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REACH Implementation

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Overview of presentation

I. Outline of the REACH Regulation
II. Registration procedure
III. Evaluation procedure
IV. Authorization procedure
V. Restriction procedure
VI. ECHA Board of Appeal developments
VII. REACH Enforcement Forum
VIII. Relation between the REACH Regulation and the Cosmetics Regulation

I. Outline of the REACH Regulation

- Principal EU chemical legislation = Regulation (EC) N°1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals ('REACH Regulation')
- Entered into force on June 1, 2007
- Directly applicable in EU/EEA Member States' legal orders without the need for formal transposition measures by a certain deadline → on the whole it may be directly invoked by a Member State against a company and by a company against another even in the presence of inconsistent national law
- Some national implementation measures are nevertheless needed in order to give effect to certain exemptions, to set up certain enforcement mechanisms and to provide for penalties in case of breach(es) of the REACH Regulation by a private operator

I. Outline of the REACH Regulation

- The REACH Regulation does not apply to: (i) radioactive substances; (ii) substances subject to customs supervision when not undergoing any treatment/processing and in temporary storage/transit; (iii) non-isolated intermediates; (iv) the carriage of dangerous substances/mixtures by rail/road/inland waterway/sea/air; and (v) waste (not deemed to be a substance)
- EU/EEA Member States may allow for exemptions from the REACH Regulation where certain substances are "*necessary in the interests of defense*"
- Chemical substances are on the whole subject to the registration, evaluation, authorization and/or restriction procedures

II. Registration Procedure

1. General principles
2. Statistics

1. General principles

- Substances on their own, in mixtures, or in articles may not be manufactured in the EU/EEA or placed on the EU/EEA market, unless they have been registered with the European Chemicals Agency ('ECHA')
- Registration requirement placed on manufacturers and importers who manufacture or import substances (on their own or in mixtures) in the EU/EEA in quantities of 1 ton or more per year
- A manufacturer or importer of a polymer must register the monomer substance(s) or any other substance contained therein (unless already registered by an actor up the supply chain) where: **1/** the polymer consists of at least 2% w/w of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s) and ***2/*** the total quantity of such monomer substance(s) or other substance(s) equals one ton or more per year (= two cumulative conditions)

1. General principles

- Registration requirement placed on producers or importers of articles for any substance contained in those articles where: **1/** the substance is present in those articles in quantities exceeding one ton per producer/importer per year and **2/** the substance is intended to be released under normal or reasonably foreseeable conditions of use (= two cumulative conditions)
- The registration obligation placed upon the EU/EEA importer of substances/mixtures/articles produced outside the EU/EEA may be assumed by an EU/EEA-based Only Representative (physical or legal person) appointed by a manufacturer established outside the EU/EEA
- Standard information requirements vary depending on whether substances are manufactured or imported in the EU/EEA in quantities of: (i) 1 ton or more/year; (ii) 10 tons or more/year; (iii) 100 tons or more/year; or (iv) 1,000 tons or more/year

2. Statistics

As of October 31, 2014, **40,229** registration dossiers (individual and joint) covering **7,992** unique substances have been filed with ECHA

Size of the business	Number of dossiers filed with ECHA	Number of substances covered (whether unique or common)
Large company	34,388	7,473
Medium company	3,269	1,437
Small company	1,751	689
Micro company	821	360

