ORGALIME INFORMATION NOTE

Article 33
of Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Communication obligations on substances in articles

SEPTEMBER 2018

CONTENTS

FOREWORD – INTRODUCTION TO THIS ORGALIME INFORMATION NOTE

This information note provides a descriptive summary (no interpretation) of the requirements of Article 33 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and provides readers with an overview of common existing practices within the industry to meet them.

The information note addresses the following main points:

- It takes stock of common existing practices of implementation of the communication obligations on substances in articles of REACH Regulation.
- It considers those practices in light of the European Court of Justice (ECJ) judgment related to case C-106/14 of 10th September 2015 that clarified the scope of the communication obligations under Article 33 of REACH further to different views of six Member States and the European Commission on how to calculate the relevant concentration threshold for complex articles. The ECJ ruled that the given concentration threshold of 0.1% does not apply to the entire complex of very complex object (as was the Commission's, ECHA and industry's common understanding so far), but to each article included in the complex or very complex object (i.e. object made up of more than one article).
- It includes the latest update of the related ECHA Guidance on requirements for substances in articles which incorporates the changes following the ECJ judgment and was completed in June 2017. Note: the interpretation from ECHA is challenged by several industry sectors in particular against the principle of proportionality established in Article 5 of the EU Lisbon Treaty (the measure shall not exceed what is necessary to achieve the given objective).

In the next pages, the following issues are tackled:

1. General introduction on the relevant terminology and definitions;
2. Description of the requirements of Article 33 of REACH;
3. Overview of common existing practices among the industry and how these should be amended following the European Court of Justice judgment.

Disclaimer: this ORGALIME information note reflects the best knowledge of industry experts from all over Europe and the state of the art at the moment of its publication. This document **aims at providing a descriptive overview of the relevant legal provisions, interpretation notes and reference documents that technology manufacturers need to be aware of when identifying the precise compliance measures to be taken for their specific products.** A binding interpretation of Community legislation is of the exclusive competence of the European Court of Justice. Subject to new information, this document may be modified to accommodate new developments. Such information will be made available on ORGALIME's website.

ORGALIME representing the European Technology Industries speaks for 45 trade federations of the mechanical, electrical, electronic, metalworking & metal articles industries of 23 European countries. The industry employs nearly 11 million people in the EU and in 2016 accounted for some €2,000 billion of output. The industry represents over a quarter of the output of manufactured products and over a third of the manufactured exports of the European Union.

1. SOME PRECISIONS ON TERMINOLOGY AND DEFINITIONS

Before entering in the details of the communication obligations laid out under Article 33 of REACH Regulation and of industry existing practices in relation to them, it is important to understand the terms used in the REACH Regulation, the Judgment of the European Court of Justice in the case C-106/14 and in the ECHA guidance on requirements for substances in articles.

1.1 Definitions in the REACH Regulation

The REACH Regulation defines the terms "article", "producer of an article", "supplier of an article" and "recipient of an article".

Article 3 on definitions of REACH Regulation states:

*Article 3(3): **Article** means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.*

*Article 3(4): **Producer of an article** means any natural or legal person who makes or assembles an article within the Community;*

*Article 3(33): **Supplier of an article** means any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market;*

*Article 3(35): **Recipient of an article** means an industrial or professional user, or a distributor, being supplied with an article but does not include consumers;*

The REACH Regulation does not contain any definition of the term "complex article" or "complex product".

1.2 Definitions in the European Court of Justice judgment in the case C-106/14 of 10th September 2015

The term "complex product" is defined in the Judgment of the European Court of Justice (ECJ) in the case C-106/14.

ECJ judgment the case C-106/14 states:

Paragraph 41: *"**a product composed of one or more articles** ".*

Paragraph 48: *a "**complex' product** is made up of a number of manufactured objects meeting the criteria laid down in Article 3(3) of the REACH Regulation.*

Paragraph 53: ***a manufactured object** meeting the criteria laid down in Article 3(3) of the REACH Regulation does not cease to be an article when it is assembled or joined with other objects in order to form with them a **complex product**. In such a situation, that manufactured object remains an 'article' within the meaning of that provision. It remains so as long as it retains a special shape, surface or design which is more decisive for its function than its chemical composition or as long as it does not become waste within the meaning of Directive 2006/12.*

Paragraph 54: *Consequently, the classification as an article remains applicable to any object meeting the criteria in Article 3(3) of the REACH Regulation and forming part of the composition of a **complex product** unless, following a production process, that object*

becomes waste or ceases to have the shape, surface or design which is more decisive in determining its function than its chemical composition.

Please note that the ECJ judgment uses the word "*product*" to refer to an article or a complex object or a very complex object. In an industrial context, "*product*" and "*article"* would usually be used as synonyms for manufactured products, while the term "*object*" is not commonly used in this context. The above paragraph 41 refers to "*the case of a product composed of one or more articles*" while paragraph 48, 53 and 54 refer to "complex product" and "manufactured object". See the below section 1.4 for a more practical understanding of the terms "articles", "complex objects" and "very complex objects".

1.3 Definitions in the ECHA guidance on requirements for substances in articles, June 2017

The ECHA guidance on requirements for substances in articles refers to the term 'complex object as defined by the European Court of Justice in the case C-106/14 of 10th September 2015 and introduces the term of 'very complex object'.

