

# Client Alert

Latham & Watkins  
Environment, Land & Resources Department

## REACH Candidate List of Priority Substances of Very High Concern (SVHC) Now Available for Comment

### *Are You Ready for SVHC-related Regulatory Milestones and Potential Value Chain Impacts?*

#### REACH at a Glance

Registration, Evaluation and Authorisation of Chemicals (REACH) is the new European Union (EU) regulation requiring:

- 1) **Registration** of nearly all commercial chemicals, both existing and new, and of certain chemical-releasing "articles;"<sup>1</sup>
- 2) **Evaluation** of chemicals by the new European Chemicals Agency (ECHA) created by REACH for the purpose of, among others, identifying "Substances of Very High Concern" or "SVHCs;" and
- 3) **Authorisation** for SVHCs to remain in commerce.

Categorized by EU officials as possibly the most complicated and complex legislation enacted to date, REACH shifts risk assessment responsibility from Member States to chemical manufacturers and importers. REACH also extends beyond these entities to chemical users throughout the supply chain. Although REACH allows users to rely on upstream suppliers to fulfill many regulatory requirements, a user may do so only by supplying information "in writing" to its supplier

and by confirming that its supplier has addressed its use(s) in the various REACH-required submissions.<sup>2</sup> Moreover, REACH imposes special obligations on producers of certain "articles."<sup>3</sup>

On June 1, 2008, REACH's first substantive provisions entered into force with a deadline by the end of 2008 to Pre-register all chemicals anticipated to be subject to one of the Registration deadlines. These deadlines, which vary depending upon substance hazard and production/import volume, begin in 2010 and extend out to 2018. Even prior to the first Registration deadline, however, REACH establishes a June 1, 2009 deadline for ECHA to publish a priority list of SVHCs. As explained in this *Alert*, this SVHC list will trigger various REACH requirements and otherwise will have a number of potentially significant value-chain implications.

#### REACH Requirements for a SVHC

REACH's Authorisation regime aims to review the highest risk substances and to require substitution, where feasible, with "safer" alternatives. The

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Authorisation process applies to any substance designated by ECHA as an SVHC. To make such a designation, ECHA must find that the substance qualifies as one of the following:

- 1) **CMRs**—substances which meet the criteria for classification as (i) carcinogenic category 1 or 2; (ii) mutagenic category 1 or 2; and (iii) toxic for reproduction category 1 or 2 according to Directive 67/548/EEC.
- 2) **PBTs**—substances which are persistent, bioaccumulative and toxic in accordance with certain criteria.<sup>4</sup>
- 3) **vPvBs**—substances which are very persistent and very bioaccumulative in accordance with certain criteria.<sup>5</sup>
- 4) **Other similar substances**—ECHA also may designate other chemicals, such as “endocrine disruptors,” as a SVHC that Member States or the Commission identify on a case-by-case basis as having serious and irreversible effects to humans and the environment equivalent to the foregoing three categories.

Ultimately, SVHCs will require Authorisation to remain in commerce. The timing and details of the Authorisation process have yet to take shape, but in general, SVHC manufacturers and importers must prepare a substitution plan that identifies “safer alternatives.” Where no such alternatives exist, the applicant must pursue them through a research and development plan. The European Commission—the decision-maker on Authorisation—will grant it only if the producer or importer can demonstrate—for each use—that the SVHC’s risks can be adequately controlled or that the socio-economic benefits outweigh the risks. This demonstration must include a comparative analysis of alternatives. Ultimately, Authorisation may result in an outright ban on the substance or a ban just of certain uses and may include use controls to address “unacceptable risks” to health or the environment.

Producers and importers of “articles” containing an SVHC also are subject to a special “Notification” obligation—which is distinct from the Registration obligation that may apply to certain “articles.” This Notification obligation will apply if the SVHC is present in quantities totaling more than 1 tpy per producer or importer and above a 0.1 percent concentration (weight by weight) unless one can “exclude exposure to humans or environment during normal or reasonably foreseeable conditions of use, including disposal,” of the article.

