Designation: F2725 – 11

Standard Guide for European Union's Registration, Evaluation, and Authorization of Chemicals (REACH) Supply Chain Information Exchange[1]

This standard is issued under the fixed designation F2725; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This guide will assist companies that manufacture, buy, or sell, or both, substances, preparations, and articles to ensure that supply chains comply with the European Union's Registration, Evaluation, and Authorization of Chemicals (REACH) regulation. This is accomplished by identifying the specific information elements that must be specified, requested and exchanged in communication between actors in the supply chain.

1.2 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

F2576 Terminology Relating to Declarable Substances in Materials

2.2 *European Union Directives and Regulations:*[3]

67/548/EEC Directive on Dangerous Substances

1999/45/EC Dangerous Preparations Directive

2006/121/EC Amending Directive 67/548/EEC

Regulation (EC) No. 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

2.3 *REACH Guidance Standards:*[3]

Annex 1: Automotive Industry Guidance

Annex 2: Aerospace Industry Guidance

Annex 3: European Engineering Industries (Orgalime) Guidance

Annex 4: Fragrance Industry Guidance

Annex 5: Semiconductor Industry Guidance

Annex 14: List of Substances Subject to Authorisation

REACH Title II Registration of Substances

REACH Title IV Information in the Supply Chain

2.4 *REACH Implementation Project (RIP) Guidance Documents:*[3]

Annex 6: RIP 3.4 Guidance on Data Sharing

Annex 7: RIP 3.5 Guidance for Downstream Users

Annex 8: RIP 3.8 Guidance on Requirements for Articles

Annex 9: EU Commission publication: REACH-in-Brief

Annex 17: List of Restricted Substances and Conditions of Restriction

3. Terminology

3.1 *Definitions:*

3.1.1 Terms and definitions related to declarable substances in materials may be found in Terminology F2576.

3.1.2 Terms and definitions in this guide not found in Terminology F2576 may be found in a common dictionary or other reference documents such as the *ASTM Dictionary of Engineering Science & Technology*.[4]

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *actors in the supply chain, n*—all manufacturers, importers, or downstream users in a supply chain.

3.2.2 *article, n*—object that during production is given a special shape, surface, or design that determines its function to a greater degree than does its chemical composition.

3.2.3 *candidate list, n*—list of substances that are subject to appear on Annex 14 (authorization) list of substances and will someday require an authorization application for use.

[1] This guide is under the jurisdiction of ASTM Committee F40 on Declarable Substances in Materials and is the direct responsibility of Subcommittee F40.02 on Management Practices and Guides.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from ec.europa.eu or www.echa.eu.

[4] Available from ASTM International, 100 Barr Harbor Dr., P.O. Box C700, West Conshohocken, PA 19428-2959, ASTM Stock Number: DEF00.

3.2.4 *chemical safety report (CSR), n*—findings of a chemical safety assessment that shall consider the hazards and risks of a substances that is manufactured or imported in quantities greater than 10 metric tonnes per year.

3.2.5 *community, n*—27-member states of the European Union.

3.2.6 *downstream user, n*—any natural or legal person established within the European 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 or her industrial or professional activities.

3.2.6.1 *Discussion*—A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to REACH Article 2 (7)(c) in Directive 2006/121/EC shall be regarded as a downstream user.

3.2.7 *exposure scenario, n*—set of conditions, including operational conditions and risk management measures, that describes how the substance is manufactured or used during its lifecycle and how the manufacturer or importer controls, or recommends downstream users to control exposures of humans and the environment.

3.2.7.1 *Discussion*—These exposure scenarios may cover one specific process or use or several process or uses as appropriate.

3.2.8 *import, v*—physical introduction into the customs territory of the community.

3.2.9 *importer, n*—any natural or legal person established within the community who is responsible for the import.

3.2.10 *intermediate, n*—substance that is manufactured for and consumed in or used for chemical processing to be transformed into another substance.

3.2.11 *manufacturer, n*—any natural or legal person established within the community who manufactures a substance within the community.

3.2.12 *manufacturing, v*—production or extraction of substances in the natural state.

3.2.13 *mixture, n*—combination or solution of two or more substances that do not react.

3.2.14 *only representative, n*—third party who may serve as importer of record on behalf of natural or legal persons established outside of the community (see *preparation*).

3.2.15 *per year, n*—per calendar year, unless stated otherwise, for phase-in substances that have been imported or manufactured for at least three consecutive years; quantities per year shall be calculated on the basis of the average production or import volumes for the three preceding calendar years.

3.2.16 *phase-in substance, n*—substance that meets at least one of the following criteria: *(1)* it is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) and *(2)* it is manufactured in the community, or in the countries acceding to the European Union on January 1995 or 1 May 2004, but not placed on the market by the manufacturer or importer at least once in the 15 years before the entry into force of the REACH regulation, provided the manufacturer or importer has documentary evidence of this.

3.2.17 *placing on the market, v*—supplying or making available, whether in return for payment or free of charge, to a third party.

3.2.17.1 *Discussion*—Import shall be deemed to be placing on the market.

3.2.18 *preparation, n*—mixture or solution composed of two or more substances; preparations can contain several substances; they are not the same as multiconstituent substances; the difference between preparation and multiconstituent substance is that a preparation is gained by blending of two or more substances without any chemical reaction occurring, whereas a multiconstituent substance is the result of a chemical reaction; examples of preparations include paints, varnishes, and inks.

3.2.18.1 *Discussion*—REACH obligations apply individually to each of those substances depending on whether within the scope of REACH. Within the GHS, a preparation is known as a "mixture."

3.2.19 *producer of an article, n*—any natural or legal person who makes or assembles an article in the community.

3.2.20 *restriction, n*—any condition for a prohibition of the manufacture, use, or placing on the market.

3.2.21 *safety data sheet, n*—hazard and risk information required by community law to be passed on from supplier to customer for dangerous substances and dangerous substances in mixtures above a certain concentration.

3.2.22 *substance, n*—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 that may be separated without affecting the stability of the substance or changing its composition.

3.2.23 *use, n*—any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transferring from one container to another, mixing, production of an article, or any other utilization.

3.3 *Acronyms:*

3.3.1 *CAS*—Chemical Abstracts Service

3.3.2 *ECHA*—European Chemicals Agency

3.3.3 *EINECS*—European Inventory of Existing Commercial Chemical Substances

3.3.4 *ELINCS*—European List of Notified Chemical Substances

3.3.5 *ELV*—End-of-Life Vehicles Directive

3.3.6 *EPA*—Environmental Protection Agency

3.3.7 *EU*—European Union

3.3.8 *GHS*—Globally Harmonized System of Classification and Labeling of Chemicals

3.3.9 *IMDS*—International Materials Data System

3.3.10 *REACH*—Registration, Evaluation, and Authorization of Chemicals

3.3.11 *RIP*—REACH Implementation Project—technical guidance documents published by EU RoHS Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment

3.3.12 *SIEF*—Substance Information Exchange Forum

3.3.13 *SVHC*—substances of very high concern

4. Summary of Guide

NOTE 1—This guide does not provide assistance on the legal requirements of REACH such as registration, evaluation, authorization, and restrictions. For a basic introduction to REACH and guidance for assessing your legal obligations under the regulation, please consult the documentation in Annex 9. For actual text of REACH, see: http://reach.jrc.it/legislation_en.htm.

4.1 *What is REACH?*

4.1.1 Regulation (EC) No. 1907/2006 of the European Parliament and the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). REACH replaces 40 existing legal acts and creates a single system for all chemical substances.

4.1.1.1 *Registration*—Registration requires producers and importers to obtain and submit relevant information on chemical substances produced in or imported to the EU market in quantities greater than 1 tonne per year.

4.1.1.2 *Evaluation*—Evaluation allows the regulatory authorities to decide on proposals for further testing and assess whether dossier information provided by industry complies with the requirements.

4.1.1.3 *Authorization*—Authorization may be required for SVHC (carcinogens; mutagens; reproductive toxins; substances toxic, persistent, and bioaccumulative; substances very persistent and very bioaccumulative; and substances giving rise to equivalent concern).

4.1.1.4 *Restriction*—The safety net of the system; any substance on its own, in a preparation or in an article may be subject to community-wide restrictions if its use poses unacceptable risks to human health or the environment.

4.1.2 *Who Are the Actors in the Supply Chain?*

4.1.2.1 Manufacturers and importers of substances and preparations are obliged to register substances they produce or import in quantities greater than 1 tonne per year. Importers and producers of articles are required to register substances imported or produced in amounts greater than 1 tonne per year that are intentionally released from the articles. Failure to register means that the substance cannot be manufactured, imported, or used in the EU market.

4.1.2.2 Downstream users of chemicals shall apply the risk management measures for dangerous substances identified on the supplier safety data sheets. They shall also ensure that any substances they use in quantities greater than 1 tonne per year, which are manufactured or imported in quantities greater than 10 tonnes per year, are supported by a chemical safety report (CSR).

4.1.2.3 Other actors in the supply chain include distributors, retailers, and storage providers, all of whom are not classified as downstream users.

4.1.2.4 Consumers are not considered actors in the supply chain, but have certain rights under REACH, including the right to receive information about the presence of SVHC's in quantities >0.1 % in articles.

4.2 *Why Must REACH Information be Exchanged in Supply Chains?*

4.2.1 REACH Title IV, Information in the Supply Chain, specifically Articles 31 through 34, legally requires manufacturers and their supply chains to exchange certain information. Information exchange both upstream and downstream in the supply chain is also the only way to acquire the information necessary to meet many other requirements of the REACH regulation. Therefore, supply chain communication is both a legal requirement and a necessary activity ancillary to complying with other aspects of REACH.

4.2.1.1 Because of the often complex nature of global supply chains, a legal requirement falling upon an EU-based importer, manufacturer, or downstream user will often have both a downstream and upstream ripple effect that will extend beyond the EU and will require support from the entire supply chain. Therefore, companies based outside the EU, for example, in the United States, with no direct business in Europe, will be drawn into the supply chain information exchange process to support their customers' requirements to provide information. All global companies may find it helpful to map out their location within supply chains to determine if any substances, preparations, or articles are imported into, exported out of, or manufactured in the EU and, hence, at risk of being impacted by REACH.

4.2.2 Fig. 1 illustrates how REACH has the potential to impact all but the most isolated supply chains. Your company need not sell product in, or buy products from, the EU to be impacted, either directly or indirectly.

4.2.3 Fig. 2 depicts an example of "selling into a supply chain that imports into the EU." Note that there is no direct sale to an EU importer in this scenario, but that you sell to Customer A, who sells to the EU-based Customer D. Customer D's need for data will be cascaded down to you via the intermediary, Customer A. For example, Customer D may ask Customer A to identify the substance content of a preparation or article. Customer A may turn to you as having knowledge of this composition. Note that it is conceivable that you will need to turn to your own supplier(s) to obtain the chemical composition. Additionally, Customer D may need to describe their application to Customer A, who then may desire to provide related handling or toxicity information or both if available to help Customer D's registration process.

4.2.4 Similarly, Fig. 3 depicts an example of "purchasing out of a supply chain that exports from the EU." In this scenario, you buy from U.S.-based Supplier D, who formulates a preparation or article from Substances A and B and Preparation C. The substances in Preparation C are provided from an EU-based exporter. Any of a number of potential issues could result in an impact, including the following scenarios:

4.2.4.1 Should any of the substances in Preparation C be incorporated into the EU's candidate for authorization list, Preparation C (and hence Preparation/Article D) may no longer be available, or at least be subject to substantially increased costs.

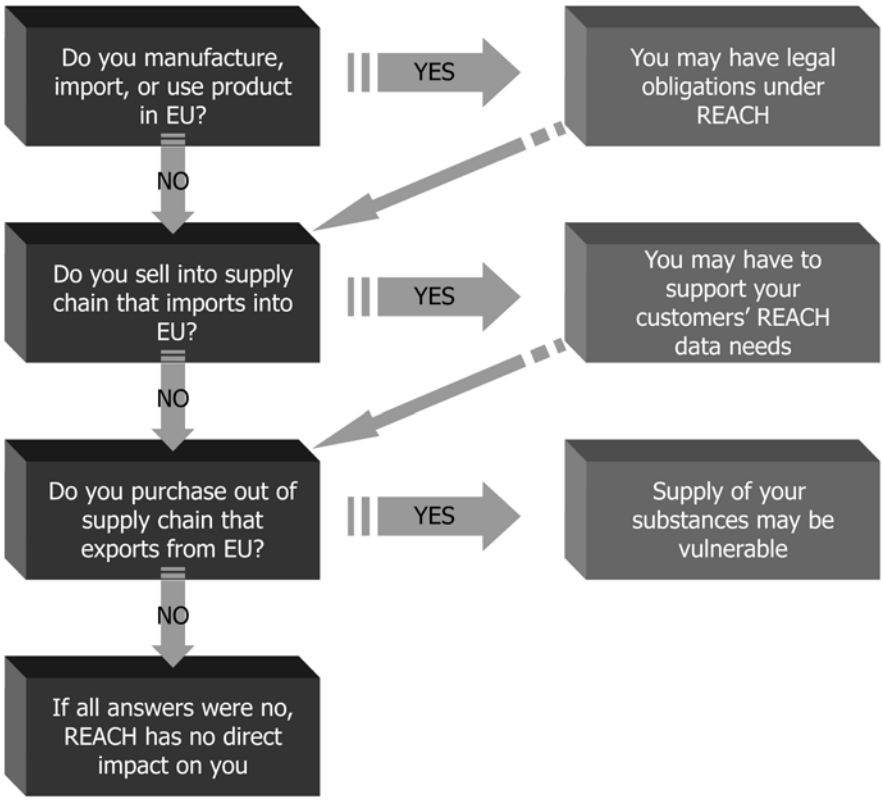
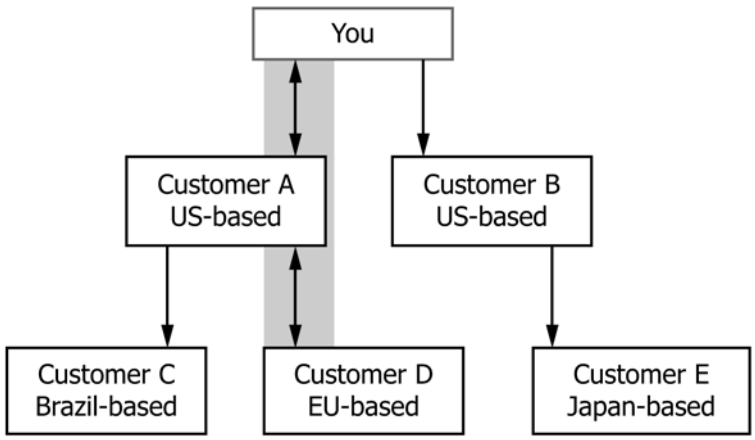


FIG. 1 Determining Your REACH Obligations



NOTE 1—Customer D requirements will be cascaded down to you via tier one supplier (Customer A)

FIG. 2 Example of Selling into a Supply Chain that Imports into EU

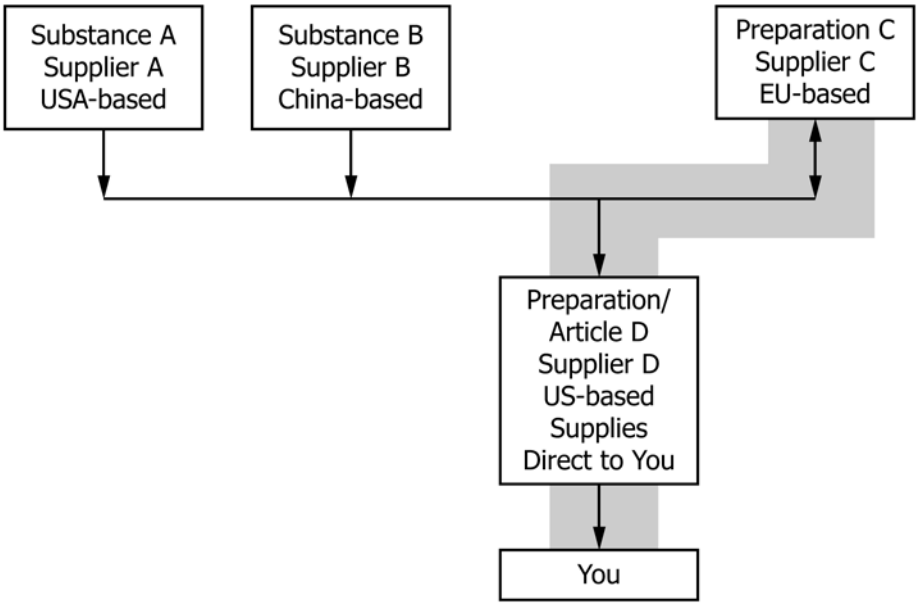
4.2.4.2 The cost of registration may exceed Supplier C's desire to continue producing Preparation C.

4.2.4.3 Supplier C may choose to substitute substances/preparations used in Preparation C and may or may not tell Supplier D, who may or may not be able to pass this information along.

4.2.5 To avert surprise supply changes or price increases or both, proactively mapping out the supply chain and making a determination about the reliability of Preparation/Article D's supply is highly recommended. Note that this effort may be complicated by the fact that you have no direct contractual relationship with Supplier C and may therefore need to coordinate the investigation via Supplier D to address confidentiality and other concerns adequately.

5. Significance and Use

5.1 This guide recommends practices and solutions for global supply chain information exchange for substances, preparations, and articles as identified by REACH. The first five annexes of REACH guidance standards serve as a central repository for REACH industry guidance that spans industry sectors and facilitates collaboration across complex global supply chains. Annexes 6-9 provide key EU guidance on information exchange in the supply chain.



NOTE 1—You have a potentially vulnerable material, since Material C is supplied by an EU-based supplier. You will want to know about substances in Material C and whether they are on the Candidate List. You may have to work via Supplier D who has the direct contractual relationship with Supplier C.

FIG. 3 Example of Purchasing out of Supply Chain that Exports from EU

5.2 Section 6 outlines the information that is to be exchanged in the supply chain both in the upstream and downstream directions. Fig. 4 provides a schematic depicting data flow in the upstream and downstream directions. A list of the

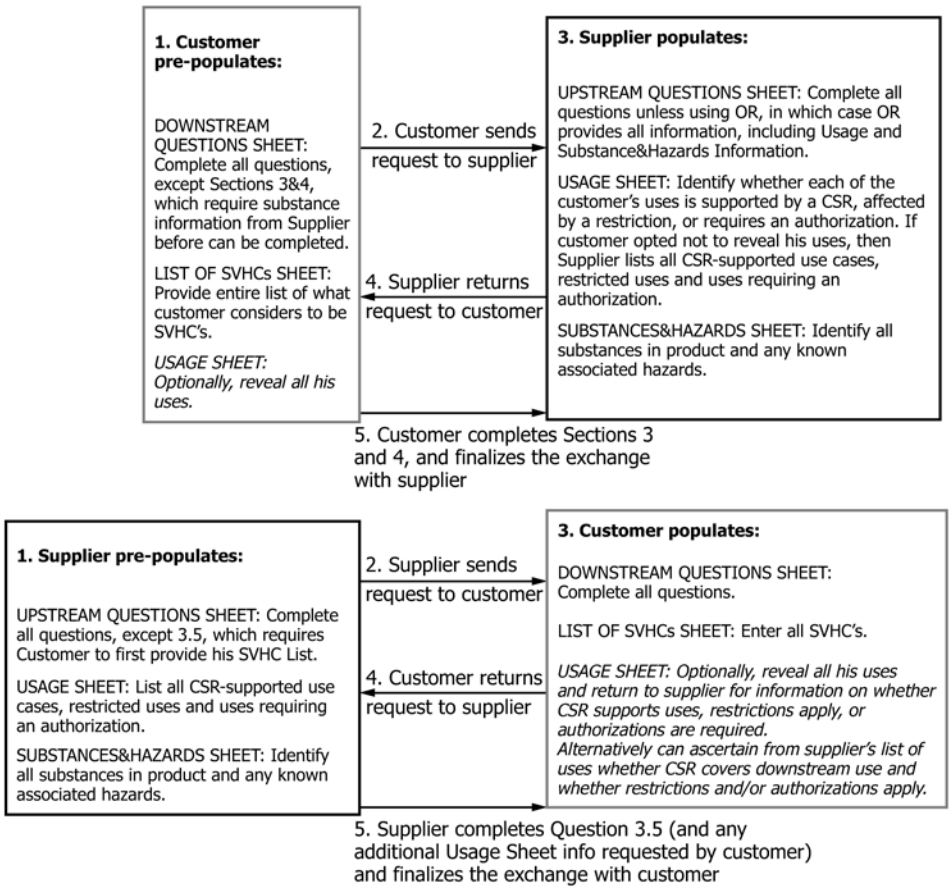


FIG. 4 Data Flow Pathway for F40 Supply Chain Communications

elements to be included in this exchange is represented in Tables 1-5 that capture the necessary data fields for information exchange. Case studies 1-3 in Annex A1 – Annex A3 provide three sample scenarios wherein a customer and supplier complete these five tables to exchange data to address their REACH compliance issues.

