

## APPENDIX 6: INFORMATION SOURCES ON RESTRICTIONS AND METHODS FOR 1016 DETERMINATION OF SUBSTANCES RELEASED FROM ARTICLES

The list contains examples of available sources on information on restricted substances in articles, 1018 declaration duties, chemical analysis of substances banned in articles, standardise release testing 1019 methods and experiences from testing and analyses related to articles. It is not a complete list of in1020 formation sources.

Product	Identification of substances	Determination of substance content	Determination of substance release
<i>Miscellaneous articles:</i>			
Marketing and use restriction for textile articles	A list of substances banned for the use in articles in general is provided: Tris(2,3 dibromopropyl) phosphate, Tris-aziridiny)-phosphin oxide, penta- and octabromo diphenylethers, Polybromo biphenyls(PBB), pentachlorophenol, mercury compounds, cadmium and its compounds, nonylphenol- and ethoxylates (processing). A list of azodyes, which could be by reductive cleavage of one or more azo groups, may release one or more of the aromatic amines, is provided. Methods for the determination of certain aromatic amines derived from azo colorants Part 1: Detection of the use of certain azo colorants accessible without extraction (EN 14362-1:2003) Part 2: Detection of the use of certain azo colorants accessible by extracting the fibres (EN 14362-2:2003)		
Construction products			Requirement for documentation of release during use according to hygiene, health and the environment. The construction work must be designed and built in such a way that it will not be a threat to the hygiene or health of the occupants or neighbours. There are ongoing activities in CEN to develop standard on selected substances such as formaldehyde and brominated flame retardants. The Commission's Expert Group on Dangerous Substances (EGDS ) are working on test methods in product standards.
AgBB-Approach	CMR substances may not be introduced in to the material		Chamber test with single product sample (DIN V ENV 134191 to 3) thresholds for Σcarcinogens, TVOC, ΣSVOC, individual substances (list of LCIs included) , Σnonassessable substances Test is similar to emissions tests for eco-labels
Eco-Label Type III ISO TR 14025, R-Symbol ARGE kdR	Declaration duties	Declaration duties	Chemical analysis of potential emission according to standardised tests
<i>Substances in vehicles:</i>			
ELV and IDIS	Database on car components containing restricted substances		

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Product	Identification of substances	Determination of substance content	Determination of substance release
Toxproof certificate	Based on a list of substances that can damage health or cause allergenic reactions The procedure of research follows in consideration of experiences from manufacturers and from other fields (indoor air, work place requirements): Identification of each material/component using a received material list. basic analysis for each material like textiles, leather, plastics analysis of each material with skin contact analysis of indoor air toxicological expert appraisal	Content testing like: banned azo-dyes (DIN EN 143261/2)	Standardized release testing methods used: Static headspace (VDA-norm 277) with flame ionization detector (FID) or mass spectrometry (MS) condensable substances (DIN 75201) gravimetric method or gas chromatography odour of emitted components (VDA 270) olfactory test subskin test (patchtest)
<b>Electrical and electronic equipment (EEE):</b>			
RoHS and WEEE	Six substances are banned in EEE: Pb, Hg, Cd, Cr VI, PBB and PBDE	Chemical analysis by existing analytical methods for all applications Further methods have to be developed.	
Material data bases for electronic equipment:	Wizard and GreenPack: IT-Communication tool Suppliers have to enlist substances in components		
<b>Child care products and toys:</b>			
Standards for child-care products	Analytical methods are given in the guideline “Child use and care articles – General and common safety guidelines” and Standard EN 14350-2.	Standard EN 14350-2 has limits of the release of certain elements from drinking equipments. The guideline provides also migration limits for certain chemicals regulated in other products. <a href="#">Chemical substances in toothbrushes</a> (DIN 53160-1)	
Toy safety	Substance lists: Dangerous substances/preparations must not be used	Chemical analysis Screening methods	The migration of heavy metals, inorganic and organic substances can be measured according to the EN 71-3 standard where the simulant 0.07 M hydrochlorous acid (HCl) simulates artificial saliva or gastric acid. Analytical method is given in Survey no. 46 (Chemical substances from tents and tunnels for children, Wooden toys: Will be published within August 2005) Survey no. 14: Mapping of Chemical Substances Discharge when heating Clay
<b>Plastic articles – food contact material:</b>			
practical guidance on food contact material	Requirements to be considered positive lists purity standards for substances special conditions of use for substances and/or the materials/articles in which they are used and SMLs	Numerous Standards for identification and quantification of substances in materials and articles and detailed rules concerning sample taking and analytical methods	Software tool Migratest Lite 2001: migration model for the simulation in migration tests. Certain conditions are defined depending on the material, the food simulant (e. g. fatty, aqueous), time and temperature

