

Ready for REACH?

Report from the Nordic workshop 8-9 December 2005 in Copenhagen

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Summary of workshop “Ready for REACH”

Copenhagen 8-9 December 2005

This report is primarily indented to the benefit of the participants for their use in planning of the work preparing the implementation of REACH in the coming years.

The aim of the workshop was to ensure a continued focused Nordic contribution to the EU REACH related activities and to prepare the Nordic authorities for REACH. The idea would be to allow the participants to exchange and to collect experiences with already completed (and maybe ongoing) RIP projects, including evaluation of the benefit of the Nordic collaboration. Further objectives of the workshop were to discuss and if possible identify new Nordic project with relevance for the REACH preparatory work.

The 1½ day workshop comprised of presentations and discussions in breakout group and in plenary.

Ms. Inger Bergmann, Head of Unit, Danish EPA Chemicals, welcomed the participants and stressed the importance of the preparatory work in order for REACH to be as smoothly and effectively implemented as possible. She underlined that the Nordic collaboration plays an important role in this preparatory work in order to effectively use the resources of the Nordic authorities.

Mr. Henrik Søren Larsen, Danish EPA, set the scene by reporting on the current status of the REACH negotiations after the European Parliaments first reading 17 November 2005 and prior to the expected political agreement in Council (which was reached 13 December 2005).

Ms. Lea Frimann Hansen, Danish EPA, outlined what tasks authorities should fulfil three years after entry into force with the view of identifying what need to be done prior for authorities to be able to fulfil these tasks.

Mr. Jukka Malm, SYKE, Finish Environment Institute, introduced the operation of REACH seen from the point of view of the European Chemicals Agency. He specially emphasised when and how collaboration with Member States takes place and critical deadlines for this work. Furthermore, he outlined how Member States will otherwise be involved in the work of the Agency e.g. by representation in the management board, the committees and the Forum, and what Member States will have to do prior to the establishment of the Agency.

Ms. Barbro Sillrén, KemI, Swedish Chemicals Inspectorate, presented the current outcome of the Nordic project analysing elements of Enforcement according to REACH. Provisions posing difficulties in relation to enforcement were compiled in this project and communicated to relevant contacts in the Nordic countries. The ultimate goal for further work would be to provide guidelines for enforcement. Possibly this could be achieved by Nordic contribution to potential EU activities such as a “RIP”-like project on enforcement and/or via the CLEEN network.

Mr. Toralf Kaland, SFT, Norwegian Pollution Control Authority, gave a detailed overview of Member States’ tasks especially in relation to evaluation, authorisation and restriction thus providing basis for identifying needs for preparatory work on the short and long term.

Mr. Ivar Lundbergh, KemI, Swedish Chemicals Inspectorate, presented the work on Technical Guidance Documents up to entry into force as organised in the REACH Implementation Projects (RIPs) and pointed at involvement of Nordic countries. He also summarised the experience drawn so far on Nordic collaboration e.g. the NOIS projects contribution to RIP 3.3 scoping study on Intelligent Information Strategy and the possible different levels of collaboration.

Mr. Peter Lindén, KemI, Swedish Chemicals Inspectorate, outlined the status of development of the REACH-IT system, the specifications of the IT-system, access and confidentiality and provided useful information on the user-friendliness and capabilities of the REACH-IT.

Mr. Torbjörn Lindh and Sten-Åke Svensson, KemI, Swedish Chemicals Inspectorate, showed how Sweden were preparing the development of a national Help Desk, including educational activities and organisation that largely would rely on education of key stakeholders (e.g. industry organisations) and local authorities. Also a web portal with educational material and a telephone hotline would be part of the package.

These presentations were followed by discussions in four breakout groups. Questions for these groups, conclusions and recommendations as presented and discussed in plenary are annexed to this report. The meeting was closed by Mr. Henrik Søren Larsen, Danish EPA, who summarised highlights from the presentations and the recommendations for further work.

Based on the presentations of the conclusions and recommendations from the breakout groups and the discussion in plenary, the organisers have distilled a number of high priority and urgent tasks appropriate for the Nordic collaboration and/or the Nordic countries in 2006.

In addition, a number of other high priority tasks were identified but having medium urgency. These tasks/activities can be found in the reports from the breakout groups. In some respects, however, these reports may lack some clarity in regard to priorities, action points or responsibilities due to the time constraints of the workshop and the state of conclusions drawn by the participants of the breakout groups. Further work may be needed to transform the ideas and thoughts of the workshop to concrete action points. Therefore, it is emphasised that the priorities highlighted below is not a consolidated set of priorities agreed by the workshop participants; thus the responsibility for highlighting those priorities exclusively lies on of the workshop organisers.

