

M&S

EST. 1884

ECP

MINIMUM STANDARDS

REACH

**Registration, Evaluation and Authorisation of
Chemicals**

**VERSION 3
NOVEMBER 2015**

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1 INTRODUCTION

1.1 What is REACH?

REACH is EU chemical legislation that was introduced in June 2007 that applies to chemicals that are manufactured within the EU or imported into the EU from other territories - the legislation is being implemented in stages over a period of over a decade.

REACH replaces about 40 pieces of chemical legislation but some specific existing legislation remains in place (e.g. on cosmetics, detergents, the health and safety of workers handling chemicals, product safety, construction products).

In some instances both REACH and existing legislation will work together (e.g. the *registration* of ingredients in a cosmetic preparation will be covered by REACH and the *risk assessment and specific safety aspects* will be covered by existing cosmetics legislation).

REACH is designed to cover all chemicals, whether industrial or household, and also those contained within articles such as textiles or electrical items.

There is a particular focus on chemicals that are used in large volumes or that are recognised as being particularly harmful - and this is reflected in the timeline for the introduction of legislation where there is a requirement to act sooner for harmful and/or large volume chemicals (focusing on Substances of Very High Concern known as SVHCs).

There are some exemptions to REACH, some of which are applicable to M&S products. For example foods, polymers, medicines and naturally occurring substances do not come under the scope of REACH.

1.2 What EU authority manages REACH?

The European Chemicals Agency (ECHA) manages all aspects of REACH, and is based in Finland.

REACH is implemented in successive stages of REGISTRATION, EVALUATION and AUTHORISATION.

1.3 REGISTRATION of substances

Manufacturers and importers must register with the ECHA the chemicals they are manufacturing or importing if the volume is over 1 tonne per annum.

The registration phase is subdivided into PRE-REGISTRATION and REGISTRATION. Pre-registration requires the manufacturer or importer of a chemical to tell ECHA what they are using and for what purpose, whereas full registration requires the manufacturer or importer to provide a TECHNICAL DOSSIER, and in some circumstances a detailed SAFETY REPORT, to ECHA for evaluation by their experts.

Companies who need to register identical substances can join together to form a Substance Information Exchange Forum (SIEF) to create the necessary dossiers and reports

There are an estimated 30,000 chemicals which need to be registered with the ECHA, and they are being registered in phases according to their hazard classification and volumes supplied. The third and final phase ends on 31st May 2018.

1.4 EVALUATION of substances

Dossiers submitted in support of registration are subjected to evaluation by the ECHA and Competent Authorities of the Member States.

Substances for evaluation are prioritised according to their potential health and environmental hazards. A regulatory outcome of evaluation could be the imposition of restrictions on the manufacture, supply or use of a substance. Substance evaluation may also lead to a substance being added to the priority list for authorisation.

1.5 SUBSTANCES OF VERY HIGH CONCERN (SVHC) and the Candidate List

Some substances have hazards that have serious consequences. The criteria for SVHC classification are:

- carcinogenic, mutagenic or toxic to reproduction (CMRs)
- persistent, bio-accumulative and toxic (PBTs)
- very persistent and bio-accumulative (vPvBs)
- substances of equivalent concern which seriously and / or irreversibly damage the environment or human health, eg endocrine disruptors, neurotoxins etc.

One of the aims of REACH is to control the use of such substances through authorisation and encourage industry to substitute these substances for safer ones.

Before a substance can be included on Annex XIV it must be identified as an SVHC and placed on the Candidate List.

Periodically, ECHA looks at the substances on the Candidate List and identifies and recommends priority substances to add to Annex XIV.

The European Commission, in collaboration with Member States and the European Parliament, will then decide which of these recommendations to take forward for addition to Annex XIV.

The inclusion of a substance in the Candidate List creates legal obligations to companies manufacturing, importing or using such substances, whether on their own, in preparations or in articles. SEE SECTION 1.6

A current list of SVHC is available at:

<http://echa.europa.eu/web/guest/candidate-list-table>

1.6 DEFINITION OF 'ARTICLE'

In 2011 in Document CA/26/2011 the European Commission issued guidance to member states. It stated that the 'article' referred to in the Regulations was, in the case of imported goods, the finished product as brought across the EU border and therefore the percentages of SVHCs allowed to be present were based on the total weight of the individual unit of product. For example, in the case of a jacket, the amount of an SVHC present in a button was offset by the fact that the button only represented a fraction of the total weight of the whole 'article'.

