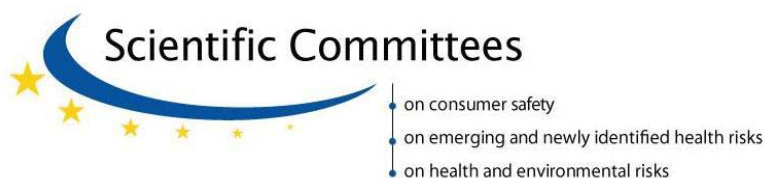




Scientific Committee on Health and Environmental Risks

SCHER

**Model implementation and quantification of the eutrophication risk associated to the use of phosphates in detergents (INIA/Green Planet – report April 2009)**



SCHER adopted this opinion at its 4<sup>th</sup> plenary of 9 November 2009

#### About the Scientific Committees

Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat. They are: the Scientific Committee on Consumer Safety (SCCS), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and are made up of external experts.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Evaluation Agency (EMA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

#### SCHER

Opinions on risks related to pollutants in the environmental media and other biological and physical factors or changing physical conditions which may have a negative impact on health and the environment, for example in relation to air quality, waters, waste and soils, as well as on life cycle environmental assessment. It shall also address health and safety issues related to the toxicity and eco-toxicity of biocides.

It may also address questions relating to examination of the toxicity and eco-toxicity of chemical, biochemical and biological compounds whose use may have harmful consequences for human health and the environment. In addition, the Committee will address questions relating to methodological aspect of the assessment of health and environmental risks of chemicals, including mixtures of chemicals, as necessary for providing sound and consistent advice in its own areas of competence as well as in order to contribute to the relevant issues in close cooperation with other European agencies.

#### Scientific Committee members

Ursula Ackermann-Liebrich, Herman Autrup, Denis Bard, Peter Calow, Stella Canna Michaelidou, John Davison, Wolfgang Dekant, Pim de Voogt, Arielle Gard, Helmut Greim, Ari Hirvonen, Colin Janssen, Jan Linders, Borut Peterlin, Jose Tarazona, Emanuela Testai, Marco Vighi

#### Contact:

European Commission  
DG Health & Consumers  
Directorate C: Public Health and Risk Assessment  
Unit C7 - Risk Assessment  
Office: B232 B-1049 Brussels

[Sanco-Sc8-Secretariat@ec.europa.eu](mailto:Sanco-Sc8-Secretariat@ec.europa.eu)

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Members of the working group are acknowledged for their valuable contribution to this opinion:

C. Janssen, (Chairman and Rapporteur), Ghent University, Belgium

J. Linders, National Institute of Public Health and Environment (RIVM), the Netherlands.

A. Gard, University of Montpellier, France.

M. Vighi, University of Milano Bicocca, Italy.

External experts:

Tom Aldenberg, National Institute of Public Health and Environment (RIVM), the Netherlands

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## 1. BACKGROUND

In November 2007, SCHER adopted an opinion on the INIA study entitled: *"Development of a European Quantitative Eutrophication Risk Assessment of Polyphosphates in Detergents"*.

SCHER recognized that the developed model represented a novel tool to assess, in a quantitative manner, the risks of eutrophication at EU level due to phosphorus release. However SCHER concluded that the scientific quality of the report was diminished due to a number of key points which were not adequately addressed, such as: (1) a limited database to develop the model which may not be representative of the European lakes, (2) the limited data used for the validation of the developed approach and the current proposal.

SCHER underlined that further work is required to enhance the specific relevance of the INIA model to the Water Framework Directive (WFD) and proposed that *"Overall, prior to the application of the model and the use of the results, the science presented in this INIA report should be further developed."*

Following extensive discussion in the meetings of the Commission Working Group on detergents, (December 2007, July, 2008) it was concluded that the Commission will continue to work in collaboration with Member States to improve the knowledgebase through the scientific improvement of the INIA model.

Therefore in line with SCHER recommendation to consider the Inter-Calibration data of WFD and available information from other EU eutrophication studies, the Commission has attempted to facilitate the contact of INIA, with (a) *JRC*: a meeting at ISPRA (June 2008) explored possibilities to use the IC data for the development of the INIA model and established a collaboration between the responsible scientists; (b) *Baltic scientists*: a workshop organized in Stockholm (September 2008) defined modes of cooperation and implementation of the INIA methodology into existing Baltic (marine water) models and research projects; (c) *Danube River Basin (DRB) projects*: In a meeting in Vienna (December 2009), INIA discussed ways of cooperation with DRB scientist which would allow to compare risk model predictions based on actual measured data and the observed biological response.

