COMMISSION OF THE EUROPEAN COMMUNITIES

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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

Pursuant to Article 16 of Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents, concerning anaerobic biodegradation

(Text with EEA relevance)

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1. INTRODUCTION

Article 16(2) of Regulation (EC) No 648/2004 on detergents[1] lays down that:

"by 8 April 2009, the Commission shall carry out a review of the application of this Regulation, paying particular regard to the biodegradability of surfactants, and shall evaluate, submit a report on, and, where justified, present legislative proposals relating to

anaerobic biodegradation;

the biodegradation of main non-surfactant organic detergent ingredients".

This report concerns the anaerobic biodegradation of detergent surfactants with a focus on linear alkylbenzene sulphonate (LAS) which is a widely-used surfactant (see table 1) that is reported to be poorly biodegradable under anaerobic conditions. The report covers the properties of LAS obtained from the scientific literature, risk assessment reports on the risks associated with the use of LAS in detergents, and a review of anaerobic testing methodology.

Anaerobic conditions occur both in nature, for example in surface water sediments, and in the sludge of waste water treatment plants. Anaerobic biodegradation of surfactants in sludge and sediment produces methane in contrast to the carbon dioxide that results from biodegradation under aerobic conditions found in waste and surface water.

As most waste-water streams and surface waters are aerobic, surfactants that are fully biodegradable under aerobic conditions should be rapidly degraded, and in principle should not enter the compartment where anaerobic conditions prevail. That is why the Detergents Regulation sets ultimate biodegradability as the main criterion for use of surfactants in detergents. Surfactants that do not meet the criterion of ultimate biodegradability can only be used in exceptional circumstances and only when it can be demonstrated by means of a risk assessment that such uses do not pose a risk. One such derogation will be granted in the near future[2].

Although no reports have been received from Member States of any environmental concerns due to surfactants since the introduction of the Detergents Regulation, it has been noted that some surfactants do accumulate in sewage sludge where they remain until the sludge is disposed of, for example as a fertiliser in agriculture, where re-exposure to aerobic conditions allows aerobic biodegradation to proceed to completion.

The environmental fate and behaviour and the toxicity of surfactants should all be considered for evaluating the effectiveness of the existing legislation in managing the overall risk. The Commission approached this task in two stages: first to establish the existing knowledge base and identify gaps, second, to fill those gaps. The first stage was completed in 2005, the second has taken from 2006 to 2009.

2. ESTABLISHING THE KNOWLEDGE BASE

2.1. The Fraunhofer study

In 2000, the Commission (DG Enterprise and Industry) contracted a study to the Fraunhofer Institute (UMSICHT) to assess the environmental impact in the EU resulting from the

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1 OJ L104, 8.4.2004, p.1

2 The derogation refers to surfactant Dehypon G 2084 for use in three industrial applications (bottle washing, cleaning in place, and metal surface cleaning)

incomplete biodegradation of detergent surfactants under anaerobic conditions. The report was completed in 2003[3] and covered among other things a survey of statistical data on detergent production and consumption in Europe as well as a set of recommendations for test methods and cost/effective measures on the anaerobic biodegradability of surfactants.

Table 1 provides an overview of the main surfactants used in detergents.

Table 1: Consumption and production (tonnes) of main detergents surfactants in Western Europe for 2007 (CESIO statistics, January 2009)

Surfactant	*Production in WE*	*Sales in WE*
LAS	502.200	403.463
Alcohol sulphates	79.629	66.201
Alcohol ethersulphates	449.685	397.448
Alkane sulphonates	76.726	66.176
Alkylphenol ethoxylates	31.602	24.892
Fatty alcohol ethoxylates	1.000.617	615.695
Other ethoxylates	38.171	24.921
Esterquats	224.315	159.352
Betaines	76.134	67.557

The main conclusions of Fraunhofer Report were:

Surfactants must be ultimately and readily biodegradable under aerobic conditions in order to prevent adverse environmental impact.

The poor biodegradability of some surfactants (e.g. LAS) under anaerobic conditions may sometimes result in a significant surfactant content in sewage sludge, especially after treatment in waste water treatment plants (WWTP) employing an anaerobic sludge stabilisation process. When the anaerobically treated sludge is used as fertiliser in agriculture, the surfactant concentration in the sludge amended soil is predicted to decrease rapidly because of the aerobic biodegradation process occurring in soil.