ECHA Guidance on requirements for substances Section 2.4 – What is a complex article? – states:

Complex object *refers to any object made up of more than one article. In complex objects, several articles can be joined or assembled together in various manners. The more articles it is made of, the more complex an object becomes. Note: The terminology "complex object" in this ECHA document corresponds to the term "complex product" as used in the Court Judgment in the case C-106/14.*

Very complex objects *refers to further combinations of simpler complex objects.*

It is also relevant to note that the ECHA guidance specifies that packaging is "*to be considered as a separate article under REACH and the same requirements apply to it as for any other article".*

1.4 Orgalime table with examples of articles, complex objects and very complex objects for the technological sector

	From "ARTICLES" →	To "COMPLEX OBJECTS" →	And "VERY COMPLEX OBJECTS"
Example 1 from ECHA Guidance on requirements for substances in articles (see page 95)	The various components of the hole mounted capacitor such as conductors, the dielectric, connectors, wires and the casing. →	Hole-mounted capacitors →	Printed circuit boards (consisting of a plain layered board with printed wires, capacitors, resistors, transistors, inductors, diodes, microprocessors, microchips, fans, screws, among other objects), mobile phones, computers, video cameras.

	From "ARTICLES"	To "COMPLEX OBJECTS"	And "VERY COMPLEX OBJECTS"
Example 2	Screws	Electric motor	Machine
Example 3	Gear wheel	Gear box	Car
Example 4	O-ring	Hydraulic Valve	Piping system

2. THE REQUIREMENTS OF ARTICLE 33 OF REACH

2.1 REACH Regulation

Article 33 of the REACH Regulation states:

Article 33
Duty to communicate information on substances in articles

1. *Any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.*

2. *On request by a consumer any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the consumer with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.*

The relevant information shall be provided, free of charge, within 45 days of receipt of the request.

2.1.1 B2B communication obligations (Article 33.1 of REACH)

For Business to Business (B2B) communication obligations, since 2008 **Article 33.1** of REACH requires that, if certain conditions are met, the supplier of an article communicates automatically to the recipient of that article sufficient information available to him on certain substances present in the article to allow safe use. The information must always include "as a minimum" the name of the substance.

Article 33.1 of the REACH Regulation states:

1. *Any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.*

Therefore, **in B2B, suppliers of articles must automatically inform their recipients** in case Article 33.1 REACH applies. Therefore, EU suppliers of articles must not wait for the request of their recipients to communicate information. It is their legal obligation to transfer any information available to them to their recipient. They may have such information because:

- they know of the presence of a Substance of Very High Concern (SVHC) above a certain threshold as result of their work on an article (e.g. they coated a part of it and the coating contained an SVHC on the Candidate List)
- their suppliers informed them about the presence of a SVHC above the threshold indicated in Article 33.

For suppliers within the EU, recipients do not have any legal obligation to send such requests. Recipients may send requests to their suppliers on a voluntary basis. Despite this not being a requirement under Article 33, they may want to proactively request information for several reasons:

1. It will allow them to gauge if there is any information that should be provided to the next recipient, including, if needed any information on safe use, as provided for by Article 33.
2. It will support the fulfilment of notification obligations under Article 7(2) REACH.
3. It will allow to have information on what is in their product.

Please see in Annex II the Orgalime model letter for structuring communication up the supply chain in order to implement Article 33(1) REACH information requirements.

For suppliers outside the EU, recipients do not have any legal obligation to send such requests either. Recipients may send requests to their suppliers on a voluntary basis for the same above reasons as for suppliers within the EU. However, they are strongly recommended to request information from suppliers outside the EU because recipients of imported products become the first EU suppliers themselves and are the first EU actor legally obliged to transfer the information to the next recipient of that article. The Orgalime model letter in Annex II can also be used for structuring communication up the supply chain outside the EU.

2.2.2 B2C communication obligations (Article 33.2 of REACH)

For **Business to Consumer (B2C) communication obligations, Article 33.2** of REACH provides that the **information requirement shall extend to consumers upon request**. The information must be provided free of charge within 45 days of receipt of the request.

Article 33.2 of the REACH Regulation states:

> *On request by a consumer any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the consumer with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.*
>
> *The relevant information shall be provided, free of charge, within 45 days of receipt of the request.*

Therefore, **in B2C, there is no such obligation to "automatically" transmit information,** as is the case for B2B in Article 33.1 of REACH.

2.2 European Court of Justice judgment in the case C-106/14

On 10th September 2015, the judgment of the European Court of Justice (ECJ) further clarified the scope of the communication obligations under Articles 7(2) and 33 of REACH further to different views of six Member States (Belgium, France, Germany, Norway, Denmark and Sweden) and the European Commission on how to calculate the relevant concentration

threshold for complex articles. The ECJ ruled that the given concentration threshold of 0.1% does not apply to the entire complex of very complex object (as was the Commission's, ECHA and industry's common understanding so far) but to each article included in the complex or very complex object (i.e. object made up of more than one article), as long as these articles keep a special shape, surface or design and do not become waste.

ECJ Judgment in Case C-106/14 dated 10 September 2015 states:

1. ***Article 7(2)*** *of the REACH Regulation must be interpreted as meaning that, for the purposes of application of that provision, it is for the producer to determine whether a Candidate List substance of very high concern, is present in a concentration above 0.1% weight by weight of any article it produces and, for the importer of a product made up of more than one article, to determine for each article whether such a substance is present in a concentration above 0.1% weight by weight of that article.*

2. ***Article 33*** *of Regulation No 1907/2006, as amended, must be interpreted as meaning that, for the purposes of application of that provision, it is for the supplier of a product one or more constituent articles of which contain(s) a substance of very high concern identified in accordance with Article 59(1) of that regulation in a concentration above 0.1% weight by weight of that article, to inform the recipient and, on request, the consumer, of the presence of that substance by providing them, as a minimum, with the name of the substance in question.*

2.3 Update of ECHA Guidance on requirements for substances in articles, June 2017

Following the judgment of the European Court of Justice in the case C-106/14 of 10th September 2015, ECHA published in June 2017 an updated Version 3.0 of their (non-legally binding) guidance on requirements for substances in articles to reflect the new interpretation of conclusions of the Court's judgment. Amongst other, the guidance provides further guidance on these obligations for complex objects, i.e. objects composed of several articles and illustrates duties under Article 33 of REACH for suppliers of articles, complex objects and very complex objects.