In a workshop organized in Madrid (March 2009) with the participation of eutrophication experts from various EU eutrophication projects, INIA presented the outcome of this validation and calibration exercise of the model, in particular concerning the effect assessment and risk characterization tools. The finalized INIA report will be resubmitted to the Commission towards the end of April-early May 2009.

Therefore, DG Enterprise would much appreciate an updated opinion of SCHER, based on the recent validation exercise of INIA on the developed risk assessment model for eutrophication, targeting the comparative assessment of different sources of phosphates and particularly the contribution from phosphate-based detergents.

More specifically:

## 2. TERMS OF REFERENCE

**(1)** SCHER is requested to comment whether the scientific quality of the report has been significantly improved following the validation exercise, and whether the characterization of the risk from eutrophication due to detergents can now be regarded as satisfactory. More specifically, SCHER is requested to comment:

**(a)** whether there was sufficient consideration and use of the available data, obtained within the inter-calibration process of WFD implementation (b) the new database of the updated model is sufficiently representative of European lakes;

**(b)** whether the use of ecotypes/eco-regions was efficient in order to properly describe the eutrophication risk at the regional level in the EU. Does SCHER agree with the conclusion of INIA analysis that both JRC and INIA databases were complementary in particular with regard to the approach of classification for the status G- or G+, and that the inclusion of the INIA database was required to ensure average coverage of the Mediterranean ecoregion.

**(c)** whether sufficient data were used for the validation of the developed approach and whether the reliability of the model is scientifically sound.

**(d)** whether:

- the mathematical-statistical description of the risk calculation approach is scientifically sound;
- the calculated risk figures can be interpreted as an empirical probability;
- the calculation method for the probability is statistically sound and consistent;
- the Bayesian approach has been correctly applied;
- the calculation method of risk differences due to a given scenario is statistically sound and consistent.

**(2)** SCHER is requested to assess whether the updated INIA report evaluated the findings of DRB and Baltic Sea studies in order to:

**(a)** consider additional factors playing role in eutrophication process,

**(b)** clarify the eutrophication process in marine waters as provided by these studies,

**(c)** comment on the updated risk estimations for laundry and dishwashing detergents provided for the Danube, Ebro and Tajo Rivers based on monitoring data

**(3)** SCHER is requested:

**(a)** to assess the new results of the INIA model, in particular, the differences between the total eutrophication risk and the risk without phosphate-based detergents;

**(b)** to comment whether or not the results of the updated model following validation and recalibration (in combination with the other information readily available to SCHER) indicate that the use of phosphates in detergents contributes significantly to the eutrophication risk at the European level.

**(4)** Overall, SCHER is requested to conclude whether all relevant aspects of the eutrophication process are sufficiently covered by the validated INIA report. Did the further research improve the soundness of the required assumptions and default parameters which may be needed to improve the predictive capacity of the model and its applicability?

### **3. OPINION**

#### **3.1. Question 1**

*SCHER is requested to comment whether the scientific quality of the report has been significantly improved following the validation exercise and whether the characterization of the risk from eutrophication due to detergents can now be regarded as satisfactory.*

In its opinion on the first version of the INIA/Green Planet model, the SCHER concluded that although the developed model can be regarded as a novel tool to assess, in a quantitative manner, the risks of eutrophication due to phosphorus release, the committee did express a number of concerns (SCHER, 2007) of which the major ones were:

- The limited database - which may not be representative of European lakes -

used to develop the model;

- The limited database used for the validation of the developed approach.

