REACH

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REACH

AND ITS IMPACT ON ELECTRICAL AND ELECTRONIC EQUIPMENT

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.

REACH will impose requirements and chemical restrictions on producers of electrical and electronic equipment ("EEE") that are exponentially higher than those they now face under the RoHS Directive. More importantly, REACH will dramatically change the way the global electronics industry supply chain operates and will require the industry to be actively involved in the EU scientific and decision making process that REACH will create.

The Regulation will require producers of EEE, or their chemical suppliers, to examine and disclose the characteristics of the substances they use in the manufacture of, and/or are contained in, their EEE and components. Moreover, it will require producers to defend the continued use of particularly dangerous substances, and may also result in an outright ban on them. Potential targets could be tetrabromisphenol A, phthalates, bisphenol A, polyvinyl chloride, hexabromocyclododecane, gallium arsenide, carbon black, and many other substances widely used in the electronics industry.

Over time, producers of EEE, could also face more limited choice as chemical suppliers seek to specialize their portfolios by narrowing the number of substances on offer and thus reducing the cost of compliance with REACH.

The REACH Regulation imposes different requirements on materials depending on whether they are preparations or articles, and on whether they are manufactured in, or imported into, the EU. Preparations are defined as mixtures or solutions of two or more substances, such as ink in bulk. Articles, on the other hand, are objects that during production are given a special shape, surface or design that determines their function to a greater degree than does their chemical composition. Most EEE are articles, but the status of some products, such as ink cartridges, is unclear.

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

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

On that basis, the Regulation is likely to impose, among other burdens, the following requirements on EU manufacturers and importers of EEE:

1. Disclosure of Information

√ As of **June 2007**, EU manufacturers of EEE are likely to be required to report to their suppliers any new information they have available on the hazardous properties 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 identified uses. The same information must also be provided to national authorities or the European Chemicals Agency upon their request.

√ By **June 2009**, the European Chemicals Agency is likely to have identified the first list of "substances of very high concern," which may later be subject to the prior authorization requirement. Substances of very high concern may include Cat. 1 and 2 carcinogens, mutagens and 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." EU manufacturers, importers or distributors of EEE containing more than 0.1% of a substance that the Agency has listed as being of very high concern must provide their professional customers with the name of the substance and information allowing the safe use of the equipment. It is yet legally unclear whether the 0.1% threshold must be measured on the basis of the entire equipment, component, or homogenous material. Producers and distributors of EEE must also supply the same information to consumers upon their request.

√ By **December 2010**, producers of EEE will be required to report to the European Chemicals Agency the chemical classification of those substances in their products that are subject to registration (e.g., contained in their articles in quantities of one ton or more per manufacturer/importer per year and intended to be released during the normal use of the article) unless such classification has already been reported as part of the substances' registration. Importers of preparations to be used in the manufacture of EEE will also have to report those substances contained in their preparations that are classified as "dangerous" or that are subject to registration (unless such classification has already been reported as part of the registration).

2. Registration of Substances

√ REACH requires the registration of substances that are manufactured or imported on their own or in preparations in quantities of one ton or more per chemical manufacturer or importer per year. Both new and old substances, including those that were listed in the EU's EINECS list, will be subject to the registration requirement. So-called "phase-in" substances (mostly EINECS listed substances) will benefit from a phase-in period only if they are pre-registered.

√ Registration will require submitting (i) a technical dossier with extensive data on the toxic and eco-toxic characteristics of the substance, which will entail substantial testing and data gathering; and (ii) a chemical safety report assessing the hazards, exposure, and risks of use during the entire life cycle for substances manufactured or imported in quantities of 10 tons or more per chemical manufacturer or importer per year. Registration will be substance

specific and chemical manufacturer or importer specific: only those chemical manufacturers and importers that have registered within the deadlines will be allowed to market their substances.

√ Substances in articles, such as EEE, are also subject to registration or notification requirements unless the use of the substance in the article has already been included in the registration of any third party. In particular, EU manufacturers and importers of EEE must register substances (i) present in their EEE in quantities exceeding one ton per manufacturer or importer per year; and (ii) intended to be released during normal and reasonably foreseeable conditions of the EEE's use. Examples of articles with substances that may be subject to registration could include ink cartridges, wheels, airbags, breaks, and batteries.

√ EU manufacturers and importers of EEE must also notify substances contained in their EEE if the following four conditions are met: (i) the substances have been listed by the Agency as substances of very high concern, (ii) the substances are present in the EEE in quantities above one ton per manufacturer or importer per year, (iii) the substances are present in the EEE in concentrations of more than 0.1%, and (iv) exposure to humans or the environment cannot be excluded. Again, it is still to be decided how the 0.1% threshold should be measured. In certain cases, the Agency may also require the registration of any substance contained in the EEE.

√ The respective registration or notification obligations lie with different persons, depending on the circumstances. EU manufacturers and importers of EEE will be liable, where relevant, for pre-registration and registration of the substances that are intended to be released from their EEE and/or for the notification of substances of very high concern present in their EEE, unless they ensure that any third party has pre-registered and registered the use in their EEE. Importers of substances or preparations to be used in the manufacture of EEE will be liable for pre-registration and registration unless their suppliers do so.

