



A Guideline for the REACH Implementation Project 3.8 *Requirements for Substances in Articles*



Zulaikha Safi
zsafi@sgia.org
Specialty Graphic Imaging Association
June, 2008

DISCLAIMER: All information contained in this document has been summarized from the actual REACH Implementation Project 3.8 document. Readers are reminded that this document is to be used as a reference and that the Specialty Graphic Imaging Association, who is responsible for the publication of this document, will not accept any liability regarding the contents of this document or arising from its use.

A Guideline for the REACH Implementation Project 3.8 *Requirements for Substances in Articles*

CONTENT

Section I: General Information _____

<i>What is the REACH Implementation Project 3.8 document about?</i> -----	4
<i>What is an article?</i> -----	4
<i>What are the elements of an article?</i> -----	4
<i>What is a substance?</i> -----	4
<i>What does “preparation” mean?</i> -----	5
<i>Who is affected by the REACH Implementation Project 3.8?</i> -----	5
<i>What are an “importer” and an “exporter”?</i> -----	5
<i>What is an “only representative”?</i> -----	5

Section II: Article 7 _____

<i>What does Article 7 [of REACH] entail?</i> -----	6
<i>When do the requirements of Article 7 [of REACH] apply?</i> -----	6
<i>How to check if the substance has already been registered for its specific use?</i> -----	7
<i>If notification is required according to Article 7, what information needs to be notified?</i> -----	7

Section III: Article 33 _____

<i>What does Article 33 [of REACH] entail?</i> -----	9
<i>What is SVHC?</i> -----	9
<i>When do the requirements of Article 33 apply?</i> -----	9
<i>How can it be determined whether the article contains a SVHC?</i> -----	9

*What if the supply chain communications did not provide the sufficient
Information needed? -----* 10

Annex I: List of Substances Exempt from Registration _____ 11

The following easy-to-read guide has been created to help SGIA members



understand the REACH Implementation Project 3.8 – a document on *requirements for Substances in Articles* in regards to registering and notifying substances in articles [according to Article 7 and 33 of REACH].

*the official ECHA REACH Implementation 3.8 can found at the ECHA website: http://echa.europa.eu/reach_en.asp

Section I. GENERAL INFORMATION

What is the REACH Implementation Project 3.8 document about?

This document describes the requirements that an article producer/importer must fulfill under **Article 7** and **Article 33**, of the European chemicals regulation REACH, in relation to the **substances** contained in **articles**. It must be stressed that registration is not required for the article itself; it is required only for substance(s) that the article possesses. Further explanation is provided in this guide.

If the producer/importer needs to fulfill the requirements, the information is sent to the European Chemical Agency (ECHA) and it will be checked for its completeness and compliance.

What is an article?

An **article** is a finished product or raw material, composed of one or more **substances, preparations,** and materials. Specific substances or preparations can also be added to give it special properties.

*Example: an **article** could be a t-shirt, and dye (which is a substance) is added to the article (fabric of t-shirt) to give it special property.*

An **article** requires that its elements are more important for its normal use than its chemical composition.

Example: For the consumer, the way a cup can be used (the ability to be held, to store solid objects or liquids, stand upright on a flat surface, etc) is more important to the consumer than the actual chemical composition of the cup.

What are the elements of an article?

- **function:** determined by the purpose of its use
- **shape:** object's 2 or 3-dimensional form
- **surface:** the outmost layer of the object
- **design:** the object's arrangement

What is a "substance"?

According to Article 3(1) of the REACH Regulation, the definition of “substance” is the following:

“**Substance** means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.”

What this simply means is that a **substance** is a chemical.

What does “preparation” mean?

According to Article 3(2) of the REACH Regulation, the definition of “preparation” is the following:

“**Preparation** means a mixture or solution composed of two or more substances.”

Who is affected by the REACH Implementation Project 3.8?

The document applies to all European article producers and to all European importers of articles into the European Union (EU). Non-EU producers (also referred as “non-EU manufacturers” in the REACH Regulation) are not obligated to comply with REACH, but the EU importers from them are. However, Non-EU companies have the option to hire an “only representative” to fulfill the registration requirements of REACH in order to relieve the EU importers, in their supply chain, of their obligation to register substances under REACH.

