

# SUPPLY CHAIN INFORMATION FOR ABSORBENT HYGIENE PRODUCTS

*BASIC INFORMATION YOU NEED TO KNOW ABOUT  
THE PRODUCT SAFETY AND REGULATORY REQUIREMENTS  
FOR PLACING ABSORBENT HYGIENE PRODUCTS ON THE MARKET  
IN THE EUROPEAN UNION*



# IMPORTANT

THIS IS A DOCUMENT THAT MAY BE AMENDED,  
EXPANDED OR OTHERWISE MODIFIED IN THE FUTURE.

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\* [Orange links](#) refer to a point or information within this document

\* [Blue links](#) will send you to a reference online

## List of abbreviations<sup>1</sup>

AHP:	Absorbent Hygiene Products
BfR:	German Federal Institute for Risk Assessment
BPR:	Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22/05/2012 concerning the making available on the market and use of biocidal products
CAS:	Chemical Abstracts Services
CLP:	Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures
ECHA:	European Chemicals Agency
GLP:	Good Laboratory Practice
GPSD:	General Product Safety Directive 2001/95/EC
INCI:	International Nomenclature of Cosmetic Ingredients
ISO:	International Organization for Standardization
IUPAC:	International Union of Pure and Applied Chemistry
MDD:	Medical Devices Directive 93/42/EEC
REACH:	Regulation (EC) No. 1907/2006 of 18/12/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SDS:	Safety Data Sheet
SVHC:	Substances of Very High Concern

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<sup>1</sup> CAS, INCI, IUPAC were added on section “list of abbreviations”.

# SUPPLY CHAIN INFORMATION FOR ABSORBENT HYGIENE PRODUCTS

## INTRODUCTION

The purpose of this Guidance is to present EDANA's position on the minimum safety and regulatory information needed by companies placing absorbent hygiene products (AHPs)<sup>2</sup> on the EU market. The first version of the Guidance was published in October 2014 and this second version was published in November 2016. This includes both information needed to ensure the **regulatory compliance** of those AHPs and their raw materials, information on best practice, **guidelines**, as well as information needed to address issues of public perception about the safety of AHPs. This agreed EDANA position has been developed by EDANA member companies in the supply chain for AHPs in the EU and EDANA staff to act as a basis for dialogue with the full supply chain. The scope of the document is therefore EU information, however, it touches upon requirements outside the EU for explanation and comparison.

This document does not address information requirements pursuant to the technical or environmental performance of AHPs or their raw materials.<sup>3</sup> In addition, the document does not address regulatory requirements related to the EU's Cosmetics Regulation in so far as these apply to lotions used in wet wipes for personal care use. The document does address lotions used in dry absorbent hygiene products.<sup>4</sup>

Agreement about "what are the most essential information requirements" is intended to help suppliers (and customers) of AHP manufacturers better understand the current regulatory landscape and guidelines for these products, and thereby to encourage improved product stewardship and dialogue in the full supply chain.

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<sup>2</sup> AHPs (Absorbent Hygiene Products) are single-use products made from nonwovens and other raw materials. They include:

- Diapers, for baby and adult incontinence (also called 'nappies')
- Absorbent feminine hygiene products such as menstrual tampons, napkins, pads and panty liners (sometimes collectively referred to as 'femcare,' 'fempro,' 'feminine hygiene' or 'sanitary protection' products)

<sup>3</sup> For further information, please find EDANA's Tampon Code of Practice on <http://www.edana.org/discover-nonwovens/products-applications/absorbent-hygiene-products> and Diaper Testing Guidelines on [www.edana.org](http://www.edana.org). EDANA's Guidelines for Sustainability Questionnaires are available upon request.

<sup>4</sup> As far as wipes are concerned, although the latter are not explicitly part of the scope of this document, the safety requirements for nonwoven substrates can be assimilated to those applying to other types of nonwovens used as components in AHPs and listed in this document.

The document distinguishes between two categories of information requirements, and divides these requirements into two sections:

**Chapter 1: The ‘Upstream’ Part.** This Chapter establishes the **minimum information which manufacturers of AHPs require from their raw material suppliers** in order to ensure the regulatory compliance of finished AHPs. This information is typically requested in the form of supply chain questionnaires, and is based directly on the content of Chapter 2. While this Chapter identifies the basic information requirements and related guidance, it is not intended to impose a format in which AHP manufacturers should request the information, nor does it exclude these manufacturers from requesting additional information as per their individual company procedures. [See Annex 2](#) for an example of such a request in the form of a conformity declaration from a manufacturer – please note that **this declaration is not an official EDANA position**, but rather an example of the sort of information that suppliers can be requested to provide to manufacturers; information which in some cases go beyond regulatory requirements.

**Chapter 2: The ‘Downstream’ Part.** This Chapter establishes the **minimum requirements for manufacturers of ‘finished’ AHPs** as they are placed on the market. These comprise primarily the core requirements as found in EU legislation, as well as a limited number of elements that are not found in legislation but which are widely-known to be adopted by most major companies and retailers in the EU.

## Chapter 1: the 'Upstream' Piece

### Regulatory Requirements and Related Guidelines

In order for AHP manufacturers to comply with their regulatory obligations in the EU (see [Chapter 2](#)) and to align with relevant guidance documents, this chapter outlines expectations for suppliers and AHP manufacturers.

#### Part A: Information Requirements and Guidance for Raw Materials

To document regulatory compliance, the below sections 1-10 outline the **minimum information** by EDANA needed from raw material suppliers and other parties involved in the supply chain.

To illustrate potential additional requests, section 11 provide examples of **optional information** that a raw material supplier may be asked to provide.

Please note that several of the below elements include footnotes that explain the reasoning for requesting this information.

1. **Material trade name / 'Supplier Code'**
2. **Supplier name** including details of main contact person
3. **Material type:** e.g., airlaid nonwoven, superabsorbent, closure system, fluff pulp etc.
4. **Material category under the REACH Regulation**<sup>5</sup>: i.e., substance<sup>6</sup>, mixture<sup>7</sup> or article<sup>8</sup>
5. **Intended End-Use:** e.g., absorbent hygiene product (for menstrual protection, incontinence care etc.)
6. **Technical specifications**, including product data sheet (if available) and a brief history of the material's use in AHPs and other product sectors. An indication if the material was developed specifically/mainly for AHPs and/or has been used in AHPs in the past; or, if the material has mainly been used for more technical (non-AHP) purposes.
7. **Specific composition**<sup>9</sup>
  - a) All intentionally-used ingredients, *including finishing agents, processing aids, crosslinkers, binders, metal catalysts, preservatives, other additives etc.*, that are expected to be present in the raw material at the time of sale/supply to the AHP manufacturer. For each ingredient, also provide where

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<sup>5</sup> As defined in REACH Article 3(1-3). Needed in order to check which section(s) of the Regulation apply to the material. E.g., Annex XVII of REACH could apply to almost every material category, whereas Article 33 only applies to articles.

<sup>6</sup> 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 which may be separated without affecting the stability of the substance or changing its composition

<sup>7</sup> Preparation/mixture: A mixture or solution composed of 2 or more substances (see above for definition of substance)

<sup>8</sup> Article: 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

<sup>9</sup> Needed in order to carry-out an exposure calculation and a risk (and quality) assessment on the chemical composition/profile of the finished product and its constituents

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#### Supply Chain Information for Absorbent Hygiene Products

applicable<sup>10</sup>:

- i. Name of original manufacturer
- ii. CAS number and designation (often the IUPAC nomenclature of organic chemistry and for cosmetic ingredients the International Nomenclature of Cosmetic Ingredients (INCI) name)
- iii. Function of the ingredient in the material
- iv. Any harmonised hazard classifications under the [CLP Regulation](#) (including CLP hazard statements, where applicable)
- v. Concentration range of the ingredient in the material (percentage of total weight)<sup>11</sup>
- vi. If known, the above details of any known 'ingredients of the ingredient' based on sub-supplier information, including the original manufacturer

In addition, the Safety Data Sheet (SDS) will also include information about hazardous components that may be present in concentrations equal to or greater than the concentration limits, as described in annex II of REACH.<sup>12, 13</sup>

#### **Note Regarding Point 7a) vi**

It is understood that this 'sub-supplier' information may be confidential and thus not available to the company completing the questionnaire. In such cases, the company completing the questionnaire should put their customer in touch with the sub-supplier. This sub-supplier should be briefed on the information requirements to be (pre)-prepared.