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Product	Identification of substances	Determination of substance content	Determination of substance release
Directives on food contact material		In Germany: recommendations for substances in polymers: <a href="http://bfr.zadi.de/kse/">http://bfr.zadi.de/kse/</a>	Release in the context of the directives means a migration of substances from material to the foodstuff. Overall migration limit (in mg/dm <sup>2</sup> as a measure for inertness of the material or mg/kg): Specific migration limits (SML, in mg/kg or mg/l)
Directive 2002/72/EC	Lists specify the use of substances: monomers and starting substances additives (Annex III) and products obtained by means of bacterial fermentation (Annex IV) possible restrictions (Annex V, VI) for usage.	Another possible method to exclude a relevant migration is to measure the quantity (Q) of a substance in the finished material or article and to compare it with the value of its specific migration (SM) known from experimentation or valid diffusion models 78/142/EEC: limits for the content of vinyl chloride in a finished material or released by this material	General analysis of overall migration For detailed information on analytical methods the directive refers to other documents like: 82/711/EEC: basic rules necessary for testing migration of the constituents of plastic materials and articles 82/572/EEC: simulates to be used in migration tests 97/48/EEC (temperature and time) Standards EN 1186 (global migration) Standards EN 13130 (specific migration)
ESD on additives used in Plastic Industry			Estimation: Potential release as emission or loss factors over service life: 10 additive types (e.g. antioxidants, anti-static agent, colourants) according to their function identified. The loss is estimated as a percentage of the amount of additives used (dependent on particle size (threshold value 40 µm) and volatility (related to the vapour pressure). It depends on the application of the additives and the values of service life.
EURO-CAD	Report formats were used to communicate Alert and EURASCP system: a report format to inform colleagues inspectors within the EU and Norway when products with an exceed limit value of cadmium are found and it seems possible that it is planned to transport them to other EU countries. Report form EuroCad company inspections.	Quantification methods for cadmium content in articles: INAA (instrumental neutron activation analysis) DIN V ENV 1122 AAS (atom adsorption spectroscopy), XRF (x-ray fluorescence spectroscopy) and others	
<b>Labeling requirements:</b>			
Nordic swan for writing instruments	Lists of substances excluded from use in these products are used. supplier has to provide a declaration of classification, content of named substances and product composition.	Only general (GLP) requirements for content analysis on substance identification and quantification are given	

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Product	Identification of substances	Determination of substance content	Determination of substance release
Blue Angle for wood panels	No use of: wood preservatives (fungicides, insecticides, fire protection agents) halogenated organic compounds Documentation of compliance: Recipe for the production of the woodbased material and of the coating.		Limit values for the emission of substances. Chamber test with product sample Formaldehyde, VOC and individual substances Phenol ("Phenol Measurement p-nitroanilin process", VDI Directive 3485) MDI phenol-containing binding agents Identification and quantification with GC-MS
Label for upholstery and mattresses	The used materials (leather, textiles, upholstery and coating material, adhesives) must not contain substances that are toxic, CRM19, known as a strong contact allergen (leather) <sup>20</sup> No use of certain dyes or pigments (substance list) The following documents are requested for compliance: recipe for the production of the wood-based material and, if the occasion arises, of the coating. test certificates statement or declaration of the suppliers product information for the used materials		Chamber test with product sample (according to RAL-UZ 76 wood products, DIN ENV 13419-1, VDA 276) LANXESS criticizes that the scenario chamber test is very expensive and time-consuming. They prefer other smaller scaled methods from the automotive industry: Headspace-method: RAL-GZ 479/VDA 277 (PV 3341), PB VWL 709/VDA 278 overall emission, for leather used in cars, RAL-GZ 479/DIN EN 717-3/VDA 275 free formaldehyde in for leather used in cars, Fogging DIN 75201/ISO 6452 condensable emission for leather used in cars
Nordic Swan for Furniture and Fitments	Not allowed are: biocides classified by WHO as Type 1A or 1B (mandatory) for wood CMR, toxic, allergenic substances halogenated organic substances heavy metals individual substances (substance list) For documentation of compliances: The producer of wood material shall submit information on total amount (in g/kg panel) of chemical substances classified as environmentally harmful. The supplier has to classify the constituents.	Methods for detection and measuring of formaldehyde depending on material are: ENV 717 (perforator method) Finnish classification system: "Emission Classification of building material" <sup>21</sup> and Climate Chamber, method, ENV-717-1 Chamber method used for correlation of emission potential (EN 120) as mg/100 , emission level expressed in ppm or mg/m <sup>3</sup> EN ISO 14184 (emission from padding materials and textiles) CEN standard 131 ( for adhesives) Nitrosamines: chamber test (ENV 13419-1 after 24 h and 30 h) or ZH ISO 1/120.2322 for air sampling; Thresholds for emission and content: formaldehyde substances harmful to the environment aromatic solvents organic solvents and substances classified environmentally harmful (e.g. quantity per m <sup>2</sup> surface	

