-methyl in or on certain products (OJ L 13, 20.1.2016, p. 12–39)

- Commission Regulation (EU) 2016/60 of 19 January 2016 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorpyrifos in or on certain products (OJ L 14, 21.1.2016, S. 1–17)

- Commission Regulation (EU) 2016/67 of 19 January 2016 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for ametoctradin, chlorothalonil, diphenylamine, flonicamid, fluazinam, fluoxastrobin, halauxifen-methyl, propamocarb, prothioconazole, thiacloprid and trifloxystrobin in or on certain products (OJ L 15, 22.1.2016, p. 2–50)

- Commission Regulation (EU) 2016/75 of 21 January 2016 amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fosetyl in or on certain products (OJ L 16, 23.1.2016, p. 8–20)

- Commission Regulation (EU) 2016/71 of 26 January 2016 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 1-methylcyclopropene, flonicamid, flutriafol, indolylacetic acid, indolylbutyric acid, pethoxamid, pirimicarb, prothioconazole and teflubenzuron in or on certain products (OJ L 20, 27.1.2016, p. 1–47)

- Commission Regulation (EU) 2016/143 of 18 January 2016 amending Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards COS-OGA, cerevisane, calcium hydroxide, lecithins, Salix spp cortex, vinegar, fructose, Pepino mosaic virus strain CH2 isolate 1906, Verticillium albo-atrum isolate WCS850 and Bacillus amyloliquefaciens subsp. plantarum strain D747 (OJ L 28, 4.2.2016, p. 12–14)

1220 Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC **(Official Journal L 70/1, 16.3.2005)**

- Commission Regulation (EU) 2016/156 of 18 January 2016 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for boscalid, clothianidin, thiamethoxam, folpet and tolclofos-methyl in or on certain products (OJ L 31, 6.2.2016, p. 1–44)

- Commission Regulation (EU) 2016/439 of 23 March 2016 amending Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards Cydia pomonella Granulovirus (CpGV), calcium carbide, potassium iodide, sodium hydrogen carbonate, rescalure and Beauveria bassiana strain ATCC 74040 and Beauveria bassiana strain GHA (OJ L 78, 24.3.2016, p. 31–33)

- Commission Regulation (EU) 2016/440 of 23 March 2016 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for atrazine in or on certain products (OJ L 78, 24.3.2016, p. 34–46)

- Commission Regulation (EU) 2016/452 of 29 March 2016 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for captan, propiconazole and spiroxamine in or on certain products (OJ L 79, 30.3.2016, p. 10–27)

- Commission Regulation (EU) 2016/486 of 29 March 2016 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyazofamid, cycloxydim, difluoroacetic acid, fenoxycarb, flumetralin, fluopicolide, flupyradifurone, fluxapyroxad, kresoxim-methyl, mandestrobin, mepanipyrim, metalaxyl-M, pendimethalin and tefluthrin in or on certain products (OJ L 90, 6.4.2016, p. 1–66)

- Commission Regulation (EU) 2016/567 of 6 April 2016 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorantraniliprole, cyflumetofen, cyprodinil, dimethomorph, dithiocarbamates, fenamidone, fluopyram, flutolanil, imazamox, metrafenone, myclobutanil, propiconazole, sedaxane and spirodiclofen in or on certain products (OJ. L 100, 15.4.2016, p. 1–60)

- Corrigendum to Commission Regulation (EU) 2016/71 of 26 January 2016 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 1-methylcyclopropene, flonicamid, flutriafol, indolylacetic acid, indolylbutyric acid, pethoxamid, pirimicarb, prothioconazole and teflubenzuron in or on certain products (OJ L 20, 27.1.2016)

1220	Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC **(Official Journal L 70/1, 16.3.2005)**	- Commission Regulation (EU) 2016/805 of 20 May 2016 amending Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards Streptomyces K61 (formerly S. griseoviridis), Candida oleophila strain O, FEN 560 (also called fenugreek or fenugreek seed powder), methyl decanoate (CAS 110-42-9), methyl octanoate (CAS 111-11-5) and terpenoid blend QRD 460 (OJ L 132, 21.5.2016, p. 95–96)
1235	Regulation (EC) No 333/2007	**- Commission Regulation (EU) 2016/582 of 15 April 2016 amending Regulation (EC) No 333/2007 as regards the analysis of inorganic arsenic, lead and polycyclic aromatic hydrocarbons and certain performance criteria for analysis (OJ.L 101, 16.4.2016, p. 3–6)**