- b)** All additional constituents that are known or likely to be present in the product, *including monomers, residuals, impurities, other traces etc.* For each constituent, give, if applicable<sup>14</sup>:
- i. The relevant CAS number and designation
  - ii. The source/origin of the constituent, if known
  - iii. Any hazard classification (including hazard statement) under the CLP Regulation and the Globally Harmonized System of Classification and Labelling (GHS)
  - iv. Concentration of the constituent in the material (percentage of total weight)
  - v. Details of testing procedure used, including frequency of testing and the results

#### **8. Compliance with the Biocidal Products Regulation (BPR)**

- a)** Identify any ingredients that meet all of the following criteria:<sup>15</sup>
- i. Are substances or mixtures as defined under REACH<sup>16</sup>, and
  - ii. Consist of, contain or generate one or more active substances<sup>17</sup> and where
  - iii. The substance/mixture is intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on, any harmful organism (by means other than mere physical or mechanical action)

<sup>10</sup> Some information is covered in the Safety Data Sheet and some of the listed information may be proprietary, and in many cases falling under specific confidentiality agreements, e.g. in relation to data sharing

<sup>11</sup> Needed in order to check compliance with regulatory limits on the total concentration of certain chemicals in finished products

<sup>12</sup> Section 7 a) has been corrected

<sup>13</sup> [https://echa.europa.eu/documents/10162/23036412/sds\\_en.pdf/](https://echa.europa.eu/documents/10162/23036412/sds_en.pdf/)

<sup>14</sup> It is understood that this information concerns constituents above trace levels and standard analytical detection limits as defined in the Green Guides of the Federal Trade Commission on <https://www.ftc.gov/sites/default/files/attachments/press-releases/ftc-issues-revised-green-guides/greenguidesstatement.pdf>

<sup>15</sup> Ingredients meeting all of these criteria may be 'biocidal products' under the BPR, leading to further obligations in the supply chain

<sup>16</sup> REACH Article 3

<sup>17</sup> Active substance: A substance or a micro-organism that has an action on or against harmful organisms

- b) For all substances/mixtures meeting the above three criteria, indicate the current **approval status**<sup>18</sup> of all active substances contained in or generated from the substance/mixture. Include details on the specific Product Type(s) ([listed in BPR Annex V](#)) for which the active substance is approved, under review or not approved.
- c) Ingredients that may be considered as treated articles<sup>19</sup> (for further information see the [EDANA Guide to the BPR](#))

## 9. Compliance with the REACH Regulation

- a) List all substances that are intended to be released from the material under normal or reasonably foreseeable conditions of use<sup>20</sup>
- b) List all known concentrations of candidate Substances of Very High Concern (SVHCs, as listed in the current version of the [Candidate List for Authorisation](#)) that are present in the material.<sup>21</sup> Where exact concentrations are unknown, confirm whether the substance is present at a concentration above 0.1% weight/weight in each component<sup>22</sup>
- c) List all substances on the Annex XIV [Authorisation List](#) that you incorporate into the material or otherwise use to create the material, and confirm that you have valid authorisations from the European Commission to use the substances for this use
- d) Declare that the material complies with all applicable requirements of the [Annex XVII](#) 'Restrictions List' ([see Annex 1](#) of this document for an illustrative list). Note that a substance may be restricted for the end-use of the material but not for its presence in the raw material

### Note Regarding Point 9d

Companies should not underestimate the importance of REACH Annex XVII, nor the amount of work potentially required in order to check compliance with its provisions. Annex XVII is subject to several updates each year and its provisions can take several forms, including but not limited to:

- Requirements to 'not use' certain substances (or categories thereof) in specific mixtures or articles
- Requirements to not place on the market mixtures or substances that contain certain substances above a given threshold (which can be much lower than the 0.1% threshold for SVHC)
- Restrictions on specific uses of the above substances in specific industries and end-uses
- Restrictions that are subject to change in the future

## 10. Miscellaneous

- a) Summary of data from existing<sup>23</sup> toxicological test reports<sup>24</sup> on the material. Reports should include

<sup>18</sup> <http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances>

<sup>19</sup> Materials treated with or intentionally incorporating active substances and/or biocidal products may be 'treated articles' under the BPR, leading to further obligations

<sup>20</sup> Substances intentionally released from articles may in certain circumstances be subject to registration requirements under REACH Article 7(1)

<sup>21</sup> Needed in order to check whether the finished product will have obligations under REACH Articles 7(2) and 33

<sup>22</sup> Following the ruling of the EUs Court of Justice, there is a requirement to look at each component of a complex article in relation to the 0.1 % concentration as presented in <http://curia.europa.eu/jcms/upload/docs/application/pdf/2015-09/cp150100en.pdf>

<sup>23</sup> In most instances, and especially for chemicals used to produce the material, historical in vivo (animal) test data will likely already be available, albeit may not necessarily have been generated under Good Laboratory Practice (GLP) conditions. New/supplementary data generated by the supplier should in most cases be derived from in vitro tests

<sup>24</sup> Needed in order to evaluate the safety of the finished product under normal or reasonably foreseeable conditions of use, as required under the General Product Safety Directive (GPSD). AHPs are intended for contact with human skin

protocol details, results, testing institute and study date, plus GLP certificates. (Note: For materials for use in adult incontinence diapers, [see Part B Section 2](#))

- b) Presence of organotin compounds in the material. Include test report (using EDANA Standard Test Methods)<sup>25</sup> confirming compliance with the following limit values:
- i. Tributyltin (TBT): <2 ppb
  - ii. Other organotins: <10 ppb per organotin

#### 11. Optional additional information

Manufacturers may ask suppliers to provide further optional information. Such information is additional to the above minimum information that is required and is often based on specific guidelines rather than legal obligations. It does not constitute information required to assure regulatory compliance or safety of the raw materials.

- a) The general status of the raw material, indicating whether it is e.g.
- Animal derived
  - Kosher
  - Halal
  - Organic
  - Vegan
  - Plant-derived
  - Third party certified (include the certificate)
  - Third party tested (include the name of testing company and status)
- b) Presence of specific substances of interest<sup>26</sup>: Company-specific questionnaires may include requests that suppliers declare the presence of other chemicals, including but not limited to: phthalates, alkylphenols, Bisphenol A, dioxins, as well as:
- Substances on the [Substitute-it-Now \(SIN\) List](#)
  - Substances on the [California Proposition 65 list](#)
  - Substance subject to limits in the [Öko-tex 100 standard](#) for textiles
  - Substances that are part of the [Nordic Ecolabelling criteria for sanitary products](#)
  - Substances that are part of the [EU Ecolabel criteria for absorbent hygiene products](#)
  - Other substances as needed

Customers may also request analytical test reports – using either solvent or synthetic urine extraction – that measure the presence or confirm the absence of substances of interest.<sup>27</sup> Please note that the levels referred to in the example of a conformity declaration in Annex II are not indicative for a safe level of a substance in the raw material or the finished product, but rather form the basis for information in the supply chain.

## Part B: Information Requirements and Guidance for categories of AHPs

This part outlines broad guidelines and references related to AHP products and their raw materials or

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<sup>25</sup> [http://www.edana.org/newsroom/reports-publications/publication/nonwovens-standard-procedures-edition-2015-\(non-member\)](http://www.edana.org/newsroom/reports-publications/publication/nonwovens-standard-procedures-edition-2015-(non-member))

<sup>26</sup> This requirement is linked to Part 7.b) above: Information is needed on the presence of harmful substances in finished products, including substances present at trace level or substances identified as endocrine disruptors, in order to conduct an exposure based risk assessment. Further, end-customers such as retailers may request that the presence of certain chemicals of concern be minimised as much as possible. This is not only from a safety or regulatory standpoint but also to comply with internal standards.

<sup>27</sup> Further information can be found on <http://www.edana.org/discover-nonwovens/products-applications/absorbent-hygiene-products/traces-in-ahp>

products with a certain end use, such as medical use. The application of these guidelines should always be carried out as a case by case assessment of the relevant end product.

### **1. For all AHPs (can be omitted for Adult incontinence products, with justification)**

Alignment with the German Federal Institute for Risk Assessment (BfR) [Guidelines for the Evaluation of Personal Sanitary Products](#)<sup>28</sup> from 1996. Considering that the Guidelines are 20 years old, readers should keep in mind that technical and other developments mean that some of the below guidance has progressed since the publication date as indicated in the footnotes. Companies can potentially deviate from the BfR's recommendations where they can justify compliance with the safety requirements by other means.

These recommendations include amongst others:

- i. Azo dyes that through cleavage of one or more azo groups may produce one of the amines listed in No. 7 (§ 3) of the German Commodities Regulation may not be used
- ii. Cellulose and wood pulp, as well as plastics and colorants, should comply with the corresponding BfR recommendations on Food Contact Materials by analogy
- iii. Any perfumed oils that are used should comply with the International Fragrances Industry (IFRA) Code of Practice
- iv. The rayon staple and cotton used in the manufacture of medicated tampons should comply with the purity requirements of the European Pharmacopoeia for non-sterile sanitary cotton made from cotton and viscose

Please note that printing inks and lotions are sometimes used in AHPs and manufacturers often align with guidelines on inks<sup>29</sup> and lotions.<sup>30</sup>

### **2. For all Medical Devices (including Adult Incontinence Products)**

a) Converters must demonstrate regulatory compliance with the [Medical Devices Directive](#), especially Annex I Chapter II Part 7 (Chemical, physical and biological properties). Authorities presume conformity in cases where harmonised standards are applied. An important standard in this context is the ISO 10993 (Biological evaluation of medical devices) series and especially its following subsets:

