

PHILIPS

sense **and** simplicity

EU REACH Regulation (EC) 1907/2006

November 2008

Disclaimer: This presentation provides basic information on REACH Regulation, mainly focused on Articles. It is based on Philips current understanding of REACH. Its is solely for information purposes, and does not intend to replace the official EC Regulation. Suppliers are responsible for their own REACH compliance based on official EC regulation.

What is REACH?

and Authorization of Chemicals

REGISTRATION, **E**VALUATION, **A**UTHORIZATION and **R**ESTRICTION of **C**HEMICALS

- Aims to ensure a high level of protection of human health and the environment
- Went into force on June 1st 2007
- Will be implemented stepwise over 11 years
- Very broad scope, affects all products & markets
- An European Regulation => only applying to the EU, but...
... reflecting itself into all geographies!
- Compared to previous legislations, REACH...
 - has a wider scope
 - financial/management onus shifts from regulators to industry
 - emphasis on substances of very high concern (SVHC) in products
 - flow of information throughout the whole supply chain

REACH aims at “ensuring high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.” (Art. 1.1)

Scope of REACH

and Authorization of Chemicals

EU REACH Regulation covers:

- All substances manufactured or imported into the EU at 1 tonne per year or more per manufacturer/importer
- Includes substances supplied in their pure form or in preparations
- Includes substances supplied in products intended to be released from the product
- Certain substances that have some adverse effect to health or environment present in products

Exclusions from REACH include, between others:

- Substances covered by other legislation such as:
 - food, pharma products, biocides, radioactive substances
- Polymers are exempt from registration & evaluation. However, monomers >2% and additives need to be registered (when above the 1 ton limit) and are subject to authorization & restriction(s)
- Some naturally occurring substances such as: ores, ore concentrates, minerals, liquefied petroleum gas (LPG), crude oil, waste, oxygen, hydrogen, nitrogen, noble gases
- Intermediates (reduced requirements)

Scope of REACH

All Chemicals & Preparations & Materials (2-3 millions substances)

**REACH: 30.000 “old” substances to be regulated
(>100.000 subst. used in EU both import & production)**



REACH SVHCs (substances of very high concern)

- CMR Cat. 1, 2 (carcinogenic, mutagenic or reprotoxic)
- PBTs (Persistent, Bioaccumulative and Toxic)
- vPvBs (very Persistent, very Bioaccumulative)
- Substances for which there is scientific evidence of probable serious effects to human health or environment (e.g. Endocrine disruptors - affect hormone system)



**RoHS
(6 subst.)**

**Philips Restricted
Substances List
circa 35 (families of)
substances**

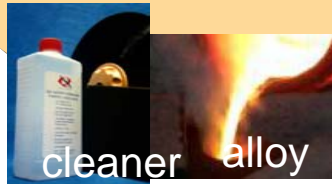
REACH Scope

REACH

Substances
(in pure form)



Preparations



Products (articles)

Containing a
substance
intended to be
released



Products (articles)
„in General“



Definition of Articles

An article is 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



*For example Final Products, Components,
Subassemblies, Subsystems,
Packaging material, Accessories, etc.*

Requirements of REACH

Substances on their own or in preparations must be registered

- Substances on their own or in preparations shall not be manufactured or placed on the market in EU unless they have been registered (for that use!). There is a pre-registration period before registration.
- Manufacturers/importers will inform suppliers on how substances are used and for what purpose, to assist in registration.

Substances intended to be released from articles must be registered

- Any producer or importer of articles must register any substance in those articles that are intended to be released under normal or reasonably foreseeable conditions of use.

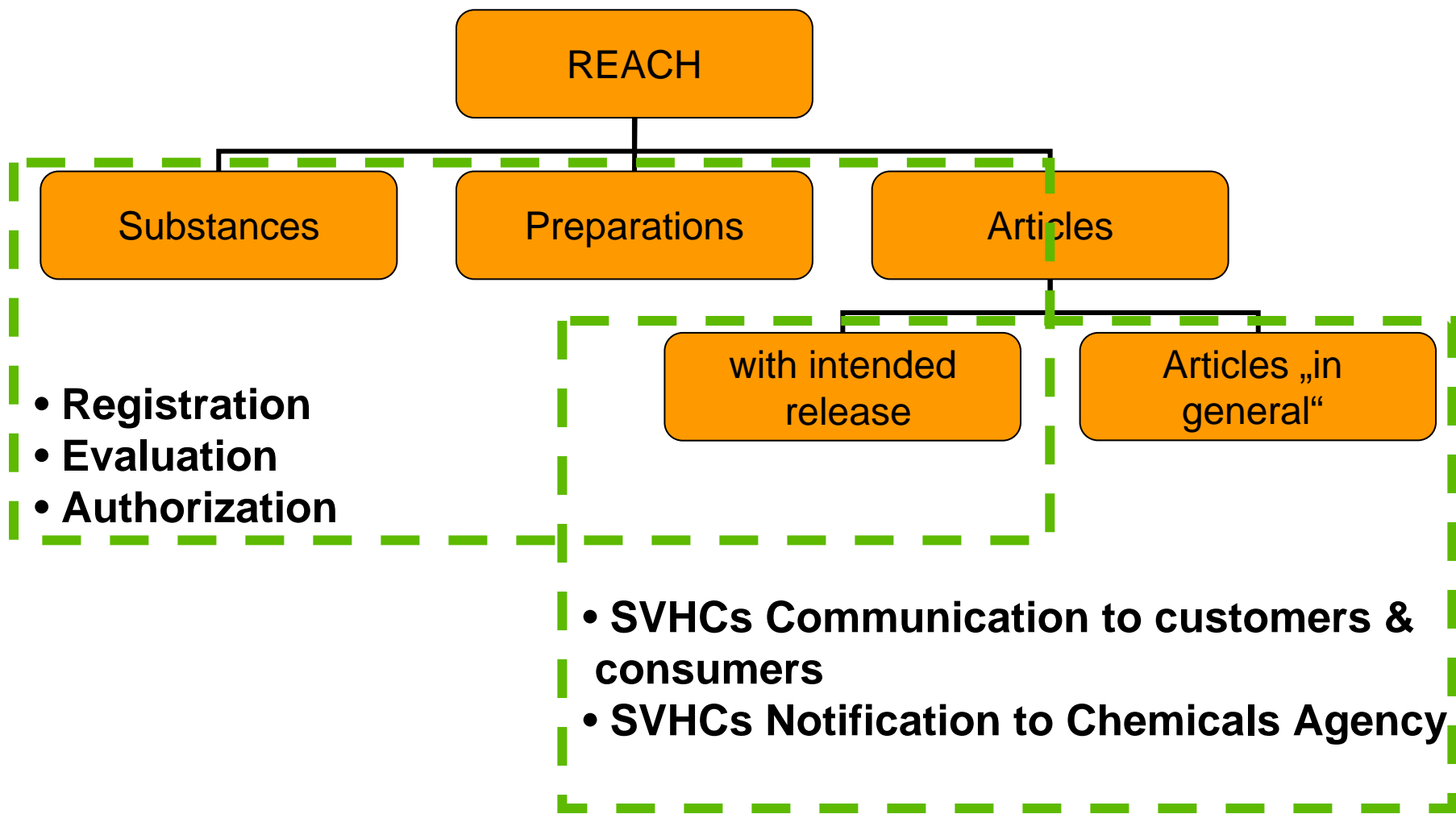
Substances in articles must be communicated to customer and consumers