<sup>19</sup> According to Directive 67/548/EEC annex I, GefStV, TRGS, MAK- und BAT-Werte-Liste

<sup>20</sup> List of the German BfR

([https://gripsdb.dimdi.de/websearch/servlet/Gate?accessid=bfrKABasic&language=de#\\_DEFANCHOR\\_](https://gripsdb.dimdi.de/websearch/servlet/Gate?accessid=bfrKABasic&language=de#_DEFANCHOR_))<sup>21</sup>  
[http://www.rts.fi/emission\\_classification\\_of\\_building\\_materials.htm](http://www.rts.fi/emission_classification_of_building_materials.htm)

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<b>Product</b>	<b>Identification of substances</b>	<b>Determination of substance content</b>	<b>Determination of substance release</b>
The IKEA way of purchasing	IKEA provides a negative list of substances, which must not be used by its suppliers. IKEA demands a minimum chemicals management of its suppliers including to list all chemicals used.	Content and release analysis is carried out to control whether products comply with IKEA specification on chemical compounds (see below).	Release analysis (e.g. chamber tests) are also carried out to identify potential risks related to long term exposure of substances
ESD on textiles			A total release is estimated for volatile substances to the atmosphere for biocides from indoor articles to wastewater through cleaning for biocides from outdoor articles to wastewater and soil.
Oeko-Tex 100	Testing methods for detection of banned substances (substance lists)	Testing methods to control compliance with thresholds for: content of pesticides and chlorinated phenols formaldehyde or containing trace amounts (significantly lower than the required legal limits)	Testing methods to control compliance with thresholds for: release of heavy metals under artificial perspiration conditions For pigment, vat or sulphurous colorants a minimum grade of colour fastness to rubbing of 3 (dry) is acceptable
EU-Flower for textiles	Documentation includes a manufacturing system diagram with flow diagram and list of all suppliers list of used chemicals, dyes and pigments in the product	Analysis of chemicals and emissions by laboratories which are accredited according ISO 17025. Test methods/standards are indicated in the criteria documents (content and release) Named substances are prohibited (substance list) Thresholds for individual substances	
ChemRisk		As a reference system ChemTest is part of the toolbox and provides available analytical methods suitable to close data gaps remaining in the knowledge based analysis. Development and validation of biomarkers are key issues of EIS-ChemRisks (low dose biomarkers). Tool working with ExpoScenarios as standard scenarios. The focus of EIS-CHEMRISKS will be to evaluate the feasibility of using data derived from modelling activities in the EU and in the world.	

## APPENDIX 7: LEGISLATION RESTRICTING THE USE OF SUBSTANCES IN ARTI1023 CLES

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Instrument	Coverage	Conditions	Notes
Directive 76/769/EEC Marketing and use restrictions Directive	Placing on the market and use of hazardous substances in Annex I	Restrictions on marketing and use of substance, may contain exemptions	Restrictions will be taken up in Annex XVII of REACH ((also see Art 137 on transitional measures regarding restrictions)
Directive 98/8/EC Biocides Directive	Biocidal products	<ul style="list-style-type: none"> <li>• Substances included in Annex I may be used as active substances in biocidal products, Annex I may contain substance specific conditions; and</li> <li>• Authorisation of biocidal products at national level.</li> </ul>	<ul style="list-style-type: none"> <li>• The use of certain biocides is restricted by Directive 76/769/EEC; and</li> <li>• restrictions of non-active substances should be under Directive 76/769/EEC.</li> </ul>
Directive 94/62	Packaging and packaging waste	Concentration limits for heavy metal content in packaging materials	
Directive 76/768	Cosmetics	List of banned and permitted substances for use in cosmetic products	
Directive 842/2006	Greenhouse gases	Restrictions on fluorinated greenhouse gases	
Directive 89/106 on construction products Directive 89/686 on personal protective equipment Directive 93/42 on medical devices Directive 98/79 on in vitro diagnostic medical devices Directive 90/385 on active implantable medical devices	“New approach” Directives	Contains general provisions on the materials from which the products covered can be made, especially specifying that they should not affect health of users and/or not release toxic gases This also has a provision on bioavailability of substances in the devices	

