

NORMAN Working Group on Prioritisation of emerging substances

WG Mandate and Workplan for 2009

I. Introduction / background

According to the current definitions published on the NORMAN website (Glossary of Terms), the terms “Emerging Substances” and “Emerging Pollutants” are defined as follows:

Emerging substance:

A substance that has been detected in the environment, but which is currently not included in routine monitoring programmes at the European level and whose fate, behaviour and (eco)toxicological effects are not well understood

Emerging pollutant:

A substance currently not included in routine environmental monitoring programmes at the European level and which may be candidate for future legislation due to its adverse effects and / or persistency.

An additional definition found in a recent publication (R. Hoenike et al., Environmental Research 105 (2007) 132 – 144) states that ‘emerging pollutants’ are:

‘...synthetic organic compounds or manufactured natural compounds where growing evidence suggests that adverse effects at environmentally relevant concentrations could occur but whose environmental releases are not regulated, and which are not routinely screened for their presence in environmental matrices’

Based on these definitions, the NORMAN network has produced a list of “frequently discussed emerging substances” which forms the basis of all NORMAN network activities. The current list consists of more than 400 compounds. The list is ever-growing as a result of its yearly update. Obviously, it is not possible to pay the same attention to all substances. One of the key tasks of the NORMAN Working Group on Prioritisation is therefore to define criteria for prioritisation of emerging substances (including, where applicable, the possible reduction of the number of substances on the list).

Existing prioritisation methodologies (e.g. already (Fraunhofer Institute, 1999), (OSPAR Commission, 2000), (INERIS, 2008), (UK Environment Agency, 2007) and other relevant documents identified by the WG) will be the starting point of the NORMAN WG on Prioritisation.

However, in most of the existing prioritisation methodologies the lack of knowledge / data / information, which is by default the most common situation for “Emerging Substances” and “Emerging Pollutants”, is used as a justification not to prioritise a substance. Several compounds have therefore already been identified as substances of interest, but they have not been put forward for EQS development or any other priority action due to the need for further information.

It is therefore felt necessary to define a prioritisation methodology (common criteria for prioritisation) specifically addressed to emerging substances.

II. Mandate for the WG

II.1.Update of the NORMAN list of emerging substances

The current list of NORMAN emerging substances should be the starting basis of the exercise. As part of this exercise this list should be updated, that is, new substances could be added to, or deleted from the existing list according to the definition of emerging substances agreed by NORMAN.

It should be reminded that the identification of emerging substances and therefore the scope of the activities of this WG should cover all environmental compartments. Moreover, it should be stressed that substances already regulated at the EU level are not considered to be “emerging”. As a result, one of the sub-activities of this WG should be to prepare a list of chemicals that can be considered as “regulated substances”.

II.2.Definition of common criteria for prioritisation of emerging substances

Preliminary draft plan for setting up prioritisation criteria

The prioritisation approach involves an assessment of:

- the potential environmental exposure of a chemical;
- its hazardous properties.

Exposure assessment

Ideally the exposure to a substance would be determined on the basis of monitoring data indicating presence/absence of the substance in the environment in one / several countries. However, monitoring data are limited or nonexistent for many chemicals. The WG will therefore consider, as part of the exposure assessment methodology, the use of modelling approaches with fixed settings, including: data on physical-chemical properties and persistence of substances, and data on their consumption and usage, representative for the EU or parts of the EU.

The WG should look in particular into aspects related to accepted level of quality and representativeness of the data to be used in the prioritisation process (including, minimum information needed to consider the information valid, minimum frequency of observation in different countries to consider the information relevant, type of data (e.g. max, annual average), type of sites (e.g. diffuse / point sources), when and how to use consumption and usage data and limitations associated with these data, which are often old or not reliable, representative, etc.)

Hazard assessment

Hazard data should include impacts on terrestrial and aquatic life, and also address human health considerations.

As an example for the aquatic environment (water column, sediment and secondary poisoning) the hazard data considered should include:

- Persistence – half lives in water and sediment and ready biodegradability
- Bioaccumulation – log Kow and Bioconcentration Factor (BCF) values in aquatic biota (as we are dealing with large numbers of chemicals, we could use general predictive methods for estimation of Kow (for instance: EPIsuite/EPIwin software), BCF and Biodegradation)
- Toxicity – acute and chronic toxicity to aquatic organisms and endocrine disrupting potential

As regards toxicity data, the WG should look in particular into the aspects related to the type of (eco)toxicity tests to be considered, how to take into account the results of new tests – novel endpoints - (the results of traditional tests being often not sufficient for emerging substances) / how to deal with uncertainty (e.g. in the derivation of P-PNEC) / how to use existing EQS and PNECs, how to use QSAR when no or insufficient information is available on (eco)toxicity. A separate activity will therefore be needed to generate predictive models for (eco)toxicity.