REACH requires ECHA to publish a priority SVHC list no later than June 1, 2009. “Notifications” for SVHC-containing “articles” that meet the aforementioned volume and exposure triggers must occur within 30 months after ECHA’s designation of an SVHC, which means that the first Notifications will come due no later than January 1, 2012.

Of course, ECHA’s designation of a chemical as an SVHC may have other implications beyond Authorisation and Notification, as well, including, but not limited to:

- ECHA may exercise its authority pursuant to REACH Article 7(5) to require Registration for all (or certain) SVHC-containing “articles” based on a finding that ECHA suspects the SVHC is released from the article and that such release poses a risk to human health or the environment.
- ECHA could take action that would trigger for the SVHC, if not already applicable, the earlier December 31, 2010 Registration deadline for CMRs and “substances very toxic to aquatic organisms.”<sup>6</sup> Failure to meet this deadline would mean that the SVHC may not continue in commerce pending the Authorisation process. Moreover, regardless of whether ECHA takes action to trigger the earlier deadline, its SVHC finding will likely lead to increased testing

and downstream exposure scenario requirements within the context of any Registration.<sup>7</sup>

- ECHA's SVHC designation also may have implications beyond the EU. In particular, the designation could trigger state and federal regulatory requirements in other countries; could be admissible in US "toxic tort" litigation; and/or could impact supply chain relationships and otherwise result in deselection.

### The Initial SVHC Priority Candidate List

On June 30, 2008, ECHA launched the first public consultation on 16 SVHC proposals put forward by EU Member States and Norway. It is the intention of the proposing states that the 16 identified substances form the initial SVHC priority "candidate list" under REACH.

The consultation on the 16 possible SVHCs runs until August 14, 2008, after which time ECHA's Member State Committee will review the dossiers on the basis of the responses. If the Member State Committee concludes that the substances meet the SVHC criteria, ECHA will place them on the priority candidate list with the implications discussed previously in this *Alert*. Notably, ECHA plans to publish its initial priority SVHCs by the end of October 2008.

The following table sets out the 16 substances which have been put forward as potential SVHCs and summarizes the stated reasons for their inclusion. The table also details some of the applications and uses of the 16 proposed SVHCs.

Substance Name	Proposing Authority	Initial Classification	Justification for Inclusion	Manufacture and Uses
Anthracene	Germany	PBT	PBT and vPvB.  Following studies on fish, Germany considers that photoenhanced effects of anthracene exposure include reduced survival and fecundity.  No risk has been identified to human health.	Anthracene can be used in the manufacture of pyrotechnic products deployed in film and theatre productions as a component of black smoke. Downstream users may use anthracene for other purposes; for example, as an intermediate for the production of anthraquinone, which can be used either as a basic material for the production of dyes or as a catalyst in the production of wood pulp.
4,4'-Diaminodiphenylmethane (MDA)	Germany	CMR	Category 2 carcinogen.  Following drinking-water studies on animals, Germany considers that MDA causes carcinogenicity after inhalation and dermal contact.  No risk has been identified to human health.	MDA is produced continuously as a liquid isomer mixture (technical grade). The product life cycle covers uses in the chemical industry, such as a hardener for epoxy resins and adhesives, as well as in some construction coatings, and as an intermediate for other products.