Pharmacologically Active Substances

1500	Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (L 15/1, 20.1.2010)	- Commission Implementing Regulation (EU) 2016/129 of 1 February 2016 amending Regulation (EU) No 37/2010 as regards the substance 'Purified semi-solid extract from Humulus lupulus L. containing approximately 48 % of beta acids (as potassium salts)' (OJ L 25, 2.2.2016, p. 44–45) - Commission Implementing Regulation (EU) 2016/305 of 3 March 2016 amending Regulation (EU) No 37/2010 as regards the substance 'gentamicin' (OJ L 58, 4.3.2016, p. 35–37) - Commission Implementing Regulation (EU) 2016/312 of 4 March 2016 correcting Regulation (EU) No 37/2010 as regards the substance 'tylvalosin' (OJ L 60, 5.3.2016, p. 3–4) - Commission Implementing Regulation (EU) 2016/576 of 14 April 2016 amending Regulation (EU) No 37/2010 as regards the substance 'rafoxanide' (OJ L 99, 15.4.2016, p. 1–3) - Commission Implementing Regulation (EU) 2016/710 of 12 May 2016 amending Regulation (EU) No 37/2010 as regards the substance 'copper carbonate' (OJ L 125, 13.5.2016, p. 6–8) - Commission Implementing Regulation (EU) 2016/885 of 3 June 2016 amending Regulation (EU) No 37/2010 as regards the substance 'eprinomectin' (OJ L 148, 4.6.2016, p. 1–3)

Food for Specific Groups FSG

2260	Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding (OJ L 25, 2.2.2016, p. 1–29)	

2280	Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes (OJ L 25, 2.2.2016, p. 30–43)	

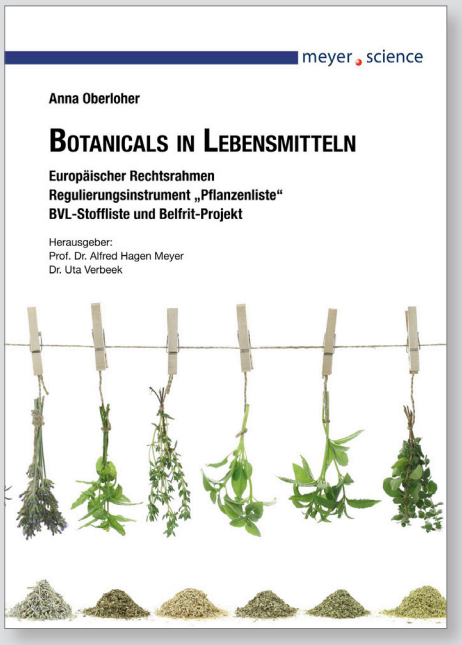
Organic Products

2620	Commission Regulation (EC) No 1235/2008 of 8 December 2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries (Official Journal L 334/25, 12.12.2008)	- Commission Implementing Regulation (EU) 2016/459 of 18 March 2016 amending Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries (OJ L 80, 31.3.2016, p. 14–16) - Commission Implementing Regulation (EU) 2016/910 of 9 June 2016 amending Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries (OJ. L 153, 10.6.2016, p. 23–24)

Alcoholic Beverages

7700	Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89 (Official Journal L 39, 13/02/2008, p. 16)	- Commission Regulation (EU) 2016/235 of 18 February 2016 amending Annex II to Regulation (EC) No 110/2008 of the European Parliament and of the Council on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks (OJ L 44, 19.2.2016, p. 7–8)

Buch Erscheinungen



Regulatory News

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Europäische Behörde für Lebensmittelsicherheit – EFSA

Verarbeitungskontaminanten auf Basis von Glycerin in Pflanzenölen und Lebensmitteln

Die EFSA hat die Gefährdung der öffentlichen Gesundheit durch die folgenden Verarbeitungskontaminanten auf Basis von Glycerin, die in Palmöl, aber auch in anderen Pflanzenölen, Margarinen und einigen verarbeiteten Lebensmitteln enthalten sind, bewertet: Glycidyl-Fettsäureester (GE), 3-Monochlorpropandiol (3-MCPD) und 2-Monochlorpropandiol (2-MCPD) sowie deren Fettsäureester. Die Stoffe werden während der Lebensmittelverarbeitung gebildet, vor allem bei der Raffination von Pflanzenölen bei hohen Temperaturen (ca. 200 °C).