- i. [ISO 10993-1 \(Evaluation and testing within a risk management process\)](#)<sup>31</sup>
- ii. (if skin compatibility testing is conducted) [ISO 10993-10 \(Tests for irritation and skin sensitization\)](#)
- iii. [ISO 10993-17 \(Establishment of allowable limits for leachable substance\)](#)
- iv. Identification of material and its chemical constituents within the framework of [ISO 10993-18 \(Chemical characterization of materials\)](#). For identifying degradation products, also use [ISO 10993-9](#) and [ISO 10993-13](#)
- v. Finally, compliance with [ISO 10993-5 \(Tests for in vitro toxicity\)](#) is sometimes asked for raw materials, including those supplied for products that are not Medical Devices

b) Based on the above and on tests conducted, suppliers should provide written justification as to why/how the existing data sufficiently describes/characterises their material, including details about management of chemical risks (e.g., avoiding carry-over)

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<sup>28</sup> These AHPs are not subject to sector-specific EU legislation. The General Product Safety Directive (GPSD) thus requires that manufacturers follow any existing national rules, standards, technical specifications and/or codes of good practice in order to establish the safety of the product

<sup>29</sup> [http://www.eupia.org/uploads/tx\\_edm/2016-11-17\\_Exclusion\\_Policy\\_for\\_Printing\\_Inks\\_and\\_Related\\_Products\\_3rd\\_ed.pdf](http://www.eupia.org/uploads/tx_edm/2016-11-17_Exclusion_Policy_for_Printing_Inks_and_Related_Products_3rd_ed.pdf)

<sup>30</sup> By analogy some manufacturers may also apply the IFRA guidance mentioned in point iv. or the EU rules for cosmetic products to lotions used in AHPs

<sup>31</sup> Part 7.1 requires that materials used to manufacture medical devices are compatible with biological tissues, cells and body fluids, taking account of the intended purpose of the device

## Chapter 2: The 'Downstream' Piece

### Minimum Regulatory Requirements for Finished AHPs

Finished AHPs are considered to be **articles** and their safety requirements are covered by general ('horizontal') EU legislation applicable to multiple consumer goods, notably:

- The [General Product Safety Directive 2001/95/EC \(GPSD\)](#), currently under revision
- [Regulation 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals \(REACH\)](#), and
- [Regulation 528/2012 concerning the Making Available on the Market and Use of Biocidal Products \(BPR\)](#), the provisions of which applied from 1 September 2013 (please see chapter 1).

Adult incontinence products (diapers, pads and pantyliners) are regulated as **medical devices** under the [Medical Devices Directive 93/42/EEC](#) (MDD). Publication of the new EU Medical Device Regulation<sup>32</sup> is expected in early 2017. The MDD defines the "essential requirements" for the free circulation of adult incontinence diapers on the EU market. These essential requirements include safety, efficacy and vigilance (see below).

*N.B. In addition to the present European legal framework, certain regulatory requirements relevant for AHPs do exist at national level, either in the EU Member States and furthermore in non-EU Member States.<sup>33</sup>*

### Part A: The General Product Safety Directive (GPSD)<sup>34</sup>

The GPSD establishes essential requirements to ensure the safety of consumer products that are not already covered by specific sector legislation (*e.g.*, toys, cosmetics, medical devices).

The Directive provides a generic definition of a safe product, namely that **products must be safe under normal or reasonably foreseeable conditions of use** by consumers. Products must comply with this definition. If there are no specific national rules governing the safety of a product, then safety of a product is assessed in accordance with:

- European standards pursuant to the product, *then*
- Community technical specifications, *then*
- Codes of good practice, *then*
- State-of-the-art and consumer expectations.

Examples of such documents are EDANA's voluntary [Code of Practice for Tampons](#), [EDANA's work on flushability](#) and [EDANA's test methods](#), some of which are classified as standards.

#### Obligations of producers and distributors

In addition to the basic requirement to place only safe products on the market, producers must inform consumers of the risks associated with the products they supply. They must take appropriate measures to prevent such risks and be able to trace dangerous products.

<sup>32</sup> <http://www.consilium.europa.eu/en/press/press-releases/2016/05/25-medical-devices/>

<sup>33</sup> It is out of the scope of this document to include requirements at national level

<sup>34</sup> Currently under revision – new proposal for a Consumer Product Safety Regulation is available at: [http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2013/0049\(COD\)&l=en#basicInformation](http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2013/0049(COD)&l=en#basicInformation)

To comply with the GPSD requirements, such measures include a rigorous in-house risk assessment of the overall product and its chemical constituents. This assessment identifies any risks pursuant to the product and leads to the implementation of risk management measures. The results of this activity are typically stored in an in-house product dossier which can be presented to Member State authorities in the event of enforcement actions.

**Note:** Risk assessment elements may also be covered by companies' obligations under the REACH Regulation. As 'Downstream Users' of chemicals, AHP manufacturers have to ensure that the human health risks from exposure to these substances are managed, and this includes exposure at all stages of the substance's life-cycle (including the life-cycle of articles). [See Part B below](#).

### **Obligations of Member States**

Under the GPSD, Member States are obliged to enforce the requirements on producers and distributors. They must appoint the authorities in charge of [market surveillance](#) and enforcement. In addition to the power to impose penalties, the Directive gives the surveillance authorities a wide range of monitoring and intervention powers.

### **Exchange of information via a rapid alert system**

The Directive provides for a rapid alert system ([the RAPEX system](#)) between Member States and the Commission. The RAPEX system ensures that the relevant authorities are rapidly informed of dangerous products. Subject to certain conditions, rapid alert notifications can also be exchanged with non-EU countries. In the case of serious product risks, the Directive provides for temporary decisions to be taken on EU-wide measures.

### **Emergency measures**

Under certain conditions, the Commission may adopt a formal decision requiring the Member States to ban the marketing of an unsafe product, to recall it from consumers or to withdraw it from the market. Such decisions at EU level can be taken:

- where the Member States have different approaches to dealing with the risks posed by such dangerous products;
- where urgency is required due to the risk posed by the product, and where no other Community laws deal with that risk;
- where such Decisions are the most effective way of eliminating the risk.

A Decision of this kind is only valid for a maximum of one year. Decisions of this kind have been on phthalates, on lighters, on dimethylfumarate (DMF) and on magnetic toys.

## **Part B: The REACH Regulation**

The REACH Regulation entered into force on 1 June 2007, and replaced a previous set of laws related to chemicals substances. It is complementary to other environmental and safety legislation but does not replace sector specific legislation (for example, legislation on cosmetics or medical devices). REACH gives greater responsibility to industry to manage the risks from chemicals and to provide safety information on the substances, including substances in mixtures and substances in articles. Manufacturers and importers are required to gather information on the properties of their chemical substances, which is aimed at allowing their safe handling, and to register the information with the European Chemicals Agency (ECHA).

### **REACH: Registration**

REACH requires all manufacturers and importers of chemicals to identify and manage the risks linked to the substances they manufacture and market. Those companies who manufacture or import substances in quantities of 1 tonne or more per year per legal entity, must submit Registration dossiers to ECHA. However, if a company places articles with intentionally-released substances on the EU market, then that 'articles manufacturer' may also have to submit a Registration dossier for those intentionally-released substances.

### **REACH: Evaluation**

Substances registered may be subject to Evaluation by ECHA and the Member States. Evaluation looks at various aspects of Registration dossiers, and can result in a variety of consequences for registrants. At the most basic level, authorities may ask registrants to update aspects of their dossiers, or even to implement stricter risk management measures than they currently do. Further, depending on the hazard profile of the substance and its exposure to humans and the environment, authorities may use Evaluation as a basis for more directly regulating that substance in specific products.

### **REACH: Authorisation**

REACH also foresees an Authorisation system, aimed at ensuring that Substances of Very High concern (SVHCs)<sup>35</sup> are adequately controlled, and progressively substituted by safer substances or technologies, or only used where there is an overall benefit for society of using the substance. Via a system of prioritisation, SVHCs are added to the Candidate List for Authorisation and possible inclusion in Annex XIV of the Regulation. Once on the Candidate List, various information obligations, to ECHA and within the supply chain, may apply if those substances are present in any component of an article in quantities greater than 0.1% weight by weight. Further, if present in mixtures in quantities greater than 0.1% weight by weight, it is mandatory to prepare a SDS mentioning the substance's name.

Further, once a substance moves beyond the Candidate List to be listed in Annex XIV, and after an applicable 'sunset date,' EU-based companies must submit an application to the European Commission for authorisation to continue using the substance. Applications for authorisation can be quite burdensome to make, and the burden of evidence required to be granted an authorisation is quite high. Overall, the Authorisation system is designed to encourage EU industry to phase out, wherever possible, the use of Annex XIV substances altogether. At present, substances on Annex XIV which have passed the sunset date do not require Authorisation if contained in or intentionally released from imported articles.

### **REACH: Restriction**

Under REACH, authorities may also impose specific Restrictions on the manufacture, use or placing on the market of chemical substances causing an unacceptable risk to human health or the environment. These specific Restrictions are listed in [Annex XVII](#) of REACH, and include various Restrictions on substances in mixtures, as well as substances in articles like AHPs. Various existing Restrictions were carried over from legislation existing before REACH.

### **'Main Obligations' for AHP Manufacturers under REACH**

Apart from the specific elements above, there are other 'typical' REACH obligations for AHP manufacturers. In particular, AHP manufacturers are obliged to generate rigorous information about the potential presence of SVHC in their articles and to comply with the related requirements.