2. Statistics

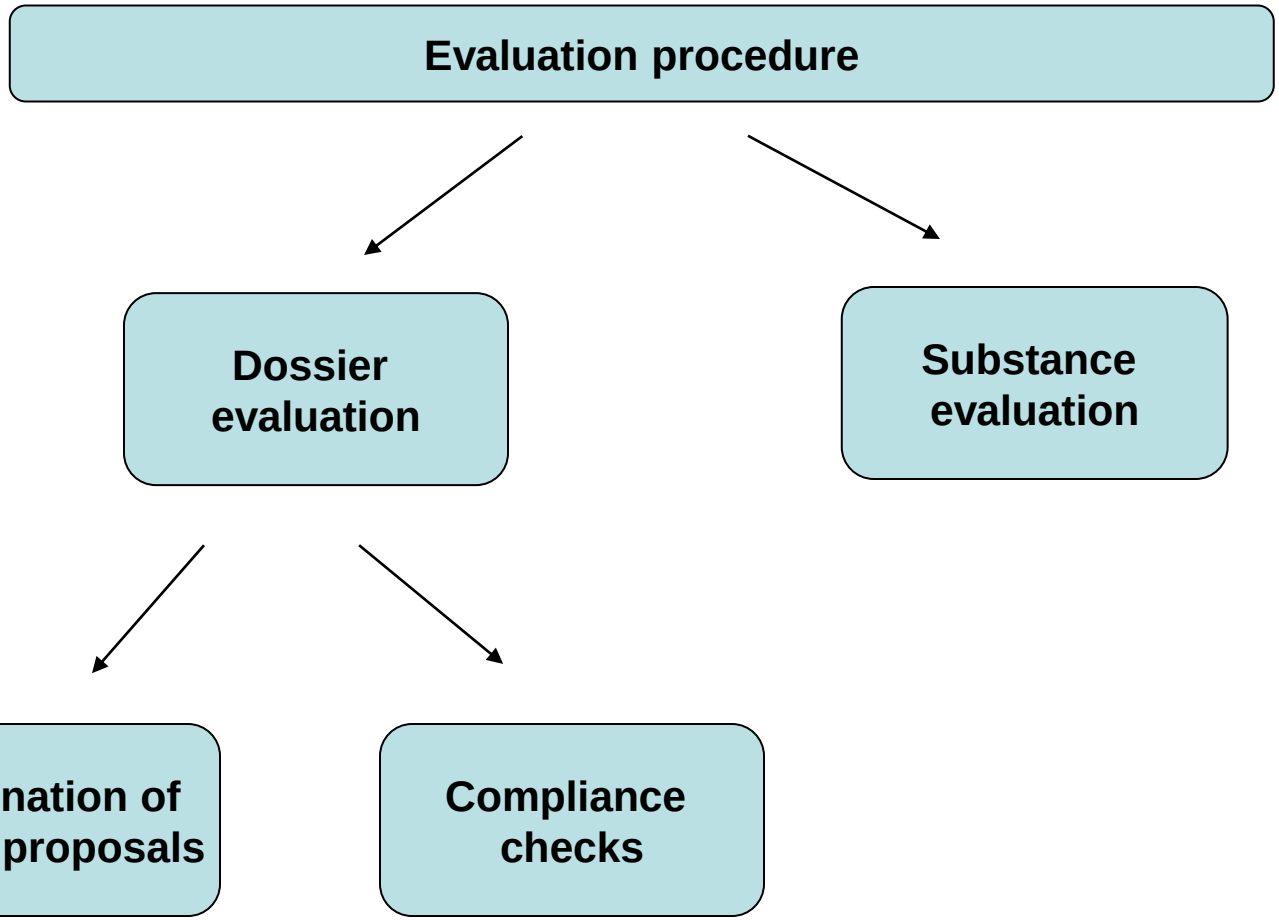
The most registered substances include the following:

- **Calcium dihydroxide:** 430 registrations
- **Ethanol:** 429 registrations
- **Iron:** 369 registrations
- **Ethylene oxide:** 366 registrations
- **Calcium sulphate:** 293 registrations
- **Fuels, diesel:** 250 registrations
- **Methyloxirane:** 250 registrations
- **Aluminium oxide:** 243 registrations
- **Calcium oxide:** 243 registrations
- **Aluminium:** 229 registrations
- **Ashes (residues), coal:** 228 registrations