Die höchsten Konzentrationen von GE wie auch von 3-MCPD und 2-MCPD (einschließlich Estern) wurden in Palmölen und Palmfetten gefunden, gefolgt von anderen Ölen und Fetten. Bei Verbrauchern ab drei Jahren waren Margarinen sowie „Backwaren und Kuchen" die Hauptquellen für die Exposition gegenüber allen Stoffen.

Glycidyl-Fettsäureester – genotoxisch und karzinogen

Die EFSA berücksichtigte bei seiner Risikobewertung zu GE Informationen über die Toxizität von Glycidol (der Ausgangsverbindung von GE) und ging von einer vollständigen Umwandlung der Ester in Glycidol nach der Aufnahme aus.

Da die genotoxische und karzinogene Wirkung von Glycidol hinreichend nachgewiesen ist, hat das CONTAM-Gremium keinen sicheren Wert für GE festgelegt. Bei der Bewertung genotoxischer und karzinogener Stoffe, die unbeabsichtigt in der Lebensmittelkette enthalten sind, berechnet die EFSA einen „Margin of Exposure" (MOE) für Verbraucher. Je höher der MOE-Wert und damit die Sicherheitsmarge für die Exposition, desto geringer sind die Bedenken für die Verbraucher.

Das Gremium kam zu dem Schluss, dass GE Anlass zu möglichen Gesundheitsbedenken hinsichtlich jüngerer Altersgruppen bei durchschnittlicher Exposition und hinsichtlich aller Altersgruppen bei hoher Exposition gibt.

Die Exposition von Säuglingen, die ausschließlich Säuglingsanfangsnahrung zu sich nehmen, gegenüber GE ist besonders besorgniserregend, da sie den Wert, der für die öffentliche Gesundheit als unbedenklich gelten würde, bis um etwa das Zehnfache übersteigt.

Exposition gegenüber 3-MCPD oberhalb des sicheren Werts; unzureichende Daten zu 2-MCPD

Die EFSA legte eine zulässige tägliche Aufnahmemenge (TDI) von 0,8 Mikrogramm pro Kilogramm Körpergewicht pro Tag (µg/kg KG/Tag) für 3-MCPD und dessen Fettsäureester fest. Dabei stützte sie sich auf Nachweise aus Tierversuchen, die diesen Stoff mit Organschäden in Verbindung bringen. Es liegen jedoch nicht genügend toxikologische Informationen vor, um einen sicheren Wert für 2-MCPD festzulegen.

Die geschätzte durchschnittliche Exposition und die hohe Exposition gegenüber 3-MCPD (beide Formen) für jüngere Altersgruppen einschließlich Heranwachsender (bis 18 Jahre) überschreiten die zulässige tägliche Aufnahmemenge und stellen ein mögliches Gesundheitsrisiko dar.

Uta Verbeek

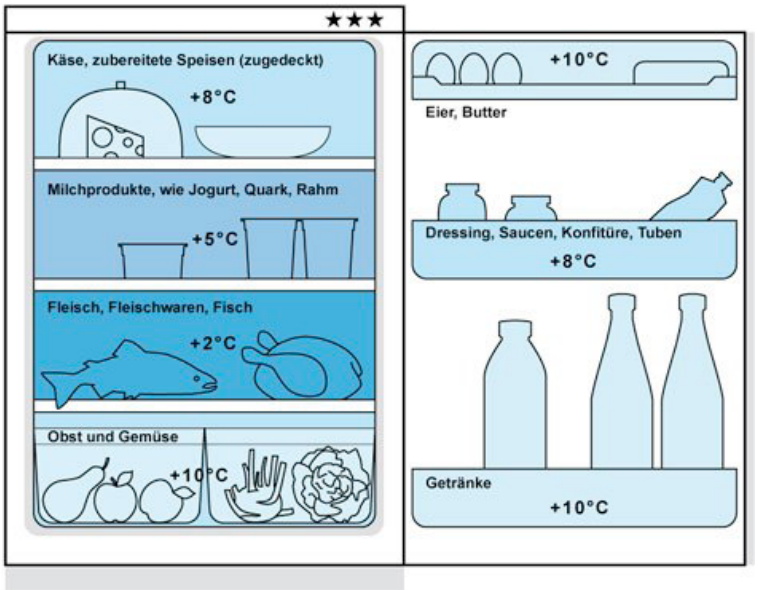
Uta Verbeek, Ph.D., is the managing director of meyer.science GmbH. She is a pharmacist and holds a Ph.D. in pharmacology and toxicology. Mrs. Verbeek gained her knowledge and experiences from working in various sectors of the pharmaceutical industry, amongst others regulatory, medical and clinical affairs. Since 2010 she works as consultant for food, cosmetic and pharmaceutical companies. The focus of her consulting work lies on borderline issues, health claims, dietetic foods, novel foods, food contact materials and risk assessment.

