

## Meeting report

This report was prepared by the chair of the Planning Committee Gunnar Bengtsson and reviewed by the Committee as a whole. The report is a compilation of arguments for further discussions. It is structured according to the expectations for the meeting as presented by the chair in the informal introduction:

- Improved contacts northern-southern Europe
- Ideas to support the implementation and development of the Barcelona and Helsinki conventions
- Discuss the marine risk assessment part of the EU Technical Guidance Document
- Identify future research needs and relation to the EU 6th Framework Research Program.

The documentation from the meeting is available on [www.kemi.se](http://www.kemi.se). The meeting was sponsored by the Spanish and Swedish Ministries of the Environment, the MISTRA NewS research programme and the Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria (INIA).

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## ***Introduction***

The sound management of hazardous chemicals has attracted increasing attention in the European Union in recent years. The EU Commission is expected to present a Regulation with proposals for measures concerning chemicals by the end of 2002. This reflects the concern about potentially harmful effects of chemicals, and about the slow progress over the last decade in assessing and managing the risks. The toxic substances to be managed include those released to the marine environment. The Policy Forum brought together three aspects on the marine risk assessment and risk management of chemicals.

1. The Commission is expected to adopt a Revised Technical Guidance Document detailing the assessment of marine risks of chemicals. The document has generated some controversy.
2. Such risks are also dealt with in the Barcelona Convention to protect the Mediterranean Sea and the Helsinki Convention to protect the Baltic.
3. The pollution of the Baltic by hazardous substances has been the subject of a major Swedish research program entitled "A New Strategy for the Risk Management of Chemicals", with the acronym NewS.

The Policy Forum is an integral part of the NewS program, as explained at the end of this report. It intends to bring together decision makers, researchers and other stakeholders from different countries to improve the dialogue on issues relevant for chemical safety strategies.

The expectations for the meeting were addressed as follows.

### ***Expectation 1: Improved contacts northern-southern Europe***

The meeting brought together around 50 participants with a range of competences and interests. The majority came from Spain and Sweden. Additional participants were from Canada, Estonia, Finland, Norway, Poland, the United Kingdom and the United States of America. Most participants were from the research community but also ministries, authorities, industry and environmental non-governmental organisations were represented. International organisations represented were the European Commission (DG Environment and DG Joint Research Centre, Ispra), the European Environment Agency, the Helsinki Commission and the United Nations Environment Program that has the Secretariat for the Barcelona Convention.

About 20 presentations dominated by Spanish and Swedish contributions were made at the 2-day meeting. These included presentations of 3 specially prepared background documents. Discussions in the meeting were very intense reflecting the broad competence of the audience. A poster session with a dozen posters drew large participation. A reception and a dinner provided further opportunities for informal discussions. There were thus many opportunities to improve contacts between Scandinavia and Spain, but also to bring scientists and policymakers together.

### ***Expectation 2: Ideas to support the implementation and development of the two conventions***

All background papers presented valuable information for the understanding of the characteristics of the two seas, contamination levels and their effects, and the actions for improvement. Furthermore, two presentations dealt with the pollution situation, one with the effects in the field and four on methodology that also included references to effects. As a

general conclusion, there are still significant gaps in the knowledge and much more research is needed. It is clear, however, that contamination levels are high enough to cause effects on biota, for instance increased ratio male/female fish embryos near a pulp mill and clear gradients in catalase activity in mixed zooplankton from rivers and cities towards the open sea. Some contaminants have decreased significantly, and this decrease has been associated with improved fish health in the pulp mill case. PCB levels decreased strongly during the 70s and 80s but have now levelled out. Concentrations of some other pollutants still increase, e.g. lead in the Mediterranean.

Effects on reproduction/sexual development in fish and invertebrates in the Baltic Sea are seen in several other cases as well. This is one of the primary research objectives of the NewS research programme.

Many interventions following the presentations and during the discussions called for information that is better adjusted for an efficient management and prioritisation of chemicals in the marine environment. Reliable information on levels and effects of contaminants is still lacking in many cases. A central issue concerns the commitment of governments to fund studies and counter measures. Follow-up studies on implementation of action plans were recommended as effective tools to enhance the likelihood that agreed improvement targets are really reached.

### ***Links between chemicals policy in the EU and the conventions***

Two presentations dealt specifically with EU chemicals policy, with focus on the new policy expressed in the 2001 White Paper (Strategy for a future Chemicals Policy, Commission Of The European Communities, Brussels, 27.2.2001, COM(2001) 88 final). The relation to the conventions was extensively discussed.