The European Court of Justice **has reviewed this regulation**, and has referred to the aim of the Regulations "*to ensure a high level of protection of human health and the environment*"

In judgement of Case C-106/14, the Advocate General **has ruled that complex products are comprised of individual articles which do not lose their status as an article when assembled into the complex product**. This preliminary judgement was published on 10th September 2015.

Therefore each 'component' of a finished article must be viewed individually in terms of its SVHC content. If greater than 0.1%, the recipient must be informed.

This imposes greater onus on Suppliers whose goods are assembled overseas to ensure that their **risk management procedures are robust enough to cope with this new interpretation**.

1.7. AUTHORISATION of substances (REACH Annex XIV)

Authorisation is one of the REACH processes for managing the risks of hazardous substances. Substances that are subject to authorisation may not be used in the EU, unless a company (and their registered users) have been authorised to do so. This will mean that eventually these substances will be phased out of all non-essential uses.

The substances that qualify for consideration for authorisation are known as Substances of Very High Concern (SVHCs)

Substances to which authorisation applies are listed in Annex XIV of REACH. For each substance included on Annex XIV, a deadline (known as the 'sunset date') is set after which use of that substance in the EU must stop unless authorised. Some substances may be accompanied by a list of specific uses that do not require authorisation.

Once the sunset date has passed for an Annex XIV substance, only uses which have been specifically authorised (or which do not require authorisation) will be allowed.

<http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list>

and

<http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations>

1.8 ANNEX XVII

Annex XVII lays down restrictions on the manufacture, placing on the market and use of certain dangerous chemical substances, mixtures and articles.

The Annex contains restrictions on the marketing and use of dangerous substances which were in place before the formation of REACH, as well as subsequent restrictions adopted under REACH.

There are more than 1000 restricted substances listed in Annex XVII. Hazardous substances that are restricted in products include lead, Azo dyes, DMFu, PAHs, Phthalates, PFOS, Nickel, etc.

The table of substances and groups of substances which are restricted by Annex XVII can be found at:

<http://echa.europa.eu/addressing-chemicals-of-concern/restrictions/list-of-restrictions/list-of-restrictions-table>

1.9 Biocidal Products Regulation

The Biocidal Product Regulation (BPR, Regulation (EU) 528/2012) concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms, like pests or bacteria, by the action of the active substances contained in the biocidal product.

Companies have to apply for approval of an active substance by submitting a dossier to ECHA. After the validation check has been performed by ECHA, the evaluating competent authority carries out a completeness check and an evaluation within one year.

The full list of approved active ingredients can be found at:

<http://echa.europa.eu/information-on-chemicals/biocidal-active-substances>

Only biocides which are on this list may be used for M&S, unless they are classified as hazardous in other ECHA listings.

IMPORTANT NOTE on Annexes and lists of chemicals

A number of other lists have been created – for instance by industry groups, REACH Consultancies and Non-Government Organisations.

These other lists have no legal status under REACH, and should not be confused with the official Candidate List or Annex XIV. Only information from the ECHA website can be trusted.

2. SUPPLIER AND M&S MAIN CONCERNS

HEADLINE	KEY CONCERN(S)	ACTIONS REQUIRED
CHEMICAL SUPPLIERS' REGISTRATION OF THEIR PRODUCT	Proof it is done – otherwise products in our Stores containing those substances may be illegal and risk later product withdrawal or recall	Suppliers of chemicals and dyes must confirm they have registered their products with ECHA, or that that exact product is already registered on ECHA listing
SVHC'S (SUBSTANCES OF VERY HIGH CONCERN) see ECHA website for current list (the link is below)	If articles contain >0.1% by weight of a substance on the candidate list, and the total amount of substance in the articles is >1 tonne per annum, and the substance has not been registered for that specific use, this must be reported to ECHA For definition of 'Article', see section 1.6 Key issue for a retailer is that a customer can demand to know if a product contains a SVHC- and the retailer <u>must</u> respond with an answer within 45 days.	Suppliers check all raw materials to confirm no presence of SVHCs If there is a risk of presence of SVHCs supplier to notify Department technologist and create an action plan to substitute that chemical with one not on the SVHC list where technically viable
45 DAY REQUIREMENT TO RESPOND TO CUSTOMER QUERIES	REACH legislation requires a response to a customer within 45 days of request This is an M&S requirement if we receive a request and failure to do this is a <u>legal offence</u>	Suppliers must be completely transparent about what chemicals and dyestuffs they use in their product. No exceptions to this rule are acceptable This information must be right up to raw material detail

