

**EXPLANATORY MEMORANDUM TO
THE DETERGENTS REGULATIONS 2005**

2005 No. 2469

1. This explanatory memorandum has been prepared by the Department for Environment, Food and Rural Affairs and is laid before Parliament by Command of Her Majesty.

2. Description

2.1 These Regulations provide for the enforcement of Regulation (EC) NO 648/2004 of the European Parliament and of the Council of 31 March on detergents. Under the Regulations a person commits an offence if he places a detergent on the market in contravention of Regulation 648/2004. Inspectors will be able to issue enforcement notices if an offence is committed before needing to resort to a prosecution, though criminal penalties can be imposed by the courts for persistent or serious offences. The Regulations also provide for powers of entry, sampling and seizure.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Legislative Background

4.1 The above Regulations are made in exercise of the powers conferred by section 2(2) of the European Communities Act 1972. They set out measures for the enforcement of Regulation 648/2004 in accordance with article 18(1) of that Regulation. They revoke the Detergents (Composition) Regulations 1978 (as amended).

4.2 Regulation 648/2004 was published in the Official Journal of 8 April 2004 and comes into force on 8 October 2005. It modernises and consolidates existing European Directives on detergents by:

- Tightening the biodegradability testing requirements for the active ingredients of detergents (known as surfactants);
- Extending testing for biodegradability to all surfactants (around 10 per cent of surfactants used in domestic and industrial/institutional detergents are currently excluded from testing requirements under existing Directives);
- Requiring fuller contents information to be provided on detergent labels;
- Repealing the following legislation on detergents: Directive 73/404/EEC, Directive 73/405/EEC, Directive 82/242/EEC, Directive 82/243/EEC, Directive 86/94/EEC and Recommendation 89/542/EEC

5. Extent

5.1 This instrument applies to the United Kingdom.

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 The policy aim of Regulation 648/2004 is to establish rules to achieve the free movement of detergents and surfactants for detergents in the internal market while, at the same time, ensuring a high degree of protection of the environment and human health.

7.2 Regulation 648/2004 introduces a two-tier testing regime on the biodegradability of the active ingredients of detergents (known as surfactants).

7.3 Under existing legislation, surfactants are only required to pass the less stringent primary biodegradability test. However, due to environmental concerns over metabolites that are produced when only the active part of the surfactant molecule biodegrades (primary biodegradability), a more stringent test has been introduced under which the whole surfactant molecule must biodegrade resulting in mineralization to the required level (ultimate biodegradability).

7.4 Surfactants that pass the more stringent ultimate biodegradability test can remain on the market. Industrial or institutional surfactants that fail the ultimate biodegradability test but pass the less stringent primary biodegradability test can remain on the market if the manufacturer is granted a derogation by the European Commission. While derogations will only be granted for surfactants that are used for industrial or institutional purposes, the majority of surfactants used in domestic detergents are already tested for ultimate biodegradability due to consumer demand for more environmentally friendly products.

7.5 The additional labelling requirements imposed on manufacturers under the Regulation will help to inform consumers when choosing products. In addition, the provision of detailed data sheets to medical personnel will assist with the treatment of allergies.

7.6 The Detergents Regulations set out measures to enforce Regulation 648/2004. They have been produced in accordance with the Government's commitment of minimising the burden on business. For example, manufacturers are not required to submit test results on every surfactant to the competent authority: following discussions with industry, it was decided that a duty to provide such information would be too burdensome because of the number of surfactants on the market (the current estimate is 5,000). Instead, manufacturers are only required to provide test results on request.

7.7 Pesticides Safety Directorate will be the competent authority in the UK for the purposes of these Regulations, though enforcement on the ground will be carried out by local authority Trading Standards Officers. Inspectors will be able to issue

enforcement notices for breaches of the Regulations without having to resort to a prosecution, though criminal penalties are available for due to the environmental and public health consequences that could result from a breach of the Regulations. Penalties along the lines of the “polluter pays” principle would not be appropriate, as it is not possible to trace a pollution incident back to any given surfactant manufacturer.

7.8 Further Regulations will be introduced setting out how derogation applications will be handled, after public consultation.

7.9 The European Commission conducted a public consultation in Autumn 2001. Between March and May 2003 Defra conducted a further round of public consultation, though only eleven responses were received. Industry supported the Regulation, but were concerned that it would mean the removal of several effective surfactants from the market that would not be granted derogations. Concern was also expressed that there would not be enough time for industry to make the necessary changes in order to comply with the Regulation. Despite the low number of responses received to the 2003 consultation, the EC proposal was described as “politically important”, when it was cleared by the Select Committee on European Scrutiny in its 19th report of session 2002-03, published on 30 April 2003. Public consultation will be conducted later in the year on Regulations dealing with derogation applications, to be introduced in Spring 2006. A further round of public consultation is possible because the Commission must issue a Technical Guidance Document before manufacturers can apply for a derogation. This may not be available until April 2007, though the Commission aims to publish it before this date. This two-stage implementation process allows for further consultation while still enabling the Government to fulfil its obligations.

8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum.

8.2 The impact on the public sector is expected to be greater immediately after the coming into force of the EC Regulation on 8 October 2005, amounting to £200,000 over the first two years on the competent authority. This may be needed to cover the cost of LA monitoring and PSD’s processing of application for derogation. This could be reduced if a charging regime is introduced following the consultation.

9. Contact

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Partial Regulatory Impact Assessment 05/07/05

Note: A glossary of terms is included at the end of this Regulatory Impact Assessment.

1. Introduction

On 8 October 2005 Regulation (EC) NO 648/2004 on Detergents comes into force. A regulation is applicable on its own throughout the European Union and is binding on all member states. However, the UK must introduce regulations setting out enforcement mechanisms and the application process for derogations. This Regulatory Impact Assessment accompanies the regulations on enforcement.

2. Title of Regulations

Detergents Regulations 2005)

3. Purpose and intended effect of measure

(i) The Objective

The objectives of the Detergents Regulations 2005 are:

- To introduce effective, dissuasive and proportionate measures to enforce Regulation 648/2004 in accordance with article 18(1) of that Regulation and
- To establish a competent authority in the UK for the purposes of Regulation 648/2004.

The objectives of Regulation 648/2004 are:

- To improve the free movement of detergents in the Internal Market;
- To modernise the existing detergents regime;
- To improve environmental protection and
- To provide more specific information to consumers on the contents of detergents.