What are an “importer” and an “exporter”?

According to REACH, article producers are manufacturers of articles within the EU and article importers are those importing articles manufactured outside the EU into the European market (EU). What this means for SGIA members is:

- If you are an SGIA member that is based in the EU and act as a manufacturer or supplier *within* the EU, you are considered a producer and must abide by REACH regulations.
- If you are an SGIA member that is based in the EU and you import products into the EU from non-EU countries, you are considered an importer and must abide by REACH regulations.
- Although non-EU based SGIA members (located outside the EU) are not obligated to comply with REACH, they are considered non-EU importers if they supply or ship products to anywhere in the EU.

What is an “only representative”?

As noted above, even though non-EU companies are not required to fulfill obligations under REACH, they can still hire an **only representative** to fulfill the substance registration requirements under REACH so that they may relieve their [EU-based] clients down their supply chain of that responsibility. Regardless of whether you hire an **only representative** or not, you will eventually be asked by someone down your supply chain for information pertaining to the substances in your articles so that they may fulfill their REACH obligations. If you would like to avoid disclosing information about the proprietary

formulas or any other details [of your substances/products] to your EU-based importers, hiring an **only representative** is one way to protect your privacy.

NOTE: only one **only representative** can be hired per substance.

According to Article 8 of the REACH Regulation, an **only representative** is a legal resident or citizen of the EU who is living within the EU and has background information and knowledge on substances; however the Regulation does not specify *how much* background knowledge is needed. However an **only representative** can simply be someone down your supply chain that is an EU-based importer.

Article 8 also specifies that it is up to the non-EU company to hire an **only representative** through “mutual agreement”; basically the company and the **only representative** have sole responsibility to create a sort of contract that will not only be confidential, but will be sufficient enough so that both agents would understand what is expected of one another.

Article 8 also notes that if a non-EU company decides to hire an **only representative** to complete registration under REACH, it is up to that company to inform all of their EU importers (down their supply chain) of their decision and to also inform the ECHA authorities of the EU-importers that are covered by their registration.

*further details on hiring an “only representative” can found in ECHA’s official guidance on registration at the following ECHA website:
http://reach.jrc.it/guidance_en.htm

Section II. ARTICLE 7

What does Article 7 [of REACH] entail?

Defines when article producers and importers must **register or notify** substances in articles to the European Chemical Agency in accordance to REACH and details the notification requirements.

When do the requirements of Article 7 [of REACH] apply?

It is necessary to first check the requirements for *registration* before checking the requirements for *notification*.

Article 7(1): **registration** must be submitted to the European Chemical Agency if all of the following conditions are met:

- substances are intended to be released during normal and reasonably foreseeable conditions of use (*example: a scented eraser*) and
- the total amount of the substances with intended release in articles exceeds 1 t/a (ton per year), per producer or importer, and
- substance has not already been registered for that use (if it has already been registered for that use, then no notification, and *no further action is needed*)

If those conditions are met, it's possible to check if any of the substances [that are identified] are exempted from registration, which is specified in Annexes IV and V of the REACH Regulation and can be found in this guide's Annex I for your convenience. If the substance is on the list then no registration and *no further action*, is required.

Article 7(2): **notification** must be submitted to the European Chemical Agency for substances of very high concern (SVHC) that are on the REACH candidate list* *and* that meet the following conditions:

- the substance has not been registered and
- the total amount of the substance produced per year exceeds 1 ton, per producer or importer, and
- the substance present in articles has a concentration above 0.1% weight by weight (w/w)

***the SVHC candidate list is currently unavailable and is being processed; it is expected to be published and available on the ECHA website by the end of October 2008.**

Note: *notification is not required* if one or both of the following conditions (of Article 7(3), or 7(6)) are met:

- the producer/importer can exclude exposure of the substances to human or the environment during normal or reasonable foreseeable conditions of use including disposal (7(3)) and
- the substance has already been registered for that specific use (7(6))

How to check if the substance has already been registered for its specific use?