- Upon request, a manufacturer/importer of an article shall inform consumers within 45 days of all SVHC with >0.1 % w/w to allow safe use and disposal.
- A manufacturer/importer of an article must inform customers of all SVHC with > 0.1 % w/w to allow safe use.

Substances in articles must be notified to the European Chemical Agency

- Any producer or importer of articles must notify the Agency (ECHA) of any substance of very high concern if it is present in those articles over 0.1 % w/w and total amount for all articles for that legal entity is > 1 ton/year.

Requirements of REACH



REACH Timeline

Potential obligations for article suppliers	Time
Start of obligation to register non-phase-in substances and phase-in substances which have not been pre-registered, if conditions of Article 7.1 are met	From 1 June 2008
Pre-registration of phase-in substances if they need to be registered according to Article 7.1 or according to Article 6 (e.g. substances imported in preparations)	1 June 2008 – 1 December 2008
Participation in SIEFs (potential registrants according to Article 6 and 7.1)	1 June, after pre-registration
Communication regarding substances on the candidate list in articles according to Article 33	28 October 2008
Notification of substances in articles according to Article 7.2	6 months after substance is included in candidate list. No notification required before 1 June 2011
Registration of pre-registered phase-in substances <ul style="list-style-type: none"> • in amounts \geq 1000 tonnes per year or more, • in amounts \geq 1 t/a if they are known carcinogens, mutagens or reprotoxic substances (category 1 and 2) and • in amounts \geq 100 t/a substances if they are classified with R50/53 	By 30 November 2010
Registration of pre-registered phase-in substances in amounts between 100 and 1000 tonnes per year	By 31 May 2013
Registration of pre-registered phase-in substances between 1 and 100 tonnes per year	By May 2018

Additional information

- ECHA (European Chemicals Agency): www.echa.europa.eu
- On this website you can find FAQs, an IT navigation tool to help industry determine its obligations under REACH, called “Navigator,” the ECHA’s own-run helpdesk and guidance on Requirements for Substances in Articles

EU Commission supporting tools:

- DG Enterprise: www.ec.europa.eu/enterprise
- DG Environment: www.ec.europa.eu/environment/chemicals

- Orgalime Practical Guide for downstream users, article producers and article importers for understanding REACH: www.orgalime.org

Conclusions for Philips

- Philips supports the objective of REACH to further improve the European Union's regulation on chemicals, including the aim to advance public health and safety and to protect the environment.
- Philips as a European manufacturer and importer of products will communicate all necessary information about chemical “substances of very high concern” (so-called SVHC substances) that are present in our products in a concentration greater than 0.1 weight percentage.
- We are working with our suppliers to determine the content of substances in our products.
- We will also use chemicals in our manufacturing processes that are (pre-)registered by our supplier.
- Substances used in Philips products are within the levels of legislation.
- Philips strives for phasing-out of SVHC's as much possible, provided that alternatives are economically and technologically available

Appendix: definitions

- **Substances:** 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
- **Preparation:** a mixture or solution composed of two or more substances;
- **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;
- **Downstream user:** any natural or legal person established within the EU, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities.
- **Use:** any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilization;
- **SVHC:** Substance of Very High Concern
- **RoHS:** Restriction of Hazardous Substances, EU Directive 2002/95/EC
- **RSL:** Royal Philips Restricted Substances List in Products: Philips chemicals management system
- **Annex XIII:** criteria for the identification of persistent, bio-accumulative and toxic substances, and very persistent and very bio-accumulative substances;
- **Annex XIV:** list of substances subject to authorization;
- **Annex XVIII:** restrictions on the manufacturing, placing on the market and use of certain dangerous substances, preparations and articles.