Regulation 648/2004:

- Extends testing for biodegradability to surfactants (the basic cleaning ingredients) used in all detergents (around 10 per cent of surfactants used in domestic and industrial/institutional detergents are currently excluded from testing requirements under existing Directives);
- Tightens the biodegradability testing requirements for surfactants in detergents;
- Requires fuller contents information to be provided on detergent labels;
- Repeals the following existing detergent Council Directives and Recommendation: Directive 73/404/EEC; Directive 73/405/EEC; Directive 82/242/EEC; Directive 82/243/EEC; Directive 86/94/EEC, and Recommendation 89/524/EEC.
- Introduces a committee procedure to Facilitate future technical amendments for the contents of the Regulation without a lengthy procedure for implementation of necessary changes.

The testing and data provision requirements of Regulation 648/2004 would primarily fall to the industrial and institutional products sector of the detergents industry. Cost of this may be passed on to consumers.

The Detergents Regulations 2005 will apply throughout the United Kingdom.

(ii) The Background

In the 1960s many member states experienced foaming problems in rivers. This problem was traced to surfactants – mainly those used in fabric washing detergents.

In response to the foaming problem, the following European legislation on biodegradability of surfactants in detergents was put in place in the early 1970s:

- Directive 73/404/EEC sets out a framework for primary biodegradability of all surfactants used in detergents with a minimum primary biodegradation level established at 90%, and
- Directive 73/405/EEC sets out a methodology for assessing the primary biodegradability of anionic surfactants.

In 1982 two further Directives were adopted:

- Directive 82/243/EEC updated 73/405/EEC methodology – in particular it established the minimum level of primary biodegradability for anionic surfactants at 80% in recognition of variability in testing procedures, and
- Directive 82/242/EEC set a methodology for assessing the primary biodegradability of non-ionic polyether surfactants - again, with an 80% minimum level.

The anionic and non-ionic surfactants addressed in Directives 73/405/EEC, 82/243/EEC and 82/242/EEC cover around 90 per cent of detergents. However, two further groups of surfactants - cationic and amphoteric, which are used in, for instance, fabric softeners and dishwasher products - were not addressed owing to lack of agreement over testing methods.

In 1995 the European Commission declared its intention to update the Detergents legislation to cover ‘ultimate biodegradability’ and to address cationic and amphoteric surfactant types. The argument for ‘ultimate biodegradability’ was based on concerns relating to the potential toxicity of persistent metabolites in the aquatic environment.

In response to health concerns in the late 1990s surrounding allergic reactions to certain detergents, the European Commission added a requirement to its draft proposals that information on the content of detergent and cleaning products should be made available to health care professionals on request. It also added a requirement that the ingredient listings of domestic detergents, which have been voluntary to date, be made mandatory.

Regulation 648/2004 includes a two-tier system of aerobic testing. Surfactants passing the ultimate biodegradability test can remain on the market. Those surfactants used in industrial or institutional detergents that fail ultimate biodegradability but pass primary biodegradation will be allowed to remain on the market if the manufacturer is granted a derogation by the Commission. Manufacturers must apply for derogations within two years of the entry into force of Regulation 648/2004. Derogations will require a complementary risk assessment to be undertaken, and are expected to be refused when use of a product occurs in high volumes, in wide-dispersive applications as opposed to low dispersive applications (e.g. by the general public, as opposed to specialist, niche uses), and where the risk to the environment or to health posed by the volume of sales and the pattern of use throughout the EU is large compared to the socio-economic benefits, including food safety and hygiene standards. Surfactants failing the primary biodegradation test will not be allowed on the market. Manufacturers will be required to keep test data for inspection by national authorities and to refrain from marketing products that do not meet the biodegradability criteria. Regulation 648/2004 had an 18-month implementation period.

Article 18(1) of Regulation 648/2004 provides that Member States must introduce appropriate legal and administrative measures to deal with any infringement of the Regulation, and dissuasive, effective and proportionate sanctions for any such infringement. Pesticides Safety Directorate (PSD) will be the competent authority in the UK for the purposes of Regulation 648/2004. Enforcement on the ground will be carried out by local authority trading standards officers.

Regulations setting out procedures for derogation applications will be introduced in Spring 2006 after further consultation.

(iii) Risk Assessment

The key risks addressed in Regulation 648/2004 and the Detergents Regulations 2005 are:

- a. Enacting regulations providing for the effective enforcement of Regulation 648/2004 will avoid infraction proceedings being taken by the Commission against the UK.
- b. Foaming in rivers is a recognised potential problem where surfactants remain active. Whilst the problem has largely been addressed through the existing Directives, there remains a risk – mainly of a limited and local nature – arising from the 10 per cent of surfactants not covered by biodegradability testing requirements. The size of this risk is, however, subject to some controversy.
- c. Possible toxicity has been demonstrated arising from certain persistent metabolites derived from surfactants. The cumulative effect of such metabolites presents a risk to the aquatic environment.
- d. Exclusion of certain products from the existing biodegradability testing regime gives scope for users to gain commercial advantage by using non-biodegradable surfactants. Under the Proposal all surfactants would be subject to the same

regime. However, it should be noted that any potential advantage applies equally to all users so that the overall impacts on competition are not necessarily negative.

- e. The existing testing methods give scope for false negatives.
- f. Certain substances contained within detergents have been linked with irritant or allergic reactions. However, instances of cases linked specifically to irritants in detergents would appear to be small in number.
- g. Differing standards concerning testing and labelling across the EU could lead to trade restrictions and reductions in product innovation, competition and consumer choice. In practice, product and labelling requirements in specific Member States will apply equally to all producers. However, consultation suggests that product and labelling requirements impede relatively more heavily on foreign producers who do not routinely factor these requirements into the production and marketing plans. Nevertheless, UK producers do not appear to perceive significant barriers to trade in detergents in the EU. Barriers that apply to Small and Medium Enterprises (SMES) seem to relate to the nature of niche markets, and are unlikely to be affected by revisions under Regulation 648/2004.

(iv) Business sectors affected

The Regulations will apply to all manufacturers and suppliers of surfactants and detergents. However, they are likely to have a greater impact on niche product suppliers in the industrial and institutional product sector. In particular, those supplying products involved in machine washing, bottle washing, dish washing, metal cleaning, floor cleaning, transportation cleaning, façade cleaning which fall outside the existing biodegradability testing requirements.

(v) Issues of equity and fairness

As mentioned at (iv) above, small-scale suppliers of niche products are likely to be proportionately more affected by Regulation 648/2004.

4. Options

There are three options:

- (i) Introduce a set of enforcement regulations placing stringent requirements on industry, including the compulsory reporting to the competent authority of all relevant test results relating to surfactants, including results of ultimate biodegradability tests.