There are two ways to check if the substance has already been registered for its specific use:

1. request the information up the supply chain
2. request the Chemical Agency for the information. A prerequisite for doing so is the identity of the substance. To submit your request, it must be done so by completing the *information request form* on the ECHA website (*Contact* page at www.echa.europa.eu)

If notification is required according to Article 7, what information needs to be notified?

The following information is to be notified:

- the identity and contact details of the producer or importer
- the registration #(s) for the substance, if available
- the identity of the substance(s), which will be available on the SVHC candidate list*
- the classification of the substance, available from the European Chemical Agency
- a brief description of the use(s) of the substance in article and of the uses of the article(s)
- the tonnage range of the substance (which can be estimated)

***the SVHC candidate list is currently unavailable and is being processed; it is expected to be published and available on the ECHA website by the end of October 2008**

Section III. Article 33

What does Article 33 [of REACH] entail?

Defines the duty of those in the supply chain for articles containing substance of very high concern (SVHC) to *communicate information* down the supply chain.

What is SVHC?

SVHC stands for substances of very high concern, in regards to human health and safety, and the environment. They are substances that are persistent, bioaccumulative, and/or toxic (PBT and vPvB).

Substances that are classified [according to Directive 67/548/EEC] under the following are also considered SVHC:

- Carcinogenic category 1 or 2
- Mutagenic category 1 or 2
- Toxic for reproduction category 1 Or 2

Note: REACH is also creating a SVHC candidate list as a reference, which is expected to be published and available on the ECHA website by the end of October 2008.

When do the requirements of Article 33 apply?

Obligation to provide the recipient* and the consumer of the article(s) with *at least* the name of the substance, and to provide the consumer with additional information on how the article(s) can be safely used, is required if:

- it is a SVHC that is included on the SVHC candidate list** for possible inclusion and
- the article contains SVHC in a concentration that exceeds 0.1% (w/w)

* According to REACH, the recipient does not mean the consumer; the recipient is an industrial or professional user being supplied with that article.

**the SVHC candidate list is currently unavailable and is being processed; it is expected to be published and available on the ECHA website by the end of October 2008.

How can it be determined whether the article contains a SVHC?

There are several ways to obtain information that would determine whether the article contains SVHC:

- Safety data sheets (SDS)

- Article 30 information
- supply chain requests

If none of these options are available or the information is inadequate, then perform the following supply chain communications:

- For article *producers*:
 - request the supplier of the substances/preparations (that are in the article) to confirm the identity and concentration range of any SVHC that is on the candidate list*.
 - For the article components, request the supplier to confirm that no SVHCs listed on the candidate list* are contained in concentrations more than 0.1% (w/w) in the article, or simply request them to specify the identity and concentration of the SVHC in the article.
- For article *importers*:
 - request the supplier to confirm if the article contains any SVHC on the candidate list* in concentrations more than 0.1% (w/w), or simply request them to specify the identity and the amount of concentration of the substances in the article.

***the candidate list is currently unavailable and is being processed; it is expected to be published and available on the ECHA website by the end of October 2008.**

What if the supply chain communications did not provide the sufficient information needed to determine whether the article contains SVHC?

If the supply chain communications was not able to provide the adequate information that is needed, then perform a chemical screening analysis to assess the content of an article and to identify SVHC.

(NOTE: it would make conducting a chemical screening analysis easier if you note *beforehand* which materials of the article may contain a SVHC.)

ANNEX I

List of Substances Exempt from Registration (under Article 7)

*The following information was obtained from the draft Annex IV and V of the REACH Regulation which can found at the ECHA website:
www.echa.europa.eu*

NOTE: because Annex IV and V of the REACH Regulation are still in its draft stage, it is subject to change.