Substance Name	Proposing Authority	Initial Classification	Justification for Inclusion	Manufacture and Uses
Dibutyl phthalate (DBP)	Austria	CMR	<p>Category 2 reproductive toxins.</p> <p>Based on rat studies detailed in a 2004 EU Risk Assessment Report, Austria considers that DBP has fertility and developmental toxicity effects.</p>	<p>The largest general use of DBP is as a plasticizer in resins and polymers such as polyvinyl chloride. DBP is also used in printing inks, adhesives, sealants/grouting agents, nitrocellulose paints, film coatings and glass fibres.</p>
Cyclododecane	France	PBT	<p>PBT and vPvB.</p> <p>Following studies on fish, France considers that cyclododecane has toxic properties.</p> <p>No risk has been identified to human health.</p>	<p>Cyclododecane is used as an intermediate in a number of contexts, including: (i) as a flame retardant, (ii) in the production of chemicals which are used to make polyamides, polyesters, synthetic lubricating oils, nylon and high-purity solvents, (iii) in perfume composition as perfume exalting, and (iv) in cleaning and washing agents.</p> <p>Cyclododecane is also used as a raw substance as a binding media for the temporary sealing, consolidation and conservation of weak or friable materials in the field of excavation and transport of archeological objects. In this context, it has further applications as a facing adhesive, release agent and consolidant for old paints, papers and textiles.</p>
Cobalt dichloride	France	CMR	<p>Category 2 carcinogen.</p> <p>Based on Annex I to Directive 67/548/EEC, France considers that cobalt dichloride may cause cancer by inhalation and is suspected to be an endocrine disruptor.</p>	<p>The main uses of cobalt dichloride are as an "oxyvore" to remove oxygen gas during metal production and as an additive in rubber tyre manufacture.</p> <p>The widespread other uses of the substance include: (i) as an absorbent for ammonia gas in the chemical industry, (ii) the production gas masks, (iii) as a humidity indicator in several applications (hygrometers, barometers, self indicating silica gels, etc.), (iv) for manufacturing vitamin B12,</p>

Substance Name	Proposing Authority	Initial Classification	Justification for Inclusion	Manufacture and Uses
				<p>(v) in the production of human and animal nutrients, (vi) in the production of nitrate fertilizers, (vii) for flux for magnesium refining, notably when recycling scrap material, (viii) as a dye mordant for the glass industry, (ix) as a solid lubricant, (x) as a catalyst in organic reactions, (xi) in the formulation of invisible inks, (xii) as a metal drier in air-drying coatings, (xiii) as a drying agent in paints, lacquers, varnishes and printing inks, (xiv) in the production of non-ferrous metals, (xv) in electroplating processes, and (xvi) in other inorganic chemical products.</p>
Diarsenic pentaoxide	France	CMR	<p>Category 1 carcinogen.</p> <p>Based on Annex I to Directive 67/548/EEC, France considers that diarsenic pentaoxide may cause cancer and is toxic by inhalation and if swallowed.</p>	<p>Diarsenic pentaoxide is used: (i) in the dyeing industry, (ii) in metallurgy (to harden copper, lead or gold in alloys), and (iii) for manufacturing certain types of glass.</p>
Diarsenic trioxide	France	CMR	<p>Category 1 carcinogen.</p> <p>Based on Annex I to Directive 67/548/EEC, France considers that diarsenic trioxide: (i) may cause cancer, (ii) is very toxic if swallowed, (iii) causes burns, and (iv) is very toxic to aquatic organisms and may cause long-term, adverse effects in the aquatic environment.</p>	<p>Diarsenic trioxide is used: (i) as a decolorizing agent for glass and enamels, (ii) as a refining and oxidizing agent for manufacturing special glass and lead crystal formulations, (ii) as a hydrogen recombination poison for metallurgical studies, (iii) as a starting point for the preparation of elemental arsenic, arsenic alloys and arsenide semiconductors, (iv) as a cytostatic in the treatment of the refractory promyelocytic (M3) subtype of acute myeloid leukemia.</p> <p>It is also used as a wood preservative (when imported from outside of the EU).</p>

