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ENTERPRISE DIRECTORATE-GENERAL

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STANDARDISATION MANDATE TO CEN FOR UPDATING NATIONAL TEST METHODS RELATED TO THE BIODEGRADABILITY OF SURFACTANTS

I. MOTIVATION

This mandate falls within the framework of the following legal acts:

- Council Directive 73/404/EEC of 22 November 1973 on the approximation of the laws of the Member States relating to detergents;
- Council Directive 73/405/EEC on the approximation of the laws of the Member States relating to methods of testing the biodegradability of anionic surfactants;
- Council Directive 82/242/EEC of 31 March 1982 on the approximation of the laws of the Member States relating to methods of testing the biodegradability of non-ionic surfactants;
- Council Directive 82/243/EC of 31 March 1982 amending Directive 73/405/EEC on the approximation of the laws of the Member States relating to testing the biodegradability of anionic surfactants;
- Proposed Regulation of the European Parliament and of the Council relating to detergents (COM(2002)485).

In the framework of the proposed Regulation on detergents, the European Commission has made a commitment to update national test methods relating to the primary biodegradability of surfactants. The proposal includes a number of biodegradability test methods in its annexes, that are, in part, national test methods taken over from the existing legislation.

The Commission recognises that some of the test methods are rather old and in need of updating. In addition, some of them are national standards and are therefore only available in their original language. It is desirable to remedy this situation by establishing European Standards that would replace the national ones and would be available in the languages of the CEN system.

The Commission intends to replace the above-mentioned national test methods in order to ensure that CEN standards will be considered the official method of analysis. The

establishment of European standards for methods of analysis is necessary to guarantee a uniform application and control of the European legislation in all Member States.

The publication of new CEN standards that would take into account, inter alia, the existing test methods (see Annex), would therefore play a key role in strengthening the effectiveness, understanding, and accessibility of these methods to manufacturers within the EU.

In addition, standardized methods of analysis are an indispensable element in guaranteeing a high level of health and environmental safety within the EU.

The acceptance of this standardisation mandate by CEN will provide a more complete set of standardised methods of analysis thereby contributing to a better functioning of the internal market of detergents.

II. DESCRIPTION OF THE MANDATED WORK

1. The Commission entrusts CEN with the following work:

- Reviewing national test methods relating to primary biodegradability of surfactants in aerobic conditions.
- Replacing national test methods relating to primary biodegradability of surfactants in aerobic conditions by establishing European standards that would replace the national ones.

2. The European standards will cover the following subjects:

- range of application (concentration levels for which the method(s) apply) ;
- method(s) description (sampling, calibration, analysis aspects) that will cover the 4 categories of surfactant;
- analytical test methods to determine the presence of the 4 categories of surfactants and measure their primary biodegradability properties in aerobic conditions.

3. The work should take into account published and ongoing ISO and OECD activities (in particular, the ISO/OECD test methods listed in Annex should be taken into account). The work to be undertaken and their results should be inter-related and compatible.

III. BODIES TO BE ASSOCIATED

The elaboration of the standards should be undertaken in co-operation with the broadest possible range of interest groups, including international and European level associations, and the main industrial associations concerned and regulatory bodies. Co-operation with the International Association of Soap, Detergent and Maintenance Product Industry (AISE) for example is essential. The European Commission and ECOS¹ will also be invited to participate in the standardisation work .

IV. EXECUTION OF THE MANDATE

1. CEN will present the published European standards to the Commission by 1 March 2006.

¹ Environmental Citizens Organisation for Standardisation

2. CEN will regularly report to the Commission on the progress of the work and will keep the Commission informed of the measures taken to execute this order and of any difficulties that arise in the process.
3. To ensure transparency, CEN will inform the Commission of any new programme of activities, not covered by this order, planned on methods of analysis in the field of detergents.
4. As well as any new work, the mandate also covers any necessary revision of existing European standards.
5. The standstill period referred to in Article 7 of Directive 98/34/EC of 22 June 1998, shall commence when the CEN accepts this standardisation mandate².

² OJ L 204 of 21.07.98, p. 37, as amended by Directive 98/48/EC (OJ L 217 of 5/8/98, p. 18)

ANNEX³

Primary biodegradability test methods for surfactants in detergents

Primary biodegradability is measured by the determination in biodegraded liquors of the remaining level of parent surfactants. This Annex begins with a list of the test-methods common to all classes of surfactants, and then lists under headings A to D the analytical test procedures specific to each class of surfactant.