6. What Information Shall be Communicated Through the Supply Chain?

6.1 The REACH regulation provides certain obligatory data elements that shall be exchanged between certain actors in the supply chain, but does not stipulate a complete base set of data to be communicated throughout all supply chains for all actors. Rather, REACH's 15 Titles and 17 Annexes detail a set of obligations that affect EU-based companies. A collection of technical guidance documents, the RIPs, then provide general guidelines as to how companies might meet these obligations through collaborative engagement of their supply chains, both inside and outside of Europe.

6.2 If, however, one looks at the dataset that would be necessary to make informed decisions regarding the critical elements of REACH, that is, preregistration, registration, evaluation, authorization, restriction, notification, testing, exemptions, hazards, risks, exposure scenarios, alternative substances, and so forth, there are certain key data elements that emerge as having highest priority.

6.2.1 Some of these elements are described in the RIPs. For the purpose of supply chain communication of critical data elements, RIPs 3.4, 3.5, and 3.8, which are included in Annexes 6, 7 and 8 of REACH RIP Guidance Documents, are important in highlighting information exchange needs.

6.3 From the REACH Regulation itself, there are some directly mandated information exchange requirements for companies doing business in the EU. Most of the case studies contained in the RIPs envision that data will be exchanged on a product-by-product basis, as products are the most convenient units of currency in data exchange throughout the supply chain. However, as REACH regulates substances in products rather than the products themselves, all this product data shall be evaluated at the substance level.

6.3.1 A summary of these requirements follows. Note that this data shall flow bidirectionally up and down the supply chain.

6.3.1.1 *Article 31*—Safety data sheet requirements data needs:

(1) CAS number
(2) Registration number
(3) Identity of substance/preparation
(4) EINECS or ELINCS number
(5) Use of substance/preparation
(6) Company identity
(7) Emergency telephone number
(8) Classification and labeling consistent with REACH Title II
(9) Concentration of constituent substances (for preparations)—shall indicate for at least all hazardous substances as defined by Directives 1999/45/EC and 67/548/EC and for other hazardous substances of equivalent concern
(10) First aid measures
(11) Fire-fighting measures
(12) Accidental release measures
(13) Handling and storage
(14) Exposure controls/personal protection
(a) Exposure limits
(b) Occupational exposure controls
(c) Environmental exposure controls
(15) Physical properties, that is, boiling point, pH, and density

TABLE 1 UPSTREAM QUESTIONS: Information Request–Upstream Direction, Supplier would populate for Customer

0.		Data	Required or Optional?	Expected Response/Comments
1. Company Information - Supplier	1.1	Company Name	Required	Name of supplier/manufacturer.
	1.2	Company ID #	Required	Supplier/Vendor ID #
	1.3	Mailing Address	Required	Physical post-office mailing address of company.
	1.4	REACH Responsible Individual Name	Required	Name of person whom all REACH communications go to.
	1.5	Contact Phone #	Required	Phone number of this person.
	1.6	Contact Fax #	Required	Fax number of this person.
	1.7	Contact Email	Required	Email address of this person.
2. Product Information	2.1	Product Name	Required	Common trade name.
	2.2	Supplier's Part/Material #	Required	Supplier's internal part/material #. May be same as customer's part/material #.
	2.3	Is product a Substance, Preparation or Article?	Required	See REACH definitions.
	2.4	If it is an Article, what is Article's weight (kg)?	Optional, provide justification if omitted	Preferably this information is exchanged as customer will need to roll-up substance info and divide by article weight to determine 0.1% threshold for SVHC's.
	2.5	Are you a Manufacturer or Importer of Product in EU?	Required	See REACH definitions.
	2.6	Are you a Downstream User of Product in EU?	Required	See REACH definitions.

TABLE 1 *Continued*

0.		Data	Required or Optional?	Expected Response/Comments
3. Substance Information NOTE: Must iterate through Section 3 for EACH SUBSTANCE IN PRODUCT	3.1	Substance Name	Optional, provide justification if omitted	Preferably official IUPAC name, but see RIP 3.10 for substance naming conventions.
	3.2	CAS number	Optional, provide justification if omitted	May not be applicable, as per RIP 3.10, CAS numbers do not always correspond to unique substances.
	3.3	EC Number (EINECS, ELINCS or NLP)	Optional, provide justification if omitted	See http://ecb.jrc.it/esis/ for #'s.
	3.4	Do you know of any company who will register this substance?	Optional, provide justification if omitted	Will rarely be available in early stages of REACH.
	3.5	Is it an SVHC, per the list we reference–see **"LIST OF SVHC's" Sheet**	Required.	Requestor should reference his own list, i.e. aerospace, automotive, EU candidate list, JIG list, or customized list.
	3.6	Is it a phase-in-substance?	Optional, provide justification if omitted	Does it already exist on the market, per REACH definition of "existing substance"?
	3.7	If in Preparation or Article, what is wt/wt concentration (%) ?	Optional, provide justification if omitted	Should be supplied at least for all substances >0.1% concentration.
	3.8	If in Article, is it intentionally released?	Required	See REACH definitions.
	3.9	What is Classification and Labeling category?	Required	See Articles 4 and 6 of 67/548/EEC for categories; also, see ECHA-published Article 112 Classification and Labeling Inventory, when it becomes available.
	3.10	Do you plan to register substance?	Required	If not, should state reason why not.
	3.11	Do you plan to pre-register substance?	Required	If not, should state reason why not.
	3.12	Envisaged tonnage band/ registration deadline	Required	1-10 t, 10-100 t, 100-1000 t, >1000 t.
	3.13	Are there any restricted uses for the substance? If so, do any prohibit requestor's (customer's) uses per **"USAGE" Sheet**?	Required	Supplier must inform customer, if and when, any restricted use is included in Annex 17 of REACH. Requestor (customer) can specify uses on **"USAGE" Sheet**, Column C. Responder (supplier) can then answer whether each individual use is restricted in Column E. Alternatively, supplier can list all restricted uses in Column H, and customer can then ascertain whether his uses are restricted per Annex 17. Keep in mind restrictions apply to particular substances rather than whole products.
	3.14	Has an authorization application been filed for use of substance in this product? If so, does it cover requestor's (customer's) uses per **"USAGE" Sheet**?	Required	Supplier should inform customer, if and when an authorization is sought. Requestor (customer) can specify uses on **"USAGE" Sheet**, Column C. Responder (supplier) can then answer whether each individual use has been applied for in Column F. Alternatively, supplier can list all authorization applications in Column I, and customer can then ascertain whether his uses will be applied for, or whether he must complete his own application for his use(s). Keep in mind authorizations apply to particular substances rather than whole products.
	3.15	If substance is subject to authorization, can it be substituted, and, if so, by what date do you plan to do so?	Required, if substance is on Annex 14 List.	For certain Annex 14 substances, if they can be adequately controlled, substitution is encouraged, but not legally required.
	3.16	Have you joined a SIEF or Consortium for this substance, and, if so, would you welcome our participation?	Optional, provide justification if omitted	Supplier may have useful information to contribute either directly to customer or as a third party data holder for the entire SIEF.
	3.17	Are there any relevant exemptions that you are aware of for uses of this substance in this product?	Required	Include exemptions from registration, evaluation, restriction, authorization, communication, etc…and any exemptions from the entire scope of REACH.
	3.18	Do you possess any hazard or toxicity data, or both, including basic physico-chemical properties of the substance? Unless this has been provided in an SDS or CSR, or both, please indicate possession of such data by placing a "Y" in appropriate column of **"SUBSTANCES & HAZARDS" Sheet**.	Required, if supplier possesses any such data. Any such data is likely to be in a lengthy report or study format and should be delivered separately from the information in this form.	The requirements of Section 3.18 can be fully met with a SDS or CSR, or both. If either of these have been communicated, Upstream Question 3.18's answer can simply reference those documents. However, since SDS's are not required for articles or for products purchased outside of EU, and CSR's are not required for substances manufactured/imported<10 tonnes/yr, hazards data will need to be communicated via this question for many products.

TABLE 1 *Continued*

0.		Data	Required or Optional?	Expected Response/Comments
4. Business Information - Supplier	4.1	Will you continue to supply this product?	Required	If not, should specify when production will cease.
	4.2	Will your CSR cover my uses of your Product? See **"USAGE" Sheet**.	Response required (although covering such uses is not legally required, so answer can be "NO").	Requestor (customer) can specify uses on **"USAGE" Sheet**, Column C. Responder (supplier) can then answer whether each individual use is supported in Column D. Alternatively, supplier can list all uses supported in Column G, and customer can then ascertain whether his uses are encompassed in Column G.
5. Only Rep Information	5.1	Registrant Name	Required if answer to 3.4 is YES	Registrant will be required to provide registration number to its customers
	5.2	Registrant Physical Address	Required if answer to 3.4 is YES	Registrant will be required to provide registration number to its customers
	5.3	Registrant Contact Individual	Required if answer to 3.4 is YES	Registrant will be required to provide registration number to its customers
	5.4	Registrant Phone #	Required if answer to 3.4 is YES	Registrant will be required to provide registration number to its customers
	5.5	Registrant Email	Required if answer to 3.4 is YES	Registrant will be required to provide registration number to its customers
	5.6	Is this Registrant your Only Representative?	Required if answer to 3.4 is YES	Only Rep will be required to provide registration number to its customers

(16) Toxicological information
(17) Ecological information
(18) Disposal information
(19) Transport information
(20) Regulatory information (at community level)

6.3.1.2 *Article 32*—Downstream supply chain communication requirements for substances and preparations that do not require safety data sheets:

(1) Is the substance subject to authorization, restriction or registration? If so, what are the details of the plan and status of the process?

(2) Any other risk management information.

6.3.1.3 *Article 33*—Downstream information requirements for articles:

(1) For SVHC, in articles at above 0.1 weight %, what are the SVHC and what are the safe use requirements?

(2) SVHC information (at a minimum, identity of the substance) shall be available to consumers within 45 days of any request.[5]

6.3.1.4 *Article 34*—Upstream supply chain communication requirements for substances and preparations:

(1) New, updated information regarding risks or hazards shall be communicated by customers to upstream suppliers as soon as it becomes available to the customers.

6.3.1.5 *Article 35*—Information access for workers:

(1) Safety data sheet information (Articles 31 and 32 of REACH) shall be furnished to any workers who may be exposed to substances or preparations.

6.4 *Industry Guidance on Information to be Exchanged:*

6.4.1 Industry sector REACH guidance has provided lists of data to be collected from the supply chain. Official industry REACH guidance for several industries is given in REACH Guidance Standards, Annexes 1-5. Some of these guidance documents list data that would need to be communicated through the supply chain. For example, the Automotive and European Engineering Industries (Orgalime) Guides[6] both recommend information content to be gathered from supply chains for REACH compliance. Many of the data elements found in industry guides are already described in 6.3, as they were taken directly from the REACH regulation.

6.4.2 Additional information requirements/supply chain questions from the industry guides not discussed in 6.3 include:

(1) Amount used per year (kg)
(2) Supplier name and address
(3) Is it imported by you?
(4) Is the substance critical for your business?
(5) Have you contacted the supplier about registration for your use?
(6) Is there a confidentiality issue regarding specific uses?
(7) Will the substance be preregistered/registered? When?
(8) Will the substance/preparation continue to be available for purchase?
(9) Can SVHCs be substituted (if it is likely to be withdrawn in future)?
(10) If you need to produce data package for registration, what data are necessary?

[5] Comments on choosing an SVHC List: If full substance disclosure is not used, suppliers must list all substances on an SVHC List. Several industries are developing their own SVHC Lists, however the Candidate List of the European Chemicals Agency will be the official legally binding list. This ASTM standard does not specify any particular industry list; it only specifies that, in the absence of full substance disclosure, some SVHC List must be referenced. Even if full supplier substance disclosure occurs, the customer must still evaluate these substances against an SVHC List.

[6] Available from www.orgalime.org.

TABLE 2 DOWNSTREAM QUESTIONS: Information Request–Downstream Direction, Customer would populate for Supplier

0.		Data	Required or Optional?	Expected Response/Comments
1. Company Information - Customer	1.1	Company Name	Required	Name of customer.
	1.2	Company ID #	Required	Customer ID #.
	1.3	Mailing Address	Required	Physical post-office mailing address of company.
	1.4	REACH Responsible Individual Name	Required	Name of person which all REACH communications go to.
	1.5	Contact Phone #	Required	Phone number of this person.
	1.6	Contact Fax #	Required	Fax number of this person.
	1.7	Contact Email	Required	Email address of this person.
2. Product Information	2.1	Product Name	Required	Common trade name.
	2.2	Customer's Part/Material #	Required	Customer's internal part/material #. May be same as Supplier's part/material #.
	2.3	Are you a Manufacturer or Importer of Product in EU?	Required	See REACH definitions.
	2.4	Are you a Downstream User of Product in EU?	Required	See REACH definitions.
3. Substance Information—Note: must be iterated for each substance in product. List of substances in product should be provided by Supplier to Customer, using **"SUBSTANCES & HAZARDS" Sheet** before Customer completes this section.	3.1	Substance Name	Required - but supplier should first provide list of substances in the product for the customer on **"SUBSTANCES & HAZARDS" Sheet**.	Take exact name from **"SUBSTANCES & HAZARDS" Sheet**, so will correspond to supplier's name.
	3.2	Do you plan to register this substance?	Required - but supplier should first provide list of substances in the product for the customer on **"SUBSTANCES & HAZARDS" Sheet**.	If not, should state reason why not.
	3.3	Do you plan to pre-register this substance?	Required - but supplier should first provide list of substances in the product for the customer on **"SUBSTANCES & HAZARDS" Sheet**.	If not, should state reason why not.
	3.4	Envisaged tonnage band/ registration deadline	Required, if answer to 3.1 or 3.2 is "YES"	1-10 t, 10-100 t, 100-1000 t, >1000 t.
	3.5	Are there any restricted uses for the substance? If so, do any prohibit your uses per **"USAGE" Sheet**?	Required - but supplier should first provide list of substances in the product for the customer on **"SUBSTANCES & HAZARDS" Sheet**.	Supplier must inform customer, if and when, any restricted use is included in Annex 17 of REACH. Requestor (supplier) can specify restricted uses on **"USAGE" Sheet**, Column H. Responder (customer) can then ascertain whether each individual use is restricted. Alternatively, customer can list all his uses in Column C, and supplier can then deterimine and inform customer whether his uses are restricted per Annex 17, by filling in Column E. Bear in mind restrictions apply to particular substances rather than whole products.
	3.6	Has an authorization application been filed for use of substance in this product? If so, does it cover your uses per **"USAGE" Sheet**?	Required - but supplier should first provide list of substances in the product for the customer on **"SUBSTANCES & HAZARDS" Sheet**.	Supplier should inform customer, if and when an authorization is sought. Requestor (supplier) can specify applied-for uses on **"USAGE" Sheet**, Column I. Responder (customer) can then ascertain whether each individual has been applied for. Alternatively, customer can list all his uses in Column C, and supplier can then deterimine and inform customer whether his uses are applied for, by filling in Column F. Bear in mind authorizations apply to particular substances rather than whole products.

(11) Who else supplies the substance or preparation and can you form a consortium?

(12) Who are your downstream users and for what use do they use the substance?

6.5 A standard REACH dataset to be exchanged within all supply chains is suggested in Tables 1-5. To use Tables 1-5, first, as per Fig. 1, determine your own legal and market obligations under REACH. Then per Figs. 2 and 3, map out

TABLE 2 *Continued*

0.		Data	Required or Optional?	Expected Response/Comments
	3.7	If substance is subject to authorization, can it be substituted, and, if so, by what date do you plan to do so?	Required, if substance is on Annex 14 List.	For certain Annex 14 substances, if they can be adequately controlled, substitution is encouraged, but not legally required.
	3.8	Have you joined a SIEF or Consortium for this substance, and, if so, would you welcome our participation?	Optional, provide justification if omitted	Customer may have useful information to contribute either directly to supplier or as a third party data holder for the entire SIEF.
	3.9	Are there any relevant exemptions that you are aware of for uses of this substance in this product?	Required - but supplier should first provide list of substances in the product for the customer on **"SUBSTANCES & HAZARDS" Sheet**.	Include exemptions from registration, evaluation, restriction, authorization, communication, etc....and any exemptions from the entire scope of REACH.
4. Business Information	4.1	Will you cease use of this Product due to REACH?	Required	If ending purchases, should specify when purchase will cease.
	4.2	Will Supplier's CSR cover Customer's uses of Product? See **"USAGE" Sheet**.	Response required (although covering such uses is not legally required, so answer can be "NO").	Requestor (supplier) can specify all uses he supports on **"USAGE" Sheet**, Column G, and responder (customer) can then ascertain whether his uses are encompassed within Column G. Alternatively, responder (customer) can list all his uses in Column C, then send back to supplier for the supplier to determine whether each individual downstream use is supported and to record the answer in Column D.

TABLE 3 LIST OF USES Referenced in Upstream and Downstream Questions 4.2, to be completed by both Customer (optionally) and Supplier

0.	TYPICAL PROTOCOL WILL BE FOR CUSTOMER TO FIRST REVEAL USES OR USE CATEGORIES IN COLUMN C TO SUPPLIER, WHO WOULD THEN ANSWER WHICH OF THESE USES WILL BE COVERED IN COLUMN D. ALTERNATIVELY, SUPPLIER COULD LIST ALL USES SUPPORTED – IN COLUMN E, AND THEN CUSTOMER COULD CHECK TO SEE IF HIS WERE COVERED ON THIS LIST, THEN MERELY ANSWER "YES" OR "NO" ON UPSTREAM QUESTION 4.2. IF ANSWER IS "NO" AND CUSTOMER DOES NOT WISH TO REVEAL USES, HE MUST CONDUCT HIS OWN SAFETY ASSESSMENT. NOTE THAT ALL QUESTIONS ARE SUBSTANCE-SPECIFIC.						
	DOWNSTREAM CUSTOMER USES THIS PRODUCT FOR THE FOLLOWING USES:	IS CUSTOMER USE SUPPORTED BY SUPPLIER CSR?	IS CUSTOMER USE PROHIBITED BY AN ANNEX 17 RESTRICTION?	IS CUSTOMER USE COVERED BY AN AUTHORIZATION APPLICATION?	UPSTREAM SUPPLIER CSR SUPPORTS THE FOLLOWING USES FOR THIS PRODUCT:	UPSTREAM SUPPLIER IS AWARE OF THE FOLLOWING ANNEX 17 RESTRICTIONS FOR SUBSTANCES IN THIS PRODUCT (LIST NAME OF SPECIFIC SUBSTANCES ALSO):	UPSTREAM SUPPLIER HAS APPLIED FOR THE FOLLOWING AUTHORIZATIONS FOR SUBSTANCES IN THIS PRODUCT (LIST NAME OF SPECIFIC SUBSTANCES ALSO):
USE #	(TO BE COMPLETED BY CUSTOMER)	(TO BE COMPLETED BY SUPPLIER, IF CUSTOMER COMPLETES COLUMN C)	(TO BE COMPLETED BY SUPPLIER, IF CUSTOMER COMPLETES COLUMN C)	(TO BE COMPLETED BY SUPPLIER, IF CUSTOMER COMPLETES COLUMN C)	(TO BE COMPLETED BY SUPPLIER, IF CUSTOMER DOES NOT WISH TO REVEAL USES BY COMPLETING COLUMN C)	(TO BE COMPLETED BY SUPPLIER, IF CUSTOMER DOES NOT WISH TO REVEAL USES BY COMPLETING COLUMN C)	(TO BE COMPLETED BY SUPPLIER, IF CUSTOMER DOES NOT WISH TO REVEAL USES BY COMPLETING COLUMN C)
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
...etc.							

your entire supply chain in upstream and downstream directions. Then, approach those actors in your supply chain in both the upstream and downstream directions.