High priorities 2006:

Enforcement:

- Nordic contribution to European project on development of guideline for enforcement of REACH (“RIP” or CLEEN)
- Organise enforcement at national level (“who do what”) and create network between different national and local enforcement authorities

Responsibilities of authorities:

- How to provide information on use of substances to the Agency and how to align use categories between Nordic Product registers and REACH. Nordic Product Register Group.
- Non-threshold carcinogens: NORAP to address how to use the new TGD in relation to REACH (registration and authorisation)
- Review of Annex II and III: common understanding of principles. Finland initiates network activity
- Assessing costs of Agency: Denmark initiates networking activity

Development of Technical Guidance Documents (TGDs):

- Non-testing methods – grouping. NOIS?
- Non-testing methods – QSAR. NOIS?
- Classification & labelling: GHS implementation and the relation to REACH. Nordic Environment Classification Group (have applied for funding (RIP 3.6)) and Nordic Human Health Classification Group?
- CSA / CSR: especially exposure and risk management tools. NORAP, Nordic Risk Management Group, Nordic Exposure Group?
- RIPs on priority setting (4.3 & 4.5). Sweden initiate networking activity

Help desk and other guidance for stakeholders:

- Nordic workshop
- Create network for continuous exchange of ideas and experience
- Collaboration between Nordic network and EU-project (MAP-programme).
NKG to discuss who

Annexes

Workshop Programme

Ready for REACH?

December 8-9, Hotel Ascot, Studiestræde 61, Copenhagen, Denmark

December 8 (Day 1)		
1.	Opening and coffee/tea	10.00-10.15
2.	Introduction to the workshop (Aim, structure and expected outcome) <i>Speaker: Inger Bergmann (MST)</i>	10.15-10.30
3.	Status for REACH negotiations <i>Speaker: Henrik Søren Larsen (MST)</i>	10.30-11.00
4.	What do we do year 3 after enter in to force of REACH? - Tasks of authorities <i>Speaker: Lea Frimann Hansen (MST)</i>	11.00-11.30
5.	European Chemicals Agency - tasks and co-operation with Member States <i>Speaker: Jukka Malm (SYKE)</i>	11.30-12.00
<i>Lunch</i>		12.00-13.00
<i>Introduction/inspiration to breakout sessions:</i>		
6.	Enforcement <i>Speaker: Barbro Sillrén (KemI)</i>	13.00-13.30
7.	Authorities responsibilities in relation to: - Substance evaluation - Authorisation - Restriction <i>Speaker: Toralf Kaland (SFT)</i>	13.30-14.00
8.	Technical Guidance Documents (up to Enter Into Force) e.g. RIP 3.2, RIP 3.3, RIP 3.5, RIP 3.8, Authorisation, GHS (status and experience with nordic collaboration) <i>Speaker: Ivar Lundbergh (KemI)</i>	14.00-14.30
9.	REACH IT – possible technical preparation and requirements <i>Speaker: Peter Linden (KemI)</i>	14.30-15.00
<i>Coffee break</i>		15.00-15.30
10.	1. Swedish draft approach to educational activities facilitating the implementation of REACH 2. First thoughts on a national Help desk <i>Speakers: Torbjörn Lindh and Sten-Åke Svensson (KemI)</i>	15.30-16.00
11.	Plenary introduction to the breakout sessions <i>Speaker: Lotte Kau Andersen (MST)</i>	16.00-16.15
12.	Discussion in Breakout groups A. Enforcement Chairman and rapporteur to be appointed	16.15-18.00

	B. Authorities responsibilities in relation to: - Substance evaluation - Authorisations - Restrictions <i>Chairman and rapporteur to be appointed</i>	
	C. Technical Guidance Documents (up to Enter Into Force)	
	<i>Chairman and rapporteur to be appointed</i>	
	D. Help desk and other activities of the authorities to facilitate the implementation of REACH	
	<i>Chairman and rapporteur to be appointed</i>	
	<i>End of Meeting day 1</i>	
	<i>Dinner will be served in the Hotel Restaurant</i>	19.00-

December 9 (Day 2)		
13.	Discussion in Breakout groups continued including coffee break A. Enforcement B. Authorities responsibilities in relation to: - Substance evaluation - Authorisations - Restrictions - The Agency Committees C. Technical Guidance Documents (up to Enter Into Force) D. Help desk and communication in the supply chain (facilitation)	9.00-10.00
14.	Report to plenary of breakout groups and discussion Half an hour per breakout group.	10.00-12.00
15.	Concluding remarks and closure of the workshop	12.00 – 12.15
	Speaker: Henrik Søren Larsen (MST)	
	<i>End of Meeting day 2</i>	
	<i>Lunch</i>	12.15-13.00

Objectives of the Workshop

The aim of the workshop is to ensure a continued focussed Nordic contribution to the EU REACH related activities and to prepare the Nordic authorities for REACH. The idea would be to allow the participants to exchange and to collect experiences with already completed (and maybe ongoing) RIP projects, including evaluation of the benefit of the Nordic collaboration. Further objectives of the workshop are to discuss and if possible identify new Nordic project with relevance for the REACH preparatory work.