III. Evaluation Procedure

1. General process
2. Community Rolling Action Plan

1. General process



1. General process

- The evaluation procedure is divided into the **dossier evaluation procedure** and the **substance dossier evaluation**
- Through the dossier evaluation procedure, ECHA and the EU/EEA Member States are tasked with reviewing **1/** testing proposals and **2/** the quality of the registration dossiers (i.e., compliance check)
- Through the substance evaluation procedure, ECHA and the EU/EEA Member States' competent authorities must determine if a particular registered substance "*constitutes a risk to human health or the environment*"
- The dossier and the substance evaluation procedures may result in the adoption by ECHA of decisions requiring the registrants to produce further information or finding registrants' testing proposals inadmissible and/or of follow up decisions to its previous requests for further information

1. General process

- EU/EEA Member States' competent authorities are involved in the decision-making process (by commenting on and proposing amendments to ECHA's draft decisions and by proposing substances for substance evaluation) and at the enforcement stage (i.e., by imposing sanctions in case of non-compliance with an ECHA decision)
- ECHA Member State Committee (i.e., body composed of Member States' representatives) must unanimously endorse ECHA's draft decision, failing which the evaluation decision is to be adopted by the European Commission ('Commission') instead of ECHA

2. Community Rolling Action Plan

On October 16, 2014, ECHA issued a proposal for updating the Community Rolling Action Plan ('CoRAP') with a view to submitting **134 substances** to the evaluation procedure for the **2015-2017** period → ECHA is expected to adopt the final CoRAP update by the end of March 2015, after considering the opinion of the ECHA Member State Committee

IV. Authorization Procedure

1. Overall objectives
2. General process
3. Legal implications of a SVHC appearing on the Candidate List of SVHC
4. Draft ECHA Recommendation on Priority Substances for Inclusion in Annex XIV
5. Legal implications of a SVHC appearing on Annex XIV to the REACH Regulation

1. Overall objectives

- Control the risks raised by Substances of Very High Concern ('SVHC'), which are deemed to have potentially serious effects on human health and/or the environment
- Ensure that SVHC's "*are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable*"
- SVHCs refer to the following substances: (i) Cat. 1 or 2 carcinogenic substances; (ii) Cat. 1 or 2 mutagenic substances; (iii) Cat. 1 or 2 substances toxic for reproduction; (iv) very persistent and very bioaccumulative ('vPvB') substances; and (v) other substances (e.g. substances having endocrine disrupting properties) "*for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern*"

2. General process

Identification of a substance as a SVHC

Proposal by ECHA (at the Commission's request) or by an EU/EEA Member State to place a SVHC on the Candidate List of SVHC

Such a proposal is published on the Registry of Intentions that is publicly accessible

Public consultation period

Consultation of the Member State Committee

2. General process

Decision by ECHA to place a substance on the Candidate List following a unanimous vote by the Member State Committee in favor of the inclusion of the SVHC in the Candidate List

Absent a unanimous vote by the Member State Committee, the Commission decides on whether to add the substance to the Candidate List

ECHA recommendation to list priority substances appearing on the Candidate List for inclusion in Annex XIV to the REACH Regulation

Commission's decision to transfer a substance from the Candidate List to Annex XIV of the REACH Regulation

3. Legal implications of a SVHC appearing on the Candidate List of SVHC

- The supplier of a SVHC appearing in the Candidate List and contained in an article above a concentration of 0.1% w/w must spontaneously provide the recipient thereof with sufficient information available to the supplier (e.g. name of the substance) to allow the safe use of that article
- The supplier of a SVHC appearing on the Candidate List and contained in an article above a concentration of 0.1% w/w must provide consumers, upon their request, with sufficient information available to the supplier (e.g. name of the substance) to allow the safe use of that article → the supply of information must be made free of charge and within 45 days as of the date of receipt of the request by the supplier of the substance
- EU/EEA suppliers of substances on the Candidate List must provide the recipients thereof with a safety data sheet
- New substances added to the Candidate List on June 16, 2014 → list now includes 155 substances

3. Legal implications of a SVHC appearing on the Candidate List of SVHC

4 substances added to the Candidate List on June 16, 2014 (latest change)