6.6 Fig. 4 illustrates the information flow pathways for these data requirements, describing first an exchange initiated by a customer and then an exchange initiated by a supplier.

TABLE 4 List of Substances

To be populated by supplier.																					
List of Substances in Product to be provided by Supplier to Customer		Supplier should place "Y" in any boxes below for any substance for which he possesses hazard data.																			
substance #	substance name	human health hazard assessment, see Annex 1, Section 1 of REACH	physicochemical hazard assessment, see Annex 1, Section 2 of REACH	environmental hazard assessment, see Annex 1, Section 3 of REACH	PBT and vPvB assessment, see Annex 1, Section 4 of REACH	exposure assessment, see Annex 1, Section 5 of REACH	risk characterization, see Annex 1, Section 6 of REACH	first aid measures, see Annex 2, Section 4 of REACH	fire fighting measures, see Annex 2, Section 5 of REACH	accidental release measures, see Annex 2, Section 6 of REACH	handling and storage, see Annex 2, Section 7 of REACH	exposure control/personal protection, see Annex 2, Section 8 of REACH	physico-chemical properties, see Annex 2, Section 9 of REACH	stability and reactivity, see Annex 2, Section 10 of REACH	toxicological information, see Annex 2, Section 11 of REACH	ecological information, see Annex 2, Section 12 of REACH	disposal considerations, see Annex 2, Section 13 of REACH	transport information, see Annex 2, Section 14 of REACH	regulatory information, see Annex 2, Section 15 of REACH	other information, see Annex 2, Section 16 of REACH
3.1.a	Use substance name from Upstream Question 3.1																				
3.1.b	Use substance name from Upstream Question 3.1																				
3.1.c	Use substance name from Upstream Question 3.1																				
3.1.d	Use substance name from Upstream Question 3.1																				
…etc.	…etc.																				

TABLE 5 LIST OF SVHC's Referenced in Upstream Question 3.5

To be populated by customer.			
Disclosure of substances on this list in any preparation or article is MANDATORY.			
List Item #	Substance Name	CAS#	EC#
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
…etc.			

6.7 Case Studies 1-3 in Annex A1 – Annex A3 illustrate the process of exchanging data for three representative scenarios.

7. Keywords

7.1 chemicals; REACH; supply chain

ANNEXES

(Mandatory Information)

A1. CASE STUDY 1: INFORMATION EXCHANGE INITIATED BY SOLDER IMPORTER (CUSTOMER) TO NON-EU SOLDER MANUFACTURER (SUPPLIER)

A1.1 Henry Ohm, who is the REACH-responsible individual for Circuit Board Importers, Inc. (CBI), prepopulates the "Downstream Questions" sheet in advance of sending out its request to his supplier, Lead Free Solder, Inc. He wishes to have Lead Free's response within two weeks and notes that in the "Please respond by" section (Section 0).

A1.2 Sections 1.1 and 1.3-1.7 are information that CBI has in its compliance database, which is used to populate automatically requests to suppliers. Section 1.2 sometimes differs for CBI from supplier to supplier, so the specific customer number "222" that Lead Free Solder uses to communicate with CBI is used in Section 1.2.

A1.3 CBI wishes to know about the solder that Lead Free sells them, which CBI imports into several EU member states (thus requiring a "yes" answer to 2.3). CBI completes the remainder of the product-specific information in Section 2 of the "Downstream Questions" sheet, identifying the product as "Special Solder" with the CBI part number "222222."

A1.4 CBI is unable to complete Section 3 of the "Downstream Questions" sheet because Lead Free needs to first provide the substance information before CBI can answer the specific question, so Section 3 is left blank in the prepopulation step.

A1.5 Section 4 also may require some input from Lead Free before CBI can complete it. Question 4.1 is difficult to answer without a knowledge of which substances are contained in the product. For example, if there are no SVHCs in the solder, there is little reason for CBI to change its purchasing patterns because of REACH. If, however, the solder contains a carcinogen per Directive 67/548/EEC, it would be more likely that CBI will begin to explore alternative sources of solder.

A1.6 Question 4.2 will also require the supplier to respond in advance of the customer's answer. If the customer does not wish to reveal his uses to the supplier, he may leave Question 4.2 blank and direct the supplier to complete the "Usage" sheet and then subsequently make the determinations as to whether the customer's uses are covered by the supplier's chemical safety report (CSR) exposure scenario(s), which will be listed by the supplier in the "Usage" sheet. In this case, CBI has no problem revealing its use as "soldering wires to connectors on board," which is listed on the "Usage" sheet in Column C. However, CBI must still wait for Lead Free to look at the "Usage" sheet, at which point, Lead Free will respond in Columns D, E, and F as to whether CBI's uses are covered by a lead-free CSR, are prohibited by an Annex 17 restriction, or are the subject of an application authorization.

A1.7 Also note that it is conceivable that occasionally other sections of the form may not be able to be completed without some input from another actor in the supply chain. For example, it is not always trivial to determine whether you or your supplier is the actual importer of record for a product (Questions 2.3 and 2.4 of "Downstream Questions" sheet). CBI's purchasing and legal staff conferred and discovered that it was importing special solder and provided the answers to Questions 2.3 and 2.4 to Henry Ohm. However, few (including Mr. Ohm) had known that CBI actually imported this product. Up until the process of gathering and exchanging REACH information, almost everyone at CBI had assumed that Lead Free was an EU-based company since nearly all of CBI's dealings had been with Lead Free's branch sales office in the United Kingdom.

A1.8 Finally, CBI imports a standard electronics industry SVHC list into the "List of SVHCs" sheet. CBI has downloaded this list from an electronics industry organization website. This (fictional) list contains 500 substances and is representative of the consensus of what constitutes an SVHC for companies in the electronics industry. CBI could also add substances to this list if it wished to consider borderline SVHCs that may end up on the EU Candidate List someday. CBI realizes that if a substance appears on the EU Candidate List, it will be responsible for querying its suppliers on the presence of that new substance in CBI products. CBI subscribes to an electronics industry alert service that notifies all industry organization members when a new substance that is not on the electronics industry SVHC list appears on the EU Candidate List website. When something like this happens, CBI immediately queries any suppliers who have not provided full substance information, allowing them 14 days to identify the new SVHC.

A1.9 CBI then e-mails the file to the general business contact at Lead Free, who, after some searching around internally, locates the right department for REACH compliance and forwards it on to Matt Tinne, who is the REACH-responsible individual at Lead Free. Fortunately, there are still seven days left to respond when Mr. Tinne receives the form.

A1.10 Mr. Tinne fills out the "Upstream Questions" sheet and requests that CBI return the fully completed form to Lead Free within 21 days and notes this in Section 0. Next, he completes the Section 1 contact information. CBI will now be able to bypass the general business contact at Lead Free in future information exchanges and communicate directly with Mr. Tinne.

A1.11 Section 2 of the "Upstream Questions" sheet is completed with the Lead Free part/material number "111111," which will correspond to the CBI part/material number "222222." Sections 2.3-2.6 are answered based on an understanding of the REACH definitions for substances/preparations/articles and the manufacturer, importer, and downstream user actors in the supply chain. Solder is a mixture of substances that are not formed into any definite shape or form and is clearly a "preparation" under REACH. As a U.S.-based company, Lead Free is a non-actor in the supply chain, so it does not fall into any of the manufacturer/importer/downstream user categories.

A1.12 Lead Free completes Section 3 based on its RoHS compliance substance database. Much of the substance information, that is, (3.1) names, (3.2) CAS numbers, and (3.7) percent composition are able to be exported from the RoHS database into the REACH form. Information that is not readily available, such as (3.3) EC number, is looked up on the EU websites, such as http://ecb.jrc.it/existing-chemicals.

A1.13 Knowledge about registrants (3.4) will generally be available by 2010 for common metals like silver, copper, and tin; but as this form is being completed in 2008, no such information yet exists. Lead Free checks the "List of SVHCs" sheet with the list of substances imported by CBI and determines that none of the three substances are SVHCs per the list, so it answers "No" to Question 3.5 for each of the three substances. All the substances are phase-in substances per REACH definitions (Question 3.6).

A1.14 As solder is a preparation, rather than an article, 3.8 is not applicable, and as Lead Free is a U.S.-based company, 3.10-3.12 are not relevant as there is no legal obligation for Lead Free to consider whether a registration is necessary or not. Although Lead Free is not legally obligated to do so, Matt Tinne consults the list of restricted uses in Annex 17 of REACH, discovers that none apply to tin, silver, or copper, and notes this for each in Question 3.13.

A1.15 As these substances are not SVHCs, 3.14 and 3.15 are not applicable as there are no immediate risks for any of the substances being added to Annex 14, which would require an authorization application.

A1.16 Because it is not an importer and its substances are not likely SVHCs, Lead Free has not seen a need to join an industry consortium and answers "no" to 3.16. From Lead Free's knowledge of REACH, there are no relevant exemptions for the product they are selling, although it is conceivable that some of Lead Free's customers may be able to avail themselves of application-specific exemptions, that is, a defense-related exemption for a military application.

A1.17 Lead Free has a variety of health and safety information from its Materials Safety Data Sheets and other sources. Although the data do not exactly correspond to what is needed under REACH, Lead Free indicates the availability of the data by answering "yes" to Question 3.18 for each of the substances. Lead Free then goes to the "Substances & Hazards" sheet and enters each of the three substance names and fills in a "Y" for each type of data it possesses on each substance. This safety will not necessarily be exchanged at this point, but CBI will now be aware that Lead Free is a potential source of this information in case CBI needs it to control adequately risks of using the substances.

A1.18 Lead Free sees no issues with continuing the supply of special solder under the new REACH regime and answers 4.1 with a "yes." Question 4.2 is not relevant as Lead Free is based in the United States and does not have to complete a CSR for its product.

A1.19 Finally, Section 5 is completely inapplicable as Lead Free has no knowledge about registrants. Upon completing all sections, Mr. Tinne has a colleague review the sheets for accuracy and then sends it on to Henry Ohm at CBI.

A1.20 Mr. Ohm considers the new information provided in "Upstream Questions" in Section 3 in "Usage" and "Substances & Hazards" by Lead Free. He is now able to complete Section 3 of "Downstream Questions" based on the substance information he now has.

A1.21 Section 3.1 is populated now with the names given by Lead Free for the three substances. Upon aggregating the amounts of each substance in all preparations and substances purchased (including preparations and substances from suppliers other than Lead Free), CBI determines that the copper and silver do not rise to the 1 tonne/year threshold for registration, but tin does require a registration dossier (Question 3.3) to be completed by 2018 as it is imported in the 1 to 10t tonnage band (Question 3.4).

A1.22 CBI agrees with Lead Free's assessment that there are no restrictions or authorizations with which to be concerned (Questions 3.5-3.7). CBI has joined a tin consortium that is open to participation from data holders such as Lead Free (3.8). CBI is not aware of any exemptions for any of the three substances and answers 3.9 with a "no" for each substance.

A1.23 Turning to Section 4, Mr. Ohm answers in 4.1 that CBI is confident that it will be able to continue purchase and import the special solder product, as it is adequately prepared to address the new REACH requirements, particularly with the support provided by Lead Free. Finally, Section 4.2 is determined to be "not applicable" since Lead Free is based in the United States and not under EU jurisdiction.

A1.24 Upon completion, Mr. Ohm transmits the form to Mr. Tinne, completing the round trip of the data and ensuring that both parties have the same copy of the information. It is, of course, possible that lapses in communication, needed clarifications, or changes to the information will require future iterations of this process, but the basic foundation of the process has now been laid.

A1.25 CBI will have to consider which suppliers and customers to turn to next to complete its dataset for its REACH-impacted products. In many cases, parties to information exchange will need to draw in other parties to complete

their communications. For example, CBI may not be able to determine whether it needs to complete a registration until CBI has aggregated the amounts of substances it purchases from all suppliers. Similarly, manufacturers of complex assemblies and preparations may need to roll up information from multiple suppliers before they can answer percentage composition questions for their own customers. In certain cases, it may be advisable to return partially completed forms indicating which data is lacking and what the expected wait time is for full completion. The other party to the information exchange may be able to make decisions such as threshold determinations based on partial information; furthermore, a significant delay in responding may put you at a competitive disadvantage relative to companies who are more responsive.

TABLE A1.1 Case Study 1, Solder—UPSTREAM QUESTIONS: Information Request–Upstream Direction, Supplier would populate for Customer

0.		Data	Required or Optional?	Expected Response/Comments	Example		
1. Company Information - Supplier	1.1	Company Name	Required	Name of supplier/manufacturer.	Lead Free Solder, Inc.		
	1.2	Company ID #	Required	Supplier/Vendor ID #	111		
	1.3	Mailing Address	Required	Physical post-office mailing address of company.	123 Leadfree Drive Rohsville, USA		
	1.4	REACH Responsible Individual Name	Required	Name of person which all REACH communications go to.	Matt Tinne		
	1.5	Contact Phone #	Required	Phone number of this person.	123-555-1111		
	1.6	Contact Fax #	Required	Fax number of this person.	123-555-1112		
	1.7	Contact Email	Required	Email address of this person.	matt.tinne@leadfree.com		
2. Product Information	2.1	Product Name	Required	Common trade name.	Special Solder		
	2.2	Supplier's Part/ Material #	Required	Supplier's internal part/material #. May be same as customer's part/material #.	111111		
	2.3	Is product a Substance, Preparation or Article?	Required	See REACH definitions.	Preparation		
	2.4	If it is an Article, what is Article's weight (kg)?	Optional, provide justification if omitted	Preferably this information is exchanged as customer will need to roll-up substance info and divide by article weight to determine 0.1% threshold for SVHC's.	N/A		
	2.5	Are you a Manufacturer or Importer of Product in EU?	Required	See REACH definitions.	No		
	2.6	Are you a Downstream User of Product in EU?	Required	See REACH definitions.	No		
3. Substance Information NOTE: Must iterate through Section 3 for EACH SUBSTANCE IN PRODUCT	3.1	Substance Name	Optional, provide justification if omitted	Preferably official IUPAC name, but see RIP 3.10 for substance naming conventions.	Silver	Copper	Tin
	3.2	CAS number	Optional, provide justification if omitted	May not be applicable, as per RIP 3.10, CAS numbers do not always correspond to unique substances.	7440-22-4	7440-50-8	7440-31-5
	3.3	EC Number (EINECS, ELINCS or NLP)	Optional, provide justification if omitted	See http://ecb.jrc.it/esis/ for #'s.	231-131-3	231-159-6	231-141-8
	3.4	Do you know of any company who will register this substance?	Optional, provide justification if omitted	Will rarely be available in early stages of REACH.	N/A	N/A	N/A
	3.5	Is it an SVHC, per the list we reference–see **"LIST OF SVHC's" Sheet**	Required.	Requestor should reference his own list, i.e. aerospace, automotive, EU candidate list, JIG list, or customized list.	No	No	No
	3.6	Is it a phase-in-substance?	Optional, provide justification if omitted	Does it already exist on the market, per REACH definition of ″existing substance″?	Yes	Yes	Yes
	3.7	If in Preparation or Article, what is wt/wt concentration (%) ?	Optional, provide justification if omitted	Should be supplied at least for all substances >0.1% concentration.	3.0%	0.5%	96.5%
	3.8	If in Article, is it intentionally released?	Required	See REACH definitions.	N/A	N/A	N/A
	3.9	What is Classification and Labeling category?	Required	See Articles 4 and 6 of 67/548/EEC for categories; also, see ECHA-published Article 112 Classification and Labeling Inventory, when it becomes available.	N/A	N/A	N/A
	3.10	Do you plan to register substance?	Required	If not, should state reason why not.	No, not manufacturer or importer	No, not manufacturer or importer	No, not manufacturer or importer

TABLE A1.1 *Continued*

0.		Data	Required or Optional?	Expected Response/Comments	Example		
	3.11	Do you plan to pre-register substance?	Required	If not, should state reason why not.	No, not manufacturer or importer	No, not manufacturer or importer	No, not manufacturer or importer
	3.12	Envisaged tonnage band/registration deadline	Required	1-10 t, 10-100 t, 100-1000 t, >1000 t.	N/A	N/A	N/A
	3.13	Are there any restricted uses for the substance? If so, do any prohibit requestor's (customer's) uses per **"USAGE" Sheet**?	Required	Supplier must inform customer, if and when, any restricted use is included in Annex 17 of REACH. Requestor (customer) can specify uses on **"USAGE" Sheet**, Column C. Responder (supplier) can then answer whether each individual use is restricted in Column E. Alternatively, supplier can list all restricted uses in Column H, and customer can then ascertain whether his uses are restricted per Annex 17. Keep in mind restrictions apply to particular substances rather than whole products.	No	No	No
	3.14	Has an authorization application been filed for use of substance in this product? If so, does it cover requestor's (customer's) uses per **"USAGE" Sheet**?	Required	Supplier should inform customer, if and when an authorization is sought. Requestor (customer) can specify uses on **"USAGE" Sheet**, Column C. Responder (supplier) can then answer whether each individual use has been applied for in Column F. Alternatively, supplier can list all authorization applications in Column I, and customer can then ascertain whether his uses will be applied for, or whether he must complete his own application for his use(s). Keep in mind authorizations apply to particular substances rather than whole products.	N/A	N/A	N/A
	3.15	If substance is subject to authorization, can it be substituted, and, if so, by what date do you plan to do so?	Required, if substance is on Annex 14 List.	For certain Annex 14 substances, if they can be adequately controlled, substitution is encouraged, but not legally required.	N/A	N/A	N/A
	3.16	Have you joined a SIEF or Consortium for this substance, and, if so, would you welcome our participation?	Optional, provide justification if omitted	Supplier may have useful information to contribute either directly to customer or as a third party data holder for the entire SIEF.	No	No	No
	3.17	Are there any relevant exemptions that you are aware of for uses of this substance in this product?	Required	Include exemptions from registration, evaluation, restriction, authorization, communication, etc….and any exemptions from the entire scope of REACH.	No	No	No
	3.18	Do you possess any hazard or toxicity data, or both, including basic physico-chemical properties of the substance? Unless this has been provided in an SDS or CSR, or both, please indicate possession of such data by placing a "Y" in appropriate column of **"SUBSTANCES & HAZARDS" Sheet**.	Required, if supplier possesses any such data. Any such data is likely to be in a lengthy report or study format and should be delivered separately from the information in this form.	The requirements of Section 3.18 can be fully met with a SDS or CSR, or both. If either of these have been communicated, Upstream Question 3.18's answer can simply reference those documents. However, since SDS's are not required for articles or for products purchased outside of EU, and CSR's are not required for substances manufactured/imported<10 tonnes/yr, hazards data will need to be communicated via this question for many products.	Yes	Yes	Yes
4. Business Information - Supplier	4.1	Will you continue to supply this product?	Required	If not, should specify when production will cease.	Yes		
	4.2	Will your CSR cover my uses of your Product? See **"USAGE" Sheet**.	Response required (although covering such uses is not legally required, so answer can be "NO").	Requestor (customer) can specify uses on **"USAGE" Sheet**, Column C. Responder (supplier) can then answer whether each individual use is supported in Column D. Alternatively, supplier can list all uses supported in Column G, and customer can then ascertain whether his uses are encompassed in Column G.	N/A, not in EU		