Expected outcome of the Workshop

- Recommendations for Nordic collaboration/projects in relation to existing and future RIP's
- Recommendations for Nordic collaboration/projects in relation to preparing Nordic authorities for REACH
- Better understanding of the activities needed and the tasks to be undertaken by authorities up to and 3 years after REACH has entered into force (including possible organisational changes).

Target group of the Workshop

- Nordic authorities involved in the Council negotiations.

- Nordic authorities involved in the RIP work
- CWG participants
- Nordic authorities involved in other REACH related activities (e.g. Nordic REACH activities)

General discussion issues in the Break-out Groups

The presentation on the subject (day 1) on “What are the authority tasks after REACH enters into force?” will be the starting point for the discussion in the breakout groups.

How do we get there?

- What are the tasks under REACH in 2007 (after entry into force) and how do we get there (i.e. tasks in 2006-2007)?
- Consider the need for reorganisation within the Nordic authorities.
- Need for Nordic projects?
- Who should be responsible?
- Added value from Nordic cooperation?

Background Documents for the Workshop

- RIP 1 Document (process description) and flow charts
(http://europa.eu.int/comm/enterprise/reach/docs/reach/reach_process_description-2004_06_15.pdf)
- Background documents from Helsinki POKER workshop:
 - The Agency Committees (CWG/WS/09/05)
 - The Evaluation Decisions (CWG/WS/10/05)
 - The Annex XIV Dossier (CWG/11/05)
 - The Application for Authorisation (CWG/12/05)
 - MS Workload and resource implications under REACH (CWG/WS/13/05)
- Questions for the breakout groups
- Overview of the Nordic participation in the RIP (and SEG) work
- A Status for the REACH related activities under NKG (prepared by Kati Suomalainen, NKG)
- Description of activities under REACH with resource implications for MS

Reports and recommendations from breakout groups

Questions to breakout groups

Expected outcome of the breakout session

- Main outcome: List of Nordic activities recommended for the interim period: who (initiator, participation), when, what incl. reasoning, preliminary budget.

As appropriate identification of tasks, exchange of experience etc.

Presented orally and supported by a Power Point presentation

General questions

- What are the tasks of the authorities under REACH (after entry into force)?
- What are the current tasks of the authorities and what needs to be changed?
- Which Nordic projects may help to facilitate changes? What is the added value?

Breakout group A: Enforcement

- What does REACH require as a minimum that authorities shall enforce?
- Do we wish or need to undertake additional enforcement activities (e.g. monitoring, enforcement campaigns, etc.)?
- What are we enforcing today? Which authorities in the individual countries are conducting the enforcement?
- Which changes are needed in the individual countries? Other authorities, other collaborations, other competencies?
- How to feed in the results from the Nordic project on enforcement of REACH into the proposed (RIP) project on enforcement?
- Can Nordic co-operation facilitate the build-up of new systems?
- Interaction with Agency Forum (e.g. interpretation of REACH provisions in relation to enforcement, Manual of Decision)?

Breakout group B: Responsibilities of authorities

- Which activities are required on dossier (CA's on Annex Ic, Test examination via RA Committee) and substance evaluation, Annex XIII candidates, evaluation of applications for authorisation, classification proposals, restriction proposals, etc.?
- Preparation of the revision of Annex II and III?
- Tasks of the various (MS, RA, SEA) committees of the Agency and how to support this work?
- What information should authorities provide to the Agency? (use in products (SPIN), monitoring data, project results, (Q)SAR results, compiling of other effect data in particular for complex substances, inorganic substances, grouping etc.)
- How to structure Nordic collaboration to support these identified tasks e.g. continue or further develop the NKG activities? (NORAP, etc.)

Breakout group C: Development of Technical Guidance Documents (TGD)

- Based on the plan of REACH Implementation Projects, do we need other types of TGDs or do we need to extent support for work on planned TGDs? (e.g. validation and use of (Q)SAR, Annex Ic, review of Annex IX (exposure based waiving), use and exposure categories, Chemical Safety Assessment for preparations, complex substances, closed system definition etc.)
- Do we need Nordic projects for preparing for EU projects (e.g. similar to NOIS) or do we need other Nordic projects? (which?, work plan 2006-2007)

- Shall we co-ordinate Nordic participation in RIPs incl. Stakeholder Expert Groups? (cf. overview of the current Nordic participation)

Breakout group D: Help desk and other guidance for stakeholders

- What advice do authorities need to provide to registrants, downstream users, other authorities, other stakeholders? And when? (obligations of Agency vs. MS)
- How can it be organised in the individual countries? (which authorities?)
- What kind of guidance activities is provided today in the individual countries on current chemicals legislation? – and on REACH?
- Need for educational programmes for industry, local authorities, consultants, etc.?
- Can Nordic collaboration facilitate the activities? (in addition to Agency)
- Participation in new EU project on help desk to SMEs?