Regulation 648/2004 places a duty on Member States to act proportionately when carrying out enforcement. In particular, MS's should not require industry to repeat tests already carried out by approved laboratories. However, requiring industry to provide lists of surfactants that had passed the ultimate biodegradability test would not amount to gold plating. Nonetheless, industry feel that the costs of this option would be high due to the thousands of surfactants in use, though we have no exact costs. This option would not be in keeping with the government's better regulation agenda, as we are aware of little evidence of non-compliance with existing legislation.

(ii) Introduce a basic set of enforcement regulations empowering local authorities and the competent authority to take action where there is evidence of the commission of an offence, and providing for powers of entry, search and seizure.

Such regulations would provide for powers of entry, sampling, seizure and detention. They would also provide for the creation of offences and penalties. Unlike the approach outlined in option (I), Such regulations would not impose onerous duties on industry to provide information, other than that required by Regulation 648/2004. The risk with any lighter touch regulations is that we could be found guilty of not properly implementing our European obligations, though advice from Defra lawyers is that the Regulations accompanying this RIA fulfil our legal requirements.

(iii) Do not introduce any additional regulations

Article 18(1) of Regulation 648/2004 states that Member States must introduce appropriate legal and administrative measures, and dissuasive, effective and proportionate sanctions. This option would therefore risk infraction proceedings being brought against the UK by the Commission under Article 226 of the EC Treaty as there would be no mechanism for enforcing Regulation 648/2004. Other member states could also initiate proceedings under Article 227, though this is much more unlikely. In addition, this option could lead to detergents being sold in the UK that did not comply with the provisions of Regulation 648/2004, thus posing a risk to public health and the environment. Costs to manufacturers would not necessarily be reduced if this option were chosen: If other Member States fulfilled their obligations and introduced enforcement measures, any British manufacturer wishing to export detergents or surfactants to those countries would have to comply with those enforcement measures. This is therefore not a practical or desirable option.

5. Benefits

Regulation 648/2004 will lead to improvements for the environment and public health, as detergents containing surfactants not meeting the biodegradability standards set out in the Regulation will not be sold in the European Community. There will also be increased benefits for consumers through clearer and more informative product labelling, and the making available of data sheets to members of the public and medical personnel. The key benefits of Regulation 648/2004 are:

- Coverage of a greater percentage of surfactants under biodegradability testing requirements. (Surfactants that are used solely as ingredients in biocidal products will be classified under Regulation 648/2004 as ‘disinfectants’, and as such will not be subject to its biodegradability testing requirements.) Extending the scope of the Regulation to cover all surfactants could lead to a reduction in the risk of foaming incidents in UK rivers. Foam is not routinely measured in the UK. However, an aesthetic quality survey by the Environment Agency in 2000 showed that foam was present at 28.5 per cent of the 452 sites covered. Of the total amount of sites where foaming was identified, 1.1 per cent were classified as bad. Foam can also be an issue at the site of some sewage treatment works, and surfactants are also linked with some reported water pollution incidents, although these were less than 0.7 per cent of total incidents in 2001. It should also be noted

that foaming in rivers can be a natural occurrence unrelated to the presence of surfactants in watercourses;

- Elimination of persistent metabolites from the aquatic environment arising from surfactants, with a resulting reduction in the risk of toxic and cumulative effects;
- Improvements might arise in the efficiency of those sewage treatment works that process significant quantities of such surfactants. Improvements might also accrue to individual companies that treat their own effluent prior to direct discharge to water courses. Surfactants reduce the oxygen transfer efficiency of sewage treatment works, so an increase in biodegradability might result in a reduction in running costs. However, no evidence is available to quantify this potential benefit, although opinion is that it is likely to be marginal;
- Improved access for health care professionals to data on substances that they consider could cause irritant or allergic reactions. This could reduce the number of cases of allergic reaction and improve the treatment of any such cases;
- Removal of any trade barriers relating to different product and labelling requirements between Member States, with associated improvements in competition and consumer choice. Although this is one of the stated aims of Regulation 648/2004, it should be noted that consultation on the proposals has suggested that UK firms do not perceive there to be significant barriers in European surfactant markets which would be addressed;
- Improved information on product ingredients for consumers, enabling them to make more informed choices as to their preferred products;
- A minimisation of the use of animal testing in the surfactants market.

6. Costs for business, charities and voluntary organisations

(i) Compliance costs

Costs relating to the initial (ultimate) biodegradability test

Costs will fall to all detergent manufacturers for implementing the testing requirement for surfactants. The intention of Regulation 648/2004 is that most surfactants would only need to be subject to a single test – the ultimate biodegradability test. The cost of this is expected to be in the region of £3,000 to £5,000 per surfactant, a range confirmed by responses to the public consultation on the previous partial RIA. Given that there are an estimated 5,000 surfactants currently used in commerce, the total cost of this exercise could theoretically be as much as between **£15m** and **£25m**. The true theoretical cost could be lower than this, since surfactants used only as disinfectants in biocides are excluded from Regulation 648/2004 and hence are not subject to its testing requirements. We do not have an estimate of what proportion of the estimated 5,000 surfactants come under this definition.

Consultation with surfactant manufacturers indicates that many surfactants have already been tested for ultimate biodegradability, and comply with the 60 per cent mineralisation standard. Only one manufacturer reported not testing for ultimate biodegradability, the remainder reporting at least 50 per cent testing. The reasons for this appear to be consumer demand for more environmentally friendly products, and a lack of reliability of the alternative tests for primary biodegradability, the current required standard.

Even where products have not already been tested for ultimate biodegradability, Regulation 648/2004 will not necessarily result in a large increase in testing, since consultation suggests that some products will simply not be subject to the new tests, especially if they are expected to fail. The result of these considerations may be that the number of surfactants being tested for ultimate biodegradability is substantially less than 5,000, with resulting implications for costs. If 50 per cent of currently regulated surfactants, and zero per cent of non-regulated surfactants, have already been tested for ultimate biodegradability, and 10 per cent of the currently unregulated surfactants would not be tested due to expected failure (based on an estimate of 20 per cent total potential failure (derived from a small number of consultation responses)), then the number being tested would be

50% of 4,500+10% of 500 =2,700, with the costs of ultimate testing falling between **£8.1m** and **£13.5m**.

$(2,700 \times £3,000 = £8.1m$

$2,700 \times £5,000 = £13.5m$

This figure could be further reduced if manufacturers cooperate in testing common substances, for instance, through industry associations. Consultation suggests this could occur, although conflicting views have been expressed as to how likely it is. In addition previous data sharing in this area is reported to have been limited. It has also been suggested that competition and confidentiality concerns could mean that a data-sharing approach will take longer than one in which all manufacturers are responsible for testing their own products.