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Instrument	Coverage	Conditions	Notes
<b>Environment-Other</b>			
Directive 2002/95/EC Restriction of Hazardous Substances (RoHS) Directive Amendment 2006/690/EC Amendment 2006/691/EC Amendment 2006/692/EC	Electrical and electronic equipment falling under categories set in Annex IA to Directive 2002/96/EC (Waste Electrical and Electronic Equipment) The use of Pb in crystal glass in specific materials and components used in electrical and electronic equipment Exemptions for applications of Pb and Cd in electrical and electronic equipment Exemptions for applications of Cr(VI) in electrical and electronic equipment	<ul style="list-style-type: none"> <li>• New equipment may not contain Pb, Hg, Cd, Cr(VI), PBB, PBDE; and</li> <li>• exemptions listed in an Annex.</li> <li>• Exemptions for applications of Pb in crystal glass</li> <li>• Exemptions granted based on a review process</li> <li>• Exempted until 1/07/2007</li> </ul>	Stakeholder consultation on proposals for additional exemptions ongoing Stakeholder consultation on proposals for additional exemptions ongoing
Directive 91/157/EEC, Directive 98/101/EC	Batteries and accumulators	Marketing of batteries and accumulators containing more than 0,00005 % of Hg prohibited (exemption: more than 2 % of Hg in button cells)	The revision of the directives is under preparation. Directive 2006/66 will replace Directive 91/157 as of 26/9/2008
Directive 2000/53/EC End-of-life vehicles (ELVs) and International Dismantling Information System (IDIS)		The use of Pb, Hg, Cg and Cr(VI) is prohibited in vehicles and their components.	The directive aims to reduce the amount of and risks from (hazardous) waste from disposal of ELVs. The IDIS software is designed from car manufacturers for providing information to dismantling companies about the content of the four banned heavy metals in car components
<b>Consumers</b>			
General Product Safety Directive (GPSD) 2001/95/EEC	All consumer products or aspects of those products that are not covered by specific European safety legislation	A number of measures, including published standards and codes of good practice may be taken into account in assessing safety.	Products must provide the safety which consumers can reasonably expect.
Directive 88/378/EEC Toys Directive	Toys as defined in Article 1	Limit values for bioavailability of metals resulting from the use of toys	Use of certain substances in toys restricted by Directive 76/769/EEC
Directive 93/11	Elastomer or rubber teats and soothers	List of permitted, authorised and banned nitrosamines and N-nitrosatable substances in elastomers or rubber teats and soothers	

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Instrument	Coverage	Conditions	Notes
Directive 89/107/EEC Food additives	Additives to be used in foodstuffs	Positive list of substances (only these to be used in foodstuffs and only certain conditions specified therein)	
Directive 1935/2004/EEC Food Contact Materials	Materials and articles intended to come into contact with foodstuffs	In Annex I groups of materials and articles are listed which shall be subject to specific directives.	Aims to ensure that all materials and articles in their finished state that come in contact to foodstuffs do not transfer substances in quantities that endanger human health or bring an unacceptable change in the composition of the foodstuffs (Art. 2).
Directive 2002/72/EC Plastic Food Contact Materials	Plastic materials and articles intended to come into contact with foodstuffs	Positive lists with authorised substances which excludes all others from use in a certain application. Annex II 'monomers and other starting substances' Information on impurities in substances and constituents of mixtures Overall and specific migration limits	The aim of a positive list of substances is to protect consumer against health risks due to exposure to substances migrating into food
Directive 84/500 Ceramic food contact materials	Symbol that may accompany materials and articles intended to come into contact with foodstuffs	determining the symbol that may accompany materials and articles intended to come into contact with foodstuffs	
Directive 78/142 Food Contact Materials	Materials and articles intended to come into contact with foodstuffs	Migration limits for vinylchloride monomer in food contact materials	
Directive 93/10 Food Contact Materials	Materials and articles intended to come into contact with foodstuffs	Migration limits for cellulose in food contact materials	
Directive 1895/2095 Food Contact Materials	Materials and articles intended to come into contact with foodstuffs	Contains list of permitted substances Food contact materials containing epoxy derivatives	