Group A: Enforcement

Chair: Annette Ekman

Rapporteur: Maren Wikheim

Scope

- CA enforcement
- **Inspection activities inspectorates**
- Implementation of the legislation – company compliance??
- FORUM 1 person per each MS
- national network

Inspectorate

- Pre- Registration – no real requirement from insp. but MS should be in touch how to follow up / which fines / penalties will be given
- Some information task – responsibility?

Registration

- Check that substances are registered or notified whether on their own, in preparations or in articles
- If not – why – exempted / or within scope
- Tonnage levels – how about aggregated tonnage?
- PPORD – check if they have a valid notification
- At the same time check C& L and SDS- information including availability of exposure scenarios / RRM / correlation with CSR
- Article 6 and specially Article 6(2bis) will be problematic in relation to enforcement

Evaluation

- No enforcement tasks for inspectors
- If evaluation ends up with a withdrawal of the registration of a substance, there need to be feedback to enforcement authorities and consideration on how such withdrawal should be enforced e.g. in relation products on the market?

Authorisation

- Check that substance is on Annex XIII

- Check “the sunset date”: has the application been done in time, has the authorisation been granted and which time limit and conditions applies for the authorisation?
- Check that customers of a supplier or a M/I use the substance in accordance with the use granted for the substance
- Check the routines for sending the information down the supply chain

Restriction

- Business as usual but need more focus
- Includes many enforcement bodies

Enforcement authorities

REACH can concern the following:

- Customs authorities
- Occupational health and safety
- Consumer protection
- Chemical inspectorates
- Food safety /cosmetics
- Environmental agencies
- Regional/local authorities
- Negotiations on the national level has to start ASAP on how to organise enforcement
- Competence at local level?

Additional enforcement activities

- Enforcement campaigns – FORUM driven
- Tasks in Article 124 – we need to have more information about what kind of monitoring activities

RIP project enforcement: organisation

- Sub group under CWG – ”SEG” ?
- Consortium – SE, DK, NO, IS? FI? Other EU member states (3-5 new MS / experience)?
- Consult / secretariat – investigate availability of a Nordic candidate (EU)
- Lead from EU-member state, NL? Investigate possible Nordic lead

RIP project enforcement: tasks

- Identify the most important enforcement tasks to make REACH work
- Good practise to make enforcement efficient
- Identify crucial cooperation needs and models to ensure effective enforcement e.g. in relation to responsibilities for placing on the market
- Identify needs for capacity building among inspectorates
- Needs and forms of exchange of information - including ALERT system

Others

- FORUM Manual of decisions for interpretations of REACH
- CLEEN/FORUM what happens to none-REACH parts of CLEEN?

Group B: Authorities responsibilities in relation to substance evaluation, authorisation and restriction

Chair: Henrik Søren Larsen

Rapporteur: Gunlaug Einarsdottir

Use and exposure information

1. Product register information

Rating: high priority – high urgency because information needed for Registration

Who: NPG Nordic Product register Group

- ⇒ How to provide the product register information to Agency in relation to
 - exposure based waiving
 - LPV substances
- ⇒ Get the use categories mutually interactive (REACH ↔ product registers)

Project ongoing, how will SPIN contribute to REACH?

2. Monitoring data

Rating: high priority - medium urgency in relation to REACH. Information will feed into Evaluation

Who: Possibly need for reorganization of existing Nordic groups or for the Human exposure group

Provide information from

- ⇒ Nordic screening project
- ⇒ Analytical monitoring of substances in consumer products

3. Substances in articles?

Rating: Medium urgency. (Ed.: at time of the workshop substances in articles would only be dealt with after prioritisation of SVHC or after 11 years. The political agreement in Council 13 December 2005 establishes, however, that registration of substances intentionally released from articles follows the normal deadlines for registration e.g. 3 years for substances > 1000 t/y while prioritised SVHC in articles may require notification 3.5 years after EoF at the earliest.

Some participants felt that the issue should have a rating of *high urgency* as it was seen as of major importance to impact negotiations during second reading with a view of changing the outcome of the political agreement.)