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<sup>35</sup> The properties of these substances are defined in Article 57 of REACH: carcinogenic, mutagenic or toxic to reproduction (CMRs category 1 and 2), persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB), or for which there is evidence for similar concern (e.g., endocrine disruptors)

**Notification (to ECHA)** is required for SVHC present in articles:

- a. in quantities totalling over 1 tonne per producer or importer per year of the substance, and
- b. above a concentration of 0.1 % weight by weight. This threshold of 0.1% applies to any component of the article as produced or imported.

Notification of SVHC in articles must be made to ECHA at the latest 6 months after the SVHC in question has/have been included in the Candidate List (unless an exemption applies).

Communication in the supply chain of SVHC-related information is another significant obligation. Where a substance on the Candidate List is present in any component of an article in a concentration above 0.1% weight by weight, the company placing that article on the market must provide all customers receiving the article with sufficient information about the safe use of the article, including, as a minimum, any component where the SVHC is present and the name of the SVHC. This information is to be provided immediately, i.e., as soon as it is known that the substance is present in any component of the article above 0.1%.

Similarly, this same information must be provided to any consumer requesting the information. In such a case, the information must be provided, free of charge, within 45 days of receipt of the request.

## Part C: The Medical Devices Directive (MDD)

Medical Device Directive (MDD) follows the so called “New Approach” of the 1990’s, which regulates only the framework of a product category while allowing the details to be covered in standards. It contains various “essential requirements,” of which a key requirement is that medical devices are safe (or at least have a positive risk/benefit ratio).

Material and toxicological safety is specifically covered in Annex I, Part 7, which, among other things, requires that “special attention” be paid towards substances that are carcinogenic, mutagenic and/or toxic for reproduction (CMR substances). However, due to the diversity of medical devices with very different risk classes, no specifics (e.g., substances, methods, limits), are regulated. This requires medical device manufacturers to justify and document the specific approach they take towards meeting the safety requirement. Medical Device dossiers are frequently checked by “Notified Bodies,” which are appointed by Member States.

Further details are given in “harmonised standards,” which are officially recognised by the European Commission to fulfil the requirements of the MDD, thus becoming “soft law.” It is still possible to deviate from these harmonised standards, but manufacturers who do so must justify this and provide proof that their individual approach is at least as good as the official one (making it usually far too burdensome).

For biological evaluation of a medical device the ISO 10993 series is harmonised as EN standards. Those standards are flexible and describe the safety assessment of a medical device by experts. The general framework is described in EN ISO 10993 1 which is recommended reading for experts in the supply chain of medical devices. Other harmonised standards apply, e.g. on quality management.

Additional information can also be found at [http://ec.europa.eu/health/medical-devices/regulatory-framework/index\\_en.htm](http://ec.europa.eu/health/medical-devices/regulatory-framework/index_en.htm).

## Annex 1:

### Example Restrictions from REACH Annex XVII Relevant for Articles

The following is a non-exhaustive extract from Annex XVII and provided illustrative purposes only.

The full Annex XVII can be subject to several amendments each year and the **only** authentic version is the most recent publication in the Official Journal of the European Union.<sup>36</sup>

	Chemical	CAS	Restriction
4	Tris (2,3 dibromopropyl) Phosphate	126-72-7	<p>1. Shall not be used in textile articles, such as garments, undergarments and linen, intended to come into contact with the skin.</p> <p>2. Articles not complying with paragraph 1 shall not be placed on the market.</p>
6	Asbestos fibres :		
a)	Crocidolite	12001-28-4	<p>1. The manufacture, placing on the market and use of these fibres and of articles and mixtures containing these fibres added intentionally is prohibited.</p> <p>However, if the use of diaphragms containing chrysotile for electrolysis installations in use on 13 July 2016 had been exempted by a Member State in accordance with the version of this paragraph in force until that date, the first subparagraph shall not apply until 1 July 2025 to the use in those installations of such diaphragms or of chrysotile used exclusively in the maintenance of such diaphragms, provided that such use is carried out in compliance with the conditions of a permit set in accordance with Directive 2010/75/EU of the European Parliament and of the Council.</p> <p>Any downstream user benefiting from such an exemption shall send, by 31 January of each calendar year to the Member State in which the relevant electrolysis installation is located, a report indicating the amount of chrysotile used in diaphragms pursuant to the exemption. The Member State shall transmit a copy to the European Commission. Where, in order to protect the health and safety of workers, a Member State requires monitoring of chrysotile in air by downstream users, the results shall be included in that report.</p> <p>2. The use of articles containing asbestos fibres referred to in paragraph 1 which were already installed and/or in service before 1 January 2005 shall continue to be permitted until they are disposed of or reach the end of their service life. However, Member States may, for reasons of protection of human health, restrict, prohibit or make subject to specific conditions, the use of such articles before they are disposed of or reach the end of their service life.</p> <p>Member States may allow placing on the market of articles in their entirety containing asbestos fibres referred to in paragraph 1 which were already installed and/or in service before 1 January 2005, under specific conditions ensuring a high level of protection of human health. Member States shall communicate these national measures to the Commission by 1 June 2011. The Commission shall make this information publicly available.</p>
b)	Amosite	12172-73-5	
c)	Anthophyllite asbestos	77536-67-5	
d)	Actinolite asbestos	77536-66-4	
e)	Tremolite asbestos	77536-68-6	
f)	Chrysotile	12001-29-5 132207-32-0	

<sup>36</sup> <http://echa.europa.eu/addressing-chemicals-of-concern/restrictions/substances-restricted-under-reach>

			<p>3. Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances and mixtures, the placing on the market and use of articles containing these fibres, as permitted according to the preceding derogations, shall be permitted only if suppliers ensure before the placing on the market that articles bear a label in accordance with Appendix 7 to this Annex.</p>
7	Tris-aziridinyl- phosphin oxide	545-55-1	<p>1. Shall not be used in textile articles, such as garments, undergarments and linen, intended to come into contact with the skin.</p> <p>2. Articles not complying with paragraph 1 shall not be placed on the market.</p>
8	Polybromobiphenyls (PBB)	59536-65-1	<p>1. Shall not be used in textile articles, such as garments, undergarments and linen, intended to come into contact with the skin.</p> <p>2. Articles not complying with paragraph 1 shall not be placed on the market.</p>
20	Organostannic compounds	Various	<p>1. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is acting as biocide in free association paint.</p> <p>2. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture acts as biocide to prevent the fouling by micro-organisms, plants or animals of:</p> <ul style="list-style-type: none"> <li>(a) all craft irrespective of their length intended for use in marine, coastal, estuarine and inland waterways and lakes;</li> <li>(b) cages, floats, nets and any other appliances or equipment used for fish or shellfish farming;</li> <li>(c) any totally or partly submerged appliance or equipment.</li> </ul> <p>3. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use in the treatment of industrial waters.</p> <p>4. Tri-substituted organostannic compounds:</p> <ul style="list-style-type: none"> <li>(a) Tri-substituted organostannic compounds such as tributyltin (TBT) compounds and triphenyltin (TPT) compounds shall not be used after 1 July 2010 in articles where the concentration in the article, or part thereof, is greater than the equivalent of 0,1 % by weight of tin.</li> <li>(b) Articles not complying with point (a) shall not be placed on the market after 1 July 2010, except for articles that were already in use in the Community before that date.</li> </ul> <p>5. Dibutyltin (DBT) compounds:</p> <ul style="list-style-type: none"> <li>(a) Dibutyltin (DBT) compounds shall not be used after 1 January 2012 in mixtures and articles for supply to the general public where the concentration in the mixture or the article, or part thereof, is greater than the equivalent of 0,1 % by weight of tin.</li> <li>(b) Articles and mixtures not complying with point (a) shall not be placed on the market after 1 January 2012, except for articles that were already in use in the Community before that date.</li> </ul>

			<p>(c) By way of derogation, points (a) and (b) shall not apply until 1 January 2015 to the following articles and mixtures for supply to the general public:</p> <ul style="list-style-type: none"> <li>- one-component and two-component room temperature vulcanisation sealants (RTV-1 and RTV-2 sealants) and adhesives,</li> <li>- paints and coatings containing DBT compounds as catalysts</li> <li>- when applied on articles,</li> <li>- soft polyvinyl chloride (PVC) profiles whether by themselves or coextruded with hard PVC,</li> <li>- fabrics coated with PVC containing DBT compounds as stabilisers when intended for outdoor applications,</li> <li>- outdoor rainwater pipes, gutters and fittings, as well as covering material for roofing and façades,</li> </ul> <p>(d) By way of derogation, points (a) and (b) shall not apply to materials and articles regulated under Regulation (EC) No 1935/2004.</p> <p>6. Dioctyltin (DOT) compounds:</p> <p>(a) Dioctyltin (DOT) compounds shall not be used after 1 January 2012 in the following articles for supply to, or use by, the general public, where the concentration in the article, or part thereof, is greater than the equivalent of 0,1 % by weight of tin:</p> <ul style="list-style-type: none"> <li>- textile articles intended to come into contact with the skin,</li> <li>- gloves,</li> <li>- footwear or part of footwear intended to come into contact with the skin,</li> <li>- wall and floor coverings,</li> <li>- childcare articles,</li> <li>- female hygiene products,</li> <li>- nappies</li> <li>- two-component room temperature vulcanisation moulding kits (RTV-2 moulding kits).</li> </ul> <p>(b) Articles not complying with point (a) shall not be placed on the market after 1 January 2012, except for articles that were already in use in the Community before that date.</p>
21	Di- $\mu$ -oxo-di-n-butylstanniohydroxyborane/Dibutyltin hydrogen borate <chem>C8H19BO3Sn</chem> (DBB)	75113-37-0	<p>Shall not be placed on the market, or used, as a substance, or in mixtures in a concentration equal to, or greater than 0,1 % by weight.</p> <p>However, the first paragraph shall not apply to this substance (DBB) or mixtures containing it if these are intended solely for conversion into articles, among which this substance will no longer feature in a concentration equal to or greater than 0,1 %.</p>
22	Pentachlorophenol and its salts and esters	87-86-5	<p>Shall not be placed on the market, or used,</p> <ul style="list-style-type: none"> <li>- as a substance,</li> <li>- as a constituent in other substances, or in mixtures, in a concentration equal to or greater than 0,1 % by weight.</li> </ul>