The conventions were first developed several decades ago when the European Community was much smaller than today and with much less competence in the environmental field. Their relative importance was thus larger. Today four of the Helsinki Convention states are EU members and four are accession countries; only Russia with a fairly small coastline has weaker ties to the Union. Environmental measures in the Union will therefore have a strong impact on the Baltic.

Four of the Barcelona Convention states are EU members and a few more are accession states. The Commission itself has also signed and ratified most of the protocols. Furthermore, the EU states are responsible for around  $\frac{3}{4}$  of the Mediterranean pollution. EU actions will therefore clearly have a strong influence on at least the western Mediterranean. They will also be informed by most of the research that has been performed for the Mediterranean levels and effects; only Egypt and Turkey have research programs approaching those of the EU members.

On the other hand, most of the 20 states in the east and south are not EU related. The economies are weaker and there are politically contentious regions such as Cyprus, Israel and the Mahgreb. Naturally, because of the political and socio-economic situation in these countries, chemical hazards will tend to have lower priority. The importance of these countries with respect to the Mediterranean pollution situation is of unclear magnitude and the progress is difficult to assess.

EU chemicals policies have been being developed in major policy areas, for instance the water framework directive and the 6<sup>th</sup> environmental action program. They are also now being developed for other areas, e.g.

- the thematic strategy for pesticides related to e.g. agricultural policy and to the Water Framework Directive
- the emerging marine strategy encompassing marine contamination and related to e.g. fisheries and transport..

The chemicals work also relates to sustainable development actions such as Baltic 21 and the Sustainable development for the Mediterranean. There are thus strong driving forces within the EU supporting the aims of the conventions.

Two opposing arguments can be made for the future relation EU-conventions. According to one line, the convention on reform of the EU calls for concentration of common work to the core areas for the Union. Other work could be left to regional agreements.

The other line would emphasise that EU efforts would be strong even without the conventions which represent duplication of efforts and inefficient use of scarce resources including available experts.

### ***Too many conventions?***

There is a large range of instruments dealing with hazardous substances in addition to the Helsinki and Barcelona conventions, including the regional convention on long-range transport (LRTAP), the OSPAR convention for the protection of the North-East Atlantic, the EU Water framework directive, the 6<sup>th</sup> Environmental Action Program, the Integrated Pollution Prevention and Control directive IPPC, and the Stockholm convention on persistent organic pollutants POPs. The need for all of these instruments was challenged. Sometimes countries are accused of “Convention shopping”: when they have a pet substance for which they want action, they look around for the instrument that seems to offer the easiest way. Also it is a recognised problem that the same country votes differently in different deciding bodies.

On the other hand, regions may have different needs and special instruments and actions are thus justified. In particular, actions on an emerging issue can easier be initiated on the smaller regional scale. Regional conventions can thus be mutually supportive with EU efforts.

It was suggested that across-the-board changes in instrument structure, such as merging or terminating conventions, may be very difficult to achieve. Instead case-by case attempts at coordination may be easier to implement. An example is the exercise to select priority substances called DYNAMEC that was feeding into the Water Framework Directive as well as OSPAR and HELCOM work. In relation to the LRTAP convention, it has been argued that lacking coherence may depend on the individual experts. One will thus try to bring together experts representing the different instruments to improve the situation

### ***Can the proposed new chemicals policy for industrial chemicals be implemented?***

One of the presentations on the new chemicals policy specifically called for simplifications in risk assessments, and for research on uncertainty treatment and preventive risk assessment. The development was characterised as going from previous unknown and complex assessment via present known and complex to future known and simple. In particular, cost reductions are now being addressed for low production volume chemicals, where assessment costs may be a large share of the total production costs.

The quest for simplicity was challenged:

- The real world is complex and assessments could well be based on complex models as long as they are simple to use. It is important that scientists do not make the value judgments that are involved in simplifications; they belong to the role of political decision makers.
- Existing tests already represent far-reaching simplifications and assessments have large uncertainties. More selective and sensitive endpoints are needed, and hazards need to be identified better.
- The need to protect health and environment should be in focus, not protection of the test owners. Information sharing can reduce the arguments against extended testing.
- The total costs of testing according to the REACH model correspond to less than one-tenth of one year of EU chemical industry trade surplus.