With regard to sediments, no accumulation of aerobically ready biodegradable surfactants has been observed, in particular for LAS even over a period of several decades. This seems to confirm that aerobic (rather than anaerobic) biodegradation plays the main role in elimination of organic compounds.

[3] Report available at: http://ec.europa.eu/enterprise/chemicals/legislation/detergents/studies/anaerobic.htm

2.2. The SCHER opinion: "Environmental Risk Assessment of non-Biodegradable Detergent Surfactants under Anaerobic Conditions".

The Fraunhofer study, together with related reports (e.g OECD on LAS[4]) were submitted in 2004 to the Commission's Scientific Committee on Health and Environmental Risks (SCHER) for an opinion on the overall scientific quality of the Fraunhofer report and specific aspects of anaerobic biodegradation such as:

(a) The nature and magnitude of the risk to the environment currently posed by those detergent surfactants that are poorly biodegradable under anaerobic conditions, but that are readily and ultimately biodegradable under aerobic conditions.

(b) The impact on the risk to the environment from detergent surfactants if the existing requirement for ready and ultimate biodegradability of surfactants under aerobic conditions were to be extended to cover anaerobic conditions as well.

In its opinion published in November 2005[5], SCHER found that the overall scientific quality of the Fraunhofer report was rather poor due to the small amount and variable quality of the data, as well as some flaws in the analysis and in the conclusions drawn from it in the effects assessment. Regarding the magnitude of the environmental risk of surfactants other than LAS, the Fraunhofer report did not include enough information to allow an evaluation of their risk to the environment.

However, SCHER agreed with the main Fraunhofer conclusion that *"the requirement for ready and ultimate biodegradability of surfactants under anaerobic conditions is not by itself regarded as an effective measure for environmental protection"*.

Considering all available reports together, SCHER expressed concerns about:

(a) a potential for risk from LAS in sludge in certain applications of worst case environmental conditions (PEC/PNEC values slightly above 1),

(b) the relatively high measured levels (0.5-1 g/kg) of other surfactants in sewage sludge, including some surfactants which are anaerobically biodegradable, such as: soaps, alcohol ethoxylates (AE) and alkyl phenol ethoxylates (APE). A lack of sufficient information did not allow the risk to be assessed.

(c) the fact that a single test is not sufficient to evaluate anaerobic biodegradability. A combination of several tests is more appropriate.

3. FILLING THE KNOWLEDGE GAPS

3.1. HERA reports on LAS and AEs from 2007

In reaction to the concerns expressed in the 2005 SCHER opinion, the European surfactant industry association (CESIO) funded additional soil toxicity studies which were performed by the Danish National Environmental Research Institute (NERI). The results of this work were included in an updated HERA (Human & Environmental Risk Assessment) report on LAS[6]

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4 Report available at: http://www.chem.unep.ch/irptc/sids/oecdsids/LAS.pdf

5 SCHER opinion available at: http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_021.pdf

6 HERA report available at: http://www.heraproject.com/RiskAssessment.cfm?SUBID=4

which was published in 2007 and concluded that: "*the risk characterisation as expressed by the PEC/PNEC ratio was below 1 for all environmental compartments, considering the recently reported PNEC values (~35 mg/kg versus 4.6 mg/kg in previous assessments)*". Therefore, the HERA report concluded that there are no adverse effects.

Concerning AE, a HERA report was produced in May 2007[7], according to which: "*AE usage in laundry cleaners and household cleaning products is not a cause for concern for the environment (in particular surface water, sediment, sewage treatment facilities, and soil)*".

It should also be noted that both HERA reports concluded that the use of LAS and AE in household laundry and cleaning poses no risk to consumer health.

In parallel, additional scientific findings on LAS and anaerobic biodegradation were published by several researchers such as: Temnik and Klapwijk (2004)[8], Krogh et al., (2007)[9], Jensen et al., (2007)[10], Schowanek (2007)[11], and Berna et al. (2007)[12].

3.2. New SCHER opinion on anaerobic biodegradation of surfactants

In March 2008, the Commission (DG Enterprise & Industry) requested SCHER to assess the overall scientific quality of the recent HERA reports on LAS and AE and comment on their conclusions, in particular those concerning the environmental risks.