The ECHA Guidance on requirements for substances in articles states:

Subchapter 3.2.1 Communication of information down the supply chain

Any supplier of an article containing a substance has to provide to the recipient of the article (Article 33(1)) or to a consumer (Article 33(2)) relevant safety information, available to him, when both the following conditions are met:

- *The substance is included in the Candidate List for authorisation, and*
- *The substance is present in articles produced and/or imported above a concentration of 0.1% (w/w),*

The information is to be provided to the recipient of the article when the article is supplied for the first time after the inclusion of the substance into the Candidate List and to the consumer upon request by that consumer, within 45 calendar days of that request and free of charge.

If no particular information is necessary to allow safe use of the article containing a Candidate List substance, e.g. when exposure can be excluded at all life cycle stages of the article including disposal, ***as a minimum the name of the substance in question has to be communicated to the recipients of the article or to consumers.*** *The information provided should make it clear that the substance is on the most recent* update of the Candidate List *and that this is the reason for giving the information.*

As concerns the obligations to communicate information on substances in articles in general (i.e. communication towards recipients and consumers), note that:

- *The Candidate List substance concentration threshold of 0.1% w/w applies to every article supplied. This threshold applies to each article of an object made up of more than one article, which were joined or assembled together (complex objects).*
- *There is no tonnage trigger for these obligations.*
- *A distributor supplying articles to consumers does not comply with his communication obligation toward a consumer upon request, just by referring the consumer to his own supplier, or the producer/importer of the articles.*
- *The communication obligations arise from the presence of the Candidate List substance in the article. These obligations apply regardless of whether or not the supplier is aware of the presence of the substances. Therefore, it is in the interests of the supplier to seek information on the presence of Candidate List substances.*
- *The communication of information at the request of a consumer is independent of whether the article was purchased by that particular consumer.*

Subchapter 3.4.1 Communication information according to Article 33

EU producers and importers of articles and all actors in the supply chain are required to communicate down the supply chain on the presence of the Candidate List substances (above 0.1% w/w). The information communicated should be sufficient to allow safe use of articles. While industrial/commercial actors in the supply chain should get this information as a matter of course, consumers have to request the information.
As the first actor in the article supply chain, an article producer or importer has to take into account all reasonably foreseeable steps and activities involving his article down his supply chain, when identifying what information to compile and communicate. The actors further down the supply chain, who may have a more precise understanding of where and how the article is used by its next user(s), should each identify any additional information available to them and relevant for the activities his customers carry out.
When identifying what information is necessary to compile and communicate to allow the safe use of the article, the supplier of an article must consider all the life-cycle stages during use of the article. These can include e.g.:

- *further industrial and professional processing or assembling of the articles;*
- *(re)packaging or storing the articles;*
- *industrial, professional and consumer end use of the articles, including installation and maintenance.*

Furthermore, the supplier should consider recycling and disposal of the articles as well as foreseeable misuse of articles, in particular, by consumers.

For each life-cycle step, the information on safe use can include:
i. use conditions, e.g. temperature, outdoor/indoor, frequency, duration;
ii. risk management measures to reduce exposure and emissions, which are possible to apply in practice and effectively.
What information is relevant to be communicated should however be assessed and decided on a case-by-case basis, in order to ensure that it fits the purpose of ensuring the safe use of articles. Type and detail of information on any one article may differ depending on who the recipient is. For example, an industrial user would normally not need the advice that an article should be kept out of reach of children, whereas such information can be appropriate for consumers. Information on how to control exposure of workers to the substance when further processing an article would be relevant to an industrial and professional actor.
The identification of what safe use information is relevant for the recipient can also be guided by exposure/risk based considerations. If exposure of humans or environment is not possible or there is evidence that it is insignificant, the level of information needed is lower, i.e. the

name of the substance may be sufficient. However, it should be kept in mind that, firstly, the communication obligations apply to substances of very high concern which are included in the Candidate List for authorisation, and secondly, exposure during all subsequent life-cycle stage including recycling and disposal should be considered.
All actors receiving information should follow the recommended use conditions and implement the recommended risk management measures. Moreover, they must pass on any relevant information to the next actor in the supply chain, or to consumers upon request, taking into account the expected uses and conditions of use of the article placed on the market.
In the case of complex objects, the communication requirements under Article 33 of REACH apply to each article, containing a Candidate List substance (>0.1% w/w), incorporated into a complex object. *This is exemplified in example 12 for one case.*

ECHA Guidance Example 12 *(What information to communicate when supplying a complex object)* ***and Example 23*** *(Bicycle)* ***indicate that either for articles on their own or incorporated into a complex object, REACH Article 33 requires three blocks of information to be systematically communicated down the supply chain and to consumers upon request:***

1. ***Name of the Candidate List substance present in the article (above 0.1% w/w);***
2. ***Name/identification of the article containing that substance;***
3. ***Any (other) information needed, as a consequence of the presence of that substance in the article, to ensure its safe use (safe use information).***

Important note: several industry sectors are challenging the below three mandatory information layers of ECHA interpretation in particular against the principle of proportionality established in Article 5 of the EU Lisbon Treaty (the measure shall not exceed what is necessary to achieve the given objective).

"REACH Article 33 requires three blocks of information to be systematically communicated down the supply chain and to consumers upon request:

1. *Name of the Candidate List substance present in the article (above 0.1% w/w);*
2. *Name/identification of the article containing that substance;*
3. *Any (other) information needed, as a consequence of the presence of that substance in the article, to ensure its safe use (safe use information)."*

The ECHA Guidance on requirements for substances in articles states:

Appendix 5 Hints for facilitating the fulfilment of the requirements for Candidate List substances in articles 3.4.1 Communication information according to Article 33

This appendix complements chapters 3 and 5 of the guidance. It proposes possible approaches and examples to overcome difficulties that may arise when trying to identify which Candidate List substances could be contained in articles incorporated in complex objects.