Name of the substance	EC number	CAS number	SVHC property
Cadmium chloride	233-296-7	10108-64-2	Carcinogenic; Mutagenic ; Toxic for reproduction; Equivalent level of concern having probable serious effects to human health
1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	271-093-5	68515-50-4	Toxic for reproduction
Sodium peroxometaborate	231-556-4	7632-04-4	Toxic for reproduction
Sodium perborate; perboric acid, sodium salt	239-172-9; 234-390-0	N/A	Toxic for reproduction

4. Draft ECHA Recommendation on Priority Substances for Inclusion in Annex XIV

ECHA may recommend the following priority SVHCs present on the Candidate List for inclusion by the Commission in Annex XIV, depending on the outcome of its public consultation procedure that ended on December 1, 2014:

1. 2 substances resulting from coal tar: (i) Anthracene oil; and (ii) Pitch, coal tar, high temp
2. 7 lead substances: (i) Orange lead (lead tetroxide); (ii) Lead monoxide (lead oxide); (iii) Tetralead trioxide sulphate; (iv) Pentalead tetraoxide sulphate; (v) Silicic acid, lead salt; and (vi) Pyrochlore, antimony lead yellow and Acetic acid, lead salt, basic
3. 4 boron substances: (i) Boric acid; (ii) Disodium tetraborate, anhydrous; (iii) Diboron trioxide; and (iv) Tetraboron disodium heptaoxide, hydrate
4. 7 phthalates: (i) Diisopentylphthalate; (ii) 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich; (iii) 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters; (iv) 1,2-Benzenedicarboxylic acid, dipentylester, branched and linear; (v) Bis(2-methoxyethyl) phthalate; (vi) N-pentyl-isopentylphthalate; (vii) Dipentyl phthalate
5. 4-Nonylphenol, branched and linear, ethoxylated
6. 1-Bromopropane (n-propyl bromide)

5. Legal implications of a SVHC appearing on Annex XIV to the REACH Regulation

- Manufacturers, importers, and downstream users may not place on the EU/EEA market or use of a substance listed on Annex XIV to the REACH Regulation, unless one of the following conditions is met:
  i. The use of that substance on its own or as part of a mixture or the incorporation of this substance into an article has been authorized by the Commission after demonstration that the risk to human health or the environment stemming from the use of that substance is 'adequately controlled' (if that primary requirement cannot be met, an authorization may still be granted should the socio-economic benefits of the use of that substance outweigh the risk to human health and/or the environment stemming therefrom and provided that there are no suitable alternative substances or technologies)
  ii. The use of that substance on its own or as part of a mixture or the incorporation of that substance into an article has been exempted from the authorization requirement
- **31 substances** currently appear on Annex XIV to the REACH Regulation

5. Legal implications of a SVHC appearing on Annex XIV to the REACH Regulation

9 substances added to Annex XIV on August 22, 2014 (latest change)

Name of the substance	EC number	CAS number	SVHC property
Formaldehyde, oligomeric reaction products with aniline	500-036-1	25214-70-4	Carc. Cat. 1B
Arsenic acid	231-901-9	7778-39-4	Carc. Cat. 1A
Bis(2-methoxyethyl) ether (diglyme)	203-924-4	111-96-6	Toxic for reproduction Cat. 1B
1,2-dichloroethane	203-458-1	107-06-2	Carc. Cat. 1B
2,2'-dichloro-4,4'-methylenedianiline	202-918-9	101-14-4	Carc. Cat. 1B
Dichromium tris(chromate)	246-356-2	24613-89-6	Carc. Cat. 1B
Strontium chromate	232-142-6	7789-06-2	Carc. Cat. 1B

5. Legal implications of a SVHC appearing on Annex XIV to the REACH Regulation

Name of the substance	EC number	CAS number	SVHC property
Potassium hydroxyoctaoxodizincate dichromate	234-329-8	11103-86-9	Carc. Cat. 1A
Pentazinc chromate octahydroxide	256-418-0	49663-84-5	Carc. Cat. 1A

V. Restriction Procedure

1. Overall objective
2. General process
3. Proposed restrictions under consideration
4. Latest change to Annex XVII to the REACH Regulation