The following groups of substances are exempt from registration:

- Substances which result from a chemical reaction that occurs incidental to exposure of another substance or article to environmental factors such as air, moisture, microbial organisms or sunlight.
- Substances which result from a chemical reaction that occurs incidental to storage of another substance, preparation or article.
- Substances which result from a chemical reaction occurring upon end use of other substances, preparations or articles and which are not themselves manufactured, imported or placed on the market.
- Substances which are not themselves manufactured, imported or placed on the market and which result from a chemical reaction that occurs when:
 - a. a stabiliser, colorant, flavouring agent, antioxidant, filler, solvent, carrier, surfactant, plasticiser, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, desiccant, binder, emulsifier, de-emulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutraliser, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended; or
 - b. a substance solely intended to provide a specific physicochemical characteristic functions as intended.
30.12.2006 EN Official Journal of the European Union L 396/305
- By-products, unless they are imported or placed on the market themselves.
- Hydrates of a substance or hydrated ions, formed by association of a substance with water, provided that the substance has been registered by the manufacturer or importer using this exemption.
- The following substances which occur in nature, if they are not chemically modified:
Minerals, ores, ore concentrates, raw and processed natural gas, crude oil, coal.
- Substances which occur in nature other than those listed in the above bulletin, if they are not chemically modified, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC or unless they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or unless they were identified in accordance with Article 59(1) at least two years previously as substances giving rise to an equivalent level of concern as set out in Article 57(f).

- The following substances obtained from natural sources, if they are not chemically modified, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC with the exception of those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36] or unless they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or unless they were identified in accordance with Article 59(1) at least two years previously as substances giving rise to an equivalent level of concern as set out in Article 57(f): Vegetable fats, vegetable oils, vegetable waxes; animal fats, animal oils, animal waxes; fatty acids from C6 to C24 and their potassium, sodium, calcium and magnesium salts; glycerol.
- The following substances if they are not chemically modified: Liquefied petroleum gas, natural gas condensate, process gases and components thereof, coke, cement clinker, magnesia.
- The following substances unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC and provided that they do not contain constituents meeting the criteria as dangerous in accordance with Directive 67/548/EEC present in concentrations above the lowest of the applicable concentration limits set out in Directive 1999/45/EC or concentration limits set out in Annex I to Directive 67/548/EEC, unless conclusive scientific experimental data show that these constituents are not available throughout the life-cycle of the substance and those data have been ascertained to be adequate and reliable: Glass, ceramic frits.
- Compost and biogas.
- Hydrogen and oxygen.

-Exemption list continued on next page-

The following list consists of specific substances that are exempt from registration:

EINECS No	Name/Group	CAS No
200-061-5	D-glucitol C ₆ H ₁₄ O ₆	50-70-4
200-066-2	Ascorbic acid C ₆ H ₈ O ₆	50-81-7
200-075-1	Glucose C ₆ H ₁₂ O ₆	50-99-7
200-294-2	L-lysine C ₆ H ₁₄ N ₂ O ₂	56-87-1
200-233-3	Fructose C ₆ H ₁₂ O ₆	57-48-7
200-334-9	Sucrose, pure C ₁₂ H ₂₂ O ₁₁	57-50-1
200-405-4	α -tocopheryl acetate C ₃₁ H ₅₂ O ₃	58-95-7
200-416-4	Galactose C ₆ H ₁₂ O ₆	59-23-4
200-432-1	DL-methionine C ₅ H ₁₁ NO ₂ S	59-51-8
200-559-2	Lactose C ₁₂ H ₂₂ O ₁₁	63-42-3
200-711-8	D-mannitol C ₆ H ₁₄ O ₆	69-65-8
201-771-8	L-sorbose C ₆ H ₁₂ O ₆	87-79-6
204-664-4	Glycerol stearate, pure C ₂₁ H ₄₂ O ₄	123-94-4
204-696-9	Carbon dioxide CO ₂	124-38-9
205-278-9	Calcium pantothenate, D-form C ₉ H ₁₇ NO _{5.1/2} Ca	137-08-6
205-756-7	DL-phenylalanine C ₉ H ₁₁ NO ₂	150-30-1
208-407-7	Sodium gluconate C ₆ H ₁₂ O ₇ .Na	527-07-1
215-665-4	Sorbitan oleate C ₂₄ H ₄₄ O ₆	1338-43-8
231-098-5	Krypton Kr	7439-90-9
231-110-9	Neon Ne	7440-01-9
231-147-0	Argon Ar	7440-37-1
231-168-5	Helium He	7440-59-7