Very complex objects are the main focus of these approaches and hints. However, they can also apply to simpler complex objects and even to (individual) articles.

The assessment of the Candidate List substances in articles requirements must always be done case-by-case for each article in a complex object and depending in particular on the manner they were joined or assembled together. The principles provided in chapter 3 for simple scenarios are applicable to the simplest as well as the most complex objects.

The determination of the presence and concentration of Candidate List substances in all articles joined or assembled together in a very complex object can be demanding where the number of articles is high, in particular for importers. It is also

noted that the identification and differentiation of all articles may be challenging in these cases. *Depending on the case and position in the supply chain, actors may need to use either a "**bottom-up" approach** (i.e. from the simplest components – articles or simplest complex objects - to the very complex object) **or "top-down" approach** (i.e. from the very complex object to the simplest components), or a combination of both, for all articles incorporated in such an object, in order to obtain the necessary information to fulfil their obligations.*

It is the responsibility of the article producers and importers, as well as of other suppliers of articles, to use the best approach adapted to each individual *case when applying the requirements under the REACH regulation for Candidate List substances in articles where articles are joined or assembled together. It is recommended always to document the approaches applied and basic considerations so that each duty holder is able to justify his conclusions towards customers and national enforcement authorities.*

2.4 Substances triggering communication obligations under Article 33

Article 33 of REACH applies to substances in articles meeting both of the following criteria:

1. The substance is identified as a substance of very high concern (SVHC) per Article 57 of REACH and the substance is included in the so-called 'Candidate List'
2. The substance is present in the article in a concentration above 0.1% weight by weight (w/w):

1. The substance is identified as a substance of very high concern (SVHC) per Article 57 of REACH and the substance is included in the so-called 'Candidate List'

The Candidate List is a publicly available list published on ECHA's website here. This list is not fixed and ECHA updates it twice a year, usually in January and July, following the process described in Annex I of this Information Note. As shown in the graph in Annex I, companies can anticipate what substances are highly likely to be added onto the Candidate List by monitoring ECHA's Registry of SVHC Intentions. Please note that EU suppliers of articles have the legal obligation to keep themselves informed about the status of the Candidate List. For this, it is recommended to suppliers of articles to subscribe to ECHA Newsletter.

REACH Regulation states:

Article 57 Substances to be included in Annex XIV (Candidate List substances):

The following substances may be included in Annex XIV in accordance with the procedure laid down in Article 58:
(a) substances meeting the criteria for classification as carcinogenic category 1 or 2 in accordance with Directive 67/548/EEC;
(b) substances meeting the criteria for classification as mutagenic category 1 or 2 in accordance with Directive 67/548/EEC;
(c) substances meeting the criteria for classification as toxic for reproduction category 1 or 2 in accordance with Directive 67/548/EEC;
(d) substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII of this Regulation;

(e) substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII of this Regulation;
(f) substances - such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) - for which there is scientific evidence of probable serious effects to human health or the environment which give rise to

an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.

Article 59 Identification of substances referred to in Article 57:

1. *The procedure set out in paragraphs 2 to 10 of this Article shall apply for the purpose of identifying substances meeting the criteria referred to in Article 57 and establishing a candidate list for eventual inclusion in Annex XIV. The Agency shall indicate, within this list, the substances that are on its work programme according to Article 83(3)(e).*
2. *The Commission may ask the Agency to prepare a dossier in accordance with relevant sections of Annex XV for substances which in its opinion meet the criteria set out in Article 57. The dossier may be limited, if appropriate, to a reference to an entry in Annex I of Directive 67/548/EEC. The Agency shall make this dossier available to the Member States.*
3. *Any Member State may prepare a dossier in accordance with Annex XV for substances which in its opinion meet the criteria set out in Article 57 and forward it to the Agency. The dossier may be limited, if appropriate, to a reference to an entry in Annex I of Directive 67/548/EEC. The Agency shall make this dossier available within 30 days of receipt to the other Member States.*
4. *The Agency shall publish on its website a notice that an Annex XV dossier has been prepared for a substance. The Agency shall invite all interested parties to submit comments within a specified deadline to the Agency.*
5. *Within 60 days of circulation, the other Member States or the Agency may comment on the identification of the substance in relation to the criteria in Article 57 in the dossier to the Agency.*
6. *If the Agency does not receive or make any comments, it shall include this substance on the list referred to in paragraph 1. The Agency may include this substance in its recommendations under Article 58(3).*
7. *When comments are made or received, the Agency shall refer the dossier to the Member State Committee within 15 days of the end of the 60-day period referred to in paragraph 5.*
8. *If, within 30 days of the referral, the Member State Committee reaches a unanimous agreement on the identification, the Agency shall include the substance in the list referred to in paragraph 1. The Agency may include that substance in its recommendations under Article 58(3).*
9. *If the Member State Committee fails to reach a unanimous agreement, the Commission shall prepare a draft proposal on the identification of the substance within three months of receipt of the opinion of the Member State Committee. A final decision on the identification of the substance shall be taken in accordance with the procedure referred to in Article 133(3).*
10. *The Agency shall publish and update the list referred to in paragraph 1 on its website without delay after a decision on inclusion of a substance has been taken.*

2. **The substance is present in the article in a concentration above 0.1% weight by weight (w/w)**:
    - **Until 10th September 2015,** the generally accepted interpretation was that in case of a complex or a very complex object, the 0,1% w/w threshold applied to the whole complex or very complex object. A supplier had to communicate the information required by Article 33 on the complex object or very complex object he was selling, only if the content of the SVHC substance was higher than the threshold concentration over the weight of the whole complex object or very complex object.

