



European Commission

Enterprise Directorate-General

# DETERGENTS REGULATION

## Regulation (EC) No 648/2004

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# Scope and Aims

## Scope:

- ▶ Biodegradability of surfactants
- ▶ Labelling of detergents

## Aims:

- ▶ Free movement of detergents in the internal market
- ▶ Protection of the environment and human health

# Biodegradability requirements for surfactants

- ▶ Ultimate biodegradability
  - Ultimate biodegradation = breakdown to  $\text{CO}_2$ ,  $\text{H}_2\text{O}$ , mineral salts and increased biomass  
(Primary biodegradation = loss of surfactant characteristics)
- ▶ Criterion for ultimate biodegradability: 60% in 28 days
- ▶ Same criterion applies to all types of surfactant i.e. ionic, anionic, cationic and amphoteric

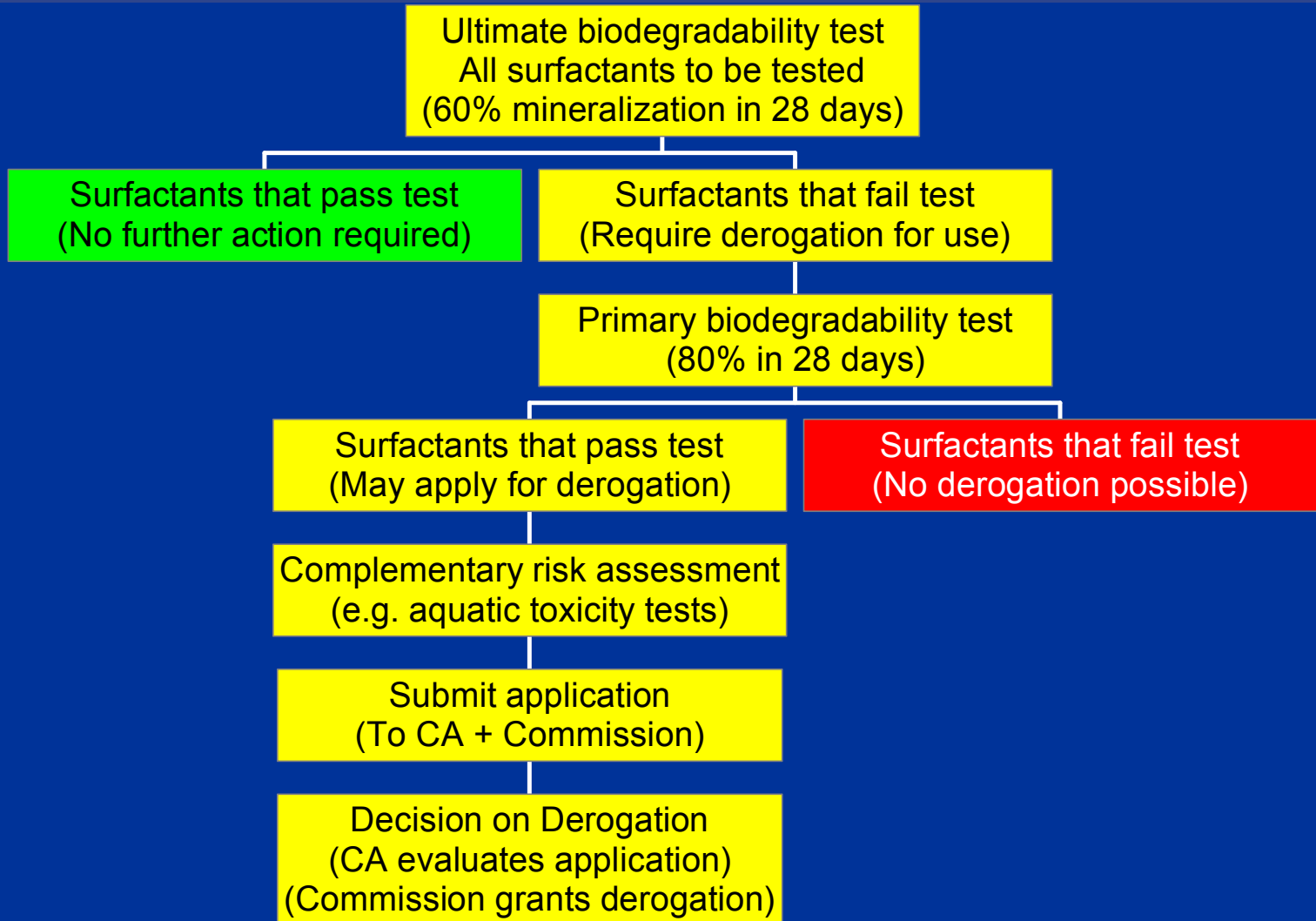
# Duties of manufacturers (1)

- ▶ “Manufacturers shall hold at the disposal of the competent authorities a technical file with the results for the test for ultimate biodegradability.”
- ▶ “In the case of surfactants that do not pass the ultimate biodegradability test, the technical file shall also contain the results of the primary biodegradability test and the complementary risk assessment.”

## Duties of manufacturers (2)

- ▶ Manufacturers are responsible for the correct performance of the tests and must be able to show that they are allowed to benefit from the property rights concerning the test results, except for those already in the public domain.
- ▶ Manufacturers shall make available the ingredient datasheet to health care professionals on demand.

# Derogations (I&I applications)



# Granting of Derogations (1)

Derogations may be granted if:

- ▶ Used in low-dispersive applications
- ▶ Used in specific I&I applications only
- ▶ Risk to environment is small compared to socio-economic benefits

- Derogations may allow, limit, or severely restrict use.
- Restrictions may include a phase-out period.

