Micromega: REACH for Nanomaterials

Synthesis of the discussion and results

of an

NIA Masterclass & Workshop

held in London (UK), 9th May 2007

Disclaimer: This paper highlights key issues that emerged from a workshop on the abovementioned topic. It is not necessarily an expression of the views of the Nanotechnology Industries Association or all of its individual members.

Cover photo: BASF PCI Nanolight® tile adhesive; nanostructures formed a patented combination of special fillers and binders. (Image courtesy: BASF AG)

Nanotechnology Industries Association

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About the Organisers

Formed in 2005, the Nanotechnology Industries Association (NIA) creates a clear single voice to represent the diverse industries' views in the multi-stakeholder debate on nanotechnology, by providing an interface with government, acting as a source for consultation on regulation and standards, communicating the benefits of nanotechnologies and interacting with the media to ensure an ongoing advancement and commercialisation of nanotechnologies.

The unique feature of the NIA is that it provides a purely industry-led perspective derived from the views of the collective membership, which is made up of many varied companies all at different stages of their life cycle and with a variety of interests in the huge range of technologies that derive their benefit from the nanoscale. This enables those seeking comment from industry to have a single point of entry to the industry and avoids the need to approach individual companies for statements on specific issues. In addition the breadth of the membership enables the NIA to put forward strong proposals to government and regulatory authorities to promote an environment that supports the application and utilisation of nanotechnologies. Initial aims of the association are:

- promoting the responsible use of nanotechnology and raising awareness of its many applications in an unbiased way among key audiences within the UK,
- generating position statements and papers in areas relevant to its members and providing responses to consultations exercises,
- technology foresight exercises examining current products, developments and future applications of nanotechnologies with an industry-based perspective on the risk-based classification of emerging technologies including nanotechnology, which is linked to a new hazard assessment methodology as the current project,
- working closely with regulators to represent the interests of the NIA to ensure the future of nanotechnology is secured and to realise its full potential,
- encouraging and stimulating industry participation and support for nanotechnology, and
- providing a forum for discussing topics of relevance to its members.

For further information visit http://www.nanotechia.co.uk.

Nanotechnology Industries Association

Executive Summary

This paper summarises the contents of the event entitled *'NIA Masterclass & Workshop: Micromega - REACH for Nanomaterials'*, held in London on the 9th May 2007. The event was organised by the Nanotechnology Industries Association and involved experts in legal and managerial aspects of the EC regulation on Registration, Evaluation and Authorisation of Chemicals (REACH), which came into force on the 1st June 2007.

The programme of the event was divided into two main parts:

(a) a *Masterclass*, delivered by REACH experts Ruxandra Cana (McKenna Long and Aldridge) and Steffen Erler (REACHReady) (please see below for short biographies), followed by

(b) a *Workshop*, chaired by the NIA, with the view to discuss scenarios under which nanomaterials might be included with the REACH Regulation.

The purpose of the *Masterclass* was to firstly shed light onto the past discussion around nanomaterials as part of the REACH Regulation, and to clarify their current status within the legislation that was passed by the European Parliament and the Council of Ministers on the 18th December 2006, and that entered into force earlier this year, 1st June 2007. The *Masterclass*, aimed to examine scenarios on the inclusion of nanomaterials within the REACH registration process, and to investigate subsequently the necessary potential management strategies.

Main conclusions:

The final version of the REACH Regulation, launched in December 2006 by the European Parliament and the Council of Ministers does not contain provisions specific for nanomaterials, or require specific authorisation of nanomaterials; all materials, independent of their size, are subject to the same requirements, especially for pre-registration and registration.

It is however, possible that nanomaterials will eventually have specific categories and corresponding procedures assigned to them within REACH, within one of the following scenarios:

(a) they would be reviewed on a case-by-case basis (substance- or company-specific), or

(b) an industry-wide practical approach would be proposed and accepted by authorities.