    - **On 10th September 2015** in the judgment for the case C-106/14, the European Court of Justice (ECJ) clarified that **the threshold applies to each article included in the complex object or very complex object,** as long as they keep a special shape, surface or design:

ECJ Judgment in Case C-106/14 dated 10 September 2015 - states:

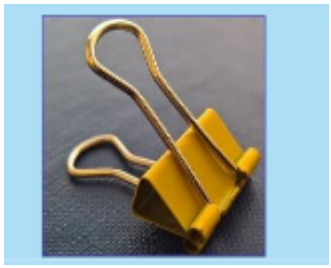
> ***Article 33*** *of Regulation No 1907/2006, as amended, must be interpreted as meaning that, for the purposes of application of that provision, it is for the supplier of a product one or more constituent articles of which contain(s) a substance of very high concern identified in accordance with Article 59(1) of that regulation in a concentration above 0.1% weight by weight of that article, to inform the recipient and, on request, the consumer, of the presence of that substance by providing them, as a minimum, with the name of the substance in question.*

Therefore, a supplier now must check the threshold concentration of 0,1% w/w in each article included in the supplied complex or very complex objects.

ECHA Guidance on requirements for substances in articles explains how to determine the concentration of Candidate List substance in an article[1].

Example[2]

Before the ECJ judgment, the previous ECHA guidance said that communication obligations kicked-in only if the SVHC was present above 0,1% on whole foldback clip



After ECJ judgment & clarification of Article 33 interpretation, communication obligations kick-in if the SVHC is present above 0,1% in the painted bent strip of steel or each one of the handles

2.5 When the communication obligations of Article 33 kick-in

The requirements of Article 33 of REACH apply to the supplied articles, complex objects or very complex objects as soon as a substance is included in the Candidate List. As of then it is known to the supplier that an article, a complex object or a very complex object he supplies contains a SVHC above 0,1% w/w, he shall communicate this to his customer.

It is irrelevant if his article, complex object or very complex object was imported or produced prior to the update of the Candidate List. What is relevant is the date of supply of the article, complex object or very complex object.

For example, if the Candidate List is updated with a new substance in July, the supplier of an article, a complex object or a very complex object, who supplies them as of July, must inform his recipient if those contain the substance newly added onto the Candidate List above 0,1% w/w.

[1] *See P. 33-40, https://echa.europa.eu/documents/10162/23036412/articles_en.pdf/cc2e3f93-8391-4944-88e4-efed5fb5112c*
[2] *Image taken from ECHA guidance on 'requirements for substances in articles'*

3. A DECADE OF REACH IMPLEMENTATION: AN OVERVIEW OF EXISTING PRACTICES ACROSS THE TECHNOLOGICAL SECTOR

Article 33 of REACH does neither prescribe how communication in the supply chain should be organised nor does it impose the use of specific formats for communication.

It is relevant to note that generally, companies face increasing requests regarding the chemical composition of their products and related information (e.g. concentration of substances used in them).

This is due not only to communication, notification and restriction requirements laid out under REACH, but also to restriction on substances in articles under other pieces of legislation in the EU (e.g. RoHS Directive 2011/65/EU) and outside the EU.

This chapter aims to provide a general non-exhaustive overview of the most common practices among the industry to address this situation and to meet the requirements of Article 33 of REACH.

The next pages explain what information should be communicated according to Article 33 of REACH and outline common practices on:

- Information supply
- Voluntary information request to suppliers
- Information management

They then consider how those practices should be amended due to the new interpretation of Article 33 REACH following the European Court of Justice (ECJ) judgment on case C-106/14 of 10th September 2015.

3.1 Information to be communicated

Article 33 of REACH requires suppliers of an article, complex object or very complex object, to provide the following information available to them:

- **As a minimum, the name of the SVHC on the Candidate List which is present in the article, a complex object or a very complex object above 0,1% weight by weight.**
  Practice shows that to avoid confusion, it is best to refer to the name of the substance used in the Candidate List and its CAS number rather than other commercial names.

- **Sufficient information to allow the safe use of the article, complex object or very complex object:** see details in the above section 2.3.

  It is relevant to note that information on the safe use of the article to be provided on the packaging or in user manuals or in the product description are often already required according to existing product safety legislation applying to Orgalime industries (*e.g.* Directive 2014/35/EU on electrical equipment designed for use within certain voltage limits or Directive 2001/95/EC on General Product Safety).

3.2 Information supply

Transfer of information in the sector in the supply chain occurs not only due to the obligations under Article 33 REACH but is also triggered by requirements under other pieces of legislation (e.g. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment - RoHS).

Practice shows that suppliers tend to provide their customers with:

- **Simple Yes/No declarations** which state that particular Candidate List substances are present, or are not present, in the supplied article, complex object or very complex object above 0,1% weight by weight.

- **Material declarations** - such declarations may either:
  - List the substances present in the article, complex object or very complex object that are subject to regulation, including substances listed on the Candidate List (when all conditions laid out under Article 33 are met). For the purpose of REACH Article 33, such declarations can state, at the specific date of issue, what SVHC are present above the given threshold in the supplied article, complex object or very complex object. Information for safe use must also be provided when needed (see point chapter '3.1 Information to be communicated').
    Following the ECJ ruling, suppliers providing these declarations need to take into account that the calculation of the SVHC threshold applies to each article in the complex object or very complex object.
    Of note, such declarations are valid at the time they are signed and need to be re-issued each time there is a variation in the article, complex object or very complex object or in the legislative framework. Suppliers of articles, complex objects or very complex objects must therefore re-issue their declaration related to Article 33, every time the Candidate List is updated and/or if there is a variation in the article, complex object or very complex object they supply.
  - List every substance in the supplied article, complex object or very complex object. Since, all substances are disclosed, regardless if they are SVHC on the Candidate List or not, this type of declarations goes beyond the requirements of Article 33.
    It is relevant to stress that experience has shown that it is highly difficult to produce/obtain such a full material declaration both for confidentiality reasons and for the complexity and length of the supply chain. The supplier may need information from his suppliers and even suppliers' suppliers to provide a full material declaration.