The SCHER recognizes that the revised INIA/Green Planet report (INIA, 2009) – which SCHER is requested to comment upon – has addressed these concerns by considerably extending the databases used for both the model development and validation. The number of data points used for model development, for example, has increased from about 300 to 2600. The SCHER commends these significant changes and is of the opinion that in quantitative terms the databases can now be considered as sufficient to allow performing the envisaged goals. However, the SCHER has concerns about the quality of the new data introduced in the model development and validation. The term ‘quality’, as used here, refers to the representativeness of the data for European waters (e.g. lake types, depth types ...) and to the clarity of the sampling protocol used. These concerns are mainly based on the fact that SCHER was unable to check how representative the new data were for pan-European surface waters. Indeed, detailed evaluation of these data - taken from WFD database – was not presented in the report and also not made available to SCHER (after inquiry). The SCHER is of the opinion that this possible weakness concerning data quality (e.g. EU relevance) may substantially influence the results of the model application. The SCHER thus concludes that if it can be demonstrated that databases used in the model are also adequate in terms of data quality, the risk of eutrophication due to detergents at a generic pan-European level can be assessed in a satisfactory manner using the model presented in the INIA/Green Planet report (2009).

*More specifically, SCHER is requested to comment:*

**(a)** *whether there was sufficient consideration and use of the available data, obtained within the inter-calibration process of WFD implementation (b) the new database of the updated model is sufficiently representative of European lakes;*

(a)The SCHER recognizes that considerable efforts were made to obtain new data to enlarge the databases used for model development and validation. The majority of these originated from the data obtained within the inter-calibration process of the WFD implementation. The original data set used in the INIA/Green Planet report (2007) was merged with the new data in a satisfactory manner.

(b) As mentioned above, it is the opinion of SCHER that the WFD data used in the INIA model was insufficiently documented in the report (e.g. lake characteristics, sampling period) to allow independent review and evaluation of the quality/relevance of the data for the envisaged purpose; i.e. characterization/modeling of the pan-European eutrophication risk due to detergents.

**(b)** *whether the use of ecotypes/eco-regions was efficient in order to properly describe the eutrophication risk at the regional level in the EU. Does SCHER agree with the conclusion of INIA analysis that both JRC and INIA databases were complementary in particular with regard to the approach of classification for the status G- or G+, and that the inclusion of the INIA database was required to ensure average coverage of the Mediterranean ecoregion*

The SCHER is of the opinion that combining the concepts of ecotypes and eco-regions, i. e. using different lake typologies in different European regions, is an appropriate approach in order to give a representative picture of European lakes.

However, the SCHER would like to express concerns about the following issues.

In the updated INIA/Green Planet (2009) database, the lake typology is not always described in a consistent and transparent manner (e.g. Mediterranean, Northern (macrophyte)). In addition, when the typology information is reported, the lake selection does not seem representative of pan-European lake typologies. For example (a) in Nordic and Baltic ecoregions the majority (1341 out of 1523) are shallow or very shallow lakes

and (b) in the Mediterranean ecoregion most (71 out of 90) lakes are reservoirs. The response to eutrophication of reservoirs is not comparable with that of natural lakes.

The JRC database can be considered as complementary to the first INIA database in terms of European ecoregions covered. However, as mentioned above, the information provided is not sufficient for judging if the complete database is representative of the European situation as far as the status G- or G+ is concerned.

In the JRC database the Mediterranean ecoregion is poorly represented, so, the inclusion of the original INIA database was required to ensure the coverage. However, as mentioned above, the representativeness of Mediterranean lakes in terms of typology is controversial.

*(c) whether sufficient data were used for the validation of the developed approach and whether the reliability of the model is scientifically sound.*

The validation of a model is correct if the model can be applied in another situation without essentially changing the model. SCHER is of the opinion that to perform a validation in this sense, a sufficient amount of independent data was taken into account by combining the original INIA data set with the JRC data set. The additional separate analysis with the Baltic and Danube data also confirm the correctness of the validation.

It should be recognized that the INIA-model is essentially a statistical (probabilistic) model that does not relate directly to physical-chemical causal relationship. In this context, a larger data set will give more reliable results provided the input data (databases) are representative and of good quality. The SCHER supports the modelling approach used in the INIA/Green Planet report (2009) but has concerns about the quality of the input data.