Arguments supporting the need for simple assessments included the following:

- The international community as a whole has been capable of producing about 50 simplified assessments per year for high production volume chemicals; the new EU policy calls for around tenfold more similar assessments per year and later further about ten times more simpler assessments for low production volume chemicals, that is, many thousands annually. The burdens on testing and assessment capacity and on laboratory animals call for carefully optimised assessment programs; the NewS program has development of related tools as a central objective.
- In a broad perspective, the effects on environment and health are what matters. The assessment for each substance need not be accurate. Follow-up programs that monitor the success of remediation on a broader scale can supplement crude assessments and associated actions.
- Already the costs of the often used base-set of test results and other data are high. Administrations are asked to do their share of assessments or follow-up with fewer resources, and this calls for simplification rather than added complexity such as more tests. One need not look for the best but for what is good enough for the intended purpose.
- Communication calls for simplicity. Value judgements are always used in managing uncertainty; with complex models transparency becomes more difficult. Despite their disadvantages, simplified indicators are needed to enable communication with wider groups.

### ***Role of scientists, NGO and industry in policy development and implementation***

There is a strong principal interest in keeping risk assessment and risk management separate; this has for instance been emphasised in the Commission communication 2000 on the precautionary principle. The scientists should provide information, political decision makers decide on problem definition and acceptability. For instance, decisions on appropriate margins of safety and on what fraction of all species to protect are basically political in character, although always finally relying on the soundness and quality of the scientific information..

The clear division between science and policymaking is to a large extent an illusion in EU chemical safety work. Of 40 directives or regulations dealing with chemical safety, 30 require action based on the hazard classification of a substance. Then the classification decision becomes a risk management decision. This means that scientists discussing classification become risk managers, in violation of the desired principal separation. Actually, similar

overlaps between risk assessment and management often occur, and also involve risk communication.

One way of resolving this conflict is to identify a category in between, the representatives of which can be called “experts”. These often have scientific background but accept to go beyond their scientific proficiency and discuss judgments, such as the management of uncertainties. It is necessary that such experts take on many decisions to relieve the pressure on political decision makers. They are often recruited from the administrations. It should be clearly recognised that such experts cannot in that role appeal to any scientific prestige they may have in their narrower field of competence, and they should now and then declare that they are not speaking as scientists but as experts with limited competence over a broader area and exerting value judgments.

The conflict can be expected to appear less often in the new REACH system where more responsibility is put on industry to perform hazard and risk assessment. The experts then involved can be expected to have their own biases. It is important then that the process of assessment is transparent and open to criticism.

Non-governmental public interest organisations have an important role to advocate transparency and facilitate communication with non-scientist target groups. They often enjoy a high credibility and trust. They are also often close to consumers, and there is a tendency that environmental organisations work with retailers as a conduit to chemicals manufacturers and downstream users of chemicals.

Decisions under uncertainty abound for hazardous chemicals. For good risk assessment, management and communication, it is essential to promote dialogue between different stakeholders, as the Policy Forum intends to do. For instance, this means that scientists should

- stand up to explain their results and their uncertainties and have the courage to defend them although always risking criticism from the scientific community.
- feel an obligation to try to understand how their results could be used by society at large
- be sensitive to requests from the policymaker although the scientific issues many times are felt as “trivial”.
- respect that decisions may be needed now rather than after considerably more research
- make efforts for early communication of new results to non-governmental organisations to facilitate their task of further communication outside of scientific circles; this obligation must however be balanced against the requirement for scientific quality as promoted by scientific publication or peer review. Indeed, scientists face a difficult challenge when they discover early signals of hazard or risk, that are far from qualifying for incorporation into the scientific corpus discussed below under Expectation 3. The question was raised, but not answered: Who has the responsibility to promote safety in the case of such early and uncertain signals? The NewS program will address the issues of weak early signals.

A compromise between the need of simplification and the requirement to address complex systems could be the development of tools that could be complex in nature, but simple to use. The development of interfaces for the input of data and the output of the results, plus a parallel description of processes involved in the selection and validation of the scientific concepts included in the tool, would allow the interpretation and communication of the uncertainty associated to the risk assessment process.

