REACH

COVINGTON & BURLING LLP

October 2008

REACH
AND ITS IMPACT ON FOODSTUFFS AND FEEDINGSTUFFS

In June 2007, the European Union's Regulation (EC) No. 1907/2006 on the Registration, Evaluation, Authorization and Restriction of Chemicals (the so-called "REACH Regulation")[1] entered into force. The REACH Regulation does not only affect chemical manufacturers and importers, but also imposes, for the first time, sweeping requirements on virtually all producers using substances in their goods and manufacturing processes. The entire supply chain will have to examine and disclose the properties of the substances they use, and ensure that the safety in their specific downstream use is adequately supported.

The Regulation contains broad exemptions for food and feedingstuffs, but there are likely to remain some important regulatory obligations. In addition, the Regulation's exemptions may be interpreted as not applying to many processing aids and intermediates used in the manufacture of food and feedingstuffs but that are not food or feed ingredients, or to most substances contained in the packaging of food and feedingstuffs. Furthermore, food and feedingstuff manufacturers may experience a reduction of the portfolio of suppliers who may also supply substances for other uses and thus be subject to stricter REACH obligations.

1. General Impact for Food and Feedingstuffs

Industry is likely to take the position that substances that are intended to be used in food and feedingstuffs are exempted from the REACH Regulation's requirements on registration, evaluation, authorization, and downstream use of substances. This is because the Regulation exempts from these requirements substances "used in food or feedingstuffs," and the European Food Regulation defines food as "any substance or product, whether processed, partially processed or unprocessed, *intended to be, or reasonably expected to be* ingested by humans."[2] Similarly, feed is defined as "any substance or product, including additives, whether processed or partially processed or unprocessed, *intended to be used* for oral feeding to animals."[3] Thus, imported foods and feedingstuffs and their ingredients would be exempted from the REACH

---

[1] A copy of the Regulation is available at:

(http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_136/l_13620070529en00030280.pdf).

[2] Article 2(1) of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety O.J [2002] L31/1 [emphasis added].

[3] *Id.*, Article 3(1)(4) [emphasis added].

requirements on registration, evaluation, authorization and downstream use.

The remaining provisions of the REACH Regulation, however, remain applicable, and are likely to include the following:

- ✓ **Disclosure of Information:** As of **June 2007**, where EU manufacturers are supplied with substances that are intended to be used in the manufacture of food and feedingstuffs but are not in the finished state intended for the final user, they will be required to report any new information they have available on the hazardous properties (from a human and environmental perspective) of the substances they use, and any information affecting the risk management measures indicated in the safety data sheets that suppliers provide to them and that affect their identified uses. EU manufacturers must also supply such information to national authorities or the European Chemicals Agency upon their request.

- ✓ **Restrictions:** The REACH Regulation also establishes a fast track procedure through which the Commission may, as from the **end of 2009** onwards, ban the marketing and use of substances that pose an "unacceptable" health or environmental risk. The procedure will probably only rarely be used for substances that are mainly used by food and feed manufacturers, but it may more easily be applied to substances with multiple uses.

In addition, suppliers of ingredients that are also used in other products may be subject to all the REACH requirements for those other uses and may decide not to further support the ingredients so as to avoid the regulatory obligations.

2. Processing Aids and Other Substances Not Used as Ingredients

The REACH Regulation's exemptions, however, could be interpreted as not applying to processing aids[4] and intermediates used in the EU manufacture of food and feed but that are not intended themselves as food or feed ingredients. Examples of intermediates are methanol and phenylanine when used in the manufacture of aspartame.

Both processing aids and intermediates may be subject to the full scope of REACH. These obligations may include the need to register substances manufactured in, or imported into, the EU in quantities of one ton or more per manufacturer/importer per year; and authorization in the case of substances of very high concern. Substances of very high concern may include Cat. 1

[4] Processing aids are defined as "any substance not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or their ingredients, to fulfill a certain technological purpose during treatment or processing and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not present any health risks and do not have any technological effect on the finished product." See Footnote 1 of Council Directive 89/107 on food additives authorized for use in foodstuffs intended for human consumption O.J. [1989] L40/27, as amended. This definition could be revised during the adoption of the Commission Proposal for a Regulation on Food Additives COM (2006) 428 final (Brussels, 28 July 2006).

and 2 carcinogens, mutagens or toxic to reproduction substances ("CMRs"); persistent, bioaccumulative and toxic substances ("PBTs"); very persistent and very bioaccumulative toxic substances ("vPvBs"); and other substances giving rise to "an equivalent level of concern."