1. Overall objective

Protect the human health and the environment from unacceptable risks raised by substances or mixtures at the EU/EEA level = overarching objective

Limitation or prohibition imposed on the manufacture, the placing on the EU/EEA market, and the use on the EU/EEA market of such substances or mixtures = means available in order to achieve that objective

2. General process

Identification of a substance/mixture raising an unacceptable risk to human health and/or the environment

Proposal by ECHA (at the Commission's request) or by an EU/EEA Member State to place such a substance on Annex XVII to the REACH Regulation

Such a proposal is published on the Registry of Intentions that is publicly accessible

Public consultation period

Consultation of the ECHA's Risk Assessment Committee and of the Committee for Socio-economic Analysis

Decision as to whether to place a substance on Annex XVII to the REACH Regulation ultimately taken by the Commission after consideration of the opinions of the above two consultative organs

3. Proposed restrictions under consideration

5 substances that are currently the object of restriction proposals at the EU/EEA level

Name of the substance	EC number	CAS number
Ammonium salts	N/A	N/A
Bis(pentabromophenyl) ether (DecaBDE)	214-604-9	1163-19-5
Bisphenol A; 4,4'-isopropylidenediphenol	201-245-8	80-05-7
Cadmium and its compounds (in paints for artists)	231-152-8	7440-43-9
Chrysotile	N/A	12001-29-5 132207-32-0

4. Latest change to Annex XVII to the REACH Regulation

- 105 substances/mixtures are currently listed in Annex XVII to the REACH Regulation
- As of June 1, 2015, the following restriction shall condition the placing or the use of 1,4-dichlorobenzene (CAS N° 106-46-7 and EC N° 203-400-5) on the EU/EEA market as follows: *"Shall not be placed on the market or used, as a substance or as a constituent of mixtures in a concentration equal to or greater than 1% by weight, where the substance or the mixture is placed on the market for use or used as an air freshener or deodorizer in toilets, homes, offices or other indoor public areas"*

VI. ECHA Board of Appeal's developments

1. Legal nature and functions
2. Statistics
3. Subject areas covered
4. Main statements of law

1. Legal nature and functions

- ECHA Board of Appeal = superior administrative body under EU law
- Composed of a Chairman and of two other members
- Hears appeals against certain ECHA decisions delivered in the registration procedure and against all ECHA decisions delivered in the dossier evaluation procedure (i.e., procedure consisting in the examination of testing proposals and in the compliance check of registrations)
- Legal challenges can be based on any ground of law
- Appeals before the Board of Appeal must be filed within 3 months as of date of notification of the ECHA decision to the appellant
- If it finds the challenge to be admissible and well founded, the ECHA Executive Director may rectify the challenged decision with the consequence that the appellant will be free to discontinue the appeal proceedings (i.e., withdraw it) or to maintain them

1. Legal nature and functions

- Suspensive effect entailed by the lodging of the appeal
- ECHA Board of Appeal decisions and those ECHA decisions not falling within the jurisdiction of the Board of Appeal may be appealed before the EU Courts (i.e., the General Court and ultimately the Court of Justice)

2. Statistics

Number of cases brought before the ECHA Board of Appeal: 28

Withdrawals

- 1 (2009)
- 4 (2011)
- 1 (2012)
- 2 (2013)
- 7 (2014)
- = 15

Procedural decisions

- 1 (2009)
- 9 (2011)
- 4 (2012)
- 2 (2013)
- 1 (2014)
- = 17

Final decisions

- 2 (2011)
- 7 (2013)
- 5 (2014)
- = 14

3. Subject areas covered

- Use of language in the registration procedure
- Animal testing and compliance check procedure
- Rejection of proposed read-across and compliance check procedure
- ECHA's administrative margin of appreciation
- Substance identity in compliance check procedure
- Compliance check deadline and principle of good administration
- Developmental toxicity testing and compliance check procedure
- Deadline for updates in compliance check procedure and principle of legal certainty