In addition, SCHER was invited, in the light of all available scientific evidence, to reconfirm the key statements mentioned in the opinion of 2005 concerning the anaerobic biodegradation of surfactants and environmental protection, as well as to review the issue of anaerobic test methodology.

In November 2008, SCHER published its opinion concerning anaerobic degradation of surfactants and biodegradation of non surfactant detergents organic ingredients[13]. The key points are:

(a) *Alcohol ethoxylates:* SCHER concluded that the PEC/PNEC ratios are sufficiently low (surface water: 0.041, sediment: 0.316, sewage treatment plant: 0.007 and soil: 0.103) that any remaining uncertainties (for example, the potential of anaerobic biodegradation of AE homologues was not considered), are not expected to invalidate the main HERA conclusion that there are no environmental risks.

(b) *LAS:* SCHER disagreed with the HERA argument that soil microbial functions are covered by the proposed PNEC and considered that a proper evaluation of the effects of LAS effects on microbial activity is essential for the derivation of a robust PNEC for soil.

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7 HERA report available at: http://www.heraproject.com/RiskAssessment.cfm?SUBID=34

8 Fate of linear alkylbenzene sulfonate (LAS) in activated sludge plants, H. Temmink, B. Klapwijk, Water Research 38 (2004) 903–912.

9 Risk assessment of linear alkylbenzene sulphonates, LAS, in agricultural soil revisited: Robust chronic toxicity tests for Folsomia candida (Collembola), Aporrectodea caliginosa (Oligochaeta) and Enchytraeus crypticus (Enchytraeidae), P.H. Krogh et al., Chemosphere 69 (2007) 872–87.

10 European risk assessment of LAS in agricultural soil revisited: Species sensitivity distribution and risk estimates, J. Jensen et al., Chemosphere 69 (2007) 880–892.

11 Probabilistic risk assessment for linear alkylbenzene sulfonate (LAS) in sewage sludge used on agricultural soil, D. Schowanek, Regulatory Toxicology and Pharmacology 49 (2007) 245–259.

12 Anaeobic biodegradation of surfactants-scientific review, J.L Berna et al., Tens.Surf.Deterg, (2007), 44, 313–347.

13 SCHER opinion available at: http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_109.pdf

Concerning the toxicity data for effects of LAS on plants, SCHER considered that the information provided was not sufficient for justifying the newly proposed PNEC value of 35 mg/kg. Thus, whereas SCHER agreed with the proposed PNEC values for aquatic organisms and sediments, it underlined that the new proposed PNEC for soil ($PNEC_{soil}$) was not properly substantiated, and unless additional justification can be provided, the previous PNEC for soil of 4.6 mg/kg should be retained. SCHER noted that although most studies show that LAS is poorly biodegradable in anaerobic laboratory tests and in the anaerobic digesters of sewage sludge treatment plant, recent environmental monitoring data (Lara-Martin et al., 2007) seem to show significant degradation of LAS under anaerobic conditions in the environment.

SCHER concludes that the use of AEs and LAS in household laundry and cleaning products poses no risk to human health.

Furthermore, due to lack of new evidence, SCHER did not change the conclusions of its 2005 opinion that: (a) poor biodegradability under anaerobic conditions is not expected to produce substantial modifications in the risk for freshwater ecosystems as the surfactant removal in the WWTP seems to be determined by its aerobic biodegradability; (b) the requirement for ready and ultimate biodegradability under anaerobic conditions is not by itself regarded as an effective measure for environmental protection.

3.3. Review of anaerobic testing methodology

In its 2008 opinion, SCHER also reviewed the screening and simulation test methods currently available to determine ultimate anaerobic biodegradability of organic substances. The potential biodegradability of organic compounds under anoxic conditions can be assessed in a standardised screening test for anaerobic biodegradability (OECD 311). However, to assess the biodegradation rate in anoxic environmental compartments, specific simulation tests should be applied, such as: TG 307 (transformation in soil) and TG 308 (transformation in aquatic sediment systems). In recent years, the OECD has revised and adopted different anaerobic test methods to fill the gap on anaerobic biodegradability testing. The need for screening methods for assessing the anaerobic biodegradability in anaerobic digesters and for determining inhibition of biogas production by chemicals, which are insoluble and/or are adsorbed onto sludge and sediments, has been covered by the OECD 311 and OECD 224 methods adopted in 2006 and 2007, respectively.