TABLE A1.1 *Continued*

0.		Data	Required or Optional?	Expected Response/Comments	Example
5. Only Rep Information	5.1	Registrant Name	Required if answer to 3.4 is YES	Registrant will be required to provide registration number to its customers	N/A
	5.2	Registrant Physical Address	Required if answer to 3.4 is YES	Registrant will be required to provide registration number to its customers	N/A
	5.3	Registrant Contact Individual	Required if answer to 3.4 is YES	Registrant will be required to provide registration number to its customers	N/A
	5.4	Registrant Phone #	Required if answer to 3.4 is YES	Registrant will be required to provide registration number to its customers	N/A
	5.5	Registrant Email	Required if answer to 3.4 is YES	Registrant will be required to provide registration number to its customers	N/A
	5.6	Is this Registrant your Only Representative?	Required if answer to 3.4 is YES	Only Rep will be required to provide registration number to its customers	N/A

TABLE A1.2 Case Study 1, Solder—DOWNSTREAM QUESTIONS: Information Request–Downstream Direction, Customer would populate for Supplier

0.		Data	Required or Optional?	Expected Response/Comments	Example
1. Company Information - Customer	1.1	Company Name	Required	Name of customer.	Circuit Board Importers, Inc.
	1.2	Company ID #	Required	Customer ID #.	222
	1.3	Mailing Address	Required	Physical post-office mailing address of company.	4911 ECHA Drive Helsinki, Finland
	1.4	REACH Responsible Individual Name	Required	Name of person which all REACH communications go to.	Henry Ohm
	1.5	Contact Phone #	Required	Phone number of this person.	011-222222
	1.6	Contact Fax #	Required	Fax number of this person.	011-222223
	1.7	Contact Email	Required	Email address of this person.	henry.ohm@cbi.com
2. Product Information	2.1	Product Name	Required	Common trade name.	Special Solder
	2.2	Customer's Part/ Material #	Required	Customer's internal part/material #. May be same as Supplier's part/material #.	222222
	2.3	Are you a Manufacturer or Importer of Product in EU?	Required	See REACH definitions.	Yes, importer
	2.4	Are you a Downstream User of Product in EU?	Required	See REACH definitions.	No

TABLE A1.2 *Continued*

0.		Data	Required or Optional?	Expected Response/Comments	Example		
3. Substance Information—Note: must be iterated for each substance in product. List of substances in product should be provided by Supplier to Customer, using **"SUBSTANCES & HAZARDS" Sheet** before Customer completes this section.	3.1	Substance Name	Required - but supplier should first provide list of substances in the product for the customer on **"SUBSTANCES & HAZARDS" Sheet**.	Take exact name from **"SUBSTANCES & HAZARDS" Sheet** Sheet, so will correspond to supplier's name.	Silver	Copper	Tin
	3.2	Do you plan to register this substance?	Required - but supplier should first provide list of substances in the product for the customer on **"SUBSTANCES & HAZARDS" Sheet**.	If not, should state reason why not.	No, not above 1 tonne/yr import.	No, not above 1 tonne/yr import.	Yes.
	3.3	Do you plan to pre-register this substance?	Required - but supplier should first provide list of substances in the product for the customer on **"SUBSTANCES & HAZARDS" Sheet**.	If not, should state reason why not.	No, not above 1 tonne/yr import.	No, not above 1 tonne/yr import.	Yes.
	3.4	Envisaged tonnage band/registration deadline	Required, if answer to 3.1 or 3.2 is "YES"	1-10 t, 10-100 t, 100-1000 t, >1000 t.	N/A	N/A	1-10t / Jun 1, 2018
	3.5	Are there any restricted uses for the substance? If so, do any prohibit your uses per **"USAGE" Sheet**?	Required - but supplier should first provide list of substances in the product for the customer on **"SUBSTANCES & HAZARDS" Sheet**.	Supplier must inform customer, if and when, any restricted use is included in Annex 17 of REACH. Requestor (supplier) can specify restricted uses on **"USAGE" Sheet**, Column H. Responder (customer) can then ascertain whether each individual use is restricted. Alternatively, customer can list all his uses in Column C, and supplier can then deterimine and inform customer whether his uses are restricted per Annex 17, by filling in Column E. Bear in mind restrictions apply to particular substances rather than whole products.	No	No	No
	3.6	Has an authorization application been filed for use of substance in this product? If so, does it cover your uses per **"USAGE" Sheet**?	Required - but supplier should first provide list of substances in the product for the customer on **"SUBSTANCES & HAZARDS" Sheet**.	Supplier should inform customer, if and when an authorization is sought. Requestor (supplier) can specify applied-for uses on **"USAGE" Sheet**, Column I. Responder (customer) can then ascertain whether each individual has been applied for. Alternatively, customer can list all his uses in Column C, and supplier can then deterimine and inform customer whether his uses are applied for, by filling in Column F. Bear in mind authorizations apply to particular substances rather than whole products.	N/A	N/A	N/A
	3.7	If substance is subject to authorization, can it be substituted, and, if so, by what date do you plan to do so?	Required, if substance is on Annex 14 List.	For certain Annex 14 substances, if they can be adequately controlled, substitution is encouraged, but not legally required.	N/A	N/A	N/A
	3.8	Have you joined a SIEF or Consortium for this substance, and, if so, would you welcome our participation?	Optional, provide justification if omitted	Customer may have useful information to contribute either directly to supplier or as a third party data holder for the entire SIEF.	No	No	Yes. Consortium is open to data holders.
	3.9	Are there any relevant exemptions that you are aware of for uses of this substance in this product?	Required - but supplier should first provide list of substances in the product for the customer on **"SUBSTANCES & HAZARDS" Sheet**.	Include exemptions from registration, evaluation, restriction, authorization, communication, etc…and any exemptions from the entire scope of REACH.	No	No	No

TABLE A1.2 *Continued*

0.		Data	Required or Optional?	Expected Response/Comments	Example
4. Business Information	4.1	Will you cease use of this Product due to REACH?	Required	If ending purchases, should specify when purchase will cease.	No
	4.2	Will Supplier's CSR cover Customer's uses of Product? See **"USAGE" Sheet**.	Response required (although covering such uses is not legally required, so answer can be "NO").	Requestor (supplier) can specify all uses he supports on **"USAGE" Sheet**, Column G, and responder (customer) can then ascertain whether his uses are encompassed within Column G. Alternatively, responder (customer) can list all his uses in Column C, then send back to supplier for the supplier to determine whether each individual downstream use is supported and to record the answer in Column D.	N/A, supplier is US-based

TABLE A1.3 Case Study 1, Solder—LIST OF USES Referenced in Upstream and Downstream Questions 4.2, to be completed by both Customer (optionally) and Supplier

0.	TYPICAL PROTOCOL WILL BE FOR CUSTOMER TO FIRST REVEAL USES OR USE CATEGORIES IN COLUMN C TO SUPPLIER, WHO WOULD THEN ANSWER WHICH OF THESE USES WILL BE COVERED IN COLUMN D. ALTERNATIVELY, SUPPLIER COULD LIST ALL USES SUPPORTED – IN COLUMN E, AND THEN CUSTOMER COULD CHECK TO SEE IF HIS WERE COVERED ON THIS LIST, THEN MERELY ANSWER "YES" OR "NO" ON UPSTREAM QUESTION 4.2. IF ANSWER IS "NO" AND CUSTOMER DOES NOT WISH TO REVEAL USES, HE MUST CONDUCT HIS OWN SAFETY ASSESSMENT. NOTE THAT ALL QUESTIONS ARE SUBSTANCE-SPECIFIC.						
	DOWNSTREAM CUSTOMER USES THIS PRODUCT FOR THE FOLLOWING USES:	IS CUSTOMER USE SUPPORTED BY SUPPLIER CSR?	IS CUSTOMER USE PROHIBITED BY AN ANNEX 17 RESTRICTION?	IS CUSTOMER USE COVERED BY AN AUTHORIZATION APPLICATION?	UPSTREAM SUPPLIER CSR SUPPORTS THE FOLLOWING USES FOR THIS PRODUCT:	UPSTREAM SUPPLIER IS AWARE OF THE FOLLOWING ANNEX 17 RESTRICTIONS FOR SUBSTANCES IN THIS PRODUCT (LIST NAME OF SPECIFIC SUBSTANCES ALSO):	UPSTREAM SUPPLIER HAS APPLIED FOR THE FOLLOWING AUTHORIZATIONS FOR SUBSTANCES IN THIS PRODUCT (LIST NAME OF SPECIFIC SUBSTANCES ALSO):
USE #	(TO BE COMPLETED BY CUSTOMER)	(TO BE COMPLETED BY SUPPLIER, IF CUSTOMER COMPLETES COLUMN C)	(TO BE COMPLETED BY SUPPLIER, IF CUSTOMER COMPLETES COLUMN C)	(TO BE COMPLETED BY SUPPLIER, IF CUSTOMER COMPLETES COLUMN C)	(TO BE COMPLETED BY SUPPLIER, IF CUSTOMER DOES NOT WISH TO REVEAL USES BY COMPLETING COLUMN C)	(TO BE COMPLETED BY SUPPLIER, IF CUSTOMER DOES NOT WISH TO REVEAL USES BY COMPLETING COLUMN C)	(TO BE COMPLETED BY SUPPLIER, IF CUSTOMER DOES NOT WISH TO REVEAL USES BY COMPLETING COLUMN C)
1	soldering wires to connectors on board	N/A (supplier non-EEA)	N	N/A (no substances on Annex 14 list)			

TABLE A1.4 Case Study 1, Solder

To be populated by supplier.																					
List of Substances in Product to be provided by Supplier to Customer		Supplier should place "Y" in any boxes below for any substance for which he possesses hazard data.																			
substance #	substance name	human health hazard assessment, see Annex 1, Section 1 of REACH	physicochemical hazard assessment, see Annex 1, Section 2 of REACH	environmental hazard assessment, see Annex 1, Section 3 of REACH	PBT and vPvB assessment, see Annex 1, Section 4 of REACH	exposure assessment, see Annex 1, Section 5 of REACH	risk characterization, see Annex 1, Section 6 of REACH	first aid measures, see Annex 2, Section 4 of REACH	fire fighting measures, see Annex 2, Section 5 of REACH	accidental release measures, see Annex 2, Section 6 of REACH	handling and storage, see Annex 2, Section 7 of REACH	exposure control/personal protection, see Annex 2, Section 8 of REACH	physico-chemical properties, see Annex 2, Section 9 of REACH	stability and reactivity, see Annex 2, Section 10 of REACH	toxicological information, see Annex 2, Section 11 of REACH	ecological information, see Annex 2, Section 12 of REACH	disposal considerations, see Annex 2, Section 13 of REACH	transport information, see Annex 2, Section 14 of REACH	regulatory information, see Annex 2, Section 15 of REACH	other information, see Annex 2, Section 16 of REACH
3.1.a	Tin	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
3.1.b	Silver	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
3.1.c	Copper	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y

TABLE A1.5 Case Study 1, Solder—LIST OF SVHC's Referenced in Upstream Question 3.5

To be populated by customer.			
Disclosure of substances on this list in any preparation or article is MANDATORY.			
List Item #	Substance Name	CAS#	EC#
1	Substance 1 from Electronics Industry SVHC List		
2	Substance 2 from Electronics Industry SVHC List		
3	Substance 3 from Electronics Industry SVHC List		
4	Substance 4 from Electronics Industry SVHC List		
5	Substance 5 from Electronics Industry SVHC List		
6	Substance 6 from Electronics Industry SVHC List		
7	Substance 7 from Electronics Industry SVHC List		
8	Substance 8 from Electronics Industry SVHC List		
9	Substance 9 from Electronics Industry SVHC List		
10	Substance 10 from Electronics Industry SVHC List		
…etc.	…etc, 500 substances on List		

A2. CASE STUDY 2: INFORMATION EXCHANGE INITIATED BY PLATED BOLT MANUFACTURER (SUPPLIER) TO NON-EU AUTOMOTIVE MANUFACTURER (CUSTOMER)

A2.1 Kadmium Stahl, who is the REACH-responsible individual for Rodenbach Bolt, Inc. (RBI), prepopulates the "Upstream Questions" sheet in advance of sending out its request to his customer, Motor City OEM. He wishes to have Motor City's response within two weeks and notes that in the "Please respond by" section (Section 0).

A2.2 Sections 1.1 and 1.3-1.7 are information that RBI has in its compliance database, which is used to populate automatically requests to customers. Section 1.2 sometimes differs for RBI from customer to customer, so the specific supplier number "333" that Motor City uses to communicate with RBI is used in Section 1.2.

A2.3 RBI wishes to inform Motor City about the status of the bolts Rodenbach sells to Motor City, which RBI exports out of several EU member states. CBI completes the remainder of the product-specific information in Section 2 of the "Upstream Questions" sheet, identifying the product as "plated bolt" with the RBI part number "333333."

A2.4 The bolt is an article, per REACH's definition, and weighs 0.022 kg (Questions 2.3 and 2.4). RBI indicates in 2.5 that they are manufacturing the product in the EU but are not a downstream user (2.6).

A2.5 RBI completes Section 3 based on its IMDS data. Much of the substance information, that is, (3.1) names, (3.2) CAS numbers, (3.3) EC number, and (3.7) percent composition are able to be transferred into the REACH form.

A2.6 Knowledge about registrants (3.4) will generally be available by 2010 for common metals such as cadmium, copper, iron, and manganese; but as this form is being completed earlier, no such numbers yet exist. RBI is unable to answer Question 3.5 as it is not certain which SVHC list Motor City will use to define what is an SVHC. All the substances are phase-in substances per REACH definitions (3.6).

A2.7 None of the substances are intentionally released from the bolt (3.8). For 3.9, cadmium's risk phrases per Directive 67/548/EEC are entered for the classification and labeling information. This information is not applicable for the others as they are not hazardous per Directive 67/548/EEC. As none of these substances are intentionally released from the article, 3.10-3.12 are not relevant as there is no legal obligation for RBI to register. Mr. Stahl then consults the list of restricted uses in Annex 17 of REACH and discovers that Restriction #23 sets forth a group of restrictions for cadmium. He then notes this information in Column H of the "Usage" sheet and reports the fact that there are restrictions in Question 3.13. He also notes that no restrictions exist for iron, copper, carbon. or manganese.

A2.8 As carbon, manganese, iron, and copper are not SVHCs, 3.14 and 3.15 are not applicable as there are no immediate risks for any of the substances being added to Annex 14, which would require an authorization application. On Question 3.14, cadmium, however, may require an authorization for use, and RBI is preparing applications, but none of this will be relevant for Motor City as they are based in the United States. For 3.15, RBI informs Motor City that it is seeking an alternative that will replace cadmium by 2009 with a less hazardous substance. This change will affect Motor City, as the substitute will be offered outside of the EU also.

A2.9 Because it is not registering anything, RBI has not joined a SIEF and answers "no" to 3.16. Carbon appears in Annex 4 of REACH, meaning that sufficient information is known about its intrinsic properties so that it is considered a minimal risk and is exempted from Titles 2, 5, and 6 of REACH (see comment for carbon in 3.17). Other than that, from RBI's knowledge of REACH, there are no relevant exemptions for the product they are selling, although it is conceivable that some of RBI's EU customers may be able to avail themselves of application-specific exemptions, that is, a defense-related exemption for a military application.

A2.10 RBI has a variety of health and safety information from its safety data sheets and other sources. Although the data does not exactly correspond to what is needed under REACH, RBI indicates the availability of the data by answering "yes" to Question 3.18 for each of the substances. RBI then goes to the "Substances & Hazards" sheet and enters each of the five substance names and fills in a "Y" for each type of data it possesses on each substance. This safety information will not necessarily be exchanged at this point, but Motor City will now be aware that RBI is a potential source of this information in case Motor City needs it to control adequately risks of using the substances and meet any U.S. health and safety requirements.

A2.11 RBI sees no issues with continuing the supply of plated bolts under the new REACH regime and answers 4.1 with a "yes." Question 4.2 is not relevant, as Motor City is based in the United States and does need a CSR for the product.

A2.12 Finally, Section 5 is completely inapplicable, as RBI has no knowledge about registrants. Upon completing all sections, Mr. Stahl has a colleague review the sheets for accuracy and then sends it on to the general business contact at Motor City OEM, who, after some searching around internally, locates the right department for REACH compliance and forwards it on to Rose Komplient, who is the REACH-responsible individual at Motor City. Unfortunately, it is past the deadline to respond when Ms. Komplient receives the form, so she promptly contacts Mr. Stahl letting him know the response will be late. In future information exchanges, Mr. Stahl and Ms. Komplient will be able to communicate directly without intermediaries who may slow down the process of information exchange.

A2.13 Ms. Komplient then populates the "Downstream Questions" sheet. She wishes to have RBI's response within six weeks and notes that in the "Please respond by" section (Section 0).

A2.14 Sections 1.1 and 1.3-1.7 are information that Motor City has in its IMDS dataset and can automatically download. Section 1.2 sometimes differs for Motor City from supplier to supplier, so the specific customer number "444" that RBI uses to communicate with Motor City is used in Section 1.2.

A2.15 Motor City is based in the United States and answers "no" to 2.3. Motor City completes the remainder of the product-specific information in Section 2 of the "Downstream Questions" sheet, identifying the product as "plated bolt" and the Motor City part number "444444."

A2.16 Ms. Komplient considers the information provided in "Upstream Questions" in Section 3 in "Usage" and "Substances & Hazards" by RBI. She is able to complete Section 3 of "Downstream Questions" based on the substance information RBI has provided.

A2.17 Section 3.1 is populated with the names given by RBI for the five substances. Sections 3.2-3.4 are irrelevant for a U.S.-based company such as Motor City. Motor City agrees with RBI's assessment that there are no restrictions or authorizations to be concerned about for a U.S.-based customer

(Questions 3.5-3.7). Motor City is not a member of any substance-specific consortium or SIEF (3.8). Motor City is not aware of any exemptions (other than the carbon-specific exemption given in REACH Annex 4) for the product and answers 3.9 with a "no" for four of the five substances.

A2.18 Turning to Section 4, Ms. Komplient answers in 4.1 that Motor City can continue to purchase the plated bolt product as long as Rodenbach moves to replace the cadmium as scheduled. Finally, Section 4.2 is determined to be "not applicable" since Motor City is based in the United States and not under EU jurisdiction.

A2.19 Note that often sections of the form may not be able to be completed without some input from another actor in the supply chain. For example, it is not always trivial to determine whether you or your supplier is the actual importer of record for a product (Questions 2.3 and 2.4 of "Downstream Questions" sheet). Motor City's purchasing and legal staff conferred and discovered that it was importing plated bolts from the EU and provided the answers to 2.3 and 2.4 to Rose Komplient. However, few (including Ms. Komplient) had known that Motor City actually sourced this product from the EU.

A2.20 Finally, Motor City imports a standard automotive industry SVHC list into the "List of SVHCs" sheet. Motor City has downloaded this list from an automotive industry organization website. This (fictional) list contains 500 substances and is representative of the consensus of what constitutes an SVHC for companies in the automotive industry. Motor City could also add substances to this list if it wished to consider borderline SVHCs that may end up on the EU candidate list someday.