Für die meisten Menschen trägt Palmöl wesentlich zur Exposition gegenüber 3-MCPD und 2-MCPD bei.

Ausblick

Die aktuelle Risikobewertung dient der Information von Risikomanagern in der Europäischen Kommission und den Mitgliedsstaaten, die mit der Regulierung der EU-Lebensmittelsicherheit beauftragt sind. Sie werden sich auf der Grundlage der wissenschaftlichen Beratung seitens der EFSA Gedanken darüber machen, wie sich die potenziellen Risiken für die Verbraucher durch die Exposition gegenüber diesen Stoffen in Lebensmitteln mindern lassen. Das Gremium hat mehrere Empfehlungen für weitere Untersuchungen ausgesprochen, um die Datenlücken zu füllen und den Kenntnisstand über die Toxizität dieser Stoffe, insbesondere über 2-MCPD, und die Exposition der Verbraucher durch Lebensmittel zu verbessern.

Weiterlesen…



VERANSTALTUNGEN

11. 8. 2016

Gießen / Universität - Qualitätsmanagement in der Lebensmittelindustrie II

(Uni Gießen) Meyer

Kennzeichnung und Aufmachung von Lebensmitteln im Spannungsfeld öffentlicher multimedialer Diskurse: Lebensmittelklarheit.de, Doodwatch, Social Media

5. - 7. 9. 2016

Feldafing a. Starnberger See - Summer School 2016

(Behr´s) Meyer

Ihr Intensivkurs im Lebensmittelrecht

- LMIV, Health Claims und aktuelle Rechtsprechung
- Food for Specific Groups – Was folgt nach dem Ende des Diätrechts?
- Insekten, Mineralien & Co. – Die neue Novel Food Verordnung 2015/2283 MOSH/MOAH: erst Adventskalender – zuletzt Nuss-Nougat-Creme
- Pyrrolizidinalkaloide (PA) – Stand der Dinge
- „Vegetarisch" und „vegan" – Auslobung der neuen Trends

mehr ...

12. - 14. 9. 2016

Freising -Weihenstephan - 45. Deutscher Lebensmittelchemikertag (im Wissenschaftlichen Komitee: Meyer)

(LChG) Meyer

20. - 21. 9. 2016

Hamburg - Hamburger Kosmetiktage 2016

(Behr´s) Reinhart A.

DAS Netz für Wissenschaft, Recht, Überwachung und Analytik

- Aktuelles aus Forschung und Kosmetikrecht
- GMP und Hygiene-Standards im Unternehmen umsetzen
- Prüfsiegel und Claims für Kosmetikprodukte unter der Lupe
- Konfliktpotential von Borderlineprodukten
- Werbung mit Trends wie „frei von" Claims und „vegan"
- Export in die Schweiz – kein Problem?
- Kontaktallergien durch kosmetische Mittel
- Tiefe Einblicke in die Überwachung
- Was bewegt die Verbraucher?

mehr ...

28. - 29. 9. 2016

Karlsruher - Kosmetiktag 2016 „Claims und Wahrheit"

(CVUA) Reinhart A.

Der Karlsruher Kosmetiktag „Claims und Wahrheit" diskutiert diese Fragen und erarbeitet Lösungsansätze. In fünf Blöcken werden folgende Themen behandelt:

- Rechtsgrundlagen, Leitlinien, Gerichtsurteile
- Entwicklung neuer Rohstoffe, Anforderung an Kosmetika
- Probleme aus Sicht der Kosmetikindustrie
- Verbrauchertests und Verbraucherschutz
- Praxis und Theorie

mehr ...

Editor
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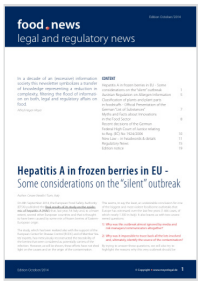

In a decade of information overload, this newsletter clarifies food-related topics in simple terms and filters the flood of legal and regulatory affairs news

Alfred Hagen Meyer

Authors of this issue

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