-Exemption list continued on next page-

EINECS No	Name/Group	CAS No
231-168-5	Helium He	7440-59-7
231-172-7	Xenon Xe	7440-63-3
231-783-9	Nitrogen N ₂	7727-37-9
231-791-2	Water, distilled, conductivity or of similar purity H ₂ O	7732-18-5
232-307-2	Lecithins. The complex combination of diglycerides of fatty acids linked to the choline ester of phosphoric acid.	8002-43-5
232-436-4	Syrups, hydrolyzed starch. A complex combination obtained by the hydrolysis of cornstarch by the action of acids or enzymes. It consists primarily of d-glucose, maltose and maltodextrins.	8029-43-4
232-442-7	Tallow, hydrogenated	8030-12-4
232-675-4	Dextrin	9004-53-9
232-679-6	Starch. High-polymeric carbohydrate material usually derived from cereal grains such as corn, wheat and sorghum, and from roots and tubers such as potatoes and tapioca. Includes starch which has been pregelatinised by heating in the presence of water.	9005-25-8
232-940-4	Maltodextrin	9050-36-6
238-976-7	Sodium D-gluconate C ₆ H ₁₂ O ₇ .xNa	14906-97-9
248-027-9	D-glucitol monostearate C ₂₄ H ₄₈ O ₇	26836-47-5
262-988-1	Fatty acids, coco, Me esters	61788-59-8
265-995-8	Cellulose Pulp	65996-61-4

-Exemption list continued on next page-

EINECS No	Name/Group	CAS No
266-948-4	Glycerides, C16-18 and C18-unsaturated. This substance is identified by SDA Substance Name: <i>C16-C18 and C18 unsaturated trialkyl glyceride</i> and SDA Reporting Number: 11-001-00.	67701-30-8
268-616-4	Syrups, corn, dehydrated	68131-37-3
269-658-6	Glycerides, tallow mono-, di- and tri-, hydrogenated	68308-54-3
270-312-1	Glycerides, C16-18 and C18-unsaturated. mono- and di- This substance is identified by SDA Substance Name: <i>C16-C18 and C18 unsaturated alkyl and C16-C18 and C18 unsaturated dialkyl glyceride</i> and SDA Reporting Number: 11-002-00.	68424-61-3
288-123-8	Glycerides, C10-18	85665-33-4
267-007-0	Fatty acids, C14-18 and C16-18-unsaturated., Me esters This substance is identified by SDA Substance Name: <i>C14-C18 and C16-C18 unsaturated alkyl carboxylic acid methyl ester</i> and SDA Reporting Number: 04-010-00.	67762-26-9
267-013-3	Fatty acids, C6-12. This substance is identified by SDA Substance Name: <i>C6-C12 alkyl carboxylic acid</i> and SDA Reporting Number: 13-005-00.	67762-36-1
268-099-5	Fatty acids, C14-22 and C16-22 unsaturated. This substance is identified by SDA Substance Name: <i>C14-C22 and C16-C22 unsaturated alkyl carboxylic acid</i> and SDA Reporting Number: 07-005-00	68002-85-7
268-616-4	Syrups, corn, dehydrated	68131-37-3

-Exemption list continued on next page-

EINECS No	Name/Group	CAS No
269-658-6	Glycerides, tallow mono-, di- and tri-, Hydrogenated	68308-54-3
270-312-1	Glycerides, C ₁₆₋₁₈ and C ₁₈ -unsaturated. mono- and di- This substance is identified by SDA Substance Name: C _{16-C18} and C ₁₈ unsaturated alkyl and C _{16-C18} and C ₁₈ unsaturated dialkyl glyceride and SDA Reporting Number: 11-002-00.	68424-61-3
288-123-8	Glycerides, C ₁₀₋₁₈	85665-33-4