Simple Yes/No declarations and material declarations can be transferred in different ways, from paper to e-mail, or by using electronic or web-based tools.
Companies and industry have developed formats for Simple Yes/No declarations and material declarations.

They may also use **standards as model for supplying declarations**, including:

- **IEC 62474 - Material Declaration for Products of and for the Electrotechnical Industry**
  IEC 62474 is an International Standard for the exchange of material composition data and provides requirements for material declarations for the electrical and electronics industry. It establishes requirements for reporting of substances and materials, standardizes protocols, and facilitates transfer and processing of data. The standard is linked to a company specific database of substances which shall be reported in the material declaration if they are present above threshold levels specified in the database. The database includes only the SVHC on the Candidate List which IEC 62474 has identified as likely to be present in electrical and electronic equipment.

- **IPC 1752A - Data Exchange Standards**
  IPC-175x family of standards establishes a standard reporting format for data exchange between supply chain participants and includes standards for materials declarations, conflict minerals and laboratory reports.

The Appendices to the standard are updated after each new Candidate List is published and allow reporting against the full list of SVHC on any version of the Candidate List.

- **ISO 14025 - Environmental labels and declarations -- Type III environmental declarations**
  Type III environmental declaration communicates Life Cycle Assessment results and, where relevant, additional environmental information. Companies already using this declaration can include detailed REACH compliance information. Type III environmental declarations as described in ISO 14025:2006 are primarily intended for use in business-to-business communication, but their use in business-to-consumer communication under certain conditions is not precluded.

3.3 Voluntary information requests to suppliers

While not required by Article 33, practice has shown that **companies may decide to proactively request information according to Article 33 of REACH to their suppliers, instead of waiting for the information to be provided to them.**

When possible, to facilitate the work of suppliers, companies have tried to identify the target substance of the Candidate List relevant for the sector to focus on those SVHC that are likely to be present in in his article(s) by considering the materials usually used in them. That would allow supplier to focus efforts to those SVHC, rather than the whole Candidate List.

There are publicly available sources that can be used to search for this type of information on ECHA's website:

- Information on uses of substances based on REACH registration dossiers is available https://echa.europa.eu/information-on-chemicals
- Notifications on the use of substances on the Candidate List received by ECHA https://echa.europa.eu/information-on-chemicals/candidate-list-substances-in-articles-table

This screening activity appears to be easier to achieve by companies which have a relatively small product portfolio. It is more challenging for companies with larger product portfolios and several article models.

Non-exhaustive list of the most common practices to request information from suppliers:

- **Common practice 1- ad-hoc enquiry:**
  - For this type of ad-hoc requests, Orgalime has drafted a model letter (see Annex II) for material declarations.
  - Experience so far has shown that answers to such ad-hoc requests take time to collect or even may be challenging to collect especially in case of suppliers based outside the EU which are not affected by REACH.

- **Common practice 2 - use of contractual agreements:**
  - Some companies include in contracts with their suppliers, requirements that the products they sell to them are compliant with the REACH Regulation. They require that suppliers inform them as soon as one of the substances included in the Candidate List is contained in the supplied articles, complex objects or very complex objects in a concentration above 0.1% w/w (e.g. partial material declarations). In case a company uses software tools, companies introduce the use of such tool in the contractual clauses.

  - Since the ECJ ruling, contracts should specify that in case of complex or very complex objects, the concentration threshold of 0.1% w/w applies to each article joined or assembled in them.

- **Common practice 3 - use of software/IT solutions:**
  - Developed in house or by third party providers, some companies have turned to software and IT solutions to collect declarations from suppliers (Yes/No declarations, material declarations or both). More information on these solutions is provided in next chapter '3.4 Information management'.

3.4 Information management

Medium and large companies have allocated human and financial resources to the management of all information needed to comply not only with REACH but also with other piece of EU and non-EU legislation.

Additionally, some have turned to the use of information management tools including for example:

- **Electronic sheets**: Some companies store the information received in electronic sheet software, e.g. Microsoft Excel. Such tools allow for an efficient storage. Manual checks and information updates are required. Use of advanced features is needed to produce declarations to be supplied with the article(s), complex objects or very complex objects.

- **Use of databases:** Some medium/large companies have created their own internal system to manage information, e.g. material declaration tools and centralised data management systems. Such tools facilitate the storage and management of information.

- **Software/IT solutions:** developed in house or by third party providers, such tools can cover activities linked to Article 33 REACH and other regulatory measures in or outside the EU (e.g. other REACH requirements, the RoHS Directive, China RoHS, California Proposition 65, Korea RoHS).
  Examples of functionalities include:
  - Collect declarations from suppliers (compliance declarations, material declarations or both)
  - Store information and allow for compliance verification
  - Share the information to users under certain conditions
  - Produce declarations to be supplied to recipients
  - Some may provide web applications for information exchange

A non-comprehensive overview of such solutions can be found in 2017 European Commission report on "Scientific and technical support for collecting information on and reviewing available tools to track hazardous substances in articles with a view to improve the implementation and enforcement of Article 33 of REACH and at the IPC website related to data exchange standards.

The list is for informative purposes only and Orgalime does not recommend the use of any tool over the other. It is up to companies to decide whether to use a tool and if so which one.