SMEs not previously subjected to these testing requirements, particularly those in the industrial and institutional sectors producing cationic and amphoteric surfactants, will be most significantly affected by these requirements and more likely to fail to meet initial tests.

It is anticipated that between three and 10 per cent of surfactants will fail the ultimate biodegradability testing requirements. This is largely due to the uncertainty associated with cationic and amphoteric surfactants.

Costs arising from a failure of the initial test (Primary Biodegradability Test and Complimentary Risk Assessment)

Only products failing the ultimate biodegradability test will have to pass a primary biodegradability test prior to being placed on the market. The cost of this test will depend on whether a screening test or more extensive tests were required. The cost of a screening test is in the region of £2,000 per surfactant, whilst a confirmatory test is in the region of £8,000 to £10,000 per surfactant. However, there could be additional costs of up to £40,000 per surfactant if analytical methods needed to be developed.

Products failing the ultimate biodegradability test but passing the primary test will also require a complementary risk assessment. This risk assessment will determine if derogation is granted and whether the product can be permitted to remain on the market. This risk assessment will involve the supply of a technical file, containing information on ultimate and primary biodegradability test results, as well as on use of the surfactant, available alternatives, and impacts on the environment. The UK competent authority or the EC may request additional information if this is required to assess the case for derogation. Industry is unsure of the potential costs that may be associated with this process. Costs are likely to depend on the results of testing, and the complexity of use patterns and pathways to the aquatic environment.

An estimate for the total costs associated with derogation proceedings could, according to the consultation results, be between £50,000 - £250,000, and could take anything from six months to several years. The exact timing depends on the protocol for risk assessment ultimately decided upon, and its interpretation by both the UK competent authority and the EC. The Commission has until April 2007 to release a Technical Guidance Document on this issue.

The number of surfactants potentially subject to primary testing is limited to those not covered by existing legislation, i.e. cationic and amphoteric surfactants, since the remainder (around 90 per cent) are already required to meet primary biodegradability standards. However, all surfactants failing ultimate biodegradability will require risk assessments to be carried out if they are to be marketed, as this is not a requirement under existing legislation. Consultation suggests that many surfactants that fail the ultimate biodegradability test will cease to be marketed, rather than be subject to primary testing, since risk assessments are expected to be too costly and time consuming to be profitable for most products.

Previously we assumed that half of the anionic and non-ionic surfactants (2,250), and 90% of cationic and amphoteric surfactants (450), would be subject to ultimate testing. If we assume that 10 per cent of these fail those tests, this means that there would be 45 candidate surfactants for primary testing, and 270 candidates for risk assessment. As mentioned above, the 2,250 anionic and non-ionic surfactants would not be tested for primary biodegradability because they are already required to meet this standard. If we further assume that 20 per cent of the 45 cationic and amphoteric surfactants would be subject to primary testing, and that 20 per cent of the total would be subject to risk assessment, this gives costs of primary testing of
20% of 45x£5,000 =£45,000 (at an estimated average of £5,000 per test), and costs of risk assessment of
20% of 270x£50,000 =£2.7m
(at an estimated average of £50,000 per assessment). This gives total costs of the primary testing and risk assessment regime of £2.745m
(£2.7m+£45,000 =£2.745m).

Costs arising from alternative product development

The EC has estimated that around three to five per cent of existing surfactants (i.e. up to 250) would fail the new test procedure for both primary and ultimate biodegradability and therefore be subjected to product bans. Given that all anionic and non-ionic surfactants are already required to meet primary biodegradability requirements, this

implies that only cationic and amphoteric surfactants are expected to be among those failing both tests. A figure of 250 failing surfactants implies that up to 50 per cent of all cationic and amphoteric surfactants could be subject to bans. However, in addition are those surfactants which are currently permitted but which, even though they passed the primary test, would not receive derogation following risk assessment. The number compares with our assumption that 54 surfactants would be subject to risk assessment. It is reasonable to assume that risk assessments will only be undertaken where manufacturers are confident the result will be positive. We are therefore left with the 552 surfactants that we have assumed would be voluntarily removed from the market by manufacturers, rather than subjecting them to the testing and assessment regime. This suggests that the EC might have underestimated the extent to which the new regime might deter manufacturers from seeking approval to continue marketing their products. The surfactants most likely to fail the testing regime are expected to fall into the following groups: Alkyl Sulphonsuccinate; AEO (C10+C13)(2-20EO) Branched; Alkyl EO/PO-OH or capped; Alkyl EO/BO-OH or capped; Fatty acid alkanolamides; Mono (C8-18); Fatty acid alkanolamides; Di (C8-18); Fatty acids MEA ethoxylated; Alkylamine ethoxylates (all); Fatty acids DEA ethoxylated; Dialkyl dimethyl quat (C18); Benzyl dimethyl quats; Imidazoline derivatives; Guerbetalcohol EO/PO-(all); Alkylated sulphonated Diphenyloxide; Alcohol ethoxylates >20EO; Alkylated aminoxides.

It is difficult to estimate the likely cost of developing alternative products. Consultation suggests that reformulations of detergent products might be relatively simple, costing a few thousand pounds only, or quite complex, with a cost closer to £50,000. The development of completely new surfactants, however, would appear to be significantly more expensive, with respondents giving estimates of between £250,000 and £750,000 per product. These latter costs are high enough to make development of new products in response to bans unlikely. We understand from some manufacturers that there have been no new surfactants introduced onto the market for several years, making the development of new surfactants unlikelier still. The question then is how many product reformulations will be required if 552 surfactants are banned or otherwise removed from the market. Even the most conservative estimate, that each surfactant is used in a single formulation, could result in costs of between **£2.76m** and **£27.6m**. Clearly, these costs could increase significantly if several formulations are dependent on a single surfactant. Even if the surfactants that disappear have ready substitutes, reformulation is still likely to entail some costs. Even if unit costs are low, the large number of instances in which they are incurred means that total costs are likely to be considerable. These figures are, however, very tentative.

It should be noted that these costs can be minimised by ensuring that the risk assessment process is appropriately risk-based, and that a step-wise approach is taken to the collection of information. In this way, the costs of collecting unnecessary or irrelevant information can be avoided, and alternatives will only need to be developed for those products for which it can be clearly demonstrated that the risks of use outweigh the benefits.