Provide information on substances in articles from surveys e.g. analytical monitoring

4. Effect of 1 t/a threshold for requiring downstream users to perform CSA:

Rating: urgent for such analysis to have an impact on coming negotiations

Who: networking

Registration

1. Review of Annex II and III; common understanding of principles behind the review.

Rating: high priority - high urgency. Annex II and III shall be reviewed 12 months after EoF

Who: networking – Finland initiates this work

2. The application of DMEL's for non-threshold carcinogens based on the new TDG
Rating: high priority - high urgency¹
Who: NORAP to look at this before implementation in REACH
3. Alloys and chemical safety of preparations
Rating: medium priority - low urgency
Who: issue for the Nordic C&L groups
NORAP has a project on MERAG in first half of 2006

Substance evaluation

1. How to influence the RIP 4.5 for setting principles for priority settings for substance evaluation
Rating: ? priority – high urgency
Who: networking, Sweden initiator
A project starts in 2006
2. Should we prioritize specific substances for substance evaluation?
Rating: medium priority – medium urgency. Substance evaluation is not relevant before registration
Who: no recommendation, could be NORAP
3. How to assess the risk management part of the substance evaluation, contribution to RIP 4.2
Rating: low priority – medium urgency – needs more thinking, in connection to Enforcement

Evaluation

1. Should we have some kind of collaboration in member state committee?
Rating: low priority – low urgency
Who: networking?
2. How enforcement should feedback if risk management is not adequate
Rating: low priority – medium urgency – needs more thinking connection to the enforcement group

Authorisation

1. Overall strategy for how the authorisation should operate
Rating: high priority - medium urgency². First recommendation for Authorisation 2 years after EiF
⇒ when to use restriction and when to use authorisation
 - criteria between
 - legal and practical aspects
2. Identify specific tasks e.g.
 - ⇒ identification of substances for the candidate list
 - ⇒ exemptions of certain uses
 - ⇒ substances in articles, import to EU

Rating: high priority - medium urgency. First recommendation for Authorisation 2 years after EiF

¹ The workshop rated this issue as high priority but unpredictable urgency. However, at the Council 13 December 2005 it became evident that the Commission will review Annex I in relation to non-threshold carcinogens and mutagens.

² Some participants felt that there was an urgent need to discuss the overall strategy of authorisation, especially the interaction between authorisation and restriction in relation to SVHC in articles, and that such discussions may impact negotiations during the second reading.

Restriction

1. Priority setting of restriction
Rating: medium priority - low urgency
2. Criteria for making a proposal
Rating: medium priority - low urgency
3. How to avoid MS having business interest in certain substances initiate restriction process and thus block action from other MS?
Rating: medium priority - low urgency

Who: Nordic Co-operation on Risk Management of Chemicals

Classification and Labelling

1. Priority setting for which substances to propose for harmonized C&L.
Rating: medium priority - low urgency
2. What would be sufficient justification for proposing harmonized C&L.
Rating: medium priority - low urgency

Who: existing Nordic groups for Classification

Access to information

1. Prepare Management Board rules for access to information
Rating: ? priority - ? Urgency?
It was agreed that access to information was a highly prioritised policy area in all Nordic countries but it was uncertain whether any Nordic Council activity was relevant. Probably outside the remits of NKG.

Agency

1. Share the workload after establishment
NKG to consider how present organisation / groups will serve in the future, in relation to Agency committees
2. Assessing cost of Agency work in setting of the fee in the fee regulation.
Rating: high priority - high urgency
Who: networking, Denmark initiates

Group C: Technical Guidance Documents (up to entry into force)

Chair: Finn Pedersen

Rapporteur: Jerker Forsell

How to influence the RIPs?

- Do we need a Nordic approach on how to influence the SEGs? (pre-meetings?)
- Do we need to prepare NKG-projects as pre-projects for RIPs? (e.g. NOIS)
- Direct participation in drafting groups?
- Direct participation in consortia?

Non-testing methods

- QSAR, read-across, grouping, categories
- Authorities should provide QSAR tools (or results?) and guidance for use for industry (1-10 tpa, year 11)
- Capacity building for authorities is needed
- Nordic network linked to OECD ad-hoc group and to EU-TCNES QSAR WG
- Maybe QSAR is not urgent, but grouping?

NOIS activity?

Socio-economic analysis

- RIP 3.9 mainly focussing on SEA for industry?
- Do we need separate guidance for authorities? (for restrictions; in reply for authorisation)

Nordic Risk Management Group?

RIP 3.2-2 CSA/CSR

- Better exposure estimation tools
- Proper risk management tools: Is there a bottom line for consumer, e.g. do not expect that they use PPE, do not allow marketing of toxic chemicals?
- Link exposure based waiving to RIP 3.3. Participation in tendering?
- Participation in drafting groups?

NORAP, Nordic RMM Group? [Ed.: Nordic Exposure Group?]