### ***Expectation 3: Discuss EU TGD marine risk assessment***

The draft Technical Guidance Document TGD was presented. It proposes a simplified assessment for substances that are strongly persistent and bioaccumulating, with some account taken of toxicity (PBT and VPVB assessment). This has been very controversial. Two main concerns have been discussed. First, the inclusion in a guidance on risk assessment of a decision based on hazard identification which obviously is not a risk assessment; second, the consideration that the specific criteria used in the PBT approach, as well as some of the proposals for conducting the risk assessment in the local and regional scenarios are not scientifically acceptable, as indicated by the CSTEE. In two presentations a whole range of problems with the proposed scientific application of the approach were presented, and a general presentation dealt with approaches to precautionary action. In that presentation, short-circuiting the slow development of a scientific “corpus” of knowledge was advocated. The corpus is the evidence that is certain enough to be entered in a textbook without qualifying references. Short-circuiting would mean that tentative assessment based on early information were brought into the discussion on countermeasures.

In the discussion it was argued that the precautionary thoughts behind the PBT approach did not belong in risk assessment but rather in risk management, but the approach could also be used for hazard identification, which instead of for adopting a final decision as suggested in the draft TGD, could be used for targeting the risk assessment. Such an approach might be reasonable only if there were no possibility of a traditional scientific risk assessment. Some participants expressed that, as demonstrated during the Policy Forum, the capability of the scientific community for offering sound risk assessments for the marine environment is in reality much higher than that considered in the draft TGD proposal. On the other hand, it was also maintained in the discussion that the uncertainty in traditional assessments sometimes is so high that they are not useful, and that early action based on science with lesser degree of evidence would enable actions to be taken at an early stage. In line with the conclusions from Policy Forum 1, such actions should be selected among a whole range of alternatives, and weaker evidence would speak for less stringent actions; these should be reconsidered when stronger evidence emerges. Provision of such evidence was proposed to be a natural duty for industry. The extent and irreversibility of consequences would modulate the stringency of early actions. Tiered approaches would enhance the flexibility. As examples of uncertainties metabolites were discussed; these are dealt with in pesticide assessments but not in the TGD. The utility of including reactivity in assessments was stressed.

There was thus a rich discussion on the TGD for marine risk assessment, and it was clear that the balances between precautionary preventive action and action based on more extensive evidence need to be further explored.

### ***Expectation 4: Identify future research needs and relation to EU 6th Framework Research Programme***

Many research needs were identified as reported under Expectations 2 and 3. Also quality assured data compilations are needed for the efficient implementation of the conventions. There are many results available and often they are not available to inform application of the conventions.

The EU 6<sup>th</sup> Framework research programme has a theme 6: Sustainable management of marine resources. Several of its specifications relate to the identified research needs. The role of environmental health research has been revised. The program is more general than the 5<sup>th</sup>

framework programme and has a relatively low budget for this theme. It calls for integration within Europe (ERA – European Research Area) and among disciplines, as well as communication to decision makers, but integration has its limits. There may well be links between global warming and health consequences of hazardous chemicals, but if the research system has very wide boundaries, the research may tend to become too superficial.

Research results might become more useful for decision makers if the substances can be searched by CAS numbers, so inclusion of these in key words etc would be beneficial, and scientific journal editors should be asked to discuss this. Unfortunately, sometimes a large number of CAS numbers may be involved in commercially available substances and preparations and this may prevent overview.

It was noted that risk reduction strategies had been little addressed at the Policy Forum.

### ***The NewS programme and the Policy Forum***

The NewS programme, <http://newstrategy.ecotox.lu.se>, proposes a new strategy for coping with potential damages to human health and to the environment from chemical substances, in accordance with the precautionary principle, with

1. An integrated model of risk assessment and risk management, based on frequent feedback and exchange of signals between scientists and regulators
2. The use of decision-theoretic methods to optimize testing, priority-setting, and risk abatement.
3. The systematic use of a chain of events model in order to obtain as early signals as possible from potential health and environmental problems.

The scientific platform of the programme is based on about 15 subprojects, which use the same model substances (musk compounds and brominated flame retardants), focus on reproductive and developmental toxicology and refer to ecotoxicological problems connected with the Baltic Sea. One of the subprojects is the Policy Forum.

The first Policy Forum was held in Falkenberg, Sweden, in April 2001 and dealt with Persistence, Bioaccumulation and Precaution ( <http://www.kemi.se/default.cfm?page=aktuellt/default.htm> ). The chair of the meeting, John Buccini, at the end of the meeting presented his conclusions that can be summarised as follows:

- Persistency and bioaccumulation are of concern
- Persistency and bioaccumulation can be used for prioritisation and sometimes risk management, particularly for chemicals that are new or found in biota
- Toxicity is not necessary to determine in all cases (precaution) to consider a range of actions, sometimes temporary
- Opinions are divided on the urgency of strong actions against substances that are very persistent and/or very bioaccumulative.