In case the REACH Regulation is amended to include technical requirements specific for nanomaterials, these requirements are likely to apply to sector-specific legislation outside of REACH as well (*e.g.* medical devices, cosmetics), without consideration of specifics. New nano-specific legislation could be implemented (a) horizontally (*i.e.* the regulation is applicable to all uses), or (b) vertically (*i.e.* product specific).

Alternatively, specific REACH nanomaterial requirements could be addressed in time pending definition and agreement of test methods/risk assessment methodologies. The advantages of this approach would be its anchoring on a sound scientific basis, while the disadvantages include a pronounced public pressure for precautionary restrictive measures (justified by scientific uncertainty).

Through confrontation with potential future scenarios of the anticipated impact of an inclusion of specific requirements for nanomaterials within REACH, the audience was challenged to consider the potential impact within their own company, and were prompted to develop cornerstones and structures to influence any future debate on this topic, resulting in the agreement of the following 'Next Steps':

1. Analyse nano-specific REACH requirements and identify consequences,

2. Assess advantages/disadvantages of industry-wide *versus* company-specific approach,

3. Communicate with EU authorities and Member States,

4. Contact EU authorities through Member State authorities,

5. Utilise the potential REACH compliance to devise a public communication strategy, and

6. Organise a pilot registration under REACH.

1. Introduction

It is still uncertain how nanomaterials will be managed under the REACH Regulation. In the absence of a common approach to address this issue within the industries involved in nanotechnology R&D and commercialisation, it is possible that a number of incongruent management strategies will be developed by individual companies. It is also possible that the Chemicals Agency decides on a particular approach in a first "test case" without formal review and consultation that then becomes a precedent for subsequent cases. This workshop will outline the current position of nanomaterials within REACH and provided a forum to discuss how industries may address nanomaterials within the framework of the regulation.

2. Masterclass: Main Obligations under REACH

The Masterclass summarised the history of the REACH regulation from the initial European Commission proposal in October 2003 until its launch the European Parliament and the Council of Ministers on the 18th December 2006 and its enforcement and application in national legislation on 1st June 2007. The structure of the REACH regulation and its main obligations, highlighted in Figure 1, were outlined with particular emphasis on the implications for industries working with existing and new substances.