Classification & Labelling

- COM is not transparent in relation to GHS implementation in EU
- Important to be involved and start to prepare now. How?

*Nordic Environment Classification Group have applied for funding of RIP 3.6
Nordic Human Health Classification Group should engage!*

Information from authorities to the Agency

- Information from authorities on wide dispersive use is required (art. 121)
- How to obtain this information?
SPIN database has some information on consumer use (but not for DK)
- Recommend registration of consumer use of chemicals!

Nordic PR Group

Consortia building for registration

- Does industry need guidance for consortia building? (RIP 3.1?)
- Guidance on how to use information on other substances in preparing registration dossier (grouping, read-across, etc.)?

Nordic home?

NB! Industry will be responsible

RIPs on priority setting

- RIP 4.3 Annex XIII (Authorisation)
- RIP 4.5 Substance evaluation

Information from Nordic SPIN is crucial

Priority

High priority 2006:

- Non-testing methods – grouping
- Non-testing methods - QSAR
- Classification & labelling
- Socioeconomic Analysis
- CSA / CSR
- RIPs on priority setting (4.3 & 4.5)

Lower priority for Nordic work in 2006:

- Guidance on consortium formation (SIEF)
- Nordic participation in RIPs

Group D: Help desk and other guidance for stakeholders

Chair: Geir Jørgensen

Rapporteur: Sten Åke Svensson

A possible timetable

- REACH into force 2007
- Pre-registration for all substances, 2008-2009
- Downstream Users who imports substances on its own or in preparations need to provide information
- Producers and importers shall notify the agency with self-classification proposals
- Communication in the supply chain need to start 2007-2008 (Will you cover my use in your registration?)

Possible early questions

- What will REACH mean to me? (Different presentations for different stakeholders)
- Are my substances inside or outside the scope of REACH?
- Are my articles/products within the scope of REACH? (Importers of articles/products)

Organisation in our different countries

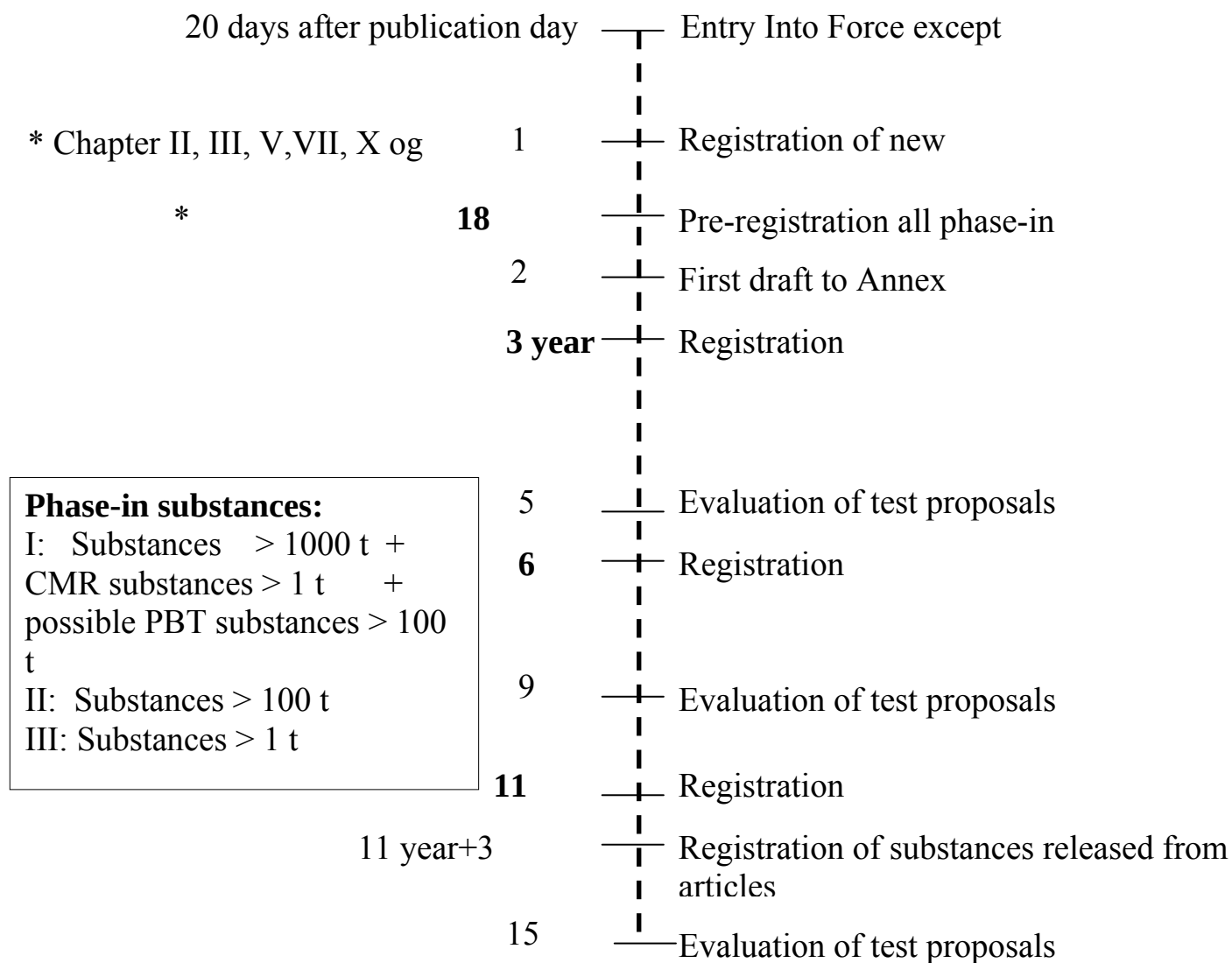
- Which authority is responsible for what? Different structures in each country. Involvement of other national bodies and institutes?
- CA need to provide training
- Staff needs, resources, organisation?
- Plans on helpdesk has started in Denmark and Sweden