Costs to consumers arising from lack of product availability

Costs to commercial and welfare sectors (i.e. those engaged in machine washing, bottle washing, dish washing, metal cleaning, floor cleaning, transportation cleaning, façade cleaning) if effective and appropriate specialist cleaning products are withdrawn from the

market or are replaced by more expensive alternatives are similarly difficult to anticipate. Consultation suggests that, even where substitutes are readily available, costs are likely to increase and/or effectiveness may be reduced. In many cases, respondents felt that good substitutes would not be readily available. However, without detailed information on patterns and price elasticities of demand, it is not possible to make an estimate of the size of these costs.

Costs of labelling changes and inventory redundancy

Regulation 648/2004 will require manufacturers and formulators to ensure that the labels on their products contain specified types of information. Those requirements relating to the ingredients of household products are already covered in the UK by voluntary agreement so no extra cost is to be expected. However, this is not the case for industrial and institutional products (IIPs). Labels will need to change to provide other details, for instance, reference to telephone lines where data sheets relevant to medical issues can be obtained. This can entail costs not only in terms of changing the labels themselves, but also in terms of rendering old stock 'redundant'.

Consultation with manufacturers suggests label changes alone cost in the region of £500 to £1,000 per product. This could apply not only to each individual surfactant, but also to every formulated product containing surfactants. A single formulator might produce several hundred or even thousand different formulations. A very conservative estimate of the number of products requiring relabelling might be 10,000, implying a one-off cost of **£5m - £10m**.

Timing is critical to the issue of inventory redundancy. Under CHIP, costs of labelling changes for the soap and detergent industry and cleaning and polishing preparations were estimated to be £32m for a 12-month transition and £192m for a 6-month transition. Costs are lower for long transition periods since they imply manufacturers are less likely to be left with unusable stocks of labels and products. Consultation with formulators indicates that 18 months is regarded as the minimum amount of time necessary to undertake relabelling and restocking for Regulation 648/2004, but that timing also needs to be seen in the context of the entire supply chain (see below). Regulation 648/2004 has an 18-month implementation period as it was published in the Official Journal in April 2004 and comes into force on 8 October 2005.

Cost of making product information more widely available

There is a requirement that manufacturers make their product information available to medical professionals on request. Consultation suggests that firms are likely to establish websites or telephone hotlines to provide this information. However, they are divided on how much this is likely to cost, with some suggesting no significant cost, and others providing estimates ranging from £10,000 to over £100,000.

There is also a requirement that firms make an ingredients datasheet available free of charge to medical professionals on request. The cost of this clearly depends on the number of requests. PA Consulting (2001) report that there were estimated to be 390 firms in the UK soap and detergents sector in 2001. At an average cost of £20,000 per website, this implies total information supply costs of **£7.8m**. This is only an estimate since the PA industry figures include firms involved in the manufacture of cleaning and

polishing preparations as well as of soap and detergents, but exclude chemicals companies that manufacture surfactants. However, it does give an indication of the likely magnitude of the costs of meeting this requirement. At an average cost of £1 per datasheet, 10 requests per year for 5,000 surfactants, the cost of supplying datasheets might be in the order of £50,000.

It is important to note that the only obligation to provide data that will apply to industrial or institutional products is to make a data sheet containing the information set out in Annex VII.C available to medical personnel. If a technical or safety data sheet containing that information is already available, no additional burden will be created.

Costs associated with formula piracy

It has been suggested that the requirements under Regulation 648/2004 to make information on product ingredients more widely available could lead to the possibility of formula piracy. However it is uncertain whether this represents a true economic cost. Piracy might have costs for some firms whose profits or market share is eroded by new competitors. However, this could be offset by increased profits for other producers, as well as benefits for consumers from lower prices. Thus, estimates of costs might simply reflect the distribution of impacts, rather than a genuine economic cost. Genuine economic costs are most likely to occur where reduced returns to product investment have deleterious impacts on incentives to undertake research and development into new and improved products. Thus the true costs are likely to be in the form of reduced product innovation.

Consultation responses suggest there is some disagreement within industry about how important and likely formula piracy might be. Some argue that the requirement to disclose information might increase the need to protect formulations through patents, raising costs and complexity. However, others argue that Regulation 648/2004 will not increase the risk of piracy since formulations can already be analysed with modern methods. Precise formulations will not be disclosed in the lists of ingredients, ingredients will merely be listed in percentage ranges. Perhaps the most telling observation was that the products of major manufacturers tend to be relatively simple applications protected by brands, and it is the more specialist, niche products manufactured by SMEs which are most at risk of being copied, since branding is not so important and customers can switch suppliers more easily.

Cost to the competent authority

Costs to the competent authority would relate to checking testing of products. Costs would be expected to be considerably higher immediately following the entry into force of Regulation 648/2004: a provisional estimate would be £125,000 per year for the first two years.

However, Regulation 648/2004 will overcome the problem of 'false negatives' that occurs with the existing testing procedures. This would reduce costs to regulators in that it would eliminate the possibility of protracted investigation and associated retesting of detergent formulations showing false negatives. Based on a possible avoidance of 25 per cent false negatives in a testing programme of 20 tests per year, at an average cost of

£5,000 per false negative, there would be savings in the order of £25,000 per year resulting from Regulation 648/2004.

Local authorities will be granted powers under the Enforcement Regulations rather than having a statutory duty placed on them. They are only likely to have to investigate where a complaint is made. This means that costs to local authorities should be minimal.

A tentative overall estimate of additional costs to regulators, therefore, relating to the first two years of operation of Regulation 648/2004 would be **£200,000**. Clearly, these costs could in practice be borne by manufacturers (and subsequently by customers) if they were recouped by the regulator in terms of, for instance, regulatory and application fees.

The issue of timing of implementation

It is important to mention the issue of the timing of the implementation of Regulation 648/2004. Under Article 18, it comes into force 18 months after publication in the Official Journal, i.e. on 8 October 2005; under Article 6 a firm has two years to request a derogation following entry into force; under Articles 5 and 6 the Commission then has the power either to grant derogation within 12 months (except in case of Article 5(4 and 6) of Decision 1999/468/EC where the period shall be 18 months), to refuse the derogation within one year, or set a transitional period of up to two years for the phase-out of the product. On the basis of these timescales there will be at least three years following adoption of Regulation 648/2004 before any product would have to be removed from the market.

Regulations will be introduced at a later date to lay down procedures for handling derogations. This is because further consultation with industry is required.