*(d) whether:*

*- the mathematical-statistical description of the risk calculation approach is scientifically sound;*

The idea to evaluate a measure of risk of eutrophication by considering cumulative distribution curves of lakes in G+ status versus lakes in G-, both over total phosphorus (TP), is a scientifically sound approach. The SCHER notes that these curves are clearly separated for different ecoregions and ecotypes. The true cumulative fraction of lakes with a TP below a certain value is between these extremes, but otherwise unknown. Therefore effects of different phosphorus scenarios can only be evaluated between certain ranges. The INIA approach does not attempt to estimate the risk of lakes to be in one eutrophication state or another. Instead, they estimate the effect (as a range) of different phosphorus scenarios on the cumulative fraction of lakes at the TP levels addressed. The SCHER is of the opinion, that calling these effects 'total risk' and 'risk without P-based detergents' can be easily misinterpreted as quantitative risks of eutrophication. Similar concerns are expressed in a recent analysis by Quo Data (Uhlir et al, 2009) Nevertheless, the SCHER is of the opinion that the mathematical-statistical description of the effect of the TP scenarios is scientifically sound.

The SCHER suggests that it is possible, however, to extend the methods applied in the INIA report, to risk measures addressing the likelihood of G+ versus G- lakes, based on the same data, and evaluate relative TP contribution on these risks. The SCHER is of the opinion that this line is useful to pursue.

*- the calculated risk figures can be interpreted as an empirical probability;*

The conditional distributions of the cumulative fraction of lakes of either type below any given TP value can be interpreted as empirical probabilities, as they are fitted to empirical distributions (see *earlier remarks on representative samples*). The INIA report did not attempt to estimate the true fraction of lakes in G+ versus G- status, so the empirical fraction of eutrophication status is not addressed. As the effects of phosphorus



scenarios are evaluated as ranges of reduction of cumulative fractions of lakes, these can be interpreted as ranges of empirical probabilities and as such are useful for evaluating eutrophication.

*- the calculation method for the probability is statistically sound and consistent;*

The calculation method of the conditional cumulative distribution function for the two classes of lakes is statistically sound and consistent. The effect of the partitioning on differences in these curves is clearly explained and evaluated in the INIA report. The SCHER is of the opinion that the calculations can be checked and are reproducible.

*- the Bayesian approach has been correctly applied;*

As the fraction of lakes in either of the states, according to the INIA report, is not known, a Bayesian analysis was not carried out in the INIA report. However, the data and emphasis on conditional distributions of classes of lakes in two states (G+ and G-) would allow for a Bayesian approach. The SCHER is of the opinion that this would be worthwhile to carry out in a follow-up study, in order to evaluate eutrophication risks from a Bayesian standpoint, and compare the results to the results in the INIA report.

*- the calculation method of risk differences due to a given scenario is statistically sound and consistent.*

As explained in the previous points, the calculated risk differences due to given scenarios are consistently calculated and reproducible. These differences can be interpreted as a ranking of the contribution of different TP loading sources, or activities. They cannot be interpreted as true risk values, as no attempt is made to estimate the risk of a lake to be in good status or not as a result of these scenarios. The SCHER is of the opinion that this could be attempted using the same data, and with the same lake status distribution fits. Although the SCHER expects that the relative contribution of, say L&D detergent sources, will be comparable to the present analysis, the committee recommends that a Bayesian analysis of eutrophication risk is carried out.

### **3.2. Question 2**

*SCHER is requested to assess whether the updated INIA report evaluated the findings of DRB and Baltic Sea studies in order to:*

*(a) consider additional factors playing role in eutrophication process,*

The model as applied by INIA/ Green Planet was developed to answer the eutrophication question at a pan-European level. The SCHER recognizes that the model performs well for this purpose. SCHER is not convinced of the usefulness of this model at the more regional level and local level of the Danube and Baltic Sea as these are completely different types of water bodies than the lake data for which the INIA model was developed.

The models and results obtained in the DRB and Baltic Sea studies are using more detailed information to describe the eutrophication process depending on a wider range of processes and influencing variables than the INIA/ Green Planet study. In the INIA/ Green Planet study this difference has been recognized but was not further developed because it was outside the remit of the investigation.

*(b) clarify the eutrophication process in marine waters as provided by these studies*

In the opinion of SCHER, it was not the intention of the INIA/Green Planet model to take into account the different factors playing a role in the eutrophication process of marine waters. The DRB and Baltic Sea data were taken as an example to compare the results with those obtained in the original INIA-report.

*(c) comment on the updated risk estimations for laundry and dishwashing detergents provided for the Danube, Ebro and Tajo Rivers based on monitoring data*

As indicated in section 2a, the SCHER is of the opinion that the model cannot be applied for the assessment of eutrophication risk at the regional and local level. As such the risk estimations for laundry and dishwashing detergents for the Danube, Ebro and Tajo rivers cannot be used. .