A2.21 Upon completion, Ms. Komplient transmits the form to Mr. Stahl, completing the round trip of the data and ensuring that both parties have the same copy of the information. It is, of course, possible that lapses in communication, needed clarifications, or changes to the information will require future iterations of this process, but the basic foundation of the process has now been laid.

A2.22 RBI is not surprised to see that cadmium appears on the automotive industry SVHC list and notes its status with a "yes" for Question 3.5 of the "Upstream Questions" sheet. "No" is entered for each of the other four substances for RBI's own records, and ideally, the altered form should be returned to Motor City for the sake of completeness (although Motor City can easily make the determination about cadmium being on its SVHC list on its own).

A2.23 RBI will have to consider which suppliers and customers to turn to next to complete its dataset for its REACH-impacted products. In many cases, parties to information exchange will need to draw in other parties to complete their communications. For example, a customer may not be able to determine whether it needs to complete a registration until it has aggregated the amounts of substances it purchases from all suppliers. Similarly, manufacturers of complex assemblies and preparations may need to roll up information from multiple suppliers before they can answer percentage composition questions for their own customers. In certain cases, it may be advisable to return partially completed forms indicating which data is lacking and what the expected wait time is for full completion. The other party to the information exchange may be able to make decisions such as threshold determinations based on partial information; furthermore, a significant delay in responding may put you at a competitive disadvantage relative to companies who are more responsive.

TABLE A2.1 Case Study 2, Plated Bolt—UPSTREAM QUESTIONS: Information Request–Upstream Direction, Supplier would populate for Customer

0.		Data	Required or Optional?	Expected Response/Comments	Example
1. Company Information - Supplier	1.1	Company Name	Required	Name of supplier/manufacturer.	Rodenbach Bolt Inc.
	1.2	Company ID #	Required	Supplier/Vendor ID #	333
	1.3	Mailing Address	Required	Physical post-office mailing address of company.	38 Article Drive Reach am Main, Germany
	1.4	REACH Responsible Individual Name	Required	Name of person which all REACH communications go to.	Kadmium Stahl
	1.5	Contact Phone #	Required	Phone number of this person.	011-333333
	1.6	Contact Fax #	Required	Fax number of this person.	011-333334
	1.7	Contact Email	Required	Email address of this person.	kadmium.stahl@rodenbachbolt.com

TABLE A2.1 *Continued*

0.		Data	Required or Optional?	Expected Response/Comments	Example
2. Product Information	2.1	Product Name	Required	Common trade name.	Plated Bolt
	2.2	Supplier's Part/ Material #	Required	Supplier's internal part/material #. May be same as customer's part/material #.	333333
	2.3	Is product a Substance, Preparation or Article?	Required	See REACH definitions.	Article
	2.4	If it is an Article, what is Article's weight (kg)?	Optional, provide justification if omitted	Preferably this information is exchanged as customer will need to roll-up substance info and divide by article weight to determine 0.1% threshold for SVHC's.	0.022
	2.5	Are you a Manufacturer or Importer of Product in EU?	Required	See REACH definitions.	Yes, manufacturer
	2.6	Are you a Downstream User of Product in EU?	Required	See REACH definitions.	No

TABLE A2.1 *Continued*

0.		Data	Required or Optional?	Expected Response/Comments	Example				
3. Substance Information NOTE: Must iterate through Section 3 for EACH SUBSTANCE IN PRODUCT	3.1	Substance Name	Optional, provide justification if omitted	Preferably official IUPAC name, but see RIP 3.10 for substance naming conventions.	Cadmium	Iron	Copper	Carbon	Manganese
	3.2	CAS number	Optional, provide justification if omitted	May not be applicable, as per RIP 3.10, CAS numbers do not always correspond to unique substances.	7440-43-9	7439-89-6	7440-50-8	7440-44-0	7439-96-5
	3.3	EC Number (EINECS, ELINCS or NLP)	Optional, provide justification if omitted	See http://ecb.jrc.it/esis/ for #'s.	231-152-8	231-096-4	231-159-6	231-153-3	231-105-1
	3.4	Do you know of any company who will register this substance?	Optional, provide justification if omitted	Will rarely be available in early stages of REACH.	N/A	N/A	N/A	N/A	N/A
	3.5	Is it an SVHC, per the list we reference–see **"LIST OF SVHC's" Sheet**.	Required.	Requestor should reference his own list, i.e. aerospace, automotive, EU candidate list, JIG list, or customized list.	Yes	No	No	No	No
	3.6	Is it a phase-in-substance?	Optional, provide justification if omitted	Does it already exist on the market, per REACH definition of ″existing substance″?	Yes	Yes	Yes	Yes	Yes
	3.7	If in Preparation or Article, what is wt/wt concentration (%) ?	Optional, provide justification if omitted	Should be supplied at least for all substances >0.1% concentration.	0.12%	99.8%	0.03%	0.03%	0.02%
	3.8	If in Article, is it intentionally released?	Required	See REACH definitions.	No	No	No	No	No
	3.9	What is Classification and Labeling category?	Required	See Articles 4 and 6 of 67/548/EEC for categories; also, see ECHA-published Article 112 Classification and Labeling Inventory, when it becomes available.	Carc. Cat. 2; R45-Muta. Cat. 3; R68-Repr. Cat. 3; R62-63-T; R48/23/25-T+; R26-N; R50-53	N/A	N/A	N/A	N/A
	3.10	Do you plan to register substance?	Required	If not, should state reason why not.	No, no intentional release	No, no intentional release	No, no intentional release	No, no intentional release	No, no intentional release
	3.11	Do you plan to pre-register substance?	Required	If not, should state reason why not.	No, no intentional release	No, no intentional release	No, no intentional release	No, no intentional release	No, no intentional release
	3.12	Envisaged tonnage band/ registration deadline	Required	1-10 t, 10-100 t, 100-1000 t, >1000 t.	N/A	N/A	N/A	N/A	N/A
	3.13	Are there any restricted uses for the substance? If so, do any prohibit requestor's (customer's) uses per **"USAGE" Sheet**?	Required	Supplier must inform customer, if and when, any restricted use is included in Annex 17 of REACH. Requestor (customer) can specify uses on **"USAGE" Sheet**, Column C. Responder (supplier) can then answer whether each individual use is restricted in Column E. Alternatively, supplier can list all restricted uses in Column H, and customer can then ascertain whether his uses are restricted per Annex 17. Keep in mind restrictions apply to particular substances rather than whole products.	Yes. None impact customer's use as customer is non-EU	No	No	No	No

TABLE A2.1 *Continued*

0.		Data	Required or Optional?	Expected Response/Comments	Example				
	3.14	Has an authorization application been filed for use of substance in this product? If so, does it cover requestor's (customer's) uses per **"USAGE" Sheet**?	Required	Supplier should inform customer, if and when an authorization is sought. Requestor (customer) can specify uses on **"USAGE" Sheet**, Column C. Responder (supplier) can then answer whether each individual use has been applied for in Column F. Alternatively, supplier can list all authorization applications in Column I, and customer can then ascertain whether his uses will be applied for, or whether he must complete his own application for his use(s). Keep in mind authorizations apply to particular substances rather than whole products.	Yes. Authorization has been filed for other customer's uses. However, since you are non-EU, authorization unecessary for you	N/A	N/A	N/A	N/A
	3.15	If substance is subject to authorization, can it be substituted, and, if so, by what date do you plan to do so?	Required, if substance is on Annex 14 List.	For certain Annex 14 substances, if they can be adequately controlled, substitution is encouraged, but not legally required.	Yes, plan for 2009 substitution. This will affect non-EU exports	N/A	N/A	N/A	N/A
	3.16	Have you joined a SIEF or Consortium for this substance, and, if so, would you welcome our participation?	Optional, provide justification if omitted	Supplier may have useful information to contribute either directly to customer or as a third party data holder for the entire SIEF.	No	No	No	No	No
	3.17	Are there any relevant exemptions that you are aware of for uses of this substance in this product?	Required	Include exemptions from registration, evaluation, restriction, authorization, communication, etc....and any exemptions from the entire scope of REACH.	No	No	No	REACH Annex 4 exemption	No
	3.18	Do you possess any hazard or toxicity data, or both, including basic physico-chemical properties of the substance? Unless this has been provided in an SDS or CSR, or both, please indicate possession of such data by placing a "Y" in appropriate column of **"SUBSTANCES & HAZARDS" Sheet**.	Required, if supplier possesses any such data. Any such data is likely to be in a lengthy report or study format and should be delivered separately from the information in this form.	The requirements of Section 3.18 can be fully met with a SDS or CSR, or both. If either of these have been communicated, Upstream Question 3.18's answer can simply reference those documents. However, since SDS's are not required for articles or for products purchased outside of EU, and CSR's are not required for substances manufactured/imported<10 tonnes/yr, hazards data will need to be communicated via this question for many products.	Yes	Yes	Yes	Yes	Yes
4. Business Information - Supplier	4.1	Will you continue to supply this product?	Required	If not, should specify when production will cease.	Yes				
	4.2	Will your CSR cover my uses of your Product? See **"USAGE" Sheet**.	Response required (although covering such uses is not legally required, so answer can be "NO").	Requestor (customer) can specify uses on **"USAGE" Sheet**, Column C. Responder (supplier) can then answer whether each individual use is supported in Column D. Alternatively, supplier can list all uses supported in Column G, and customer can then ascertain whether his uses are encompassed in Column G.	Yes				

TABLE A2.1 *Continued*

0.		Data	Required or Optional?	Expected Response/Comments	Example
5. Only Rep Information	5.1	Registrant Name	Required if answer to 3.4 is YES	Registrant will be required to provide registration number to its customers	N/A
	5.2	Registrant Physical Address	Required if answer to 3.4 is YES	Registrant will be required to provide registration number to its customers	N/A
	5.3	Registrant Contact Individual	Required if answer to 3.4 is YES	Registrant will be required to provide registration number to its customers	N/A
	5.4	Registrant Phone #	Required if answer to 3.4 is YES	Registrant will be required to provide registration number to its customers	N/A
	5.5	Registrant Email	Required if answer to 3.4 is YES	Registrant will be required to provide registration number to its customers	N/A
	5.6	Is this Registrant your Only Representative?	Required if answer to 3.4 is YES	Only Rep will be required to provide registration number to its customers	N/A

TABLE A2.2 Case Study 2, Plated Bolt—DOWNSTREAM QUESTIONS: Information Request–Downstream Direction, Customer would populate for Supplier

0.		Data	Required or Optional?	Expected Response/Comments	Example
1. Company Information - Customer	1.1	Company Name	Required	Name of customer.	Motor City OEM
	1.2	Company ID #	Required	Customer ID #.	444
	1.3	Mailing Address	Required	Physical post-office mailing address of company.	2008 ELV Drive RoHS Pointe, USA
	1.4	REACH Responsible Individual Name	Required	Name of person which all REACH communications go to.	Rose Komplient
	1.5	Contact Phone #	Required	Phone number of this person.	123-555-4444
	1.6	Contact Fax #	Required	Fax number of this person.	123-555-4445
	1.7	Contact Email	Required	Email address of this person.	rose.komplient@motorcity.com
2. Product Information	2.1	Product Name	Required	Common trade name.	Plated Bolt
	2.2	Customer's Part/Material #	Required	Customer's internal part/material #. May be same as Supplier's part/material #.	444444
	2.3	Are you a Manufacturer or Importer of Product in EU?	Required	See REACH definitions.	No
	2.4	Are you a Downstream User of Product in EU?	Required	See REACH definitions.	No

TABLE A2.2 *Continued*

0.		Data	Required or Optional?	Expected Response/Comments	Example				
3. Substance Information—Note : must be iterated for each substance in product. List of substances in product should be provided by Supplier to Customer, using **"SUBSTANCES & HAZARDS" Sheet** before Customer completes this section.	3.1	Substance Name	Required - but supplier should first provide list of substances in the product for the customer on **"SUBSTANCES & HAZARDS" Sheet**.	Take exact name from **"SUBSTANCES & HAZARDS" Sheet**, so will correspond to supplier's name.	Cadmium	Iron	Copper	Carbon	Manganese
	3.2	Do you plan to register this substance?	Required - but supplier should first provide list of substances in the product for the customer on **"SUBSTANCES & HAZARDS" Sheet**.	If not, should state reason why not.	No, not released in article	No, not released in article	No, not released in article	No, not released in article	No, not released in article
	3.3	Do you plan to pre-register this substance?	Required - but supplier should first provide list of substances in the product for the customer on **"SUBSTANCES & HAZARDS" Sheet**.	If not, should state reason why not.	No, not released in article	No, not released in article	No, not released in article	No, not released in article	No, not released in article
	3.4	Envisaged tonnage band/ registration deadline	Required, if answer to 3.1 or 3.2 is "YES"	1-10 t, 10-100 t, 100-1000 t, >1000 t.	N/A	N/A	N/A	N/A	N/A
	3.5	Are there any restricted uses for the substance? If so, do any prohibit your uses per **"USAGE" Sheet**?	Required - but supplier should first provide list of substances in the product for the customer on **"SUBSTANCES & HAZARDS" Sheet**.	Supplier must inform customer, if and when, any restricted use is included in Annex 17 of REACH. Requestor (supplier) can specify restricted uses on **"USAGE" Sheet**, Column H. Responder (customer) can then ascertain whether each individual use is restricted. Alternatively, customer can list all his uses in Column C, and supplier can then deterimine and inform customer whether his uses are restricted per Annex 17, by filling in Column E. Bear in mind restrictions apply to particular substances rather than whole products.	Yes. None impact customer's use as customer is non-EU	No	No	No	No
	3.6	Has an authorization application been filed for use of substance in this product? If so, does it cover your uses per **"USAGE" Sheet**?	Required - but supplier should first provide list of substances in the product for the customer on **"SUBSTANCES & HAZARDS" Sheet**.	Supplier should inform customer, if and when an authorization is sought. Requestor (supplier) can specify applied-for uses on **"USAGE" Sheet**, Column I. Responder (customer) can then ascertain whether each individual has been applied for. Alternatively, customer can list all his uses in Column C, and supplier can then deterimine and inform customer whether his uses are applied for, by filling in Column F. Bear in mind authorizations apply to particular substances rather than whole products.	N/A outside EU	N/A outside EU	N/A outside EU	N/A outside EU	N/A outside EU
	3.7	If substance is subject to authorization, can it be substituted, and, if so, by what date do you plan to do so?	Required, if substance is on Annex 14 List.	For certain Annex 14 substances, if they can be adequately controlled, substitution is encouraged, but not legally required.	N/A outside EU	N/A outside EU	N/A outside EU	N/A outside EU	N/A outside EU

TABLE A2.2 *Continued*

0.		Data	Required or Optional?	Expected Response/Comments	Example				
	3.8	Have you joined a SIEF or Consortium for this substance, and, if so, would you welcome our participation?	Optional, provide justification if omitted	Customer may have useful information to contribute either directly to supplier or as a third party data holder for the entire SIEF.	No	No	No	No	No
	3.9	Are there any relevant exemptions that you are aware of for uses of this substance in this product?	Required - but supplier should first provide list of substances in the product for the customer on **"SUBSTANCES & HAZARDS" Sheet**.	Include exemptions from registration, evaluation, restriction, authorization, communication, etc....and any exemptions from the entire scope of REACH.	No	No	No	REACH Annex 4 exemption	No
4. Business Information	4.1	Will you cease use of this Product due to REACH?	Required	If ending purchases, should specify when purchase will cease.	No, provided cadmium is phased out by 2009				
	4.2	Will Supplier's CSR cover Customer's uses of Product? See **"USAGE" Sheet**.	Response required (although covering such uses is not legally required, so answer can be "NO").	Requestor (supplier) can specify all uses he supports on **"USAGE" Sheet**, Column G, and responder (customer) can then ascertain whether his uses are encompassed within Column G. Alternatively, responder (customer) can list all his uses in Column C, then send back to supplier for the supplier to determine whether each individual downstream use is supported and to record the answer in Column D.	N/A				

TABLE A2.3 Case Study 2, Plated Bolt—LIST OF USES Referenced in Upstream and Downstream Questions 4.2, to be completed by both Customer (optionally) and Supplier

0.	TYPICAL PROTOCOL WILL BE FOR CUSTOMER TO FIRST REVEAL USES OR USE CATEGORIES IN COLUMN C TO SUPPLIER, WHO WOULD THEN ANSWER WHICH OF THESE USES WILL BE COVERED IN COLUMN D. ALTERNATIVELY, SUPPLIER COULD LIST ALL USES SUPPORTED – IN COLUMN E, AND THEN CUSTOMER COULD CHECK TO SEE IF HIS WERE COVERED ON THIS LIST, THEN MERELY ANSWER "YES" OR "NO" ON UPSTREAM QUESTION 4.2. IF ANSWER IS "NO" AND CUSTOMER DOES NOT WISH TO REVEAL USES, HE MUST CONDUCT HIS OWN SAFETY ASSESSMENT. NOTE THAT ALL QUESTIONS ARE SUBSTANCE-SPECIFIC.						
	DOWNSTREAM CUSTOMER USES THIS PRODUCT FOR THE FOLLOWING USES:	IS CUSTOMER USE SUPPORTED BY SUPPLIER CSR?	IS CUSTOMER USE PROHIBITED BY AN ANNEX 17 RESTRICTION?	IS CUSTOMER USE COVERED BY AN AUTHORIZATION APPLICATION?	UPSTREAM SUPPLIER CSR SUPPORTS THE FOLLOWING USES FOR THIS PRODUCT:	UPSTREAM SUPPLIER IS AWARE OF THE FOLLOWING ANNEX 17 RESTRICTIONS FOR SUBSTANCES IN THIS PRODUCT (LIST NAME OF SPECIFIC SUBSTANCES ALSO):	UPSTREAM SUPPLIER HAS APPLIED FOR THE FOLLOWING AUTHORIZATIONS FOR SUBSTANCES IN THIS PRODUCT (LIST NAME OF SPECIFIC SUBSTANCES ALSO):
USE #	(TO BE COMPLETED BY CUSTOMER)	(TO BE COMPLETED BY SUPPLIER, IF CUSTOMER COMPLETES COLUMN C)	(TO BE COMPLETED BY SUPPLIER, IF CUSTOMER COMPLETES COLUMN C)	(TO BE COMPLETED BY SUPPLIER, IF CUSTOMER COMPLETES COLUMN C)	(TO BE COMPLETED BY SUPPLIER, IF CUSTOMER DOES NOT WISH TO REVEAL USES BY COMPLETING COLUMN C)	(TO BE COMPLETED BY SUPPLIER, IF CUSTOMER DOES NOT WISH TO REVEAL USES BY COMPLETING COLUMN C)	(TO BE COMPLETED BY SUPPLIER, IF CUSTOMER DOES NOT WISH TO REVEAL USES BY COMPLETING COLUMN C)
1	fastening components with bolts during assembly	Y	N	N/A		REACH Annex 17, Restriction #23 applies to Cadmium	

TABLE A2.4 Case Study 2, Plated Bolt

To be populated by supplier.																				
List of Substances in Product to be provided by Supplier to Customer		Supplier should place "Y" in any boxes below for any substance for which he possesses hazard data.																		
substance #	substance name	human health hazard assessment, see Annex 1, Section 1 of REACH	physicochemical hazard assessment, see Annex 1, Section 2 of REACH	environmental hazard assessment, see Annex 1, Section 3 of REACH	PBT and vPvB assessment, see Annex 1, Section 4 of REACH	exposure assessment, see Annex 1, Section 5 of REACH	risk characterization, see Annex 1, Section 6 of REACH	first aid measures, see Annex 2, Section 4 of REACH	fire fighting measures, see Annex 2, Section 5 of REACH	accidental release measures, see Annex 2, Section 6 of REACH	handling and storage, see Annex 2, Section 7 of REACH	exposure control/personal protection, see Annex 2, Section 8 of REACH	physico-chemical properties, see Annex 2, Section 9 of REACH	stability and reactivity, see Annex 2, Section 10 of REACH	toxicological information, see Annex 2, Section 11 of REACH	ecological information, see Annex 2, Section 12 of REACH	disposal considerations, see Annex 2, Section 13 of REACH	transport information, see Annex 2, Section 14 of REACH	regulatory information, see Annex 2, Section 15 of REACH	other information, see Annex 2, Section 16 of REACH
3.1.a	Cadmium	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
3.1.b	Iron	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
3.1.c	Copper	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
3.1.d	Carbon	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
3.1.e	Manganese	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y

TABLE A2.5 Case Study 2, Plated Bolt—LIST OF SVHC's Referenced in Upstream Question 3.5

To be populated by customer.			
Disclosure of substances on this list in any preparation or article is MANDATORY.			
List Item #	Substance Name	CAS#	EC#
1	Substance 1 from Automotive Industry SVHC List		
2	Substance 2 from Automotive Industry SVHC List		
3	Substance 3 from Automotive Industry SVHC List		
4	Substance 4 from Automotive Industry SVHC List		
5	Substance 5 from Automotive Industry SVHC List		
6	Substance 6 from Automotive Industry SVHC List		
7	Substance 7 from Automotive Industry SVHC List		
8	Substance 8 from Automotive Industry SVHC List		
9	Substance 9 from Automotive Industry SVHC List		
10	Substance 10 from Automotive Industry SVHC List		
…etc.	…etc, 500 substances on List		

A3. CASE STUDY 3: INFORMATION EXCHANGE INITIATED BY FORMULATOR (CUSTOMER) TO SPECIALTY FORMULATOR (SUPPLIER)—CONFIDENTIAL BUSINESS INFORMATION ISSUE

A3.1 Ima Formulator, who is the REACH-responsible individual for Friendly Formulating (FF), prepopulates the "Downstream Questions" sheet in advance of sending out a request to her supplier, Secret Substances (SS). She wishes to have SS's response within three weeks and notes that in the "Please respond by" section (Section 0).