Consultation responses suggest that an 18-month time period is seen as the absolute minimum necessary to ensure compliance with these regulations at manageable cost. However, this time period applies separately to the various stages of the detergents supply chain. Thus, 18 months to two years would appear to be necessary to permit the testing of around 3,000 surfactants (based on discussions with a major UK commercial laboratory). However, only once these tests are completed will manufacturers know which products will need to be removed from sale, and substitute formulations developed. This process has also been estimated to take 18-months. Finally, 18-months has also been suggested as the minimum time required to meet the labelling and information provision requirements. Therefore, although the timescales for adoption and implementation of Regulation 648/2004 are technically sufficient, it might be necessary for industry to coordinate their response, to avoid bottlenecks in the various stages of the production cycle.

Total Compliance Costs to businesses

Costs of testing for ultimate biodegradability	£8.1m-£13.5m
Costs of testing for primary biodegradability, derogations and risk assessment	£2.745m
Costs of alternative product development	£2.76m-£27.6m

Costs Associated with Labelling changes	£5m-£10m
Costs of website development	£8.7m
Total	c£26.6m-c£61.8m

This estimate does not take into account economies of scale, or the proportion of surfactants that would be classed as disinfectants under Regulation 648/2004 and hence not be subject to its requirements. The costs would also be spread over at least two years. However, it includes no allowance for the costs of formula piracy (assumed to be relatively low), and costs to consumers from restricted product availability. There is also considerable uncertainty surrounding some of the components of the estimate.

In addition the provision of data requirements to any medical personnel, free of charge as stipulated in Annex VIII.c. of Regulation 648/2004 may result in some additional costs for industry.

(ii) Costs for a typical business

The range of business sizes in the soap, detergent and cleaning and polishing sectors is estimated as follows: (1999 estimates)

Size of firm (no of employees)	Number of businesses	Total Employment	Turnover (£m)
1-9	425	1,000	158
10-49	130	3,000	289
50-249	60	7,000	558
250+	35	31,000	5,119

Because of the range of size of firms in this sector, and the diversity of products produced, it is only possible to give a rough approximation of the cost for a ‘typical business’.

All businesses in the sector will be faced with the costs of ultimate biodegradability testing (£3,000 - £5,000) per surfactant (unless they use surfactants already tested). A common approach within the sector may help to develop economies of scale in testing and optimum utilisation of outstanding testing capacity. Such an approach may help smaller producers.

Costs beyond those of ultimate biodegradability testing will depend on which surfactants are used, what alternatives are available, and whether the firm decides to pursue the derogation route for surfactants that fail the ultimate biodegradability test.

As a very crude gauge, the total number of businesses (650) divided by the total compliance cost estimates results of around **£45,000 – £90,000** per business. This provides a first estimate but, as has been suggested, costs are likely to be incurred disproportionately by smaller firms, although, in absolute terms, costs will be higher for larger operators.

7. Consultation with small business: the ‘Small Firms Impact Test’

Regulation 648/2004 and accompanying implementation measures introduced by the Government will apply to all manufacturers and suppliers of detergent products.

However, consultation with trade associations in 2001 suggested that they would impact primarily on SMEs manufacturing and supplying products that fall outside the existing biodegradability testing requirements, in particular, those producing cationic and amphoteric surfactants. The businesses affected operate in the soap, detergent and cleaning and polishing sectors and supply products involved in machine washing, bottle washing, dish washing, metal cleaning, floor cleaning, transportation cleaning and façade cleaning.

Trade associations contacted by the DTI who responded to the Commission's consultation included the United Kingdom Cleaning Products Industry Association (UKCPI), the British Association of Chemical Specialities (BACS) and the Chemical Industries Association (CIA). In addition, European industry bodies such as CESIO (Comité Européen des Agents de Surface et leurs Intermediaires Organiques) and AISE (Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien) responded at a European level. As well as representing large multinational companies and other trade associations, these bodies also represent SMEs operating in niche markets.

The trade associations welcomed the revision of the legislation as it was in line with their policy of promoting the use of biodegradable surfactants where possible. However, concerns were expressed regarding the timescale for implementation of Regulation 648/2004, particularly the length of time that a company would have in which to apply for a derogation, and the phase-out period that would exist if a surfactant were not granted a derogation, while new products were developed and stock already on the market was sold. Industry also felt that Regulation 648/2004 could lead to the withdrawal of several effective, small volume surfactants used in the industrial and institutional sector.

Since 2001 the UK Government and the Commission have maintained regular contact with industry. Defra conducted a public consultation in 2003, on which the costs in this RIA are based. Trade associations such as AISE and CESIO have been heavily involved in the production of technical guidance documents.

A possible scenario would be a small firm that uses 12 surfactants in its products. The cost of submitting these to the ultimate biodegradability test would be:

$$12 \times (\text{£}3,000 - \text{£}5,000) = \text{£}36,000 - \text{£}60,000$$

Assuming that a third of the surfactants fail the ultimate biodegradability test, the producer has the option of submitting the failed surfactants to the primary biodegradability test with a view to seeking derogation. If the producer decided to submit all of the products for testing then, depending on whether screening of confirmatory tests were needed, the costs would be:

$$4 \times (\text{£}2,000) = \text{£}8,000, \text{ or}$$
$$4 \times (\text{£}8,000 - \text{£}10,000) = \text{£}32,000 - \text{£}40,000$$

If the manufacturer were required to establish further testing methods then this would add a further **£40,000** per product.

The manufacturer would also be obliged to undertake risk assessments on those projects for which he was seeking derogation. The cost of undertaking these would be:

$$4 \times (\pounds 50,000 - \pounds 250,000) = \pounds 200,000 - \pounds 1\text{m}$$

Finally, there would be development costs to find alternative surfactants. This is difficult to estimate but a notional **£50,000** per product is suggested.

There is a view within the industry that there will be few applications for derogations, as an application would represent a significant economic outlay and may well not be granted. It has also been suggested during discussions with industry by one manufacturer that larger quantities of less effective surfactants passing ultimate biodegradability might be used to replace those smaller volume surfactants that were not granted a derogation, instead of developing alternative surfactants.

The first stage of derogation applications will be handled by the Member State, and PSD intends to hold a public consultation later this year on the procedure that should be put in place to handle derogation applications to minimise the burden on business, including the impact on SMEs.

8. Competition assessment

Regulation 648/2004 will create a variety of costs for business, which, in the main, will arise from requirements relating to ultimate biodegradability tests, primary biodegradability tests, complimentary risk assessments and costs arising from seeking alternative product development. The extent of these costs for individual businesses will be largely dependent upon the extent to which businesses have already incorporated the ultimate biodegradability testing into their process and whether the business produces surfactants which would fail the ultimate test and the numbers of these. The intention is that most surfactants would only be subject to a single test. However, if a surfactant fails the ultimate test, it is possible that additional tests might be necessary. This might require that the product be subject to a period of derogation, removal or necessitate the development and use of an alternative substitute product. Following consultation with trade bodies, it is anticipated that the effect of Regulation 648/2004 will be relatively greatest on small firms in the industrial and institutional detergents sector, where they produce low tonnage specialist surfactants (detergents), which could be more likely to fail the initial biodegradability test.