4. Main statements of law

Ullrich Biodiesel GmbH v. ECHA (A-020-2013)
Decision of November 13, 2014

- Duty of every registrant to act in a diligent and prudent way when performing its REACH obligations
- If a registrant is of the opinion that its rights of defense have not been complied with in the administrative procedure that resulted in the adoption of the contested ECHA decision, it is its responsibility to warn ECHA of that non-compliance situation ‘in good time’
- Human errors (e.g. errors resulting from a change of staff) do not qualify as ‘exceptional and unforeseeable events’ that may excuse a breach of a REACH provision by a registrant

4. Main statements of law

Handlowe UTEX v. ECHA (A-008-2012)
Decision of April 2, 2014

- A registration dossier may relate to one substance only: two distinct substances may not be part of the same registration dossier, even if they bear the same hazard properties or similar toxicological and ecotoxicological properties
- The decision as to which substance to register with ECHA belongs to the manufacturer or the importer only
- It is not ECHA's responsibility to instruct a manufacturer or an importer to register a specific substance through its compliance check procedure: only EU Member States' competent authorities may, under Article 126 of the REACH Regulation, adopt enforcement measures (incl. penalties) in the face of a failure by a manufacturer or importer to register a substance

VII. REACH Enforcement Forum

1. Composition and functions
2. Recent developments

1. Composition and functions

- The Forum for Exchange of Information on Enforcement ('REACH Enforcement Forum') = a network composed of representatives of Member States' competent authorities (one representative per Member State) and of five co-opted members selected on the basis of their expertise
- Members of the REACH Enforcement Forum elect their President
- All members serve a 3-year renewable mandate
- Principal functions include: (i) oversee the exchange of inspectors; (ii) development of an electronic information exchange procedure; (iii) advising on enforceability of restriction proposals; (iv) select common issues for inclusion in the Member States' annual reports on REACH enforcement; (v) suggest, review and manage harmonized enforcement projects; and (vi) put forward enforcement strategies

2. Recent developments

Plenary meeting of November 10, 2014

- Next major project to focus on enforcement of Annex XVII restrictions under the REACH Regulation → confirmation of the scope of the restrictions in 2015 → inspections scheduled in 2016 → publication of final report expected in 2017
- Small-scale project designed to ascertain whether the packaging of chemicals accessible to the general public includes appropriate child-resistant fastenings
- Small-scale project intended to review specific cases where ECHA has recognized the existence of deficiencies in harmonized classification and labeling

VIII. Relation between the REACH Regulation and the Cosmetics Regulation

- Under Regulation (EC) No 1223/2009 ('Cosmetics Regulation'), cosmetic products may not be placed on the EU market in the event that the final formulation, ingredients in a final formulation, or a finished product have undergone animal testing
- Chemical ingredients found in cosmetic products may be subject to the REACH registration requirement and, therefore, to possible animal testing requirements
- In order to reconcile the prohibition on animal testing under the Cosmetics Regulation with the virtual need for animal testing under the REACH Regulation and, thus, avoid conflict of norms, the Commission and ECHA have issued a joint statement on October 27, 2014 on the relation between the two legal instruments
- The joint statement distinguished between three situations based on the function of the substance in the cosmetic and on the purpose of the animal testing → the testing bans in the Cosmetics Regulation do not cover animal testing required for environmental endpoints, for exposure of workers and for non-cosmetic uses of substances under the REACH Regulation

VIII. Relation between the REACH Regulation and the Cosmetics Regulation

Substances used in cosmetics and for other functions	Substances used exclusively in cosmetics	For all environmental end points
Animal testing permissible only as a last resort measure for all human health endpoints	No animal testing permitted when meeting the information requirements of REACH human health endpoints, except for those animal tests necessary in order to assess the risks to workers (i.e., those involved in the production or handling of chemicals on an industrial site) exposed to the substance contained in the cosmetic → compliance with the REACH information requirements will require use of alternatives to animal testing (e.g. read-across, weight of evidence)	Animal testing permissible only as a last resort and regardless of whether the substance is used exclusively in the cosmetic or has other functions