Substance Name	Proposing Authority	Initial Classification	Justification for Inclusion	Manufacture and Uses
Sodium dichromate, dihydrate	France	CMR	<p>Category 2 carcinogen.</p> <p>Based on Annex I to Directive 67/548/EEC, France considers that sodium dichromate dihydrate: (i) may cause cancer, (ii) may cause heritable genetic damage, (iii) may impair fertility, (iv) may cause harm to the unborn child, (v) is harmful in contact with skin, (vi) is toxic if swallowed, (vii) is very toxic by inhalation, (viii) causes burns, (ix) may cause sensitization by inhalation and skin contact, (x) is toxic (with a danger of serious damage to health by prolonged exposure through inhalation), and (xi) is very toxic to aquatic organisms and may cause long-term, adverse effects in the aquatic environment.</p>	Sodium dichromate, dihydrate is used in a number of applications including: (i) the manufacture of other chromium compounds as chromium sulfate, (ii) the manufacture of inorganic chromate pigments, (iii) as metal finishing, aiding corrosion resistance, (iv) in the manufacture of vitamin K, (v) in the preparation of colored glass and ceramic glazes, (vi) as a mordant in dyeing, and (vii) in manufacture of essential oil and perfumes.
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	Netherlands	vPvB	<p>vPvB.</p> <p>Based on mice studies contained in a 2005 EU Risk Assessment Report, the Netherlands considers that musk xylene has carcinogenic properties.</p>	The imported crystalline solid (obtained from China) is used as an ingredient in fragrance compositions. Musk xylene is used in cosmetic products and in detergents, fabric softeners, household cleaning products, as well as in other fragranced products.
Bis (2-ethyl(hexyl)phthalate) (DEHP)	Sweden	CMR	<p>Category 2 reproductive toxin.</p> <p>Based on a 2008 EU Risk Assessment Report and other studies on animals, Sweden considers that DEHP has detrimental fertility and foetal developmental effects.</p>	DEHP is widely used as a plasticizer in polymer products, mainly in PVC. Flexible PVC is used in many different articles (for example, in toys), in building material such as flooring, cables, profiles and roofs, as well as in medical products (including blood bags and dialysis equipment).
Hexabromocyclododecane (HBCDD)	Sweden	PBT	<p>B, vB and T.</p> <p>Based on a 2008 EU Risk Assessment Report and other studies on animals, Sweden considers that HBCDD has detrimental fertility and developmental effects.</p>	Widely used on its own or in conjunction with other flame retardants, mainly in polystyrene products but also in some textiles.

Substance Name	Proposing Authority	Initial Classification	Justification for Inclusion	Manufacture and Uses
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins, SCCPs)	United Kingdom	PBT	PBT and vPvB.  Following studies on fish and aquatic invertebrates, the UK considers that SCCPs have toxic effects on the environment, especially in relation to growth.  No risk has been identified to human health.	SCCPs were widely used a decade ago as metal working lubricants and as a leather liquor. These two applications were restricted under EU legislation in 2002. Use in the EU has declined sharply and the main remaining applications are thought to be as flame retardants in textiles and rubber, and in paints, sealants and adhesives.
Bis(tributyltin)oxide (TBTO)	Norway	PBT	PBT.  Following studies on aquatic species, Norway considers that TBTO has endocrine effects on the environment.  No risk has been identified to human health.	The main industrial use registered for TBTO in the last few years is the manufacture of transportation equipment, namely in the building and repairing of ships and pleasure and sporting boats. High amounts of TBTO have also been used in the past for manufacture of chemicals and chemical products.
Lead hydrogen arsenate	Norway	CMR	Category 1 carcinogen and category 1 reproductive toxin.  Norway refers to existing EU regulations of arsenic and its compounds as justification for the inclusion of lead hydrogen arsenate.  (See also triethyl arsenate.)	Once widely used in pesticides and wood preservatives, these applications have now been largely restricted by EU legislation. However, there is concern that arsenic compounds are still being imported, particularly in circuit boards of electrical and electronic equipment.  (See also triethyl arsenate.)
Triethyl arsenate	Norway	CMR	See the comments in relation to lead hydrogen arsenate, above.	See the comments in relation to lead hydrogen arsenate, above.
Benzyl butyl phthalate (BBP)	Austria	CMR	Category 2 reproductive toxins.  Based on fish studies detailed in a 2007 EU Risk Assessment Report, Austria considers that BBP has reproductive toxicity and endocrine effects.  No risk has been identified to human health.	The main current use of BBP is as a softener ( <i>i.e.</i> , a plasticizer) in PVC products, with flooring as the largest single-use category. BBP is also used with other polymers in, for example, sealants, adhesives, paints, inks and lacquers.

A coalition of non-governmental organizations (NGOs) (Greenpeace, WWF, the Health and Environmental Alliance (HEAL), CHEMTrust and others) have argued that the 16 possible SVHCs proposed by the EU Member States and Norway are too few in number. They argue that ECHA instead should automatically include on the SVHC priority list any substance which is already classified by existing EU legislation as CMR or PBT. Specifically, the NGOs plan to launch their own REACH "Substitute it Now (SIN)" list in September, which could comprise up to 300 substances.