TEGEWA, a trade association of the German chemical industry, has recently carried out a study on the suitability of the OECD 311 method to study the anaerobic biodegradability of surfactants (Schwarz et al., 2008)[14]. To address the observed limitations of the screening methodology for assessing anaerobic biodegradability and its poor reproducibility for testing surfactants, a modified approach for the assessment of anaerobic biodegradation was proposed by Willing et al. in 2008[15]. Its main differences compared to the standard OECD 311 method are the use of undiluted sludge as the test medium and the presence of an additional non-surfactant source of carbon. SCHER notes that the amount of data generated using the modified method is rather limited, and believes that further work should be done in order to validate this modified test method.

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[14] Schwarz et al. (2008). Methodology of Anaerobic Biodegradability of Surfactants. *7thWorld Surfactants.* Congress CESIO, Paris, June 2008.

[15] Willing A. (2008) A new approach for the assessment of the anaerobic biodegradability of surfactants. *7th World Surfactant Congress CESIO*, Paris, June 2008.

Overall, SCHER believes that the existing OECD methods for anaerobic biodegradation together with the simulation test currently under revision provide an appropriate methodology for the assessment of the anaerobic biodegradability of organic compounds. However, due to stringent (methanogenic) conditions used in the laboratory tests, inhibitory effects cannot be excluded and it is therefore accepted that a poor result may not be a final proof of anaerobic recalcitrance.

4. STAKEHOLDER CONSULTATION

The findings of the Fraunhofer and HERA reports as well as their evaluations in the various SCHER opinions have been discussed at several meetings of the Detergents Working Group responsible for the implementation of the Detergents Regulation (February and November 2006, November 2007, July 2008, and February 2009). Those meetings were attended by representatives of the competent authorities of Member States and industry associations such as AISE (Association de la Savonnerie, de la Détergence et des Produits d'Entretien), CESIO (Comité Européen des Agents de Surface et de leurs Intermédiares Organiques) and their research partnership ERASM (European Risk Assessment and Management).

In February 2006, the Detergents Working Group concluded that it would not be proportionate to take legislative action on the basis of the 2005 SCHER opinion, given that the environmental impact of anaerobic biodegradation has not yet been fully clarified. Instead, the issue should be re-examined in the light of any new information nearer to the reporting date of April 2009. In November 2006, Industry (CESIO/ERASM) communicated to the WG, their ongoing efforts to improve the current knowledge on the risk assessment of LAS in anaerobic sludge and soils through the performance of new soil toxicity studies, the outcome of which would be reflected in updated reports by ERASM (2006) and HERA (2007).

In the Working Group meeting of November 2007, ERASM/CESIO presented recently conducted studies on the anaerobic biodegradability of surfactants. New information, published in international journals, was provided on the soil ecotoxicity and sludge risk assessment for LAS, which significantly affected the risk assessment. ERASM stressed that as the $PNEC_{soil}$ for LAS had been revised from 4.6 to 35 mg/kg due to new ecotoxicity data, the new PEC/PNEC ratio (decreased by a factor of 7) would indicate a significantly lower environmental risk for LAS in anaerobic sludge. ERASM underlined that as the revised deterministic and probabilistic risk assessment showed no risk for LAS at all observed sludge levels, soil types and typical disposal scenarios, regulatory limit values for LAS in sludge are not required.

ERASM also concluded that:

– According to the new Risk Assessment Reports, environmental protection is ensured provided that readily biodegradable surfactants, as required by Regulation (EC) No 648/2004, are treated under aerobic conditions in WWTP. The detergent and surfactant industry agrees with the statement by SCHER that "*the requirement for ready ultimate biodegradability under anaerobic conditions is not by itself considered an effective measure for environmental protection.*"

– No correlation between (lack of) anaerobic biodegradability and environmental problems has been reported. Rapid aerobic biodegradation is what is important to ensure no risk to the environment.

In January 2009, CESIO/ERASM communicated their position[16] on the SCHER opinion of 2008. ERASM emphasizes the need to improve the quality of existing screening tests for anaerobic biodegradation to improve their reproducibility and to reduce the incidence of false negative results. ERASM announced that the TEGEWA project (funded by German surfactant industry association) is working in that direction, aiming to optimize the experimental conditions of the ECETOC/OECD 311 screening method and that results will be available in about 2 years.