## Granting of Derogations (2)

### Applications for derogation:

- ▶ Only for surfactants on the market before 08 Oct 2005
- ▶ Application must be made before 08 Oct 2007
- ▶ Decision by Commission within 12 months
- ▶ In case of refusal of derogation, a phase out period not exceeding 2 years may be allowed.



# Surfactants with biocidal properties

- ▶ Surfactants with biocidal properties must also comply with the Biocides Directive 98/8/EC
- ▶ No duplication of testing
- ▶ Surfactants authorized as active substances under the biocides directive are exempt from biodegradability testing under the detergents regulation
- ▶ Detergents containing such biocidal surfactants must be labeled as containing “disinfectant”

# Labelling

- ▶ Provisions of the Directives on Dangerous Substances and Dangerous Preparations apply
- ▶ Information on composition (class of constituent)
- ▶ Preservation agents, enzymes, disinfectants, perfumes
- ▶ Those allergenic fragrances (26) that appear in Annex III fragrances of the cosmetics directive 76/768/EEC (>0.01%)
- ▶ Dosage information as described in Decision 1999/476/EC (eco-label)

# Labelling according to the DPD

Labelling rules of the Dangerous Preparations Directive (DPD) apply in addition to the rules specific to Detergents

Example: A detergent contains a substance classified as R4 under the DSD, i.e. “**Risk of serious damage to eyes**”.

Under the DPD the detergent is classified:

**either** according to the concentration of the substance, i.e.

▶ <5%: no classification, no risk phrase, no symbol.

▶ 5-10%: classified R36, “**Irritating to eyes**”, symbol:

**or** “according to its effects on man” *Art 6(3)*.

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## Labelling for contents by class: Annex VII A

- ▶ Constituents by class (concentrations  $> 0.2\%$ )
  - Phosphates, phosphonates, anionic surfactants, cationic surfactants, amphoteric surfactants, non-ionic surfactants, oxygen-based bleaching agents, chlorine-based bleaching agents, EDTA, NTA, phenols, parachlorobenzene, aromatic hydrocarbons, aliphatic hydrocarbons, halogenated hydrocarbons, soap, zeolites, polycarboxylates (18 classes)
  - Weight percentage ranges:  $<5\%$ ,  $5 - 15\%$ ,  $15 - 30\%$ ,  $>30\%$
- ▶ Constituents by class (if deliberately added)
  - enzymes, disinfectants, optical brighteners, perfumes, preservation agents
- ▶ Constituents in concentrations  $> 0.01\%$ 
  - allergenic fragrances (26 listed in the Cosmetics Directive)

## Information concerning the Manufacturer

The packaging of detergents must be labelled for:

- ▶ Name and trade mark of the product
- ▶ Name or trade name or trade mark and full address and telephone number of manufacturer
- ▶ Address, email address and telephone number from which the ingredient datasheet may be obtained.

## Dosage information, Annex VII B

The packaging of laundry detergents must be labelled for:

- ▶ Recommended dosage for a standard washing machine load (4.5kg or 2.5kg) for soft, medium and hard water, taking into account one or two wash cycles.
- ▶ The number of standard washes contained in the package for medium water hardness.
- ▶ The capacity of any measuring cup in ml or grams, and markings to indicate appropriate dosage.

# Ingredients datasheet, Annex VII C

The manufacturer shall make available to medical personnel on demand an ingredients datasheet containing:

- ▶ The name of the detergent and the manufacturer.
- ▶ All ingredients in order of decreasing abundance subdivided into weight percentage ranges of:
  - a) <0.1%, b) 0.1% - 1%, c) 1% - 10%, d) > 10%(Impurities are not considered to be ingredients)
- ▶ The IUPAC, INCI and European pharmacopoeia names of the ingredients, and their CAS number.

## List of ingredients, Annex VII D

Manufactures shall make available on a website a list of ingredients containing:

- ▶ All ingredients in order of decreasing abundance.
- ▶ The INCI names of the ingredients where possible.

This is information to be available to the general public



# Ingredient datasheet

The purpose of the datasheet is to assist investigation into whether a link exists between the development of an allergic response and exposure to a particular chemical substance.

- ▶ “The manufacturer shall upon request make available to any health care professional a full list of ingredients.”
- ▶ “The list shall contain all ingredients in decreasing abundance by weight and the list shall be divided into the following weight percentage ranges:  
a)  $> 10\%$ , b)  $1 - 10\%$ , c)  $0.1 - 1\%$ , d)  $<0.1\%$ .”

# Future Perspectives

Three issues identified for future action in the Detergents Regulation (Article 16)

By 8 April 2007:

- ▶ The use of phosphates in detergents

By 8 April 2009:

- ▶ Anaerobic biodegradation of surfactants
- ▶ Biodegradation of non-surfactant organic ingredients

# Guidelines for interpreting the Detergents Regulation

- ▶ **A.I.S.E. Guideline** on Implementation of the Detergent Regulation Biodegradability of Surfactants and Annex VII (Labelling and Ingredient Datasheet)
- ▶ **Tiered Approach Guidance Document**: Methodology for the Tiered Approach to Testing in the Context of Annex IV of Regulation (EC) No 648/2004

[http://europa.eu.int/comm/enterprise/chemicals/legislation/detergents/index\\_en.htm](http://europa.eu.int/comm/enterprise/chemicals/legislation/detergents/index_en.htm)

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