Possible Nordic collaboration

- Arrange a Workshop
Who? (Ed.: NKG to discuss)
- What advice, information and guidance should authorities give to different stakeholders? Learn from each other
- Set up a timetable: Information to whom and when

- Create network for continuous exchange of ideas and experiences
Who? (Ed.: NKG to discuss)
- Exchange of experiences from educational and informational activities
- Collaboration between the Nordic network and the EU-project (MAP-programme)

Timeline for implementation of REACH



Status of REACH related activities under the Nordic Chemicals Group (NKG)

Kati Suomalainen
Secretary of the Nordic Chemicals Group

Nordic REACH Workshop
Hotel Ascot – Copenhagen, 8-9 December 2005

Since the proposal for a new EU regulatory framework for chemicals called REACH was introduced in October 2003, the Nordic Chemicals Group has initiated many activities around the proposal. The activities have mainly been conducted through the many project groups of the NKG. The NKG itself has also been engaged in some of the tasks that have been proposed by the Senior Officials Committee for Environmental Issues (Ämbetsmannakommittén, ÅK-M) or the Working Committee of the Senior Officials Committee (Arbetsutskottet, AU) under the Nordic Council of Ministers (NCM). The last REACH activity the NKG was directly involved was helping the Nordic Council of Ministers responding to the Nordic Council's enquiry on REACH enforcement in the Nordic countries.

As stated earlier NKG has coordinated REACH activities mainly through its project groups. The activities have mainly been direct inputs to the REACH Implementation Projects (RIP's); a program that was launched by the Commission to produce when necessary guidance and training material and necessary changes for the present working structures towards REACH creation during the interim period. The work has been very successful and several Nordic point-of-views can be found in the working documents.

In the following a list of REACH related activities of the NKG project groups:

The Nordic Risk Assessment Project NORAP (Nordiskt samarbete i riskbedömning) has been very active in the REACH work. The group has been engaged in the RIP Guidance Document development. The group has a "Nordic Information Strategies" (NOIS) project that has prepared direct inputs to the RIP 3 (RIP 3: Development of Guidance Documents for Industry). The project has several separate subprojects of which ongoing are e.g. Bioaccumulation, Repeated Dose Toxicity and Mutagenicity and Cancer. The results of these subprojects will be used in the preparations of RIP 3.

Last summer the NOIS project published two reports in TemaNord-series. "*Threshold of Toxicological Concern (TTC) – literature view and applicability*" is used as a direct input in the RIP 3.2 (Technical Guidance Document on preparing the Chemical Safety Report) and RIP 3.3 (Technical Guidance Document on Information Requirements on Intrinsic Properties of Substances) and it is available on <http://www.norden.org/pub/sk/showpub.asp?pubnr=2005:559>. Another direct input to RIP 3 was the report "*Nordic Project on Information Strategies (NOIS) for Fulfilling Data Requirements under REACH*" that is available on <http://www.norden.org/pub/sk/showpub.asp?pubnr=2005:754>.

The group for Nordic Co-operation in Risk Management of Chemicals ([Nordiskt samarbete i riskhantering på kemikalieområdet](#)) has also been active in the work with RIP's. For example RIP 3.9 on Socio-economic Analysis (SEA) and RIP 4.4 on Annex XIV Dossier have been in target for the Risk Management Group. The Group organised a workshop in SEA in Helsinki in March 2005. The discussions of the workshop have been used in RIP 3.9 preparation.