3.5 New ECHA waste database on Article 33 REACH Candidate List substances in articles

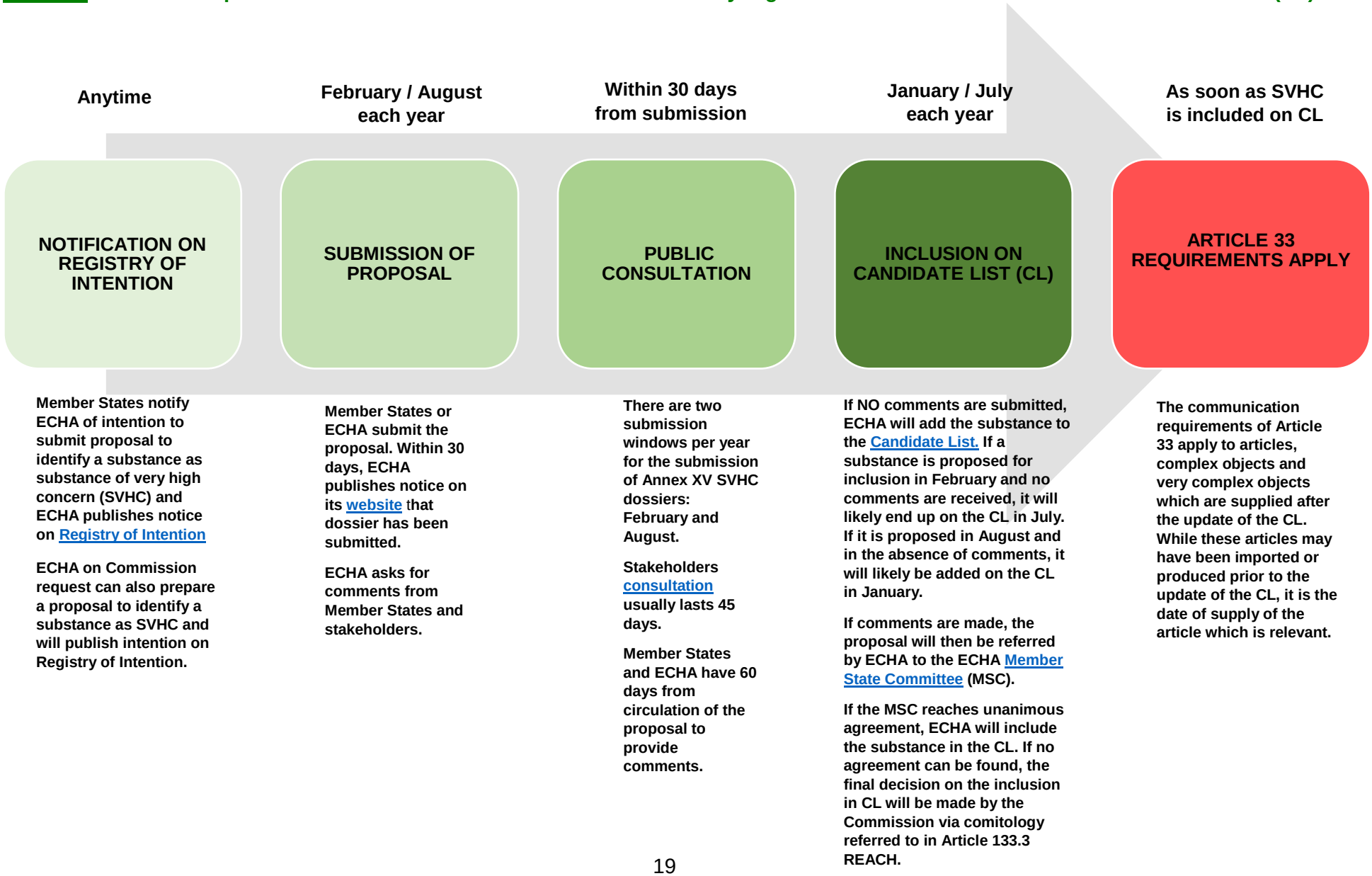
The Article 9 of the revised Waste Framework Directive adopted under the Waste Legislative Package which entered into force on 4 July 2018 requires the European Chemicals Agency (ECHA) to set up by 5 January 2020 a new database for the data to be submitted following Article 33 REACH by article manufacturers to ECHA as from 5 January 2021.

Article 9 of the revised Waste Framework Directive states:

> **Article 9.1:** *Member States shall take measures to prevent waste generation. Those measures shall, at least:*
> *(i): promote the reduction of the content of hazardous substances in materials and products, without prejudice to harmonised legal requirements concerning those materials and products laid down at Union level, and ensure that any supplier of an article as defined in point 33 of Article 3 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council provides the information pursuant to Article 33(1) of that Regulation to the European Chemicals Agency as from 5 January 2021;*
>
> **Article 9.1a:** *The European Chemicals Agency shall establish a database for the data to be submitted to it pursuant to point (i) of paragraph 1 by 5 January 2020 and maintain it. The European Chemicals Agency shall provide access to that database to waste treatment operators. It shall also provide access to that database to consumers upon request.*

This information note will be updated when detailed information about the new ECHA database will be available.

ANNEX I: Overview of process for the identification of a Substance of Very High Concern and its inclusion on the Candidate List (CL)



ANNEX II: Orgalime model letter for structuring communication up the supply chain in order to implement Article 33(1) REACH information requirements

This letter, which can be used by suppliers within or outside the EU (see section 2.1.1 B2B communication obligations) aims at supporting communication in the supply chain as laid out under Article 33(1). Companies who import from non-EU countries, who could be affected by notification obligations under Article 7(2), would need to adapt the letter to request further information from their non-EU suppliers, such as the weight of the article and the concentration of the Candidate List substance.

{Date}

Dear supplier,

We are writing to you to gather information on certain substances present in articles that you supply to us. This will allow you and {*if supplier outside the EU: remove "you and*"} us to fulfil our legal obligations with regards Article 33 of the European REACH Regulation N°1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals.

Article 33(1) of the REACH Regulation, whose interpretation has been further clarified by the European Court of Justice judgment in case C-106/14 and by the European Chemicals Agency guidance on 'requirements for substances in articles', obliges suppliers of articles to inform the recipients of the articles of the presence in the articles of substances of very high concern included in the "candidate list" (Article 59 REACH) above a concentration of 0.1% weight by weight (w/w). Article suppliers have to provide their recipients with sufficient information available to them to allow safe use, including, as a minimum, the name of the substance.