Fugacity modelling

The inclusion of fugacity modelling as part of the overall prioritisation process should be assessed by the WG (see also above – Exposure assessment). These models predict the distribution of a chemical in the environment and can therefore be used to help identify the environmental medium (water, sediment, soil, air) in which a chemical is most likely to be found.

II.3.Application of the ranking process to the NORMAN list of emerging substances

Once the criteria are established the NORMAN substances will undergo the process of priority ranking. The outcome of such ranking should give a clear guidance about how individual substances should be dealt with, for example, should they be taken forward for EQS development, should additional data be obtained, should more powerful analytical methods be developed, should additional research be conducted, etc.

In practice, based on this new prioritisation methodology it should be possible to identify among the emerging substances:

- The emerging Substances for which there is already sufficient evidence (sufficient information) to justify priority action
- The emerging substances that appear to be present in the environment, but for which further research is needed (evidence needed) on their effects on the ecosystems and human health
- The emerging substances for which there is evidence of hazard but for which analytical capabilities are not yet satisfactory (need for methods development, or validation or harmonisation)

- The emerging substances to be reconsidered (safety net): the objective is to avoid excluding them incorrectly. A safety net can in this case be advised in order to consider in more detail:
 - Combined effects of minor pollution sources
 - Trends which may indicate increasing importance of the pollutant
 - Presence of pollutants with similar mode of toxic action and potentially additive / synergistic effects
- The emerging substances that can be considered for second priority action, etc.

Review

The prioritisation approach should incorporate a process for reviewing the priority ranking at regular intervals.

III. Workplan / Roadmap for 2009

<i>Task</i>	<i>Timeline</i>
Approval of the mandate and list of participants in the drafting group	
Collection of the most relevant documents for prioritisation from the members of the Working Group	<i>T0 + 1 month</i>
Circulation of the current list of emerging substances (NORMAN list) among the members of the WG (+ all NORMAN Contact Points) in order to: <ul style="list-style-type: none"> - Check what new¹ substances should be added to the list and what existing substances should be deleted (based on expert judgement) - Collect, for each of the substances on the existing list, preliminary information about the specific items listed below (see proposed items / questions in the Annex below – Section VII). The objective of this first exercise is to update the NORMAN list of emerging substances and to have preliminary feedback on how the current list of emerging substances respond to possible prioritisation criteria.	<i>T0 + 3 months (including collection of feedback)</i>
Based on the results of this exercise, preparation of the first draft of the list of prioritisation criteria and prioritisation methodology (further to allocation of tasks among the participants in the drafting group)	First draft by October 2009
Finalisation of the prioritisation methodology	Final doc by Dec 2009

¹ Possible sources for the identification of new candidate substances:

- Existing monitoring programmes
- Results of research studies
- National or regional priority lists
- Other data sources (e.g. pesticides of possible relevance, Annex III of the “EQS Directive” Directive 2008/105/EC, etc.)

Application of the Ranking process	First draft ranking by Dec 2009
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IV. Organisation of the work

Co-ordination: INERIS

Working Group: max 10-15 parties

Travelling costs for participation in the meetings can be reimbursed by NORMAN (based on the available budget of 5000€)

Most of the work / exchanges will be organised via e-mail and teleconferences in order to reduce travelling costs.

Two meetings can be organised in 2009:

1. 1st meeting of the WG (Brussels, or Paris) after completion of the Questionnaire: to discuss the results and first discussion about draft prioritisation methodology.
2. 2nd meeting (probably November 2009) to discuss the methodology before finalisation of the document.

V. Deliverables for 2009

- Prioritisation methodology (final doc)
- Results of the first round ranking exercise on the list of NORMAN substances

Refining of the methodology and regular updating of the information / methodology will remain as a task for 2010 and the workplan of the WG will be updated accordingly.