[The Risk Management Group](#) has started a new project in substitution of dangerous chemicals to less dangerous ones. Principle of substitution is considered to play a central role as a work tool under REACH. The project started in the autumn 2005 with a study of the use of an English database in chemical's substitution. There is already one database available, but only available in Danish. If considered relevant this would then be translated into English.

[The group for Nordic Co-operation in](#) Chemicals Inspection (Tillsynsgruppen) has an ongoing project "Analysis of REACH from the Enforcement Perspective" that will be finalized soon with a report publication. The project has studied need and quality of enforcement needed in REACH. This project will probably be continued with a new one project called "REACH and downstream users". Focus of the project is the small companies that are considered to be the main group influenced by REACH.

The group for Nordic Co-operation in Chemicals and Product Registers (Nordiskt kemikalie- och produktregistersamarbete) has a project analysing the need, pros and cons of national product registers, including the joint Nordic product register database SPIN, in REACH as this includes an idea of establishing a joint chemicals register. The object of the project is to identify overlaps in register routines of REACH with experiences obtained from the Nordic registers. During 2004, the group organised also a workshop in Nordic productregister with a focus on REACH.

The groups for Nordic Co-operation in Environmental and Health Hazard Classification (Nordiskt samarbete i miljö- och hälsoklassificering) have worked with the RIP 3.6 on Classification and Labelling with the project "Guidance for the Classification within REACH and GHS" (Global Harmonised System for Classification and Labelling). The status of the work is unclear as the RIP 3.6 has not really started yet.

NKG has also on-going activities in human exposure related issues as the area in whole is missing guidance documents. The work is going to have a strong REACH-relation.

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- Nordic Information Strategies NOIS
Project leader: Bert-Ove Lund - Swedish Chemicals Inspectorate, KemI, Sweden
- Nordic Co-operation in Risk Management of Chemicals
Project leader: Kirsi Sihvonen - National Product Control Agency for Welfare and Health, STTV, Finland
- "Analysis of REACH from the Enforcement Perspective"
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- Nordic Co-operation in Chemicals and Product Registers
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- Nordic Co-operation in Environmental Hazard Classification
Project leader: Jonas Falck - Swedish Chemicals Inspectorate, KemI, Sweden
- Nordic Co-operation in Health Classification
Project leader: Solveig Dysvik - Norwegian Pollution Control Authority, SFT, Norway
- Human exposure
Project leader: Jouni Räisänen - National Product Control Agency for Welfare and Health, STTV, Finland

Overview of REACH Implementation Projects and Nordic involvement

RIP	Project name	DK	FIN	N	S
3.1	TGD on preparing the registration dossier (start 06.10)				
3.2-2	TGD on CSA/CSR (start 05.12)	Poul Bo Larsen (SEG for RIP-3.2-1)	Jaana Heiskanen (SEG for RIP-3.2-1)	-	Alf Lundgren (SEG for RIP-3.2-1)
3.3-2	TGD on information requirements (start 05.12)	Henrik Tyle/Lotte Kau Andersen (PMG for consortium)			Ivar Lundbergh (PMG for consortium?)
3.4	TGD on data sharing (start 06.04)				
3.5-2	TGD on downstream users (start 06.03)	Lise Emmy Møller (SEG for RIP-3.5-1)	Riitta Leinonen (SEG for RIP-3.5-1)	Inger-Grethe England (SEG for RIP-3.5-1)	Anna Fransson (SEG for RIP-3.5-1)
3.6	TGD on C&L under GHS (start 06.10)				
3.7	TGD on application for authorisation (start 06.04)				
3.8	Article identification (ongoing)	Lea Frimann Hansen (consortium) Hanne Thygesen (SEG)	Eliisa Irpola (SEG)	Inger-Grethe England (consortium)	Karin Thoran (consortium)
3.9-2	TGD on SEA (start 06.04)	Lars Fock (SEG for RIP-3.9-1)	Heikki Salonen (SEG for RIP-3.9-1)	Inger-Grethe England (SEG for RIP-3.9-1)	Jerker Forssell (SEG for RIP-3.9-1)
3.10	TGD on substance identification (ongoing)				
3.?	CSA for preparation (IND proposal)				
4.1	TGD on dossier evaluation				
4.2	TGD on substance evaluation				
4.3	TGD on inclusion of substances in Annex XIII (start 06.01)				
4.4	TGD on Annex XIV dossiers (ongoing)		Kirsi Sihvonen (SEG)	Toralf Kaland (SEG)	Anna Lovisa Heijkenskjold (SEG)
4.5	TGD on priority setting for evaluation (start 06.01)				
4.?	TGD on enforcement (proposed by S)				
5.2	REACH help desk (start 06.04)				

For new projects that are second phase of previous projects, the Nordic participation in the first phase is indicated for information. This, of course, does not preclude that the countries may decide otherwise for the second phase.

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