We kindly ask you to let us know whether the articles that you supply to us contain one (or several) of the listed substances above a concentration of 0.1% w/w. Where needed, please also provide information for safe use, including maintenance, related to chemical exposure. Please return this information to us as soon as possible, but no later than xxx {*to be completed*}. Please note that if we receive no answer from your side by this date, this will be understood as meaning that you declare that the supplied articles do not contain the above-mentioned candidate list substances in a concentration above 0.1% w/w.

In case you supply to us an object made of more than one article, which were joined or assembled together to make that object, the calculation of the concentration threshold of 0.1% (w/w) applies to each article[3].

Since we are also article suppliers, we may consolidate the information received to further communicate in the supply chain according to Article 33 REACH. We commit to guarantee confidentiality of sources when gathering and consolidating data.

The candidate list will be regularly updated. Please note that you have the legal obligation to {*if supplier outside the EU: remove "note that you have the legal obligation to*"} keep yourself informed about the substances that may be added to the candidate list and automatically inform us about their presence in the articles that you supply to us in accordance with Article 33(1) REACH.

Further information on the candidate list is available on the website of the European Chemicals Agency website at the following address: https://echa.europa.eu/candidate-list-table

We thank you for your time and look forward to hearing from you,

Yours sincerely

[3] *Information on how to calculate the threshold is provided by the European Chemicals Agency guidance document on 'requirements on substances in articles' p. 33*

Attachment: Questionnaire to be completed in view of achieving compliance with Article 33(1) REACH

- Please indicate if one (or several) of the substances listed on the candidate list available at the ECHA website are present in the supplied articles above a concentration of 0.1% w/w.

Reference of the article being supplied	**Substance name**	**CAS number**	**EC number**	**Information for safe use (where needed)**

Please have this attachment duly completed and return it to {*name of company sending the letter*} no later than xxx {*to be completed*}. By signing this Annex you acknowledge the content of the cover letter and certify that you are aware of your legal obligation to {*if supplier outside the EU: remove "are aware of your legal obligation to*"} keep yourself regularly updated with substances that may be added to the candidate list. You further acknowledge that you are responsible to inform {*name of company sending the letter*} about the presence of any such substance(s) listed in the candidate list in the article that you supply to us in accordance with Article 33(1) REACH {*if supplier outside the EU: remove the whole sentence*}.

Name, function and contact details of the contact person responsible for REACH issues:

Date

Signature

ANNEX III: Reference documents

Disclaimer: *the below list of reference documents and links is non-exhaustive.*

- **REACH Regulation** (Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals).
- **Revised Waste Framework Directive** (Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 on amending Directive 2008/98/EC on waste)
- **European Court of Justice Judgment** in Case C-106/14, 10 September 2015

- **Documents and links from the European Chemicals Agency (ECHA):**
  - ECHA Guidance update on requirements for substances in articles, June 2017 (full Guidance document)
  - Webpage about communication in the supply chain Article 33 of REACH
  - Webpage about substances of very high concern (SVHC) identification
  - Registry of SVHC intentions
  - Candidate List of SVHC
  - ECHA Newsletter

- 2017 **European Commission report** on "Scientific and technical support for collecting information on and reviewing available tools to track hazardous substances in articles with a view to improve the implementation and enforcement of Article 33 of REACH

- **Documents from Member States and industry:**
  - July 2013: joint Guidance from Belgium, France, Germany, Norway, Denmark and Sweden for Suppliers of Articles - The REACH duties to inform about Candidate List substances
  - September 2016: Orgalime comments on draft ECHA REACH Guidance on Requirements for Substances in Articles (version 4.0)
  - January 2018: Guidance from Denmark (in English) about Candidate List substances in Articles - Guidance on the duty to communicate information under REACH Candidate List substances in Articles (joint Guidance from Ministry of Environment and Food of Denmark, Danish Chamber of Commerce, Confederation of Danish Industry and Danish Building Centres)
  - February 2018: AGORIA REACH toolbox – Belgian Technology Industry guideline (in English) on the new communication and notification obligations of Substances of Very High Concern in articles under REACH. View Dutch and French summaries.
  - February 2018: ASD (Aerospace and Defence Industries Association in Europe) Sectorial Guidance for Substances in Articles under REACH
  - June 2018: Automotive Industry Guideline on REACH including Article 33 communication.

- **Standards:**
  - IEC 62474 - Material Declaration for Products of and for the Electrotechnical Industry
  - IPC 1752A - Data Exchange Standards
  - ISO 14025 - Environmental labels and declarations -- Type III environmental declarations
  - IPC website related to data exchange standards.

ANNEX IV: ORGALIME Members

The below list is dated July 2018. We recommend to you to check possible updates of this list on the website of ORGALIME.

Austria FEEI FMTI	**France** FIEEC FIM	**Lithuania** LINPRA	**Spain** SERCOBE	**ASSOCIATE MEMBERS**
Belgium AGORIA	**Germany** VDMA WSM ZVEI	**Luxembourg** Fedil Metal	**Sweden** Teknikföretagen	**Turkey** MAKFED
Bulgaria BASSEL	**Hungary** MAGEOSZ	**Netherlands** FME METAALUNIE	**Switzerland** SWISSMEM	**European Sector Associations** AQUA AFECOR CECE C.E.F.A.C.D CEIR EFCEM EGMF ELA EURALARM EUROPACABLE EUROPUMP FEM PNEUROP
Croatia CEA HGK	**Ireland** IEEF	**Norway** Norsk Industri	**United Kingdom** BEAMA EAMA GAMBICA	
Denmark DI	**Italy** ANIE ANIMA	**Portugal** AIMMAP		
Finland Technology Industries of Finland	**Latvia** MASOC	**Slovenia** GZS-MPIA		

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