A3.2 Sections 1.1 and 1.3-1.7 are information that FF has in its files, and Ima uses this data to populate requests to suppliers. Section 1.2 sometimes differs for FF from supplier to supplier so the specific customer number "666" that SS uses to communicate with FF is used in Section 1.2.

A3.3 FF wishes to know about the product that SS sells them, which FF incorporates into several preparations for customers in the EU. Note that FF is based in Liechtenstein, an European Economic Area member, where REACH is incorporated into the laws providing for the free movement of goods within the Customs area, so the scope of REACH applies to FF, as if they were an EU-based company. FF completes the remainder of the product-specific information in Section 2 of the "Downstream Questions" sheet, identifying the product as "Preparation X" with the FF part number "666666."

A3.4 FF is unable to complete Section 3 of the "Downstream Questions" sheet because SS needs to provide first the substance information before FF can answer the specific questions, so Section 3 is left blank in the prepopulation step.

A3.5 Section 4 also may require some input from SS before FF can complete it. Question 4.1 is difficult to answer without a knowledge of which substances are contained in the product. For example, if there are no SVHCs in the preparation, there is little reason for FF to change its purchasing patterns as a result of REACH. If, however, the preparation contains a carcinogen per Directive 67/548/EEC, it would be more likely that FF will begin to explore alternative sources of supply.

A3.6 Question 4.2 will also require the supplier to respond in advance of the customer's answer. If the customer does not wish to reveal his uses to the supplier, he may leave 4.2 blank and direct the supplier to complete the "Usage" sheet and then subsequently make the determinations as to whether the customer's uses are covered by the supplier's CSR exposure scenario(s) which will be listed by the supplier in the "Usage" sheet. In this case, FF has no problem revealing its use as "mixing Preparation X with Preparation Y" which is listed on the "Usage" sheet in Column C. However, FF must still wait for SS to look at the "Usage" sheet, at which point SS will respond in Columns D, E, and F as to whether FF's uses are covered by the SS CSR, are prohibited by an Annex 17 restriction, or are the subject of an application authorization.

A3.7 Also note that it is conceivable that occasionally other sections of the form may not be able to be completed without some input from another actor in the supply chain. For example, it is not always trivial to determine whether you or your supplier is the actual importer of record for a product (Questions 2.3 and 2.4 of "Downstream Questions" sheet).

A3.8 Finally, FF references the EU's Candidate List into the "List of SVHCs" sheet. FF has downloaded this list from the European Chemicals Agency website. This list (please note this list does not exist yet in reality!) contains 500 substances and is the official definition on what is an SVHC. FF could also add substances to this list if it wished to consider additional SVHCs that may end up on the EU Candidate List someday. FF realizes that if a new substance subsequently appears on the EU Candidate List, it will be responsible for querying its suppliers on the presence of that new substance in FF products. FF carefully monitors the European Chemicals Agency website to see when a new substance appears on the EU Candidate List. When this happens, FF immediately queries any suppliers who have not provided full substance information, allowing them 14 days to identify the new SVHC.

A3.9 FF then e-mails the file to the general business contact at SS who, after some searching around internally, locates the right department for REACH compliance and forwards it on to John Doe, who is the REACH-responsible individual at SS. Because of the delay in reaching the proper contact, there are only two days left to respond when Mr. Doe receives the form.

A3.10 Mr. Doe fills out the "Upstream Questions" sheet and requests that FF return the fully completed form to SS within 60 days and notes this in Section 0. Next, he completes the Section 1 contact information; FF will now be able to bypass the general business contact at SS in future information exchanges and communicate directly with Mr. Doe.

A3.11 Section 2 of the "Upstream Questions" sheet is completed with the SS part/material number "555555" which will correspond to the FF part/material number "666666" Sections 2.3-2.6 are answered based on an understanding of the REACH definitions for substances/preparations/articles and the manufacturer, importer, and downstream user actors in the supply chain. Preparation X is a mixture of substances that are not formed into any definite shape or form and is clearly a "preparation" under REACH. SS is a manufacturer of Preparation X in the EU.

A3.12 SS completes Section 3 only to the extent that it is comfortable with sharing the recipe for Preparation X. SS management decides that all substances except acrylonitrile shall not be shared with customers. John Doe obtains basic information on acrylonitrile from websites such as www.cas.org and http://ecb.jrc.it/existing-chemicals providing the content for Section 3.1 (names), Section 3.2 (CAS numbers), and Section 3.3 (EC numbers). Mr. Doe is given permission to reveal the composition of acrylonitrile in Preparation X to FF, and therefore, he is able to complete Section 3.7 (percent composition), entering the value of 17 %. For the remaining 83 % of Preparation X, SS is not willing to disclose any information. This will present some special challenges under REACH for SS and its customers, but it is not worth the risk of losing its competitive edge for SS to allow this information to be transmitted.

A3.13 Continuing his disclosures on acrylonitrile, Mr. Doe is unable to provide the name of a registrant (3.4) since he is not aware of any registrations that have been completed for acrylonitrile. He checks the "List of SVHCs" sheet against the list of substances in Preparation X and determines that acrylonitrile is in fact an SVHC per the list, so he answers "yes" to Question 3.5 for acrylonitrile.

A3.14 Acrylonitrile has been on the market many years and is considered a phase-in substance (3.6). Preparation X is a preparation, rather than an article, so 3.8 is not applicable. Classification and labeling information (3.9) is provided for acrylonitrile after Mr. Doe looks it up from Annex 1 of Directive 67/548/EEC.

A3.15 For questions 3.10-3.12, SS will register acrylonitrile at the 100- to 1000-tonnage band and shall complete that registration by June 1, 2013. Some of the confidential substances will also be registered, but SS is not revealing any information to FF at this time about those substances.

A3.16 John Doe then consults the list of restricted uses in Annex 17 of REACH and discovers that none apply to any of the substances in Preparation X and notes this in Question 3.13.

A3.17 As none of the confidential substances are SVHCs, Questions 3.14 and 3.15 are not applicable for them. For acrylonitrile, no authorization application has been filed, but SS is gathering information in preparation of preparing an application and is researching alternative substances in advance preparation of the requirements of the authorization process.

A3.18 SS has joined an acrylonitrile SIEF, which is open to downstream user data holders, such as FF. For the other substances, SS is in SIEFs that are much more careful about how data holders participate and require SS to indemnify other members for breaches in confidentiality, so lawyers are still investigating how best to allow FF to contribute in these SIEFs (3.16). From SS's knowledge of REACH, there are no relevant exemptions for acrylonitrile in Preparation X, although it is conceivable that some of SS's customers may be able to avail themselves of application-specific exemptions, that is, a medical device exemption. SS is aware that some of the confidential substances can be considered intermediates under certain contexts and use conditions and notes this for Question 3.17, although it will be of little use to FF since they do not even know what the substances are and cannot determine under what conditions they might be considered intermediates.

A3.19 SS has a variety of health and safety information for acrylonitrile from its Materials Safety Data Sheets and other sources. Although the data does not exactly correspond to what is needed under REACH, SS indicates the availability of the data by answering "yes" to Question 3.18 for acrylonitrile. SS then goes to the "Substances & Hazards" sheet and enters acrylonitrile, and fills in a "Y" for each type of data it possesses on it. This health and safety data will not necessarily be exchanged at this point, but FF will now be aware that SS is a potential source of this information in case FF needs it to control adequately risks of using the substances. For the confidential substances, no health and safety information will be shared at this point. This may be a serious concern for FF, as it must trust SS's assurances that there are no issues with these substances without the ability to make an independent evaluation of that assertion.

A3.20 SS sees no issues with continuing the supply of Preparation X under the new REACH regime and answers 4.1 with a "yes." Question 4.2 is answered "yes" as SS will complete a CSR for acrylonitrile and, after viewing "Usage" Column C, provides assurance in Column D that "mixing Preparation X with Preparation Y" will fall under a class of use categories supported under the CSR for acrylonitrile.

A3.21 Finally, Section 5 is completely inapplicable, as SS has no ability to locate a registrant. Upon completing all sections, Mr. Doe has a colleague review the sheets for accuracy and then sends it on to Ms. Formulator at FF.

A3.22 Ms. Formulator considers the new information provided in Section 3, "Upstream Questions," in "Usage" and "Substances & Hazards" by SS. She is now able to complete Section 3 of "Downstream Questions" based on the substance information she now has received.

A3.23 Section 3.1 is populated now with the names given by SS for the substances. Upon aggregating the amount of acrylonitrile FF purchases from all suppliers, they discover it is used in >1000 tonne/year, but FF does not need to prepare a registration dossier (Question 3.2) as it is neither a manufacturer nor importer of the substance. However, as a downstream user of >1 tonne/year of acrylonitrile, FF shall ensure there is a CSR for their use of the substance. FF answers Questions 3.2-3.4 accordingly, as it cannot register.

A3.24 FF agrees with SS's assessment that there are no restrictions or authorizations with which to be concerned (Questions 3.5-3.7). FF has not joined a consortium, but they will consider joining the acrylonitrile SIEF as a third-party data holder (3.8). FF is not aware of any exemptions for acrylonitrile and answers 3.9 with a "no" and an "N/A" for the unknown substances.

A3.25 Turning to Section 4, Ms. Formulator answers in 4.1 that FF is confident that it will be able to continue purchase of Preparation X, as it is adequately prepared to address the new REACH requirements, particularly with the support provided by SS. Because of the confidential substances, excellent communications will be necessary in this business relationship to ensure all substances are properly compliant with REACH. Finally, Section 4.2 is answered with a "yes" based on SS's assurances that its CSR will cover FF's use.

A3.26 Upon completion, Ms. Formulator transmits the form to Mr. Doe, completing the round trip of the data and ensuring that both parties have the same copy of the information. It is, of course, possible that lapses in communication, needed clarifications, or changes to the information will require future iterations of this process, but the basic foundation of the process has now been laid.

A3.27 FF will have to consider which suppliers and customers to turn to next to complete its dataset for its REACH-impacted products. In many cases, parties to information exchange will need to draw in other parties to complete their

communications. For example, FF may not be able to determine whether it needs to complete a CSR for acrylonitrile until FF has aggregated the amounts of substances it purchases from all suppliers. Similarly, manufacturers of complex assemblies and preparations may need to roll up information from multiple suppliers before they can answer percentage compositions questions for their own customers. In certain cases, it may be advisable to return partially completed forms indicating which data is lacking and what the expected wait time is for full completion. The other party to the information exchange may be able to make decisions such as threshold determinations based on partial information; furthermore, a significant delay in responding may put you at a competitive disadvantage relative to companies who are more responsive.

TABLE A3.1 Case Study 3, CBI—UPSTREAM QUESTIONS: Information Request–Upstream Direction, Supplier would populate for Customer

0.		Data	Required or Optional?	Expected Response/Comments	Example
1. Company Information - Supplier	1.1	Company Name	Required	Name of supplier/manufacturer.	Secret Substances, Ltd.
	1.2	Company ID #	Required	Supplier/Vendor ID #	555
	1.3	Mailing Address	Required	Physical post-office mailing address of company.	55 Trade Secret Drive Proprietary Park, UK
	1.4	REACH Responsible Individual Name	Required	Name of person which all REACH communications go to.	John Doe
	1.5	Contact Phone #	Required	Phone number of this person.	011-555555
	1.6	Contact Fax #	Required	Fax number of this person.	011-555556
	1.7	Contact Email	Required	Email address of this person.	john.doe@ secretsubstances.com
2. Product Information	2.1	Product Name	Required	Common trade name.	Preparation X
	2.2	Supplier's Part/Material #	Required	Supplier's internal part/material #. May be same as customer's part/material #.	555555
	2.3	Is product a Substance, Preparation or Article?	Required	See REACH definitions.	Preparation
	2.4	If it is an Article, what is Article's weight (kg)?	Optional, provide justification if omitted	Preferably this information is exchanged as customer will need to roll-up substance info and divide by article weight to determine 0.1% threshold for SVHC's.	N/A
	2.5	Are you a Manufacturer or Importer of Product in EU?	Required	See REACH definitions.	Yes, Manufacturer
	2.6	Are you a Downstream User of Product in EU?	Required	See REACH definitions.	No

TABLE A3.1 *Continued*

0.		Data	Required or Optional?	Expected Response/Comments	Example	
3. Substance Information NOTE: Must iterate through Section 3 for EACH SUBSTANCE IN PRODUCT	3.1	Substance Name	Optional, provide justification if omitted	Preferably official IUPAC name, but see RIP 3.10 for substance naming conventions.	Various Confidential Substances	acrylonitrile
	3.2	CAS number	Optional, provide justification if omitted	May not be applicable, as per RIP 3.10, CAS numbers do not always correspond to unique substances.	N/A	107-13-1
	3.3	EC Number (EINECS, ELINCS or NLP)	Optional, provide justification if omitted	See http://ecb.jrc.it/esis/ for #'s.	N/A	203-466-5
	3.4	Do you know of any company who will register this substance?	Optional, provide justification if omitted	Will rarely be available in early stages of REACH.	N/A	N/A
	3.5	Is it an SVHC, per the list we reference–see **"LIST OF SVHC's" Sheet**.	Required.	Requestor should reference his own list, i.e. aerospace, automotive, EU candidate list, JIG list, or customized list.	No	Yes
	3.6	Is it a phase-in-substance?	Optional, provide justification if omitted	Does it already exist on the market, per REACH definition of ″existing substance″?	No	Yes
	3.7	If in Preparation or Article, what is wt/wt concentration (%) ?	Optional, provide justification if omitted	Should be supplied at least for all substances >0.1% concentration.	83% total	17.0%
	3.8	If in Article, is it intentionally released?	Required	See REACH definitions.	N/A	N/A
	3.9	What is Classification and Labeling category?	Required	See Articles 4 and 6 of 67/548/EEC for categories; also, see ECHA-published Article 112 Classification and Labeling Inventory, when it becomes available.	N/A	F; R11- Carc. Cat. 2; R45-T; R23/24/25-Xi; R37/38-41-R43-N; R51-53
	3.10	Do you plan to register substance?	Required	If not, should state reason why not.	Will register some substances	Yes
	3.11	Do you plan to pre-register substance?	Required	If not, should state reason why not.	Will pre-register some substances	Yes
	3.12	Envisaged tonnage band/ registration deadline	Required	1-10 t, 10-100 t, 100-1000 t, >1000 t.	Various dates	100-1,000t / Jun 1, 2013
	3.13	Are there any restricted uses for the substance? If so, do any prohibit requestor's (customer's) uses per **"USAGE" Sheet**?	Required	Supplier must inform customer, if and when, any restricted use is included in Annex 17 of REACH. Requestor (customer) can specify uses on **"USAGE" Sheet**, Column C. Responder (supplier) can then answer whether each individual use is restricted in Column E. Alternatively, supplier can list all restricted uses in Column H, and customer can then ascertain whether his uses are restricted per Annex 17. Keep in mind restrictions apply to particular substances rather than whole products.	No	No

TABLE A3.1 *Continued*

0.		Data	Required or Optional?	Expected Response/Comments	Example	
	3.14	Has an authorization application been filed for use of substance in this product? If so, does it cover requestor's (customer's) uses per **"USAGE" Sheet**?	Required	Supplier should inform customer, if and when an authorization is sought. Requestor (customer) can specify uses on **"USAGE" Sheet**, Column C. Responder (supplier) can then answer whether each individual use has been applied for in Column F. Alternatively, supplier can list all authorization applications in Column I, and customer can then ascertain whether his uses will be applied for, or whether he must complete his own application for his use(s). Keep in mind authorizations apply to particular substances rather than whole products.	N/A	No
	3.15	If substance is subject to authorization, can it be substituted, and, if so, by what date do you plan to do so?	Required, if substance is on Annex 14 List.	For certain Annex 14 substances, if they can be adequately controlled, substitution is encouraged, but not legally required.	N/A	Gathering data for substitution alternatives; plans unknown yet.
	3.16	Have you joined a SIEF or Consortium for this substance, and, if so, would you welcome our participation?	Optional, provide justification if omitted	Supplier may have useful information to contribute either directly to customer or as a third party data holder for the entire SIEF.	Yes. Will send information on how you might contribute.	Yes, joined SIEF and yes, data holders welcome.
	3.17	Are there any relevant exemptions that you are aware of for uses of this substance in this product?	Required	Include exemptions from registration, evaluation, restriction, authorization, communication, etc….and any exemptions from the entire scope of REACH.	Some substances are intermediates	No
	3.18	Do you possess any hazard or toxicity data, or both, including basic physico-chemical properties of the substance? Unless this has been provided in an SDS or CSR, or both, please indicate possession of such data by placing a "Y" in appropriate column of **"SUBSTANCES & HAZARDS" Sheet**.	Required, if supplier possesses any such data. Any such data is likely to be in a lengthy report or study format and should be delivered separately from the information in this form.	The requirements of Section 3.18 can be fully met with a SDS or CSR, or both. If either of these have been communicated, Upstream Question 3.18's answer can simply reference those documents. However, since SDS's are not required for articles or for products purchased outside of EU, and CSR's are not required for substances manufactured/imported<10 tonnes/yr, hazards data will need to be communicated via this question for many products.	No	Yes
4. Business Information - Supplier	4.1	Will you continue to supply this product?	Required	If not, should specify when production will cease.	Yes	
	4.2	Will your CSR cover my uses of your Product? See **"USAGE" Sheet**.	Response required (although covering such uses is not legally required, so answer can be "NO").	Requestor (customer) can specify uses on **"USAGE" Sheet**, Column C. Responder (supplier) can then answer whether each individual use is supported in Column D. Alternatively, supplier can list all uses supported in Column G, and customer can then ascertain whether his uses are encompassed in Column G.	Yes	
5. Only Rep Information	5.1	Registrant Name	Required if answer to 3.4 is YES	Registrant will be required to provide registration number to its customers	N/A	
	5.2	Registrant Physical Address	Required if answer to 3.4 is YES	Registrant will be required to provide registration number to its customers	N/A	
	5.3	Registrant Contact Individual	Required if answer to 3.4 is YES	Registrant will be required to provide registration number to its customers	N/A	
	5.4	Registrant Phone #	Required if answer to 3.4 is YES	Registrant will be required to provide registration number to its customers	N/A	
	5.5	Registrant Email	Required if answer to 3.4 is YES	Registrant will be required to provide registration number to its customers	N/A	
	5.6	Is this Registrant your Only Representative?	Required if answer to 3.4 is YES	Only Rep will be required to provide registration number to its customers	N/A	