23	Cadmium and its compounds	7440-43-9	<p>For the purpose of this entry, the codes and chapters indicated in square brackets are the codes and chapters of the tariff and statistical nomenclature of Common Customs Tariff as established by Council Regulation (EEC) No 2658/87 (OJ L 256, 7.9.1987, p. 42).</p> <p>1. Shall not be used in mixtures and articles produced from the following synthetic organic polymers (hereafter referred to as plastic material):</p> <ul style="list-style-type: none"> <li>○ polymers or copolymers of vinyl chloride (PVC) [3904 10] [3904 21]</li> <li>○ polyurethane (PUR) [3909 50]</li> <li>○ low-density polyethylene (LDPE), with the exception of low-density polyethylene used for the production of coloured masterbatch [3901 10]</li> <li>○ cellulose acetate (CA) [3912 11] —</li> <li>○ cellulose acetate butyrate (CAB) [3912 11]</li> <li>○ epoxy resins [3907 30]</li> <li>○ melamine-formaldehyde (MF) resins [3909 20]</li> <li>○ urea-formaldehyde (UF) resins [3909 10]</li> <li>○ unsaturated polyesters (UP) [3907 91]</li> <li>○ polyethylene terephthalate (PET) [3907 60]</li> <li>○ polybutylene terephthalate (PBT)</li> <li>○ transparent/general-purpose polystyrene [3903 11]</li> <li>○ acrylonitrile methylmethacrylate (AMMA)</li> <li>○ cross-linked polyethylene (VPE)</li> <li>○ high-impact polystyrene</li> <li>○ polypropylene (PP) [3902 10]</li> </ul> <p>Mixtures and articles produced from plastic material as listed above shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight of the plastic material.</p> <p>By way of derogation, the second subparagraph shall not apply to articles placed on the market before 10 December 2011. The first and second subparagraphs apply without prejudice to Council Directive 94/62/ EC (**) and acts adopted on its basis. By 19 November 2012, in accordance with Article 69, the Commission shall ask the European Chemicals Agency to prepare a dossier conforming to the requirements of Annex XV in order to assess whether the use of cadmium and its compounds in plastic material, other than that listed in subparagraph 1, should be restricted.</p> <p>2. Shall not be used or placed on the market in paints with codes [3208] [3209] in a concentration (expressed as Cd metal) equal to or greater than 0,01 % by weight. For paints with codes [3208] [3209] with a zinc content exceeding 10 % by weight of the paint, the concentration of cadmium (expressed as Cd metal) shall not be equal to or greater than 0,1 % by weight. Painted articles shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,1 % by weight of the paint on the painted article.</p> <p>3. By way of derogation, paragraphs 1 and 2 shall not apply to articles coloured with mixtures containing cadmium for safety reasons.</p>
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		<p>4. By way of derogation, paragraph 1, second sub paragraph shall not apply to:</p> <ul style="list-style-type: none"> <li>○ mixtures produced from PVC waste, hereinafter referred to as ‘recovered PVC’,</li> <li>○ mixtures and articles containing recovered PVC if their concentration of cadmium (expressed as Cd metal) does not exceed 0,1 % by weight of the plastic material in the following rigid PVC applications: <ul style="list-style-type: none"> <li>(a) profiles and rigid sheets for building applications;</li> <li>(b) doors, windows, shutters, walls, blinds, fences, and roof gutters;</li> <li>(c) decks and terraces;</li> <li>(d) cable ducts;</li> <li>(e) pipes for non-drinking water if the recovered PVC is used in the middle layer of a multilayer pipe and is entirely covered with a layer of newly produced PVC in compliance with paragraph 1 above. Suppliers shall ensure, before the placing on the market of mixtures and articles containing recovered PVC for the first time, that these are visibly, legibly and indelibly marked as follows: ‘Contains recovered PVC’ or with the following pictogram:</li> </ul> </li> </ul> <div style="text-align: center;">  </div> <p>In accordance with Article 69 of this Regulation, the derogation granted in paragraph 4 will be reviewed, in particular with a view to reducing the limit value for cadmium and to reassess the derogation for the applications listed in points (a) to (e), by 31 December 2017.</p> <p>5. For the purpose of this entry, ‘cadmium plating’ means any deposit or coating of metallic cadmium on a metallic surface. Shall not be used for cadmium plating metallic articles or components of the articles used in the following sectors/applications:</p> <ul style="list-style-type: none"> <li>(a) equipment and machinery for: <ul style="list-style-type: none"> <li>○ food production [8210] [8417 20] [8419 81] [8421 11] [8421 22] [8422] [8435] [8437] [8438] [8476 11]</li> <li>○ agriculture [8419 31] [8424 81] [8432] [8433] [8434] [8436]</li> <li>○ cooling and freezing [8418]</li> <li>○ printing and book-binding [8440] [8442] [8443]</li> </ul> </li> <li>(b) equipment and machinery for the production of: <ul style="list-style-type: none"> <li>○ household goods [7321] [8421 12] [8450] [8509] [8516]</li> <li>○ furniture [8465] [8466] [9401] [9402] [9403] [9404]</li> <li>○ sanitary ware [7324]</li> <li>○ central heating and air conditioning plant [7322] [8403] [8404] [8415]</li> </ul> </li> </ul> <p>In any case, whatever their use or intended final purpose, the placing on the market of cadmium-plated articles or components of such articles used in the sectors/applications listed in points (a) and (b) above and of articles manufactured in the sectors listed in point (b) above is prohibited.</p>
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			<p>6. The provisions referred to in paragraph 5 shall also be applicable to cadmium-plated articles or components of such articles when used in the sectors/applications listed in points.</p> <p>(a) and (b) below and to articles manufactured in the sectors listed in (b) below:</p> <p>a) equipment and machinery for the production of:</p> <ul style="list-style-type: none"> <li>○ paper and board [8419 32] [8439] [8441] textiles and clothing [8444] [8445] [8447] [8448] [8449] [8451] [8452]</li> </ul> <p>(b) equipment and machinery for the production of:</p> <ul style="list-style-type: none"> <li>○ industrial handling equipment and machinery [8425] [8426] [8427] [8428] [8429] [8430] [8431]</li> <li>○ road and agricultural vehicles [chapter 87]</li> <li>○ rolling stock [chapter 86]</li> <li>○ vessels [chapter 89]</li> </ul> <p>7. However, the restrictions in paragraphs 5 and 6 shall not apply to:</p> <ul style="list-style-type: none"> <li>— articles and components of the articles used in the aeronautical, aerospace, mining, offshore and nuclear sectors whose applications require high safety standards and in safety devices in road and agricultural vehicles, rolling stock. and vessels, — electrical contacts in any sector of use, where that is necessary to ensure the reliability required of the apparatus on which they are installed.</li> </ul> <p>8. Shall not be used in brazing fillers in concentration equal to or greater than 0,01 % by weight. Brazing fillers shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight. For the purpose of this paragraph brazing shall mean a joining technique using alloys and undertaken at temperatures above 450 °C. 9.</p> <p>9. By way of derogation, paragraph 8 shall not apply to brazing fillers used in defence and aerospace applications and to brazing fillers used for safety reasons. 10. Shall not be used or placed on the market if the concentration is equal to or greater than 0,01 % by weight of the metal in: (i) metal beads and other metal components for jewellery making; (ii) metal parts of jewellery and imitation jewellery articles and hair accessories, including: — bracelets, necklaces and rings, — piercing jewellery, — wrist-watches and wrist-wear, — brooches and cufflinks. 11. By way of derogation, paragraph 10 shall not apply to articles placed on the market before 10 December 2011 and jewellery more than 50 years old on 10 December 2011.</p>
24	Monomethyl tetrachlorodiphenylmethane, Ugilec 141	76253-60-6	<p>1. Shall not be placed on the market, or used, as a substance or in mixtures.</p> <p>Articles containing the substance shall not be placed on the market</p> <p>2. By way of derogation, paragraph 1 shall not apply:</p> <p>(a) in the case of plant and machinery already in service on 18 June 1994, until such plant and machinery is disposed of;</p> <p>(b) in the case of the maintenance of plant and machinery already in service within a Member State on 18 June 1994.</p> <p>For the purposes of point (a) Member States may, on grounds of human health protection and environmental protection, prohibit within their territory the use of such plant or machinery before it is disposed of.</p>