Surfactants failing the ultimate biodegradability test and therefore being subjected to primary biodegradability tests and complimentary risk assessments are likely to be confined to distinct separate markets. As stated previously it is likely that the industrial and institutional sector will be most significantly affected by additional testing requirements. However, the effects felt by SMEs in relation to increased costs associated with the risk assessment process are likely to be more disproportionate than those felt by larger manufacturers.

It is also important to note that Regulation 648/2004 may result in a potential competitive disadvantage for EU producers of surfactants in non-EU markets where surfactant manufacturers are not faced by additional testing requirements. This might come from an

overall increase in costs of EU producers relative to non-EU producers. The potential size of this effect will depend on the extent of EU-non-EU trade, since only products manufactured in the EU but exported to non-EU markets will be subject to a potential cost disadvantage. Information has not been obtainable on the extent of this trade.

The majority of surfactant manufacturers tend to produce a broad range of products and therefore although some surfactants may fail testing requirements alternative income streams will go some way to cushioning any negative effects from the proposal. Although some specialist manufacturers of surfactants may be affected it would be reasonable to assume that their exit from the industry would not greatly affect the level of concentration or market structure, as the European detergents market was estimated to be worth 5 Billion euro in 2001. Therefore, it would be reasonable to assume that the proposals should not have a significant effect on competition at this level.

It is likely that, given the small percentage of surfactants expected to require replacement, there would not be a significant effect on competition. The costs arising from alternative product development would be expected to fall heavily on downstream formulators. For example, if a surfactant manufacturer decides to remove a specific surfactant because it is likely to fail risk assessment, this may have significant impacts for specialist niche formulators. It is clearly desirable for formulators to have as much time as possible to identify alternative surfactants if this is required. Surfactant manufacturers can help by letting formulators know as early as possible if a surfactant is likely to be withdrawn because of Regulation 648/2004, or whether the manufacturer intends to apply for a derogation. The Government can ensure that necessary information is disseminated as widely as possible, so that small downstream formulators who may not otherwise be aware of the new requirements can engage with manufacturers as early as possible. PSD published guidance on Regulation 648/2004 on 12 July, and is working with the Small Business Service (SBS) to ensure the more effective dissemination of guidance.

Finally, it is possible that if manufacturers choose to collaborate with formulators to share test results and avoid duplication, costs associated with testing may be reduced.

9. Social Impacts

(I) Health Impact Assessment

Regulation 648/2004 could lead to a slight overall improvement in public health, as the labelling requirements placed on manufacturers will enable consumers to make more informed choices about the products they buy. In addition, manufacturers of detergents will be required to make available data sheets to medical professionals on request, giving more detail as to the ingredients contained in detergents. This should address concerns raised in the late 1990s linking some detergents to allergies.

However, any health improvements brought about by more stringent labelling requirements are unlikely to impact significantly on the average consumer. This is because UK manufacturers of detergents already label standard household detergents in accordance with the provisions of Regulation 648/2004.

Regulating the biodegradability of detergents more tightly, and increasing the scope of the existing legislation to include cationic and amphoteric surfactants, may lead to an

improvement in water quality, which in turn could have knock-on effects for public health. As mentioned above, surfactants have been linked to the problem of foaming in rivers and at sewage plants, though it is not clear to what extent foaming is caused by surfactants.

There are no adverse health consequences arising out of Regulation 648/2004.

(II) Sustainable Development

PSD does not consider that implementing these Regulations will have any impact on sustainability issues.

(III) Racial equality

PSD does not consider that implementing these Regulations will have any impact on racial equality issues.

10. Enforcement and sanctions

PSD will be the competent authority for the purposes of Regulation 648/2004. It will be enforced on the ground through the Detergents Regulations 2005 by local authority trading standards officers. There is likely to be an initial cost (a tentative estimate of £200,000 is suggested at Section 6 above) relating to the handling of derogation applications and the analysis of test results. However, this could be negated by the charging of fees. Thereafter there should be net savings against existing cost projections owing to the elimination of false negatives from the testing methodology.

Enforcement officers will be able to issue enforcement notices if there is a breach of the Regulations. These notices will set out the action that a manufacturer needs to take to rectify the problem and state by when such action should be taken. However, due to the environmental and public health problems that could arise through a breach of the Regulations, courts will be able to impose criminal penalties for persistent or serious offences. Sanctions along the lines of the “polluter pays” principle would not be appropriate, as it would not be possible to trace pollution incidents back to one individual manufacturer. The most serious offences against these Regulations will be triable either way and punishable by up to 2 years imprisonment and/or an unlimited fine. We expect any impact on the prison population to be minimal, as we are not aware of any significant levels of non-compliance with the existing legislation. The Home Office is content with the offences and penalties contained in the Detergents Regulations 2005.

11. Monitoring and review

Regulation 648/2004 establishes a Committee procedure to review matters in the Regulation. By 2009 the Commission will produce a report on the effectiveness of Regulation 648/2004. It may also produce proposals to regulate the anaerobic biodegradability of surfactants and the biodegradability of the main non-surfactant ingredients in organic detergents.

12. Consultation

The views of the detergents industry on an earlier draft of the proposal were canvassed by DTI in Summer 2001, and the Commission (DG Enterprise) conducted a public consultation in autumn of the same year.

Defra carried out a public consultation on the proposals during the period March-May 2003.

A further period of public consultation will take place in Autumn 2005 on the Regulations to be put in place for the handling of derogation applications.

As well as formal consultation, Government officials have met regularly with industry representatives and attended industry events.

13. Implementation and delivery plan

Regulation 648/2004 was published in April 2004. As it does not come into force until 8 October 2005, industry and the UK Government has had an 18-month implementation period. This has given industry time to start preparing for the changes demanded by Regulation 648/2004, including changes to labelling.

Following the publication of Regulation 648/2004, PSD has continued discussions with stakeholders, including detergent manufacturers, local authorities (who will be enforcing the legislation on the ground) and the Home Office (over the level of penalties that should be available to the courts). PSD is also working with the industry and the SBS so that information on Regulation 648/2004 is disseminated as widely as possible, so that it reaches SMEs who may not be fully aware of either the Regulation's implications or previous public consultation. This could include the placing of notices in specialist publications, referring firms to guidance that PSD released in July.