VI. List of participants

Drafting Group:

<i>Name</i>	<i>Organisation</i>
Valeria Dulio	INERIS - FR
Jaroslav Slobdnik	EI/WRI – SK
Peter von der Ohe	UFZ – GE
Willie Peijnenburg	RIVM – NL
Christian Goetz	EAWAG – CH
Eva Brostrom	IVL - SE
Heinz RUEDEL	Fraunhofer Institute - GE

Marina COQUERY	Cemagref – FR
Michiel Kotterman	WUR - NL
Patrick Roose	MUMM – BE
Stefano Polesello	CNR-IRSA – IT
Anja Derksen	Aquasense – NL
Jonathan Moore	NPL - UK

Observers:

<i>Name</i>	<i>Organisation</i>
Dean Leverett (to be confirmed)	UKEA – UK
Vera Ocenaskova	T.G.M – SK
Valérie INGRAND	VEOLIA - FR
Maria de Fatima Alpendurada	IAREN - PT
Pirjo Sainio	SYKE - FI
Anne Christine LE GALL	INERIS - FR
Pierre-François STAUB	ONEMA - FR

VII. ANNEX: Specific questions to be addressed for the update of the list of NORMAN emerging substances

Exposure assessment

Monitoring information assessment

1. Was the substance detected in any media in your country/river basin/other (Y/N/Not known)
2. If Y, which one (Water/Sediment/SPM/Biota/Soil/Air/Other)
3. If Y, what was the concentration (range min-max and no. of positive measurements above LOD)
4. Is the substance officially part of national / regional priority lists (e.g. list of Other Pollutants (river basin specific pollutants) in your country/river basin) (Y/N/Not known)
5. Is the EQS or PNEC available (Y/N/Not known)
6. If Y, report threshold value + unit
7. How the EQS or PNEC were derived (brief method description)
8. Is the EQS reliable (Y/N/Not known)?

Use assessment

1. How much of the substance is used annually in your country/river basin/other (Number/Not known)
2. What is the use pattern (Is the substance used in agriculture (indoor, outdoor), urban areas (indoor, outdoor) or in an industrial process (controlled system, isolated intermediate)? What is the function of the substance?

Analytical methods available

1. Do you judge that the analytical methods available provide **satisfactory performance** at the level of concentrations to be analysed in the relevant environmental matrices? (Y/N/ not known)
2. What is the LOD or LOQ of the available analytical methods for this substance in the relevant environmental matrices?
3. Are validated methods available (Y/N/Not known)?
4. If Y, what is level of validation according to NORMAN approach (V1 – research lab validation; V2 – expert lab validation; V3 – routine lab validation)? (V1/V2/V3, Not Known)

Hazard assessment

1. Is the compound classified as persistent (Y/N/Not known)
2. If Y, what is the half-life in water (in days/not known) and in which type of water (fresh/marine)
3. If Y, what is the half-life in sediment (in days/not known) and in which type of sediment (fresh/marine)
4. If Y, other criteria for persistence

5. Is the compound classified as bioaccumulative (Y/N/Not known)
6. If Y, what is the bioconcentration factor (BCF) (Number/Not known)
7. If Y, what is the Log Kow (Number/Not known)

8. Is the compound classified as toxic (Y/N/Not known)

9. If Y, what are the L(E)C50 acute test result for the three trophic levels (Number/Not known)
10. If Y, what are the chronic NOEC test result for the three trophic levels (Number/Not known)
11. Are there data available for "novel endpoints"?
12. Is the substance suspected or known to have endocrine disrupting effects (Y/N/Not known)
13. If Y, what is the classification of the substance according to the BKH (2000) report² or the SEC(2004) 1372 report³ of the EU Commission?

Existing evaluations and regulatory information

1. Are there existing evaluations available for this substance (e.g. substance identified as PBT or vPvB substance⁴, classification under Pesticides Dir. 91/414/Ec, classification under Dangerous Substances Dir. 76/464/EC, Risk Assessment Report finalised or on going under ESR, etc.) (Y/N)?
2. If Y, cite the reference (Number/Not known)
3. R-Phrase and labelling`?
4. Risk reduction/mitigation measures?

² Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption - preparation of a candidate list of substances as a basis for priority setting. FINAL REPORT (Incorporating corrigenda to final report dated 21 June 2000). M0355008/1786Q/10/11/00

³ Commission Staff Working Document on implementation of the Community Strategy for Endocrine Disrupters - a range of substances suspected of interfering with the hormone systems of humans and wildlife (COM (1999) 706)

⁴According to "Status report for the 13th Joint Meeting of the Competent Authorities for the Implementation of Council Directive 67/548/EEC (New Substances) and Council Regulation (EEC) 793/93 (Existing Substances)"