The NGOs apparently plan to pressure ECHA with the SIN list to expand its initial priority SVHC list. Whether or not this NGO tactic achieves success, any company with any interest in the 16 substances put forward as possible SVHCs (be they producers or importers of those substances or suppliers of articles containing those substances) should follow the current consultation closely and seriously consider submitting comments to ECHA that create a clear record regarding the substance. Failure to act now could lead to a situation where a substance gets a priority SVHC designation and not only ultimately becomes subject to the arduous Authorisation procedures under REACH, but even prior to that time, possibly triggers enhanced REACH Registration and/or special "articles" Notification requirements. Such a SVHC designation may lead to ancillary regulatory, litigation and business impacts beyond the EU, as well.

#### Endnotes

<sup>1</sup> REACH defines "article" as "an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition." (Article 3.3).

<sup>2</sup> REACH defines "use" as "any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilization." (Article 3.24) "Downstream User: means any natural

or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer . . . shall be regarded as a downstream user." Article 3.13.

<sup>3</sup> "Articles" where a "substance is intended to be released under normal or reasonably foreseeable conditions of use" trigger Registration requirements. In addition, as discussed in Part II, ECHA may designate an "article" as subject to Registration based on a finding of suspected risk.

<sup>4</sup> To be classified as a PBT substance, a substance has to fulfill all three of the following criteria: (1) *Persistence* (i) the half-life in marine water is higher than 60 days, or, (ii) the half-life in fresh- or estuarine water is higher than 40 days, or, (iii) the half-life in marine sediment is higher than 180 days, or, (iv) the half-life in fresh- or estuarine water sediment is higher than 120 days, or, (v) the half-life in soil is higher than 120 days; (2) *Bioaccumulation* (i) the bioconcentration factor (BCF) is higher than 2000; and (3) *Toxicity* (i) the long-term no-observed effect concentration (NOEC) for marine or freshwater organisms is less than 0.01 mg/l, or, (ii) the substance is classified as carcinogenic (category 1 or 2), mutagenic (category 1 or 2), or toxic for reproduction (category 1, 2, or 3), or, (iii) there is other evidence of chronic toxicity, as identified by the classifications: T, R48, or Xn, R48 according to Directive 67/548/EEC.

<sup>5</sup> To be classified as a vPvB substance, a substance has to fulfill all two of the following criteria: (1) *Very Persistence* (i) the half-life in marine, fresh- or estuarine water is higher than 60 days, or, (ii) the half-life in marine, fresh- or estuarine water sediment is higher than 180 days, or, (iii) the half-life in soil is higher than 180; and (2) *Very Bioaccumulative* (i) the bioconcentration factor is greater than 5000. By December 1, 2008, the Commission must review criteria for identifying vPvB substances.

<sup>6</sup> The first Registration deadline—December 1, 2010—applies to, among other substances: (1) Carcinogens, Mutagens or Reproductive Toxicants (CMRs) manufactured or imported in excess of 1 tpy. Such compounds are those with a category 1 or 2 classification according to Directive 67/548/EEC.

(2) Substances qualifying as “very toxic to aquatic organisms which may cause long-term adverse effects in the aquatic environment” manufactured or imported in excess of 100 tpy. Such compounds are those with either an R50 or R53 classification according to Directive 67/548/EEC.

<sup>7</sup> For substances manufactured or imported at 10 tpy or more, the Registration also must include a *Chemical Safety Report* (CSR). The CSR must document the hazards and contain an assessment of whether the substance qualifies as a PBT or vPvB. If it does so qualify, then the CSR also must describe Exposure Scenarios for specific uses of the substance. The *Exposure Scenarios* requirement also extends to a substance, even if not PBT or vPvB, “(i) with dispersive or diffuse use(s) particularly where such substances are used in consumer preparations or incorporated into consumer articles and (ii) for which it is predicted (*i.e.*, by application of (Q)SARs or other evidence) that they are likely to meet the [other] classification criteria for any human health or environmental effects endpoints under Directive 67/548/EEC.”

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