25	Monomethyl-dichloro-diphenylmethane, Ugilec 121, Ugilec 21		Shall not be placed on the market, or used, as a substance or in mixtures. Articles containing the substance shall not be placed on the market
26	Monomethyl-dibromo-diphenylmethane, DBBT	99688-47-8	Shall not be placed on the market, or used, as a substance or in mixtures.  Articles containing the substance shall not be placed on the market.
27	Nickel and its compounds	7440-02-0	<p>1. Shall not be used:</p> <p>(a) in any post assemblies which are inserted into pierced ears and other pierced parts of the human body unless the rate of nickel release from such post assemblies is less than 0,2 µg/cm<sup>2</sup>/week (migration limit);</p> <p>(b) in articles intended to come into direct and prolonged contact with the skin such as:</p> <ul style="list-style-type: none"> <li>○ earrings,</li> <li>○ necklaces, bracelets and chains, anklets, finger rings,</li> <li>○ wrist-watch cases, watch straps and tighteners,</li> <li>○ rivet buttons, tighteners, rivets, zippers and metal marks, when these are used in garments,</li> </ul> <p>if the rate of nickel release from the parts of these articles coming into direct and prolonged contact with the skin is greater than 0,5 µg/cm<sup>2</sup>/week.</p> <p>(c) in articles referred to in point (b) where these have a non-nickel coating unless such coating is sufficient to ensure that the rate of nickel release from those parts of such articles coming into direct and prolonged contact with the skin will not exceed 0,5 µg/cm<sup>2</sup>/week for a period of at least two years of normal use of the article.</p> <p>2. Articles which are the subject of paragraph 1 shall not be placed on the market unless they conform to the requirements set out in that paragraph.</p> <p>3. The standards adopted by the European Committee for Standardisation (CEN) shall be used as the test methods for demonstrating the conformity of articles to paragraphs 1 and 2</p>
43	Azocolourants and Azodyes		<p>1. Azodyes which, by reductive cleavage of one or more azo groups, may release one or more of the aromatic amines listed in Appendix 8, in detectable concentrations, i.e. above 30 mg/kg (0,003 % by weight) in the articles or in the dyed parts thereof, according to the testing methods listed in Appendix 10, shall not be used, in textile and leather articles which may come into direct and prolonged contact with the human skin or oral cavity, such as:</p> <ul style="list-style-type: none"> <li>○ clothing, bedding, towels, hairpieces, wigs, hats, nappies and other sanitary items, sleeping bags,</li> <li>○ footwear, gloves, wristwatch straps, handbags, purses/wallets, briefcases, chair covers, purses worn round the neck,</li> <li>○ textile or leather toys and toys which include textile or leather garments,</li> <li>○ yarn and fabrics intended for use by the final consumer.</li> </ul> <p>2. Furthermore, the textile and leather articles referred to in paragraph 1 shall not be placed on the market unless they conform to the requirements set out in that paragraph.</p>

			3. Azodyes, which are contained in Appendix 9, 'List of azodyes' shall not be placed on the market, or used, as substances, or in mixtures in concentrations greater than 0,1 % by weight, where the substance or the mixture is intended for colouring textile and leather articles.
46	(a) Nonylphenol C <sub>6</sub> H <sub>4</sub> (OH)C <sub>9</sub> H <sub>19</sub> (b) Nonylphenol ethoxylates (C <sub>2</sub> H <sub>4</sub> O) <sub>n</sub> C <sub>15</sub> H <sub>24</sub> O	25154-52-3 EC 246-672-0	Shall not be placed on the market, or used, as substances or in mixtures in concentrations equal to or greater than 0,1 % by weight for the following purposes:  (1) industrial and institutional cleaning except: <ul style="list-style-type: none"> <li>○ controlled closed dry cleaning systems where the washing liquid is recycled or incinerated,</li> <li>○ cleaning systems with special treatment where the washing liquid is recycled or incinerated.</li> </ul> (2) domestic cleaning;  (3) textiles and leather processing except: <ul style="list-style-type: none"> <li>○ processing with no release into waste water,</li> <li>○ systems with special treatment where the process water is pre-treated to remove the organic fraction completely prior to biological waste water treatment (degreasing of sheepskin);</li> </ul> (4) emulsifier in agricultural teat dips; (5) metal working except: uses in controlled closed systems where the washing liquid is recycled or incinerated;  (5) metal working except: <ul style="list-style-type: none"> <li>○ uses in controlled closed systems where the washing liquid is recycled or incinerated;</li> </ul> (6) manufacturing of pulp and paper;  (7) cosmetic products; (8) other personal care products except: <ul style="list-style-type: none"> <li>○ spermicides;</li> </ul> (9) co-formulants in pesticides and biocides. However national authorisations for pesticides or biocidal products containing nonylphenol ethoxylates as co-formulant, granted before 17 July 2003, shall not be affected by this restriction until their date of expiry.
50	Polycyclic-aromatic hydrocarbons (PAH)  a) Benzo[a]pyrene (BaP)  b) Benzo[e]pyrene (BeP)  c) Benzo[a]anthracene (BaA)  d) Chrysen (CHR)  e) Benzo[b]fluoranthene (BbFA)	50-32-8 192-97-2 56-55-3 218-01-9 205-99-2	(...) 5. Articles shall not be placed on the market for supply to the general public, if any of their rubber or plastic components that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reasonably foreseeable conditions of use, contain more than 1 mg/kg (0,0001 % by weight of this component) of any of the listed PAHs.  Such articles include amongst others: <ul style="list-style-type: none"> <li>○ sport equipment such as bicycles, golf clubs, racquets</li> <li>○ household utensils, trolleys, walking frames</li> <li>○ tools for domestic use</li> <li>○ clothing, footwear, gloves and sportswear</li> <li>○ watch-straps, wrist-bands, masks, head-bands</li> </ul>

	<p>f) Benzo[j]fluoranthene (BjFA)</p> <p>g) Benzo[k]fluoranthene (BkFA)</p> <p>h) Dibenzo[a,h]anthracene (DBAhA)</p>	<p>205-82-3</p> <p>207-08-9</p> <p>53-70-3</p>	<p>6. Toys, including activity toys, and childcare articles, shall not be placed on the market, if any of their rubber or plastic components that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reasonably foreseeable conditions of use, contain more than 0,5 mg/kg (0,00005 % by weight of this component) of any of the listed PAHs.</p> <p>7. By way of derogation from paragraphs 5 and 6, these paragraphs shall not apply to articles placed on the market for the first time before 27 December 2015.</p> <p>8. By 27 December 2017, the Commission shall review the limit values in paragraphs 5 and 6 in the light of new scientific information, including migration of PAHs from the articles referred to therein, and information on alternative raw materials and, if appropriate, modify these paragraphs accordingly.</p>
51	<p>(a) Bis (2-ethylhexyl) phthalate (DEHP)</p> <p>(b) Dibutyl phthalate (DBP)</p> <p>(c) Benzyl butyl phthalate (BBP)</p>	<p>117-81-7</p> <p>84-74-2</p> <p>85-68-7</p>	<p>1. Shall not be used as substances or in mixtures, in concentrations greater than 0,1 % by weight of the plasticised material, in toys and childcare articles.</p> <p>2. Toys and childcare articles containing these phthalates in a concentration greater than 0,1 % by weight of the plasticised material shall not be placed on the market.</p> <p><i>(3. Regulation (EU) No 326/2015: paragraph 3 is deleted.)</i></p> <p>4. For the purpose of this entry 'childcare article' shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children.</p>
52	<p>(a) Di-'isononyl' phthalate (DINP)</p> <p>(b) Di-'isodecyl' phthalate (DIDP)</p> <p>(c) Di-n-octyl phthalate (DNOP)</p>	<p>28553-12-0 and 68515-48-0</p> <p>26761-40-0 and 68515-49-1</p> <p>117-84-0</p>	<p>1. Shall not be used as substances or in mixtures, in concentrations greater than 0,1 % by weight of the plasticised material, in toys and childcare articles which can be placed in the mouth by children.</p> <p>2. Such toys and childcare articles containing these phthalates in a concentration greater than 0,1 % by weight of the plasticised material shall not be placed on the market.</p> <p><i>(3. Regulation (EU) No 326/2015: paragraph 3 is deleted.)</i></p> <p>4. For the purpose of this entry 'childcare article' shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children.</p>
60	Dimethylfumarate (DMF)	CAS No 624-49-7	<p>Shall not be used in articles or any parts thereof in concentrations greater than 0,1 mg/kg.</p> <p>Articles or any parts thereof containing DMF in concentrations greater than 0,1 mg/kg shall not be placed on the market.</p>

## Annex 2:

### Example of a Conformity Declaration

**For raw materials for dry hygiene/personal care articles: baby diapers, feminine care and incontinence products – please note this is an example from a manufacturer and does not constitute the official EDANA opinion<sup>37</sup>**

#### **Scope of Conformity Declaration (CD):**

##### **Conformity Declaration**

(for raw materials for dry hygiene/personal care articles: babycare and femcare products, breast pads and inco products)

#### **Scope of Conformity Declaration (CD):**

Consumer Articles must not endanger human health and therefore have to be safe as laid down in the legally binding European Directive for General Product Safety <sup>[1]</sup> and, in particular, in the German Code on foodstuff, consumer articles and feedstuff (LFGB) <sup>[2]</sup>. All references can be found at the end of Annex 2. Further legal provisions of the European Biocidal Regulation (BPR) <sup>[3]</sup> have to be followed, but also provisions as laid down in the US Consumer Product Safety Act (CPSA) <sup>[4]</sup> and more specifically in California Proposition 65 <sup>[5]</sup>.