### **3.3. Question 3**

*SCHER is requested:*

*(a) to assess the new results of the INIA model, in particular, the differences between the total eutrophication risk and the risk without phosphate-based detergents;*

The differences between the total eutrophication risk and the risk without phosphate-based detergents depend on the contribution of detergent phosphate to TP load.

SCHER does want to emphasize that in the INIA/ Green Planet report, the estimation of the phosphorus contribution from different sources is calculated from EU-27 data, including many countries where detergent phosphorus has been already banned or controlled up to very low levels. As such, the use of these data for the calculation led to the conclusion that at the pan-EU continental level, the reduction of risk due to elimination of detergent phosphorus is low.

It should be clear that if only data are used from countries where detergent phosphorus is still used, the detergent phosphorus contribution may be much greater leading to different estimations of risk.

Recognizing these limitations summarized above, the SCHER is of the opinion that the INIA approach is appropriate for assessing the differences between the total eutrophication risk and the risk without detergent at the pan-European level only.

*(b) to comment whether or not the results of the updated model following validation and recalibration (in combination with the other information readily available to SCHER) indicate that the use of phosphates in detergents contributes significantly to the eutrophication risk at the European level*

Overall, the results of model indicate that, at the present time, at pan-European scale the contribution of the P-based detergents is not playing a major role in the eutrophication process. However, in coming to this conclusion it is the opinion of SCHER that it is important to be aware of all the reservations about the quality data used in the report that have been stated above.

### **3.4. Question 4**

*Overall, SCHER is requested to conclude whether all relevant aspects of the eutrophication process are sufficiently covered by the validated INIA report. Did the further research improve the soundness of the required assumptions and default parameters which may be needed to improve the predictive capacity of the model and its applicability?*

The SCHER is of the opinion that the validated INIA/Green Planet (2009) report has – in comparison with the previous INIA/ Green Planet study (2007) – considerably improved in terms of the assumptions and default values used and in terms of the quantity of data used for the development and validation of the model. As indicated, the SCHER has concerns on the quality and relevance (for this purpose) of the extended database. Provided these concerns can be addressed and the extended database is deemed representative for EU lakes, the SCHER is of the opinion that the approach can be used to assess the risk of eutrophication due to P-based detergents in a generic manner at the pan-European level. The SCHER is of the opinion that the relevant generic aspects of the

eutrophication process are included in the new model. The SCHER would like to emphasize that the model can be considered as satisfactory only for its intended use: i.e. the characterization of the risk from eutrophication due to P-based detergents. As such the model should be considered as a generic Tier I assessment tool and should not be used for country/region-specific or local assessments. It is the opinion of SCHER that at these levels a number of other processes need to be considered to allow a reliable eutrophication (risk) assessment. The models developed for the Danube and the Baltic region, for example, demonstrate the complex nature of eutrophication and the types of processes which need to be accounted for.

The SCHER agrees with the changes made to the assumptions and default parameters as both types of information are now supported by sufficient scientific evidence. The model has also considerably improved in the size and geographic coverage of the surface water data used to develop, re-calibrate and validate the model. The SCHER is of the opinion that this modelling approach may be considered appropriate for the envisaged purpose. However, considering its concern expressed above relating to the inability to check the relevance/ quality of the extended database, the SCHER is not able to comment on its improved predictive capacity. The SCHER would like to emphasize – once more – that the applicability of model, provided the data relevance/quality issues are resolved, is limited to its intended use, i.e. a pan-European generic assessment of the risk of eutrophication due to detergents.

#### **4. LIST OF ABBREVIATIONS**

DRB	Danube River Basin
G-	Less than good status
G+	Good status
JRC	Joint Research Centre
L&D	Laundry and Dishwashing
TP	Total Phosphorus
WFD	Water Framework Directive

#### **5. REFERENCES**

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INIA/Green Planet (2009) Development of an European Quantitative Eutrophication Risk Assessment of Polyphosphates in Detergents – Model Validation Using the WFD Intercalibration Data, Model Re-Calibration and Pan-European Assessment of the Eutrophication Risk Associated to the Use of Phosphates in Detergents; by B M de Madariaga, M J Ramos and J V Tarazona