TABLE A3.2 Case Study 3, CBI—DOWNSTREAM QUESTIONS: Information Request–Downstream Direction, Customer would populate for Supplier

0.		Data	Required or Optional?	Expected Response/Comments	Example	
1. Company Information - Customer	1.1	Company Name	Required	Name of customer.	Friendly Formulating	
	1.2	Company ID #	Required	Customer ID #.	666	
	1.3	Mailing Address	Required	Physical post-office mailing address of company.	2008 EEA Drive Reach-applies-in, Liechtenstein	
	1.4	REACH Responsible Individual Name	Required	Name of person which all REACH communications go to.	Ima Formulator	
	1.5	Contact Phone #	Required	Phone number of this person.	123-555-6666	
	1.6	Contact Fax #	Required	Fax number of this person.	123-555-6667	
	1.7	Contact Email	Required	Email address of this person.	ima.formulator@friendly.com	
2. Product Information	2.1	Product Name	Required	Common trade name.	Preparation X	
	2.2	Customer's Part/Material #	Required	Customer's internal part/material #. May be same as Supplier's part/material #.	666666	
	2.3	Are you a Manufacturer or Importer of Product in EU?	Required	See REACH definitions.	No	
	2.4	Are you a Downstream User of Product in EU?	Required	See REACH definitions.	Yes	
3. Substance Information—Note : must be iterated for each substance in product. List of substances in product should be provided by Supplier to Customer, using **"SUBSTANCES & HAZARDS" Sheet** before Customer completes this section.	3.1	Substance Name	Required - but supplier should first provide list of substances in the product for the customer on **"SUBSTANCES & HAZARDS" Sheet**.	Take exact name from **"SUBSTANCES & HAZARDS" Sheet**, so will correspond to supplier's name.	Various Confidential Substances	acrylonitrile
	3.2	Do you plan to register this substance?	Required - but supplier should first provide list of substances in the product for the customer on **"SUBSTANCES & HAZARDS" Sheet**.	If not, should state reason why not.	No, we do not know what substances are	No, customer will register
	3.3	Do you plan to pre-register this substance?	Required - but supplier should first provide list of substances in the product for the customer on **"SUBSTANCES & HAZARDS" Sheet**.	If not, should state reason why not.	No, we do not know what substances are	No, DU cannot pre-register
	3.4	Envisaged tonnage band/ registration deadline	Required, if answer to 3.1 or 3.2 is "YES"	1-10 t, 10-100 t, 100-1000 t, >1000 t.	N/A	N/A
	3.5	Are there any restricted uses for the substance? If so, do any prohibit your uses per **"USAGE" Sheet**?	Required - but supplier should first provide list of substances in the product for the customer on **"SUBSTANCES & HAZARDS" Sheet**.	Supplier must inform customer, if and when, any restricted use is included in Annex 17 of REACH. Requestor (supplier) can specify restricted uses on **"USAGE" Sheet**, Column H. Responder (customer) can then ascertain whether each individual use is restricted. Alternatively, customer can list all his uses in Column C, and supplier can then deterimine and inform customer whether his uses are restricted per Annex 17, by filling in Column E. Bear in mind restrictions apply to particular substances rather than whole products.	N/A	No
	3.6	Has an authorization application been filed for use of substance in this product? If so, does it cover your uses per **"USAGE" Sheet**?	Required - but supplier should first provide list of substances in the product for the customer on **"SUBSTANCES & HAZARDS" Sheet**.	Supplier should inform customer, if and when an authorization is sought. Requestor (supplier) can specify applied-for uses on **"USAGE" Sheet**, Column I. Responder (customer) can then ascertain whether each individual has been applied for. Alternatively, customer can list all his uses in Column C, and supplier can then deterimine and inform customer whether his uses are applied for, by filling in Column F. Bear in mind authorizations apply to particular substances rather than whole products.	N/A	N/A
	3.7	If substance is subject to authorization, can it be substituted, and, if so, by what date do you plan to do so?	Required, if substance is on Annex 14 List.	For certain Annex 14 substances, if they can be adequately controlled, substitution is encouraged, but not legally required.	N/A	N/A

TABLE A3.2 *Continued*

0.		Data	Required or Optional?	Expected Response/Comments	Example	
	3.8	Have you joined a SIEF or Consortium for this substance, and, if so, would you welcome our participation?	Optional, provide justification if omitted	Customer may have useful information to contribute either directly to supplier or as a third party data holder for the entire SIEF.	No	No
	3.9	Are there any relevant exemptions that you are aware of for uses of this substance in this product?	Required - but supplier should first provide list of substances in the product for the customer on **"SUBSTANCES & HAZARDS" Sheet**.	Include exemptions from registration, evaluation, restriction, authorization, communication, etc….and any exemptions from the entire scope of REACH.	No	No
4. Business Information	4.1	Will you cease use of this Product due to REACH?	Required	If ending purchases, should specify when purchase will cease.	No	
	4.2	Will Supplier's CSR cover Customer's uses of Product? See **"USAGE" Sheet**.	Response required (although covering such uses is not legally required, so answer can be "NO").	Requestor (supplier) can specify all uses he supports on **"USAGE" Sheet**, Column G, and responder (customer) can then ascertain whether his uses are encompassed within Column G. Alternatively, responder (customer) can list all his uses in Column C, then send back to supplier for the supplier to determine whether each individual downstream use is supported and to record the answer in Column D.	Yes	

TABLE A3.3 Case Study 3, CBI—LIST OF USES Referenced in Upstream and Downstream Questions 4.2, to be completed by both Customer (optionally) and Supplier

0.	TYPICAL PROTOCOL WILL BE FOR CUSTOMER TO FIRST REVEAL USES OR USE CATEGORIES IN COLUMN C TO SUPPLIER, WHO WOULD THEN ANSWER WHICH OF THESE USES WILL BE COVERED IN COLUMN D. ALTERNATIVELY, SUPPLIER COULD LIST ALL USES SUPPORTED – IN COLUMN E, AND THEN CUSTOMER COULD CHECK TO SEE IF HIS WERE COVERED ON THIS LIST, THEN MERELY ANSWER "YES" OR "NO" ON UPSTREAM QUESTION 4.2. IF ANSWER IS "NO" AND CUSTOMER DOES NOT WISH TO REVEAL USES, HE MUST CONDUCT HIS OWN SAFETY ASSESSMENT. NOTE THAT ALL QUESTIONS ARE SUBSTANCE-SPECIFIC.						
	DOWNSTREAM CUSTOMER USES THIS PRODUCT FOR THE FOLLOWING USES:	IS CUSTOMER USE SUPPORTED BY SUPPLIER CSR?	IS CUSTOMER USE PROHIBITED BY AN ANNEX 17 RESTRICTION?	IS CUSTOMER USE COVERED BY AN AUTHORIZATION APPLICATION?	UPSTREAM SUPPLIER CSR SUPPORTS THE FOLLOWING USES FOR THIS PRODUCT:	UPSTREAM SUPPLIER IS AWARE OF THE FOLLOWING ANNEX 17 RESTRICTIONS FOR SUBSTANCES IN THIS PRODUCT (LIST NAME OF SPECIFIC SUBSTANCES ALSO):	UPSTREAM SUPPLIER HAS APPLIED FOR THE FOLLOWING AUTHORIZATIONS FOR SUBSTANCES IN THIS PRODUCT (LIST NAME OF SPECIFIC SUBSTANCES ALSO):
USE #	(TO BE COMPLETED BY CUSTOMER)	(TO BE COMPLETED BY SUPPLIER, IF CUSTOMER COMPLETES COLUMN C)	(TO BE COMPLETED BY SUPPLIER, IF CUSTOMER COMPLETES COLUMN C)	(TO BE COMPLETED BY SUPPLIER, IF CUSTOMER COMPLETES COLUMN C)	(TO BE COMPLETED BY SUPPLIER, IF CUSTOMER DOES NOT WISH TO REVEAL USES BY COMPLETING COLUMN C)	(TO BE COMPLETED BY SUPPLIER, IF CUSTOMER DOES NOT WISH TO REVEAL USES BY COMPLETING COLUMN C)	(TO BE COMPLETED BY SUPPLIER, IF CUSTOMER DOES NOT WISH TO REVEAL USES BY COMPLETING COLUMN C)
1	mixing Preparation X with Preparation Y	Y	N	N/A			

TABLE A3.4 Case Study 3, CBI

To be populated by supplier.																				
List of Substances in Product to be provided by Supplier to Customer		Supplier should place "Y" in any boxes below for any substance for which he possesses hazard data.																		
substance #	substance name	human health hazard assessment, see Annex 1, Section 1 of REACH	physicochemical hazard assessment, see Annex 1, Section 2 of REACH	environmental hazard assessment, see Annex 1, Section 3 of REACH	PBT and vPvB assessment, see Annex 1, Section 4 of REACH	exposure assessment, see Annex 1, Section 5 of REACH	risk characterization, see Annex 1, Section 6 of REACH	first aid measures, see Annex 2, Section 4 of REACH	fire fighting measures, see Annex 2, Section 5 of REACH	accidental release measures, see Annex 2, Section 6 of REACH	handling and storage, see Annex 2, Section 7 of REACH	exposure control/personal protection, see Annex 2, Section 8 of REACH	physico-chemical properties, see Annex 2, Section 9 of REACH	stability and reactivity, see Annex 2, Section 10 of REACH	toxicological information, see Annex 2, Section 11 of REACH	ecological information, see Annex 2, Section 12 of REACH	disposal considerations, see Annex 2, Section 13 of REACH	transport information, see Annex 2, Section 14 of REACH	regulatory information, see Annex 2, Section 15 of REACH	other information, see Annex 2, Section 16 of REACH
3.1.a	Various confidential substances	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
3.1.b	acrylonitrile	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y

TABLE A3.5 Case Study 3, CBI—LIST OF SVHC's Referenced in Upstream Question 3.5

To be populated by customer.			
Disclosure of substances on this list in any preparation or article is MANDATORY.			
List Item #	Substance Name	CAS#	EC#
1	Substance 1 from ECHA Website Candidate List		
2	Substance 2 from ECHA Website Candidate List		
3	Substance 3 from ECHA Website Candidate List		
4	Substance 4 from ECHA Website Candidate List		
5	Substance 5 from ECHA Website Candidate List		
6	Substance 6 from ECHA Website Candidate List		
7	Substance 7 from ECHA Website Candidate List		
8	Substance 8 from ECHA Website Candidate List		
9	Substance 9 from ECHA Website Candidate List		
10	Substance 10 from ECHA Website Candidate List		
…etc.	…etc, 500 substances on List		

A4. CASE STUDY 4: REACH GUIDELINES CASE STUDY FOR ARTICLE MANUFACTURER

A4.1 This case study represents a simplified format for article manufacturers. Aspects of the previous case studies may be utilized as needed.

A4.2 Jose Chang operates Easy Does It Co. that manufactures a Model CE1 carpet extraction machine manufactured in the United States and sold domestically and in Europe. Jose includes 500 mL of specially formulated carpet shampoo with the model CE1. Because the carpet extractor is only one means of applying the shampoo to the carpet (it can also be used in a spray bottle as a spotter), and the shampoo can also be purchased separately, Jose determines that the shampoo is considered to be a preparation under Article 6. In order to determine whether or not he must respond to the REACH regulation, Jose first calculates the amount of substances shipped per bottle of shampoo.

A4.3 500 mL of the carpet shampoo weighs 830 g. The chemical breakdown by weight is as follows:

Ethanol/SD Alcohol 40	4 % (33.2 g)
1,1'-Oxydi-2-propanol	7 % (58.1 g)
Sodium xylenesulfonate	1.5 % (12.45 g)
Alcohols, C12-14-secondary, ethoxylated	4 % (33.2 g)
Distilled Water	83.5 % (693.05 g)

A4.4 Jose ships 20,000 bottles of the carpet shampoo to the European Union each year, including 10,000 bottles included with the carpet extractor.

A4.5 Having the breakdown of each substance by weight, and knowing how many bottles of carpet cleaner are sold each year, Jose answers a series of questions to determine his obligations under REACH. Annex A5 provides a flow chart and illustrates the basic process.

A4.6 The questions Jose answers are as follows:

A4.6.1 Does the company import, produce or supply articles for the European Union market? The answer is yes; Easy Does It Co. manufactures products that are marketed within the European Union market.

A4.6.2 Does the article produced contain substances that are intentionally released during normal use? The answer is no. Although the carpet shampoo is applied to the carpet while operating the carpet extractor during use, it can also be applied and used separately. The carpet extractor, in this case, is considered to be a special container for the shampoo. Both the extractor and the shampoo can be used independently of each other.

A4.6.3 Are any of the substances in the preparation used in quantities greater than 1 tonne per year? Jose prepares and bottles the carpet shampoo in house and only sells it through EDI dealers. By selling 10 000 L of carpet shampoo (500 mL per bottle) per year in the European Union, overall quantities for each substance are as follows:

Ethanol/SD Alcohol 40	0.664 tonne
1,1'-Oxydi-2-propanol	1.162 tonne
Sodium xylenesulfonate	0.249 tonne
Alcohols, C12-14-secondary, ethoxylated	0.664 tonne
Distilled Water	138.61 tonne

Only two of the substances contained within the carpet shampoo are used in quantities greater than one tonne per year, 1,1'-Oxydi-2-propanol and distilled water. Jose checks the list of exemptions in Annex IV and finds that distilled water is exempt from registration. Therefore, the answer to the question is yes. One substance, 1,1'-Oxydi-2-propanol is used in quantities greater than 1one tonne per year and requires registration.

A4.6.4 Are any of the substances in the preparation considered to be a Substance of Very High Concern (SVHC)? Jose reviews the current list of candidate SVHCs and determines that none of the substances in the shampoo are on the list. The answer is no.

A4.6.5 Are any substances within the article (carpet extractor) considered to be a Substance of Very High Concern (SVHC)? Jose reviews the current list of candidate SVHCs and determines that power cord and internal wiring contains SVHCs that are on the list. The answer is yes. The extractor employs a 22-ft power cord, 6-ft of internal wiring with heavy insulation and 2.5-ft of internal wiring with thinner insulation. All use DEHP as a plasticizer for processing SVT. The amount of DEHP used for each item is shown in the table below.

Component	Length (ft)	Total mass (g)	PVC mass (g)	%DEHP w/w	DEHP mass (g)
Power cord	22	387.20	376.2	25	94.05
Internal wiring (thick insulation)	6	26.40	16.80	22	3.70
Internal wiring (thin insulation)	2.5	9.00	3.00	24	0.72
				Total mass of DEHP (g):	98.47

Product mass (kg)	13.15
DEHP mass (kg)	0.0847
% DEHP per product w/w	0.65
Number products sold per year	10000
Total mass of DEHP per year (kg)	984.66

A4.6.6 Jose determines that there is 0.65 % w/w of DEHP per product (total of 98.47 g per product). This exceeds the 0.1 % w/w concentration limit. Since he sells 10 000 products per year in Europe, he calculates the total amount of DEHP used per year to be 984.66 kg. This is less than the 1 tonne minimum. Therefore, there is no need to notify ECHA. However, Jose maintains a record of usage that is available for review and inspection and tracks his sales carefully, so that he may take action if the total annual amount exceeds 1 tonne. He has also verified that there are no restrictions in Annex XVII for his particular use. Jose recognizes his obligations under the REACH regulation to communicate with his consumers. He has included information regarding the possible presence of DEHP in the power cord within the instruction manual, and has included precautionary statements regarding the handling of the cord. He has also provided information relating to the use of DEHP to his importers. He has also communicated with the vendors of the cord and wiring requesting all relevant information regarding the use of DEHP and to determine if the substance has already been registered.

NOTE A4.1—Whenever a restricted substance or SVHC is incorporated within an article the manufacturer should obtain all relevant documentation from the supplier regarding use, registration, notification, authorization and the like relevant to the particular substance. The manufacturer should also verify that the substance has not previously been registered.

A4.7 Because Easy Does It Co. manufactures in the United States, Jose does not have any formal legal obligations under REACH. However, he still has a role in the supply chain and can facilitate exportation of the article and carpet shampoo to their EU customers.

A4.7.1 Jose designates one of his importers, Simon M. Porter, a legal entity residing within the European Union, as the "Only Representative" for Easy Does It Co. A contract is signed between Easy Does It Co., a non-Community manufacturer, and Simon assigning all REACH obligations to Simon. Simon will be responsible for registering the 1,1'-Oxydi-2-propanol. In addition, if the use of DEHP should exceed the 1 tonne limit, it will be Simon's responsibility to notify the ECHA.

A4.7.2 Although Easy Does It Co, uses other importers within the European Union, Simon M. Porter sole legal obligations for Easy Does It Co. in the European Union, and is

responsible for providing clear documentation to the enforcement authorities regarding the imports covered by the registration.

A4.7.3 Other importers are considered to be down-stream users for this particular supply chain.

A5. REACH GUIDELINES PROCEDURE FOR ARTICLE MANUFACTURER

Glossary

NOTE A5.1—This annex is intended as an example only. Regulations and tables are continuously reviewed and revised. Complete information can be obtained on the ECHA website (http://guidance.echa.europa.eu/navigator_en.htm).

NOTE A5.2—This annex contains terms included in the terminology

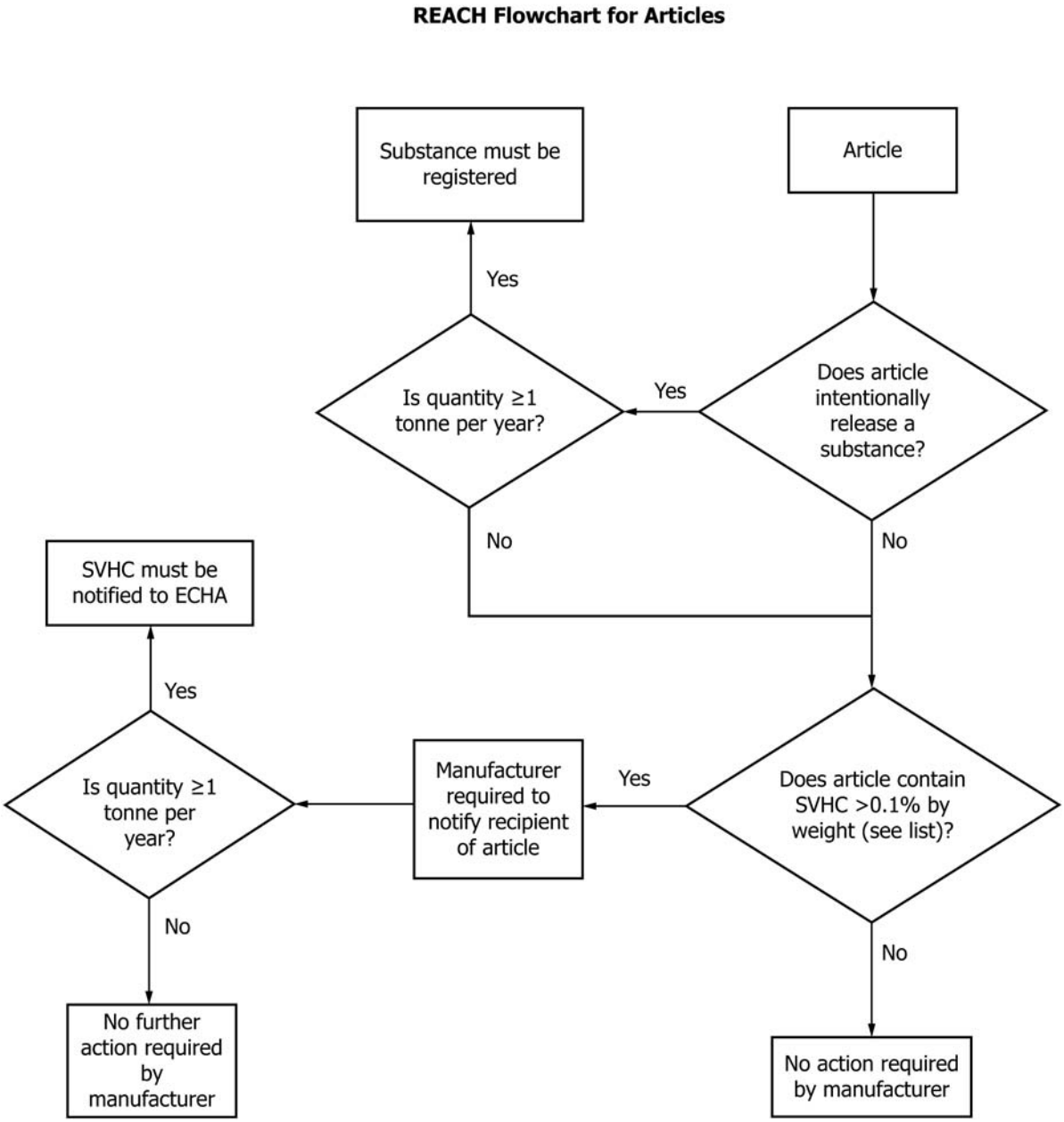


FIG. A5.1 REACH Flowchart for Articles

section, but which are repeated here for ease of use. Also, the information provided here may be more detailed.