Besides these legal obligations for Consumer Articles also non-legal requirements have to be followed or need to be taken into account in particular when caused by the safety perception expressed in public opinion.

Therefore it is mandatory for X manufacturer to have its raw materials checked for the following compliance rules and information duties as far as applicable for the various raw materials.

Additionally the EU Regulation for registration, evaluation, authorisation and restriction of chemicals (REACH) <sup>[6]</sup> requires that downstream user have to fulfil certain obligations for finished articles according to Article 7 of the EU Regulation.

Please fill in this questionnaire for compliance, comment on non-compliance and attach documents as necessary; please also indicate the type of proof. Since it is difficult to formally cover all aspects of legal compliance and safety of a raw material into one short formatted document efforts should be taken to fill in this questionnaire as adequate as applicable; explanatory comments are therefore highly appreciated.

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<sup>37</sup> All suppliers are advised to request similar examples from their customers

Please sign document by responsible (contact) person!

Name of Raw Material: ...

If raw material is a composite material/chemical mixture and/or finishing agent/technical auxiliary etc. please specify.

Type of Raw Material:

Please specify intended use of raw material in hygiene product.

Topsheet	
Back sheet film	
Elastic ear	
Front ear	
ADL	
Absorbent core (fluff/SAP/airlaid/viscose/cotton)	
Frontal tape	
Closure tape	
Back sheet nonwoven	
Cuff	
Dyestuff/ink	
Adhesive/glue	
Release paper	
Soft sides	
Removal thread (tampons)	
Perfume	
Lotion	
Tissue	
Other (please specify:	

Does direct skin contact takes please due to the intended use of the raw material?

yes	
no	

Are ISO 10993-1/5/10/11 certificates available for cases where direct skin contact from raw material is intended?

yes *	
no	

\* Please provide certificate.

Has raw material been tested with experimental animals?

yes *	
no	

\* Please provide year, rationale and any further explanation for testing.

CAS-No. ...  
(if applicable)

Producer/Importer: ...  
(name and address of producer/importer)

Contact Person: ...  
(name and address, including telephone number and e-mail)



- California Proposition 65 (for further reading see <sup>[5]</sup>):**  
**It is noted that California Proposition 65 may be difficult to cope with, therefore further detailed explanatory comments are necessary for acceptance of compliance.**

Does the raw material delivered to XX Manufacturer fulfil California proposition 65, i.e. it does not contain chemicals known to the state of California to cause cancer or reproductive toxicity? yes/no

Comments:

- Other legal obligations**

**Note, if you do not know, whether your supplier’s raw material may fulfil the following criteria (see second column), please ask for your suppliers written statement. If you do not get it, mark “no” in respective column and comment accordingly.**

No.	Requirements [Reference]	Criteria fulfilled?		Type of proof: T = Test report is available F = Proof follows from the Formulation D = Declaration of supplier(s) is available	Comments (Comments on why criteria are not applicable may be made here) It should be noted, that requirements of [5] need to be fulfilled <u>as if</u> they would directly apply for a raw materials for use in hygiene products
		yes	no		
1	Requirements of Annex XVII; No. 43 of [6] and of Section 26 of [7] resp. for azocolourants are fulfilled?				
2	Requirements of Annex XVII, of [6] for Polychlorinated Terphenyls and Section 13 of [7] for Polychlorinated Biphenyls/Terphenyls (PCB/PCT) are fulfilled?				
3	Requirements of Annex XVII; of [6] and of Section 15 of [7] resp. for PentaChloro-Phenol (PCP) are fulfilled?				
4	Requirements of Section 16 of [7] for chlorinated hydrocarbons are fulfilled?				
5	Requirements of Annex XVII; of [6] and of Section 25 of [7] resp. for polybromated substances are fulfilled?				
6	Carcinogenic, mutagenic, reprotoxic (CMR) substances, Cat 1A, 1B and 2 according to CLP Regulation [7], or substances with effects on or via lactation are not intentionally added? (Note, this covers hazard statements H340, H350, H360, H362 [see 6] or risk phrases R45, R46, R49, R60, R61, R64 according to Directive 67/548/EEC) (Note, criteria are identical to requirements from Cosmetic Directive [8])				
7	Requirements of Annex XVII; No. 46 of [6] and of Section 27 of [7] resp. for nonylphenol/nonylphenol ethoxylates are fulfilled?				

8	Requirements of Annex XVII; No. 51 & 52 of [6] for phthalates are fulfilled?				
9	Requirements of Annex XVII of [6] and of Section 32 of [7] resp. for PerFluorOctane Sulfonates (PFOS) are fulfilled?				
10	Requirements of Annex XVII, No. 50 of [6] and of Section 29 of [7] resp.as well as Requirements of Regulation No 1272/2013 [22] for Polycyclic Aromatic Hydrocarbons (PAH) are fulfilled?				
11	Requirements of Section 4, of [7] for dioxins [PolyChlorinated Dibenzo para Dioxins (PCDDs) and PolyChlorinated DibenzoFurans (PCDFs)] are fulfilled?				

## Chapter 2: Obligations according to applicable safety requirements

**Note, the requirements listed in this chapter are applied to raw materials for the manufacture of personal hygiene products, although they may have been created for other sectors of use originally. Their fulfilment establishes an important safety standard because the exposure is relevant for direct skin contact.**

Ref. No.	Requirements [Reference]	Criteria fulfilled?		Type of proof: T = Test report is available F = Proof follows from the Formulation D = Declaration of supplier(s) is available	Comments (Comments on why criteria are not applicable may be made here)
		yes	no		
12	Phthalates listed in Annex II of [9] are not intentionally added during the manufacturing process?				
13	<p>Compliance with German guidelines for the evaluation of personal sanitary products according to [10]? Note, this is a general official recommendation which partly also covers Ref. No. 14.</p> <p>If spin finishes are not in compliance please provide proof for their biocompatibility.</p> <p>Biocompatibility testing (i.e. cytotoxicity assay; HET-CAM assay) is available?</p> <p>Other supportive (test) data are available?</p>	yes	no		<p><b>Note:</b> Due to similar human exposure, guidelines for food contact materials are followed, <u>as if</u> dry hygiene personal care article would be used respectively; <u>for fiber finishes compliance with [14] is recommended.</u></p> <p>Note that for raw materials in direct contact with skin compliance is mandatory for either items 13 or 14.</p>
14	Compliance with requirements for the manufacture of materials in contact with foodstuff according to [11; 12; 13] with regard to the listing of substances				

item 15 only to be filled in for/only applies to SuperAbsorbent Polymer (SAP)				
15	Quality criteria of superabsorbent polymer (SAP) according to [12]? Note: see in particular Recommendation LIII of [12]			only to be filled in for SAP
item 16 only to be filled in for/only applies to cellulose				
16	Quality criteria of cellulose for use in tampons according to [14]?			only to be filled in for cellulose
item 17 only to be filled in for/only applies to perfume(s)				
17	Use of perfumes is according to [7, 13]? Note, safety assessment has to be executed according to [15]; attention is drawn to presence of allergenic substances.			only to be filled in for perfume
18	No bleaching with elemental chlorine according to [16] is performed?			
19	Compliance with or assignment of Oeko-tex Standard 100, class I (baby) [17] can be shown?			This item is essential for raw materials with direct skin contact.
20	TAMC (Total aerobic microbial count): < 100 CFU/g TYMC (Total combined yeast/moulds count): < 100 CFU/g Absence of specific human pathogens, i.e. <i>E. coli</i> ; <i>Ps. aeruginosa</i> ; <i>St. aureus</i> ; <i>Cand. albicans</i> , <i>A. brasiliensis</i> Microbial quality criteria according to Ph. Eur. 2.6.12 / 2.6.13 for requirements for non-sterile products for dermal application [14]?			
21	Compliance of any dyestuff(s) with food packaging requirements can be shown according to [18]?			This item is essential for dyed materials. Appropriate explanation of type of dyeing of raw material should be given.
22	Compliance of colorant(s) with Cosmetic Regulation [9] or compliance with Food Additive Regulation [21] can be shown?			This item is essential for dyed materials. Appropriate explanation of type of dyeing of raw material should be given.

### Chapter 3: Obligations covering requirements for trace levels of substances

Note, products, which are placed on the market for consumers, have also to fulfil certain criteria with respect to criteria published and advocated by consumer protection organisations, competent authorities or by the media. XX Manufacturer therefore does need assurance that all trace levels, listed below, are not exceeded.