ERASM disagrees with SCHER conclusions concerning the LAS risk assessment results for the soil compartments. ERASM is still of the opinion that the PNEC value of 35 mg/kg in the HERA report is the correct one for the impact of LAS on the soil environmental compartment. Nevertheless, ERASM recognises that the issue raised by SCHER as to whether LAS in soil affects the reduction of iron in soil should be further investigated by studies extending over longer periods of time.

In February 2009, CESIO/ERASM informed the Commission of their initiative to undertake further research in order:

- to develop an improved method for measuring the anaerobic biodegradability under sludge digester condition, and

- to evaluate the LAS degradation in sediments and review any scientific evidence in order to precisely estimate the PEC value for LAS.

Industry will present the outcome of their research at a next meeting of the Detergents WG and if required, a further opinion could be requested from SCHER in the future.

5. SUMMARY AND CONCLUSIONS

The Commission has taken a number of steps to establish a knowledge base sufficient to review the anaerobic biodegradation of surfactants as required by Article 16 (2) of Regulation 648/2004.

The results of a study conducted in 2003 on anaerobic biodegradation, mandated by the Commission to an external consultant, together with the findings of risk assessment studies of major surfactants which were conducted by Industry in 2007 on a voluntary basis and the outcome of their evaluation by SCHER, were discussed with delegates from Member States and industry associations in a number of meetings of the Commission Detergents Working Group.

Following a systematic evaluation of the risks from the presence of non-degradable surfactants in various anaerobic compartments, it was concluded that, in contrast to the adverse effects observed in the absence of aerobic degradation, the lack of anaerobic degradation does not seem to be correlated with any apparent risk for these environmental compartments. It can therefore be concluded that anaerobic biodegradability should not be used as an additional pass/fail criterion for the environmental acceptability of surfactants such as LAS which are readily biodegradable under aerobic conditions.

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16 http://circa.europa.eu/Members/irc/enterprise/wgdet/library?l=/meetings/meeting_february_1/working_documents&vm=detailed&sb=Title

Concerning the recently produced data on the terrestrial toxicity of LAS leading to an increased $PNEC_{soil}$ (which reduces the PEC/PNEC ratio and thereby diminishes the predicted environmental risk from LAS in anaerobic sludge and soil) this should be better substantiated as requested by SCHER in its opinion of 2008.

The remaining concerns therefore focus on the possible environmental toxicity of surfactants, rather than on their biodegradability. At present, however, there is no evidence that would justify legislative measures at EU level, such as regulatory limit values for LAS in sludge.

The information requirements of the REACH registration dossiers will ensure that comprehensive data on the health and environmental effects of detergents ingredients - including surfactants such as LAS - will be submitted by industry to the European Chemical Agency (ECHA). In fact, for substances manufactured or imported in quantities of 1 000 tonnes or more per year registrations are due by December 2010 and chemical safety reports as part of the registration dossiers will need to demonstrate the safe use throughout their life cycle. The REACH registration information should therefore be sufficient to decide whether restrictions on certain surfactants in detergents formulations are needed on environmental grounds in addition to those already imposed by the Detergents Regulation. If so, the restriction procedure of REACH would be the most appropriate instrument to impose such restrictions.

6. LIST OF ABBREVIATIONS

AE:	Alcohol ethoxylates
AISE:	Association Internationale de la Savonnerie, de la détergence et des produits d'Entretien
APE:	Alkylphenol ethoxylates
CESIO:	Comité Européen des Agents de Surface et de leurs Intermédiares Organiques
ECETOC:	European Chemical Industry Ecology and Toxicology Centre
ERASM:	European Risk Assessment and Management
HERA:	Human & Environmental Risk Assessment on ingredients of European household cleaning products
LAS:	Linear alkyl benzene sulphonates
NERI:	Danish National Environmental Research Institute
OECD:	Organisation for Economic Co-operation and Development
PEC:	Predicted Environmental Concentration
PNEC:	Predicted No Effect Concentration
REACH:	Registration Evaluation Authorisation of Chemicals

SCHER:	Scientific Committee on Health and Environmental Risks
TEGEWA:	TExtilhilfsmitteln, GErbstoffe und Waschrohstoffe
UMSICHT:	Institut für Umwelt-Sicherheit und Energietechnik
WG:	Working Group
WWTP:	Wastewater Treatment Plant