A5.1 *Article*—An article is an object that during production is given a special shape, surface, or design that determines its function to a greater degree than does its chemical composition. Examples of articles include an ink pen, computer, automobile and screw, nut and bolt.

A5.2 *Authorization* :

A5.2.1 The REACH Regulation requires that ECHA identifies from the candidate list certain substances to be included in Annex XIV of REACH (the "Authorization List") and recommends transitional arrangements and, where relevant, exemptions and review periods for these substances to the European Commission. Applications for authorization need to be made within the set deadlines for each use that is not exempted from the authorization requirement.

A5.2.2 In some cases an authorization can be based solely on 'adequate control' (demonstrated in the Chemical Safety Report (CSR)) of the substance for the use in question. Applications for an authorization must be accompanied by an analysis of possible alternatives. Authorizations are subject to a time-limited review that will enable further consideration of the availability of alternatives at some point in the future.

A5.3 *Intentionally Released Aubstances*—Some articles intentionally release a substance as part of their normal or foreseeable use. The substances released from these articles must be registered. Examples of articles that intentionally release a substance are ink jet and laser printers, aerosol sprays and air fresheners. There are cases when a substance may be unintentionally released from an article. Examples of unintentional release include tire and brake wear in automobiles and carbon dust emission from commutator motors. These substances do not require registration. There are examples of articles that, although intended to release a substance during use, are not packaged or sold with the substance being released. Examples include paint and pesticide sprayers and carpet extractor vacuum cleaners. If the substance is not packaged and provided with the article, registration is not required. If the substance is packaged and provided with the article, then the substance must be registered. For the purpose of REACH a substance or mixture that is manufactured within the European Community, imported to the European Community or intentionally released from an article in quantities equal to or greater than 1 tonne per year must be registered. Failure to register a substance or pre-register a phase-in substance will limit a substances use to less than 1 tonne per year until registration is complete.

A5.4 *Mixture*—Mixture or solution composed of two or more substances; preparations can contain several substances; they are not the same as multiconstituent substances; the difference between preparation and multiconstituent substance is that a mixture is gained by blending of two or more substances without any chemical reaction occurring, whereas a multiconstituent substance is the result of a chemical reaction; examples of preparations include paints, varnishes, and inks.

A5.5 *Non-Phase-in Substance* —These are new substances that must be registered immediately and are not eligible for the extended deadlines provided for phase-in substances.

A5.6 *Only Representative*—A third party established within the European Community who may serve as importer of record on behalf of natural or legal persons established outside of the European Community. The Only Representative must not fulfill the obligations required for registering substances, but must also fulfill all other responsibilities of an importer under the REACH directive. The only representative is required to have sufficient background in the practical handling of substances and the information related to them.

A5.7 *Phase-in Substance*—This is a substance that meets at least one of the following criteria: *(1)* the substance is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) or *(2)* the substance is manufactured in the community, or in the countries acceding to the European Union on January 1995 or 1 May 2004, but not placed on the market by the manufacturer or importer at least once in the 15 years before the entry into force of the REACH regulation, provided the manufacturer or importer has documentary evidence of this. Only phase-in substances may be pre-registered under REACH. Non-phase-in substances are substances that do not meet the definition of phase-in substances as provided in Article 3(20) of the REACH Regulation. Non-phase-in substances are therefore normally new substances. It is important to proceed with registration as soon as possible from 1 June 2008 for these substances in order to minimize possible disruptions of manufacturing or placing on the market.

A5.8 *Registration and Pre-registration*—Pre-registration ended on 1 December 2008. Since that time pre-registration is allowed only under specific conditions. Registration began on 1 December 2008. Manufacturers and importers located within the European Community of articles that intentionally release substances under normal or reasonably foreseeable conditions of use and in which the substance is present in those articles in quantities of ≥1 tonne per year are required to gather information on the properties of their chemical substances, which will allow their safe handling, and to register the information in a central database run by the European Chemicals Agency (ECHA) in Helsinki. The producer must verify that the substance has not already been registered for that use as a prerequisite for notification or registration. Companies that manufacture substances, formulate mixtures or produce articles outside the European Community cannot register directly, since non-European manufacturers are not obligated under the REACH guidelines. Non-European manufacturers must nominate an Only Representative that is established within the European Community to carry out the required registration of their substances that are imported into the European Community. Pre-registration allows companies to continue manufacturing and importing their phase-in substances for several years until the registration deadline is reached. The extended deadlines are based upon weight and the hazardous properties of the substance. The extended deadlines are:

30 November 2010	Deadline for registration of chemicals of very high concern and substances produced or imported in high volumes (greater than 1 000 tonnes per year).
31 May 2013	Deadline for registration of chemicals produced or imported in quantities between 100 and 1 000 tonnes per year.
31 May 2018	Registration of low volume chemicals between 1-100 tonnes per year.

Non-phase-in substances cannot be pre-registered.

A5.9 *Registered Substance*—A non-phase-in substance that is notified in accordance with Directive 67/548/EEC is regarded as registered and therefore does not need to be pre-registered under REACH.

A5.10 *Responsible Entity*—Manufacturers located outside the European Community do not have any direct obligations under the REACH directive. Only manufacturers within the European Community and importers have a direct obligation. A manufacturer is defined as any natural or legal person established within the Community who manufactures a substance within the European Community. Non EU companies exporting substances on their own, in preparations or in articles to the Community may appoint an Only Representative to fulfill the obligations of an importer.

A5.11 *Substance*—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 that may be separated without affecting the stability of the substance or changing its composition. There are phase-in substances and non-phase-in substances. Pre-registration for phase-in substances ran from June 1, 2008 through December 1, 2008. Manufacturers of phase-in substances can benefit from extended deadlines. Manufacturers of non-phase-in substances must register the substance as quickly as possible in order to minimize or eliminate disruption of manufacturing or placing on market. Any phase-in substance not pre-registered by December 1, 2008 may not be placed on market in quantities greater than 1 tonne per year until registration is complete. REACH applies to all substances with a few exemptions: radioactive substances, substances under customs supervision, the transport of substances and non-isolated intermediates are not covered under REACH. Waste is also specifically exempted. A number of other substances are exempted from parts of the provisions of REACH, where other equivalent legislation applies (for example substances used in medicinal products). Polymers are for the time being exempted from registration. Special rules apply for substances used for research and development and for the registration of isolated intermediates. Note that for substances intended to be released from an article, the substance must be registered for the particular use. There are two special classes of substances that may be exempt from registration. They are:

A5.11.1 *Substances included in Annex IV*—Annex IV lists 40 substances for which it is understood that sufficient information is available to consider them as causing minimum risk to human health and the environment. These substances are typically of natural origin and the list of exempted substances includes, for example, nitrogen (N2). Substances included in Annex IV are exempted from the registration provisions. The list is based on Annex I to Regulation (EC) No 987/2008 amending the REACH Regulation as regards Annexes IV and V. The registration exemption applies to the substance as such, not to a particular use. Substances included in Annex IV are subject to periodic review and adjustment. As time goes on more substances are expected to be added to the list. Therefore, the attached Annex V is to be considered as incomplete. A complete list of Annex IV substances may be obtained from the European Chemical Agency website (http://www.echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp).

A5.11.2 *Substances covered by Annex V*—Annex V lists thirteen broad categories of substances for which registration is deemed inappropriate or unnecessary. They are exempted from the registration and evaluation provisions, but not necessarily from authorization or restrictions. The registration exemption applies to the substances as such, provided however that they meet the conditions for the exemption which are given in the particular category of Annex V. For example, for hydrates or hydrated ions, copper (II) sulphate pentahydrate formed by association of copper (II) sulphate with water, will not require registration by its manufacturer provided the copper (II) sulphate was registered (or exempted) from registration. The list is based on Annex II to Regulation (EC) No 987/2008 amending the REACH Regulation as regards Annexes IV and V. Substances included in Annex V are subject to periodic review and adjustment. As time goes on more substances are expected to be added to the list. Therefore, the attached Annex IV is to be considered as incomplete. A complete list of Annex IV substances may be obtained from the European Chemical Agency website (http://www.echa.europa.eu/chem_data/authorisation_process/candidate_list_en.asp).

A5.12 *Substances of Very High Concern (SVHC)*—These are substances that are considered to have hazardous properties of such high concern that it is necessary to regulate them centrally through a mechanism that ensures that the risks related to their actual uses are assessed, considered and then decided upon on an EU-wide basis. Some substances are required to be authorized for their use and placing on the market. Substances required to be authorized are substances that are classified as: CMR—carcinogenic, mutagenic or toxic for reproduction category 1 and 2; PBT or vPvBs—persistent, bio-accumulative and toxic or very persistent and very bio-accumulative according to given criteria, and/or give rise to an 'equivalent level of concern' to those mentioned above where there is scientific evidence of probable serious effects to humans or the environment (for example, endocrine disruptors) which will be identified on a case-by-case basis. The first list of SVHCs was published in October 2008 and is provided in Table A5.1. Substances included in the list of SVHCs are subject to periodic review and adjustment. As time goes on more substances are expected to be added to the list. Therefore, the attached first list of SVHCs is to be considered as incomplete. A complete list of SVHCs may be obtained from

TABLE A5.1 First List of Candidate Materials for SVHC for Authorization

NOTE 1—This table is intended as an example of known SVHC materials and should be considered as incomplete. A complete and current list can be found on the ECHA website.

Substance Identification					
Substance Name	EC (CAS No.)	Substance Composition Impurities (where relevant C&L, PBT/vPvB)	Date of Inclusion	Reason for Inclusion	Decision Number
Triethyl arsenate	427-700-2	–	28-10-08	Carcinogenic (art. 57a)	ED/67/2008
Anthracene	204-371-1	–	28-10-08	PBT (art. 57d)	ED/67/2008
4,4' – Diaminodiphenylmethane (MDA)	202-974-4	–	28-10-08	Carcinogenic (art. 57a)	ED/67/2008
Dibutyl phthalate (DBP)	201-557-4	–	28-10-08	Toxic for reproduction (art. 57c)	ED/67/2008
Cobalt dichloride	231-589-4	–	28-10-08	Carcinogenic (art. 57a)	ED/67/2008
Diarsenic pentaoxide	215-116-9	–	28-10-08	Carcinogenic (art. 57a)	ED/67/2008
Diarsenic trioxide	215-481-4	–	28-10-08	Carcinogenic (art. 57a)	ED/67/2008
Sodium dichromate	234-190-3 (7789-12-0 and 10588-01-9)	–	28-10-08	Carcinogenic, mutagenic and toxic to reproduction (art. 57a, 57b and 57c)	ED/67/2008
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	201-329-4	–	28-10-08	vPvB (art. 57e)	ED/67/2008
Bis (2-ethylhexyl)phthalate (DEHP)	204-211-0	–	28-10-08	Toxic for reproduction (art. 57c)	ED/67/2008
Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified):	247-148-4 and 221-695-9	–	28-10-08	PBT (art. 57d)	ED/67/2008
Alpha- hexabromocyclododecane	(134237-50-6)				
Beta- hexabromocyclododecane	(134237-51-7)				
Gamma- hexabromocyclododecane	(134237-52-8)				
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	287-476-5	–	28-10-08	PBT and vPvB (art. 57d, 57e)	ED/67/2008
Bis(tributyltin)oxide (TBTO)	200-268-0	–	28-10-08	PBT (art. 57d)	ED/67/2008
Lead hydrogen arsenate	232-064-2	–	28-10-08	Carcinogenic and Toxic to reproduction (art. 57a and 57c)	ED/67/2008
Benzyl butyl phthalate (BBP)	201-622-7	–	28-10-08	Toxic for reproduction (art. 57c)	ED/67/2008

the European Chemical Agency website. (http://www.echa.europa.eu/chem_data/authorisation_process/candidate_list). Articles containing SVHC above a concentration limit of 0.1 % and above a total SVHC mass/volume of 1 tonne per year manufactured in or imported into the European Community must be notified to the European Chemicals Agency by June 2011. Notification is not required if the substance has already been registered for that use or where exposure to humans and environment can be excluded during normal conditions of use including disposal. There is no obligation to notify SVHC in articles if the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use and disposal The notification of SVHC in articles shall be made at the latest six months after it has been included on the candidate list for authorization but only starting from 1st June 2011. Information on substances on the candidate list contained in articles is to be forwarded by the supplier of the article to the recipients of the article directly after a substance is included in that list. A table of common uses for SVHCs is provided in Table A5.2.

TABLE A5.2 Common Uses of Some SVHC Materials

NOTE 1—The list of uses shown are some typical examples and may not include every use of the substance.

	Substance Name	Proposing Authority	Initial Classification	Justification for Inclusion	Manufacture and Uses
1	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.
2	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.
3	Dibutyl phthalate (DBP)	Austria	CMR	Category 2 reproductive toxins. Based on rat studies detailed in a 2004 EU Risk Assessment Report, Austria considers that DBP has fertility and developmental toxicity effects.	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.
4	Cyclododecane	France	PBT	PBT and vPvB. Following studies on fish, France considers that cyclododecane has toxic properties. No risk has been identified to human health.	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. 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.
5	Cobalt dichloride	France	CMR	Category 2 carcinogen. 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.	The main uses of cobalt dichloride are as an "oxyvore" to remove oxygen gas during metal production and as an additive in rubber tire manufacture. 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, (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.

TABLE A5.2 *Continued*

	Substance Name	Proposing Authority	Initial Classification	Justification for Inclusion	Manufacture and Uses
6	Diarsenic pentaoxide	France	CMR	Category 1 carcinogen. 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.	Diarsenic pentaoxide is used: (i) in the dying industry, (ii) in metallurgy (to harden copper, lead or gold in alloys), and (iii) for manufacturing certain types of glass.
7	Diarsenic trioxide	France	CMR	Category 1 carcinogen. 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.	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. It is also used as a wood preservative (when imported from outside of the EU).
8	Sodium dichromate, dihydrate	France	CMR	Category 2 carcinogen. 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.	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.
9	5-tert-butyl-2,4,6-trinitrom-xylene (musk xylene)	Netherlands	vPvB	vPvB. Based on mice studies contained in a 2005 EU Risk Assessment Report, the Netherlands considers that musk xylene has carcinogenic properties.	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.
10	Bis (2-ethyl(hexyl)phthalate) (DEHP)	Sweden	CMR	Category 2 reproductive toxin. Based on a 2008 EU Risk Assessment Report and other studies on animals, Sweden considers that DEHP has detrimental fertility and foetal developmental effects.	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).
11	Hexabromocyclododecane (HBCDD)	Sweden	PBT	B, vB and T. Based on a 2008 EU Risk Assessment Report and other studies on animals, Sweden considers that HBCDD has detrimental fertility and developmental effects.	Widely used on its own or in conjunction with other flame retardants, mainly in polystyrene products but also in some textiles.
12	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.

TABLE A5.2 *Continued*

	Substance Name	Proposing Authority	Initial Classification	Justification for Inclusion	Manufacture and Uses
13	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.
14	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.)
15	Triethyl arsenate	Norway	CMR	See the comments in relation to lead hydrogen arsenate, above	See the comments in relation to lead hydrogen arsenate, above
16	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.e., 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.

TABLE A5.3 L 268/16 EN Official Journal of the European Union 9.10.2008
ANNEX IV
EXEMPTIONS FROM THE OBLIGATION TO REGISTER IN ACCORDANCE WITH ARTICLE 2(7)(a)

NOTE 1—This list provides a compilation of substances exempted when the document was first written. The list will vary over time and should be considered as being incomplete. A complete list can be found on the ECHA website.

Einecs No	Name/Group	CAS No
200-061-5	D-glucitol $C_6H_{14}O_6$	50-70-4
200-066-2	Ascorbic acid $C_6H_8O_6$	50-81-7
200-075-1	Glucose $C_6H_{12}O_6$	50-99-7
200-233-3	Fructose $C_6H_{12}O_6$	57-48-7
200-294-2	L-lysine $C_6H_{14}N_2O_2$	56-87-1
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 $C_6H_{12}O_6$	59-23-4
200-432-1	DL-methionine $C_5H_{11}NO_2S$	59-51-8
200-559-2	Lactose $C_{12}H_{22}O_{11}$	63-42-3
200-711-8	D-mannitol $C_6H_{14}O_6$	69-65-8
201-771-8	L-sorbose $C_6H_{12}O_6$	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 $C_9H_{17}NO_{5.1/2}Ca$	137-08-6
205-756-7	DL-phenylalanine $C_9H_{11}NO_2$	150-30-1
208-407-7	Sodium gluconate $C_6H_{12}O_7$.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
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_2O	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 $C_6H_{12}O_7$.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
266-948-4	Glycerides, C_{16-18} and C_{18}-unsaturated This substance is identified by SDA Substance Name: C_{16-C18} and C_{18} unsaturated trialkyl glyceride 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, 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

TABLE A5.4 L 268/16 EN Official Journal of the European Union 9.10.2008
ANNEX V
EXEMPTIONS FROM THE OBLIGATION TO REGISTER IN ACCORDANCE WITH ARTICLE 2(7)(b)

1.	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.
2.	Substances which result from a chemical reaction that occurs incidental to storage of another substance, preparation or article.
3.	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.
4.	Substances which are not themselves manufactured, imported or placed on the market and which result from a chemical reaction that occurs when: (a) a stabilizer, colorant, flavoring agent, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, desiccant, binder, emulsifier, de-emulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutralizer, 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.
5.	By-products, unless they are imported or placed on the market themselves.
6.	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.
7.	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.
8.	Substances which occur in nature other than those listed under paragraph 7, 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).
9.	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.
10.	The following substances if they are not chemically modified: Liquefied petroleum gas, natural gas condensate, process gases and components thereof, coke, cement clinker, magnesia.
11.	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 lifecycle of the substance and those data have been ascertained to be adequate and reliable: Glass, ceramic frits.
12.	Compost and biogas.
13.	Hydrogen and oxygen.