√ In contrast, EU manufacturers using substances or preparations procured from EU suppliers in the manufacture of their EEE, but that are not intended to be released from them, are considered as "downstream users" in terms of the REACH Regulation and may only rely on their suppliers' pre-registrations and registrations. It is thus strongly in the interest of these EU manufacturers of EEE to ensure that their EU chemical suppliers file such pre-registrations and registrations.

√ By **June 2008**, producers of EEE will have to ensure that "new" substances (mostly not EINECS listed substances) contained in, or used in the EU manufacture of, their EEE are registered.

√ Between **June 2008 and December 2008**, producers must ensure that all "phase-in" substances contained in, or used in the manufacture of, their EEE are pre-registered. Where the substance is not pre-registered within the deadline, producers must ensure that the substance is fully registered by December 1, 2008 before continuing its use.

√ Between **December 2010 and June 2018**, producers must ensure that pre-registered "phase-in" substances contained in, or used in the manufacture of, their EEE are registered. The first deadline (i.e., November 30, 2010) applies to Category 1 and 2 CMRs, R50/53

substances (i.e., classified as very toxic to aquatic organisms that may cause long term adverse effects in the aquatic environment) if manufactured or imported in quantities of 100 tons or more per manufacturer/importer per year, and other substances manufactured or imported in quantities of 1000 tons or more per manufacturer/importer per year.

√ By **June 2011**, EU manufacturers and importers of EEE must notify the Agency of the presence in their EEE of substances listed as being of very high concern unless the use of the substance in the EEE has already been included in the registration of any third party.

3. Downstream User Obligations

√ As explained above, EU manufacturers of EEE are downstream users for those substances that they use in the manufacture of, or are contained in, their products, but are not intended to be released from them. Where their chemical suppliers register those substances, EU manufacturers will be required to check whether their specific use of the substance is covered in the exposure scenarios communicated in the supplier's safety data sheet, which should reflect those of the supplier's chemical safety report. If their specific use of the substance is not covered, EU manufacturers may be required to submit a limited notification to the Agency and prepare a chemical safety report of their particular uses of their substance if the substances or the preparations containing them are classified as "dangerous," or are PBTs, vPvBs, or substances raising "an equivalent level of concern;" and they use the substance in quantities of one ton or more per year and in concentrations above specified thresholds (e.g., 0.1%).

The chemical safety report must assess the health and environmental risks resulting from the use of the substance during the manufacture of, or its presence in, the EEE.

4. Prior Authorization Requirements

√ EU manufacturers (but not importers) of EEE may be required to apply for prior authorization of substances of very high concern (i.e., Category 1 and 2 CMRs, PBTs, vPvBs, and substances raising "an equivalent level of concern") that they use in the manufacture of their equipment.

√ By the end of 2009, the European Commission could adopt its first list of substances of very high concern subject to authorization. Priority substances to be listed include PBTs and vPvBs and substances with wide or in high volume use.

The list will specify the date by which EU manufacturers of EEE must ensure that they or their suppliers have applied for an authorization to use the substance in the manufacture of EEE, and the date (so-called "sunset date") after which non authorization applicants or holders must no longer market or use the substance.

In particular, EU manufacturers must ensure that they or their suppliers apply for the authorization of the specific use of listed substances that they use in concentrations above specified thresholds (e.g., 0.1%) in the manufacture of their EEE (independently of whether the substance ends contained in the equipment). Authorization applicants will be required to show that the risks resulting from the use of their substances are adequately controlled, or that the socio-economic benefits of the use outweigh the risks and there are no suitable

alternative technologies. Applicants will also have to search for substitutes and present a substitution plan where substitutes are available.

All marketed preparations, including those used in the manufacture of EEE, containing substances that have been authorized must be labeled with the number of the authorization that the EU manufacturer of EEE or its chemical supplier has obtained. Where suppliers obtain an authorization covering the use of the substance during the manufacture of EEE, EU manufacturers must notify their use of the substance to the Agency.

5. Restrictions Procedure

√ The REACH Regulation also establishes a fast track procedure through which the Commission may ban the marketing and use of substances that pose an "unacceptable" health or environmental risk. In particular, the Regulation foresees that this procedure should be applied to substances that have been identified as being of very high concern (i.e., Category 1 and 2 CMRs, PBTs, vPvBs and substances raising an "equivalent level of concern") and that are present in articles, such as EEE.

√ From the end of 2009 onwards, the Commission could issue, under REACH, its first bans in order to address the human health and environmental risks arising from the use of substances during the manufacture of, or their presence in, EEE.

6. The RoHS and Batteries Directives

√ The REACH requirements will apply in addition to the chemical restrictions of specific vertical legislation, such as the RoHS and Batteries Directives. For example, even if an application of a substance (e.g., lead) is exempted under the RoHS Directive, an EU manufacturer of EEE may still be required to ensure that the same substance obtains an authorization to be used in the manufacture of its EEE under the REACH authorization procedure.

In addition, it is likely that the disclosure of information on substances under the REACH Regulation will trigger further restrictions under this other vertical legislation. Furthermore, the Commission may be tempted to use the REACH restrictions fast track procedure to impose chemical bans specific to the EEE sector.

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The REACH Regulation is technical in nature and several important provisions are open to different interpretations. It will be important to monitor how the rules are being implemented in more detailed provisions and guidelines.

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.

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Further information on the REACH requirements, its impact on specific product categories, and on Covington's REACH practice is also available at: (http://www.cov.com/practice/environmental_carbon_markets_and_clean_technology/reach/). 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.