Processing aids and intermediates, however, could be exempted from the registration requirement if they are (i) natural, (ii) not chemically modified, and (iii) not classified as "dangerous." Certain substances listed in Annex IV to the Regulation, which are widely used in the manufacture of food and feedingstuffs, such as pure sucrose, sunflower oil, corn oil, and D-mannitol, are also exempted from the requirement of registration. These substances could, nevertheless, still be subject to other REACH requirements, such as authorization and restrictions.

In addition, food intermediates may benefit from the REACH Regulation's specific exemptions for intermediates. In REACH terms, an intermediate is "a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance." For example, so-called "non-isolated" intermediates, *i.e.*, intermediates that during the synthesis of another substance are not intentionally removed from the equipment where the synthesis takes place, may be entirely excluded from the scope of the REACH Regulation. On-site and transported isolated intermediates "manufactured and used under strictly controlled conditions" may be subject to limited registration requirements, and are exempted from the prior authorization requirement.

3. Substances Used in Packaging

The requirements of the REACH Regulation could be interpreted as applying to substances contained in the packaging of food and feedingstuffs. For example, importers and producers of packaging and packaged food may be required to notify to the European Chemicals Agency those substances that (i) have been identified as being of very high concern, (ii) are present in the packaging in concentrations above 0.1%, (iii) are present in the packaging or other articles imported/produced by the importer/producer in quantities above one ton per year, and (iv) have not had their use in packaging already registered. This requirement, however, would not apply where the importer/producer can exclude exposure to humans or the environment during normal or reasonably conditions of use of the packaging, including its disposal.

Importers and producers could also be required to pass down information to their customers on the presence in their packaging of substances of very high concern in concentrations above 0.1%. Similarly, substances used in the EU manufacturing of packaging could be subject to most of the REACH requirements.

However, the chemical safety report part of the registration dossier need not address the health aspects of substances used in food contact materials. Similarly, the prior authorization requirement does not apply to substances used in food contact materials that are Category 1 and 2 CMRs or substances raising an equivalent level of "health concern." Nevertheless, substances used in food contact materials are subject to the environmental aspects of REACH.

Finally, certain substances contained in active materials[5] and intelligent packaging[6] could be considered as food and exempted from the Regulation's requirements on registration, evaluation, authorization and downstream use of substances.

MAIN RECOMMENDATIONS

Food and feedingstuff companies may want to consider the impact of REACH on their business. In particular, they may consider the following steps:

- ✓ Identify all substances used in production within the EU but not contained in the finished food or feedingstuff, and, for each substance, determine their regulatory status (*e.g.*, EINECS listed, current and likely chemical classification, Annex IV), gather information on its properties, and assess volumes, specific uses, and concentrations.
- ✓ Review with suppliers the ongoing availability of ingredients and substances used during manufacturing processes, especially with regard to substances that are also used in non-food products and manufacturing processes. Even if the substances are not subject to most of the REACH requirements when used in the final product, food and feedingstuff manufacturers may be affected by the restrictions applying to their suppliers.
- ✓ Carefully monitor, and where appropriate participate in, the process of interpretation and implementation of the REACH Regulation in more detailed legislation and guidelines.

* * *

The REACH Regulation is technical in nature and this note can only provide a brief overview. There will also be important developments in the interpretation and implementation of the Regulation.

The information in this memorandum is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

For further information, please contact:

Peter Bogaert	+32.(0)2.549.5243	pbogaert@cov.com
Clausen Ely	202.662.51.52	cely@cov.com
Cándido García Molyneux	+32.(0)2.549.5261	cgarciamolyneux@cov.com

[5] Active food contact materials and articles are those "intended to extend the shelf-life or to maintain or improve the condition of packaged food." See Article 2(2)(a) of Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food O.J. [2004] L338/4.

[6] Intelligent food contact materials and articles are those that "monitor the condition of packaged food or the environment surrounding the food." See Article 2(2)(a) of Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food O.J. [2004] L338/4.

Covington & Burling LLP is one of the world's preeminent law firms known for handling sensitive and important client matters. This alert is intended to bring breaking developments to our clients and other interested colleagues in areas of interest to them. Please send an email to unsubscribe@cov.com if you do not wish to receive future alerts.

© 2008 Covington & Burling LLP. All rights reserved.