As mentioned above, implementation of Regulation 648/2004 will take place in two stages. Enforcement Regulations will come into force on 8 October 2005 at the same time as Regulation 648/2004. In July PSD released guidance 12 weeks before the entry into force of the legislation. This guidance can be found on the PSD website and will be updated as necessary. Officials will also work with local authorities to produce guidance for trading standards officers who will be enforcing the Regulations.

Officials will attend industry and local authority conferences over the summer in order to communicate as widely as possible the implications of the new legislation.

Although the industry has had an 18-month implementation period between the publication and the coming into force of Regulation 648/2004, a "light touch" approach will initially be taken to enforcement. Many products bearing old-style labels will still be on the shelves after 8 October, as they will have actually been placed on the market before that date. The Commission has informally indicated that products that have left the manufacturer will be considered to be on the market and can be sold for an unlimited period. This includes products stored in warehouses and on retailers' shelves.

The second stage of the implementation process will take place next year when Regulations setting out the procedures for derogation applications are introduced. Over the autumn a public consultation will take place on the contents of these Regulations.

Risks

The main risk is that industry will be unclear as to what is required by Regulation 648/2004. Concern particularly surrounds the definition of “placing on the market”, and what information is required to appear on detergent labels. If industry is unclear, this could result in inadvertent non-compliance. This risk can be managed through the issuing of guidance and by dealing with queries from industry as they arise. This risk could be compounded if trading standards officers believe that products bearing old-style labels are automatically in breach of Regulation 648/2004, when in fact they were placed on the market before 8 October. Again, this risk can be mitigated through the production of guidance.

There is a risk that manufacturers will attempt to apply for derogations before the Regulations setting out the application process have been introduced, as they only have until October 2007 to make an application. Before manufacturers can apply for a derogation, the Commission must release a Technical Guidance Document explaining what information manufacturers need to submit in support of their application. Under Regulation 648/2004, the Commission has until April 2007 to release this document. As the public consultation will be held later in 2005, and Regulations will be introduced in 2006, this means that Regulations setting out procedures for handling derogation applications should be in place 18 months before the deadline by which derogation applications must be submitted. Even if the technical guidance document is released before April 2007, it is not thought likely that derogation applications will be received before Regulations for their handling have been introduced. Industry will need to assess the requirements for a derogation application in the light of the final guidance document. There is also an argument that manufacturers may leave it as late as possible to apply, in case a surfactant is not granted a derogation and has to be withdrawn.

A risk associated with the implementation of all EU legislation is that the UK could face infraction proceedings from the Commission if it does not fully implement its obligations. This could occur if Enforcement Regulations were not in place throughout the UK by 8 October or if the contents of those Regulations did not provide adequate provision for the enforcement of Regulation 648/2004. We are working closely with the devolved administrations to ensure that Regulations are in place by 8 October. We are of the view that the provisions of the Enforcement Regulations enable us to fulfil our obligations without placing unnecessary burdens on industry.

Key dates

12 July	Initial guidance issued 12 weeks before Regulation 648/2004 and implementing Enforcement Regulations come into force
Summer 2005	Officials attend industry and local authority conferences to communicate the requirements of the legislation.
8 October 2005	Regulation 648/2004 and Detergents Regulations 2005 come into force.
Autumn/winter 2005	Public consultation to take place on the Regulations setting out the application

	process for derogations.
Spring 2006	Regulations dealing with derogation applications are introduced.
April 2007	The latest possible release date for the Commission's Technical Guidance Document on derogations.
Ongoing	Officials continue dialogue with industry and local authority trading standards officers.

14. Summary and recommendation

Option	Total Cost	Total Benefit
Introduce stringent enforcement regulations, placing increased burdens on industry to provide information	C£26.6m - c£61.8m, plus additional costs depending on the precise content of the enforcement Regulations. This approach would place an unnecessary burden on industry.	Improvements to human health and the aquatic environment
Introduce basic enforcement Regulations that enable us to fulfil our obligations under Regulation 648/2004	C£26.6m - £61.8m	Improvements to human health and the aquatic environment
Do not introduce enforcement Regulations	C£26.6m - £61.8m	Nil. In addition, this approach could lead to infraction proceedings and damage to the environment, as well as costs to industry who wished to export their products to other EU MS's that did properly fulfil their obligations under the Regulation.

15. References

PA Consulting (2001) a competitiveness analysis of the soap and detergents industry, report prepared for DTI, London, 2001.

16. Declaration

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed by the responsible Minister,

Lord Bach, Parliamentary Under Secretary, on 4 September 2005.

Glossary

Aerobic testing	Testing biodegradability in the presence of oxygen
Anaerobic testing	Testing for biodegradability in the absence of oxygen.
CHIP	The Chemicals (hazard information and packaging for supply) Regulations 2002.
Derogation	If a surfactant used for industrial or institutional purposes fails the ultimate biodegradability test but passes the primary biodegradability test, a manufacturer can apply to the Member State and the Commission for a derogation to keep the surfactant on the market.
Detergent	Detergent is defined in article 2 of Regulation 648/2004 as: “Any substance or preparation containing soaps and/or other surfactants intended for washing and cleaning purposes. Detergents may be in any form (liquid, powder, paste, bar, cake, moulded piece, shape etc.) and marketed for or used in household, or institutional or industrial purposes.” In addition, auxiliary washing preparations, laundry fabric-softeners, cleaning preparations and washing preparations are considered as detergents.
False negatives	Results that wrongly show a surfactant to have failed a biodegradability test. The test methods for primary biodegradability contained in the existing legislation are said to be unreliable and false negatives occur.
Primary biodegradation	Where only the active properties of the surfactant are degraded. The minimum biodegradation level is set at 80%
Regulation 648/2004	Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents
Surfactant	The active cleaning ingredient of a detergent. Surfactants have one end that is hydrophilic (clings to water and avoids oil) and one end that is hydrophobic (clings to oil and avoids water); this makes them effective dirt removing ingredients in detergents. There are four groups of surfactants: <ul style="list-style-type: none"> • Non-ionic

	<ul style="list-style-type: none"> • Anionic • Cationic • Amphoteric. Non-ionic and anionic surfactants were covered by the legislation that this Regulation revokes.
Technical file	A file that must accompany a derogation application, containing results from the ultimate and primary biodegradation tests, and a complimentary risk assessment.
Ultimate biodegradation	Where the whole surfactant molecule (not just the active part in the environment) is degraded resulting in its breakdown to carbon dioxide, water and mineral salts. To pass the ultimate biodegradability test, mineralisation of the molecule must reach either 60 or 70% within 28 days, depending on the test method used.