Ref. No.	Requirements [Reference]	Criteria fulfilled?		Type of proof: T = Test report is available F = Proof follows from the Formulation D = Declaration of supplier(s) is available	Comments (Comments on why criteria are not applicable may be made here)
		yes	no		
23	Trace level of formaldehyde < 0.5 mg/kg?				
24	Trace level of certain (extractable) heavy metals: (limit values for Oekotex Standard class I (baby) [17]) <ul style="list-style-type: none"> <li>■ Antimony (Sb): &lt; 30 mg/kg?</li> <li>■ Arsenic (As): &lt; 0.2 mg/kg?</li> <li>■ Chromium (Cr(VI)): &lt; 0.5 mg/kg?</li> <li>■ Lead (Pb): &lt; 0.2 mg/kg?</li> <li>■ Mercury (Hg): &lt; 0.02 mg/kg?</li> <li>■ Nickel (Ni): &lt; 1.0 mg/kg?</li> </ul>				
25 <sup>38</sup>	Sum of 8 Polycyclic Aromatic Hydrocarbons (PAH) according to REACH annex XVII < 0.5 mg/kg?				
26	Trace level of Adsorbable Organic Halogens (AOX) < 0.5 mg/kg?				
27	Trace level of Extractable Organic Halogens (EOX): < 2.0 mg/kg?				
28	1,3-Dichloro-2-propanol (DCP) and 3-Monochloro-1,2-propandiol (3-MCPD): Trace level for DCP < 2 µg/kg? Trace level for 3-MCPD < 12 µg/kg?				
29	Organotin compounds: Trace level of TBT (Tributyltin) < 2 µg/kg? Trace level of DBT, TPhT, MBT, MOT, DOT < 10 µg/kg?				
30	Trace level of Glyoxal (Ethandial) < 1.5 mg/dm <sup>2</sup> ?				
31	Isothiazolinones (MIT, BIT or CIT) are <b>not</b> used in the production process?				
<b>items 32 to 34 only to be filled in for/only apply to perfume(s)</b>					
32	Trace level of 26 potentially allergenic substances as listed in [9]: < 1 mg/kg in the perfume?				
33	Trace level of Majantol (CAS# 103694-68-4): < 1 mg/kg in the perfume?				
34	Trace level of nitromusk and polycyclic musk compounds: < 1 mg/kg in the perfume?				

<sup>38</sup> Entry 25 (PAH) of the table under Chapter 3: Obligations covering requirements for trace levels of substances has been corrected

#### Chapter 4: Informative data about certain substances in raw materials

Note, that your raw material(s) need(s) to be checked for the substances as listed below.

Ref. No.	Requirements [Reference]	Criteria fulfilled?		Type of proof: T = Test report is available F = Proof follows from the Formulation D = Declaration of supplier(s) is available	Comments (Comments on why criteria are not applicable may be made here)
		yes	no		
35	Colophonium and its derivatives are <b>not</b> intentionally added?				
36	Polyvinyl Chloride (PVC) is <b>not</b> intentionally added?				
37	Rubber latex is <b>not</b> intentionally added?				
38	Optical brighteners are not used/are <b>not</b> present?				Note, optical brighteners may be added for technical reasons, which should be stated in Comments.
39	Derivatives from animal origin are <b>not</b> used/are not present?				<b>Note:</b> Certain derivatives like from tallow need to follow procedures as laid down in [17].
40	Derivatives from genetically modified organisms (GMO) [20] are <b>not</b> used/are not present?				
41	Bisphenol A (BPA; CAS 80-05-7) is not part of the formulation?				
<b>items 42 and 43 only to be filled in for/only apply to perfume(s)</b>					
42	Compliance with IFRA Recommendations [15] for fragrances?				
43	Compliance according to REACH Regulation [6] for intentional release of perfumes?				

Date: \_\_\_\_\_

Signature: \_\_\_\_\_

Position: \_\_\_\_\_

## References/Sources:

Note: All references are to be checked for their latest amended version.

- [1] Directive 2001/95/EC of 03/12/2001 on general product safety  
Official Journal (OJ) L 11 of 15/01/2002, p. 4; available at:  
<http://eur-lex.europa.eu/>
- [2] LFGB: German Code on foodstuff, consumer articles and feedstuff of 03/06/2013  
German Federal Register ("Bundesgesetzblatt") I No. BGBl. I No 27 of 10/06/2013 p. 1426; available at:  
<http://bundesrecht.juris.de/>
- [3] BPR: Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22/05/2012 concerning the making available on the market and use of biocidal products  
OJ L 167 of 27/06/2012, p.1; available at:  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:167:0001:0123:EN:PDF>
- [4] CPSA: codified at 15 U.S.C. §§ 2051–2089; available at:  
<http://www.cpsc.gov/PageFiles/105435/cpsa.pdf>
- [5] State of California Proposition 65: Safe Drinking Water and Toxic Enforcement Act of 1986; available at:  
[http://www.oehha.org/prop65/prop65\\_list/Newlist.html](http://www.oehha.org/prop65/prop65_list/Newlist.html)
- [6] REACH: Regulation (EC) No. 1907/2006 of 18/12/2006 concerning the registration, evaluation, authorisation and restriction of chemicals ...  
OJ L 396 of 30/12/2006, p. 1, corr. OJ L 136 of 29/05/2007, p. 3 and OJ L 36 of 05/02/2009, p. 84; available at:  
<http://eur-lex.europa.eu/>
- [7] German Ordinance on the prohibition and restrictions for marketing of dangerous substances, preparations and articles ("Chemikalienverbotsverordnung") of 13/06/2003  
German Federal Register I of 25/06/2003, p. 867 (and following amendments); available at:  
<http://bundesrecht.juris.de/>
- [8] Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16/12/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006  
OJ L 353 of 31/12/2008; available at:  
<http://eur-lex.europa.eu/>
- [9] Regulation (EC) No 1223/2009 of 30/11/2009 on cosmetic products  
OJ L 342 of 22/12/2009, p. 59; available at:  
<http://eur-lex.europa.eu/>
- [10] Guidelines for evaluation of personal sanitary products ("Hinweise zur Beurteilung von Intimhygieneerzeugnissen") Federal Health Gazette („Bundesgesundheitsblatt“) 39, 124 (1996); available at:  
<http://bfr.zadi.de/kse/faces/resources/INTENGLISCH.pdf>
- [11] Commission Regulation (EU) No 10/2011 of 14/01/2011 on plastic materials and articles intended to come into contact with food  
OJ L 12 of 15/01/2010, p. 1; available at:  
<http://eur-lex.europa.eu/>
- [12] German Recommendations for materials in contact with foodstuff: (in particular recommendations: III, VII, IX, XV, XXXVI and LIII); available at:  
<http://bfr.zadi.de>
- [13] CFR: Code of Federal Regulations: (in particular 21 CFR §§ 176.210, 176.170, 177.2800, 177.1850, 177.1520, 175.105); available at:  
<https://www.gpo.gov/fdsys/browse/collectionCfr.action?selectedYearFrom=-1&go=Go>
- [14] European Pharmacopeia; available at:  
<http://www.edqm.eu>
- [15] Code of Practice of the International Fragrance Association; available at:  
<http://ifraorg.org>
- [16] Alliance for Environmental Technology; available at:  
<http://www.aet.org>
- [17] Oeko-tex standard 100 (product class I: baby); available at  
[https://www.oeko-tex.com/en/business/certifications\\_and\\_services/ots\\_100/ots\\_100\\_test\\_criteria/ots\\_100\\_test\\_criteria.html](https://www.oeko-tex.com/en/business/certifications_and_services/ots_100/ots_100_test_criteria/ots_100_test_criteria.html)
- [18] European Council of Paint, Printing Ink and Artists` Colours Industry (CEPE): Exclusion policy for printing inks and related products, 3<sup>rd</sup> edition, November 2016; available at:  
[http://www.eupia.org/uploads/tx\\_edm/2016-11-17\\_Exclusion\\_Policy\\_for\\_Printing\\_Inks\\_and\\_Related\\_Products\\_3rd\\_ed.pdf](http://www.eupia.org/uploads/tx_edm/2016-11-17_Exclusion_Policy_for_Printing_Inks_and_Related_Products_3rd_ed.pdf)

- [19] Regulation (EC) No. 1069/2009 of 21/10/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No. 1774/2002 (Animal by-products Regulation)  
OJ L 300 of 14/11/2009, p. 1; available at:  
<http://eur-lex.europa.eu/>
- [20] Directive 2001/18/EC of the European Parliament and of the Council of 12/03/2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC  
OJ L 106 of 17/04/2006, p. 1; available at:  
<http://eur-lex.europa.eu/>
- [21] Regulation (EC) No. 1333/2008 of the European Parliament and of the Council of 16/12/2008 on food additives;  
OJ L 354 of 31/12/2008, p. 16; available at:  
<http://eur-lex.europa.eu/>
- [22] COMMISSION REGULATION (EU) No 1272/2013 of 6 December 2013 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards polycyclic aromatic hydrocarbons; available at:  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:328:0069:0071:EN:PDF>

EXAMPLE ONLY