The pass criterion for primary biodegradability shall be a level of at least 80%, as measured according to the test methods below.

The reference method for the laboratory testing of surfactants in this Regulation is based on the Confirmatory test procedure in the OECD method, described in Annex VIII.1. Changes to the Confirmatory test procedure are permissible provided that they comply with EN ISO 11733.

I/ TEST METHODS COMMON TO ALL CLASSES OF SURFACTANTS

A/ NATIONAL TEST METHODS (TO BE REPLACED)

- (1) The method in use in France, approved by the "arrêté du 24 décembre 1987" published in the Journal officiel de la République française of 30 December 1987, p. 15385, and by the standard NF 73-260 of June 1981, published by the Association française de normalisation (AFNOR).
- (2) The method in use in Germany, established by the "Verordnung über die Abbaubarkeit anionischer und nichtionischer grenzflächenaktiver Stoffe in Wasch- und Reinigungsmitteln" of 30 January 1977, published in the Bundesgesetzblatt of 1977, Part I, p. 244, as set out in the Regulation amending that Regulation of 4 June 1986, published in the Bundesgesetzblatt of 1986, Part I, p. 851.
- (3) The method in use in the United Kingdom called the "Porous Pot Test" and described in Technical Report No 70 (1978) of the Water Research Centre.

B/ ISO / OECD TEST METHODS (TO BE TAKEN INTO ACCOUNT)

- (1) The OECD method published in the OECD's technical report of 11 June 1976 on the "Proposed Method for the Determination of the Biodegradability of Surfactants in Synthetic Detergents".
- (2) The "Confirmatory test procedure" in the OECD method, described in Annex VIII.1 (including possible changes in operating conditions as proposed in EN ISO 11733). This is also the reference method used for the settlement of litigation.

³ This Annex is similar to Annex II from the draft Regulation of European and of the Council on Detergents (COM 2002 (45))

II/ TEST METHODS SPECIFIC TO EACH CLASS OF SURFACTANT

A. ANALYTICAL METHODS FOR ANIONIC SURFACTANTS

The determination of anionic surfactants in the tests shall be done by the Methylene Blue Active Substance (MBAS) analysis according to the criteria established in Annex VIII.2

For those anionic surfactants not reacting to the above-mentioned MBAS method, or if it seems more appropriate for reasons of efficiency or precision, appropriate specific instrumental analyses such as high performance liquid chromatography (HPLC) or gas chromatography (GC) are to be applied. Samples of the pure surfactant of interest shall be provided by the manufacturer to the competent authorities of the Member States upon request.

B. ANALYTICAL METHODS FOR NON-IONIC SURFACTANTS

The determination of non-ionic surfactants in the tests shall be done by the Bismuth Active Substance (BiAS) method, according to the analytical procedure established in Annex VIII.3.

For those non-ionic surfactants not reacting to the abovementioned BiAS method, or if it seems more appropriate for reasons of efficiency or precision, appropriate specific instrumental analyses such as HPLC or GC are to be applied. Samples of the pure surfactant of interest shall be provided by the manufacturer to the competent authorities of the Member States upon request.

C. ANALYTICAL METHODS FOR CATIONIC SURFACTANTS

The determination of cationic surfactants in the tests shall be done by the Disulfine Blue Active Substance (DBAS) analysis according to the following DBAS procedures:

The method in use in the Federal Republic of Germany, (1989) DIN 38 409 – Ausgabe: 1989-07.

For those cationic surfactants not reacting to the abovementioned test method, or if it seems more appropriate for reasons of efficiency or precision (this must be justified) appropriate specific instrumental analyses such as HPLC or GC are to be applied. Samples of the pure surfactant of interest shall be provided by the manufacturer to the competent national authorities of the Member States upon request.

D. ANALYTICAL METHODS FOR AMPHOTERIC SURFACTANTS

The determination of amphoteric surfactants in the tests shall be done by analysis following the procedures listed below:

1. If cationics absent: The method in use in the Federal Republic of Germany, (1989) DIN 38 409-Teil 20.
2. Otherwise: Orange II method (Boiteux, 1984).

For those amphoteric surfactants not reacting to the above-mentioned tests, or if it seems more appropriate for reasons of efficiency or precision (this must be justified) appropriate specific instrumental analyses such as HPLC or GC are to be applied. Samples of the pure surfactant of interest shall be provided by the manufacturer to the competent authorities of the Member States upon request.