

REACH AND ITS IMPACT ON PRINTERS

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. REACH will impose requirements and chemical restrictions on producers of electronic printers ("printers") that are exponentially higher than those they now face under the RoHS Directive.

The Regulation will require producers of printers, 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 printers, ink cartridges, and toners. 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 printers 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, such as printers and their components.

The latest interpretation of the European Commission and Member States suggests that ink cartridges and toners are likely to be classified as preparations in containers rather than articles intended to release substances. Thus, this memorandum distinguishes between the ink preparations contained in ink cartridges and toners and the containers of those ink cartridges and toners. It assumes that while the containers of the ink cartridges and toners are articles, inks in contained in those products are preparations, and therefore, are likely to be subject to the stricter requirements that apply to substances in preparations.

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 printers, toners, and ink cartridges:

1. Disclosure of Information

- ✓ **As of June 2007**, EU manufacturers of printers, ink cartridges, and toners are 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 **October 2008**, 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.” Where a substance of very high concern is present in printers or the containers of toners and ink cartridges in concentrations above 0.1%, their EU manufacturers, importers or distributors must provide their professional customers with the name of the substance and information allowing the safe use of the article. They must also supply the same information to consumers upon their request.
- ✓ By **December 2010**, EU manufacturers and importers of ink cartridges and toners will be required to report to the European Chemicals Agency the chemical classification of those substances in their products that are classified as dangerous under the Dangerous Substances Directive and that are subject registration (e.g., manufactured or imported in quantities above one ton and not subject to a registration exemption) unless such classification has already been reported as part of the substances’ registration. Importers and manufacturers of ink in bulk and other preparations will be subject to similar requirements.

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 between June 1 and December 1, 2008.

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 ink preparations contained in toners and ink cartridges are subject to registration if they are manufactured or imported in quantities of one ton or more per year and they do not benefit from a registration exemption.

Substances present in articles, such as printers and the containers of the ink cartridges and toners, may also be subject to registration or notification requirements unless the use of the substance in the article has already been included in the registration of any other third party. In particular, EU manufacturers and importers of articles must register substances (i) present in their articles 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 article's use.

EU manufacturers and importers must also notify substances contained in their articles 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 articles in quantities above one ton per manufacturer or importer per year; (iii) the substances are present in the articles in concentrations of more than 0.1%; and (iv) exposure to humans or the environment cannot be excluded. In certain cases, the Agency may also require the registration of any substance contained in the articles.

The respective registration or notification obligations lie with different persons, depending on the circumstances. EU importers of ink in bulk and other substances will be liable for the registration of the substances in the ink preparations. Where an importer imports ink cartridges and toners, he will also be liable for the registration of the substances of the ink preparation contained in the toners and ink cartridges.

EU manufacturers and importers of printers, ink cartridges and toners will also be liable for the notification of those substances listed as being of very high concern that are present in the printers and the containers of the ink cartridges and toners in concentrations above 0.1%.

In contrast, EU manufacturers using substances or preparations procured from EU suppliers in the manufacture of their printers, ink cartridges and toners are considered as "downstream users" in terms of the REACH Regulation and may rely on their suppliers' pre-registrations and registrations. It is strongly in the interest of these EU manufacturers to ensure that their EU suppliers file such pre-registrations and registrations.

The registration and notification of substances are subject to different deadlines:

- ✓ By **June 2008**, producers of printers, ink cartridges, and toners must ensure that “non phase-in” substances (mostly substances that are not listed in the EINECS) contained in, or used in the EU manufacture of, their products are registered.
- ✓ Between **June 1 and December 1, 2008**, producers must ensure that all “phase-in” substances contained in, or used in the manufacture of, their printers, toners, and ink cartridges are pre-registered. Where the substance is not pre-registered within the deadline, producers will be liable for their registration as of June 1, 2008.
- ✓ Between **December 2010 and June 2018**, producers must ensure that pre-registered “phase-in” substances contained in, or used in the manufacture of, their printers, toners, and ink cartridges are registered. The first deadline (*i.e.*, December 1, 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 printers and the containers of ink cartridges and toners must notify the Agency of the presence in their articles in concentrations above 0.1% of substances listed as being of very high concern unless the use of the substance in the article has already been included in the registration of any third party.

3. Downstream User Obligations

- ✓ As explained above, EU manufacturers of printers, ink cartridges, and toners are downstream users for those substances that they use in the manufacture of their products if they procure those substances from European suppliers. 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 if the substances or the preparations containing them are classified as “dangerous,” 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 printers, toners, and ink cartridges.

4. Prior Authorization Requirements

- ✓ EU manufacturers and importers of ink preparations contained in ink cartridges and toners may be required to apply for the prior authorization of the substances of very high concern (*i.e.*, Category 1 and 2 CMRs, PBTs, vPvBs, and substances raising “an equivalent level of concern”) that are subject to authorization and that they use in the manufacture of their products. The same requirement may apply to EU manufacturers (but not importers) of printers and the containers of ink cartridges and toners.
- ✓ By the **June 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 producers may apply for an authorization to market or use the substance subject to authorization and the date (so-called “sunset date”) after which non authorization applicants or holders may no longer market or use the substance.

In particular, importers of ink cartridges and toners must obtain an authorization of the specific use of the listed substances that are contained in concentrations above specified thresholds (*e.g.*, 0.1%) in the ink of their products. EU manufacturers of printers and containers of ink cartridges and toners 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 products. Similarly, EU manufacturers of the ink preparations contained in the ink cartridges and toners must ensure that they or their suppliers apply for the authorization of listed substances.

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, such as ink in bulk and the ink contained in the ink cartridges and toners, containing substances that have been authorized must be labeled with the number of the authorization that the EU manufacturer or its chemical supplier has obtained. Where suppliers obtain an authorization covering the use of the substance during the manufacture of printers, ink cartridges or toners, the producers of these products 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 printers or the containers of toners and ink cartridges.
- ✓ 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, printers, toners, and ink cartridges.

* * *

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.

For further information, please contact:

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

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.