Up to date information on compliance with REACH requirements is available at:
http://echa.europa.eu/reach_en.asp

All substances (base chemicals) and ingredients of formulations that are made in, or imported into Europe, have to be registered according to the timetable set out by EU authorities.

Different rules apply for textile and leather articles that are made in or imported into Europe. REACH only applies to substances that are intended to be **released** from an article or substances that are labelled as Substances of Very High Concern (SVHC).

When viable substitutes to SVHC become available Marks and Spencer intends to move its manufacturing routes away from SVHC to these substitutes.

A current list of SVHC is available at:

<http://echa.europa.eu/web/guest/candidate-list-table>

If you are based in Europe you should get assurances from your dye and chemical suppliers that all their chemicals are registered in accordance with EU requirements and that their products do not contain SVHC's

If your factory is outside the EU you should get assurances from your dye and chemical suppliers that their products do not contain SVHC's.

You should discuss REACH requirements with Marks & Spencer technologists if you intend to manufacture products where there is intended release of chemicals (for example perfumed textiles, moisturising finishes, etc).

The European Chemicals Agency (ECHA) stated in June 2009 that registration of chemicals is required under the following circumstances:

- **“The substance is intended to be released from the produced and/or imported articles during normal or reasonable foreseeable conditions of use”.**
- **“The total amount of the substance present in all articles produced and/or imported, from which the substance is intended to be released, exceeds 1 tonne per year.”**

If the substance being released by an article is a Substance of Very High Concern (SVHC) and is present at over 0.1% and is used in quantities of over 1 tonne then ECHA have to be NOTIFIED.

Notification is essentially an official declaration of the situation and needs to be done so that ECHA can make a decision on whether further information is necessary.

3 SUPPLIER AND M&S OBLIGATIONS

<p>REACH Registration, Evaluation and Authorisation of Chemicals Supplier and M&S obligations</p>
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SUPPLIER OBLIGATIONS	M&S OBLIGATIONS	M&S ONGOING STEPS
<ul style="list-style-type: none"> • Chemicals and Dyes – Suppliers to confirm that their wet processing facilities are using dye and chemical sources which are registered to REACH requirements • SVHCs – in products (refer to current listing on ECHA website). Suppliers must inform Marks & Spencer if any SVHCs are present above 1000ppm (0.1%) W/W • Intentional release products (for example candles, Fragrances, etc.) – suppliers must provide proof of registration if the amount of released chemicals is an SVHC or could exceed 1 tonne per annum • Rapid Response – Suppliers must have the capability to rapidly respond to chemical content requests (including SVHCs in their own and/or 3rd party sourced components) to allow M&S to meet the 45 day response legal requirement 	<ul style="list-style-type: none"> • REACH policy – M&S will create and keep updated a policy that reflects and guides on our, and our suppliers obligations • SVHC list – We will keep updated from the ECHA website and communicate this to M&S teams and our suppliers. • Intentional release products – Data to be available on contracts.com from the suppliers. • Customer information – System operational to respond to customer ‘chemical or SVHC in product’ enquiries within 45 days or request through Retail Customer Services. <i>Note – This requires full cooperation and rapid response for information from suppliers and their raw material sources of chemicals and SVHCs in product.</i> 	<ul style="list-style-type: none"> • REACH integrated into ECP and communicated to all M&S teams and suppliers. • M&S customer services capability to respond to customer issues within 45 days of enquiry – and will be tested to ensure capability fully operational. • M&S will manage REACH compliance training and registration, working with external expert companies and consultants