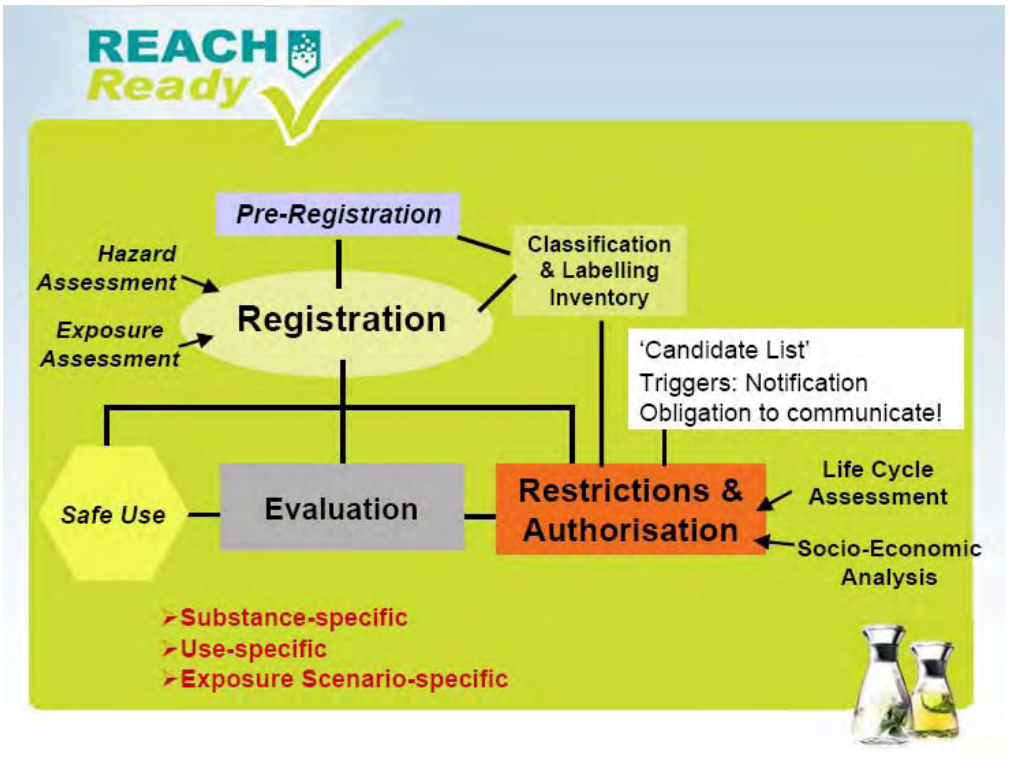

Figure 2: Illustration of the structure and main obligations of the REACH regulation (courtesy of Dr Steffen Erler, REACHReady).

The REACH Regulation is based on the precautionary principle, which is implemented according to the following examples:[*]

- Safety assessment: If there is uncertainty over scientific evidence (*e.g.* conflicting data exist), the safety assessment should normally be based on the evidence that gives rise to highest concern.
- Risk management measures: While a company is awaiting further test data on a particular hazard it should make sure that the risk management measures appropriate for the potential risk are in place and describe these measures in the safety assessment; in the case of PBTs and vPvBs, industry is requested to minimise exposure at all times.
- Authorisation: Industry is required to seek authorisation for uses of substances of very high concern (SVHC, such as endocrine disruptors, PBTs, etc.), regardless of the measures taken to control the risks; in some cases, the authorisation is granted only if there are no alternatives, again regardless of the measures taken to control the risks.
- Restrictions: Member States and the Commission can suggest immediate restrictions in case there are indications of severe risks associated with the use of a given chemical. In this way the PP could be implemented in cases where it would take too long to establish the data necessary for a scientific evaluation or where data does not allow the risk to be determined with sufficient certainty.

Only substances manufactured or imported in volumes starting at 1 tonne need to be registered. The European Commission currently estimates that 30.000 existing substances are marketed in volumes at or above 1 tonne.[†] Manufacturers and importers of substances on the European Inventory of Existing Commercial Chemical Substances (EINECS) or other substances with 'phase-in' status will have to pre-register their substances from 1st June 2008 to 1st December 2008; the list of all pre-registered substances will be made publicly available by the Agency in January 2009.

All substances present in a preparation (*i.e.* mixture) at or above 1 tonne must be registered, irrespective of whether they are classified or not. If a substance alone or in a preparation or even intentionally released from an article (*i.e.* finished product) exceeds the threshold of 1 tonne per importer/manufacturer per year, a technical dossier needs to be prepared; if the quantity exceeds 10 tonnes per year, a Chemical Safety Report (CSR) needs to be prepared.

Substances manufactured or imported in quantities below 1 tonne do not require registration, even if hazardous; however, hazardous substances must be included in the 'Classification & Labelling Inventory' by 1st December 2010 (see Figure 1). This requires action from any relevant company manufacturing or importing such a substance

[*] 'Questions and Answers on REACH', European Commission, February 2007; obtainable from http://ecb.jrc.it/reach/rip/.

[†] The European Inventory of Existing Commercial Chemical Substances (EINECS) lists more than 100.000 existing substances that were on the market when the inventory was compiled, but not all of those are manufactured or imported in volumes at or above 1 tonne. The EINECS is published in the Official Journal of the European Community (OJ EC, C 146 A of 15 June 1990: see also 4 http://ecb.jrc.it/new-chemicals/).

regardless of tonnage, including its presence in a preparation or an article with intended release.

The main obligations of the REACH regulation are:

(a) **Pre-Registration** applies to existing substances (so-called 'phase-in') and indicates the intention to register a substance within 11 years, and does not require indication on use. Pre-registration occurs between 1st June 2008 and 30th November 2008; each company wishing to take advantage of the delayed registration deadlines for 'phase-in' substances must pre-register; a substance that is not pre-registered must be registered immediately, if production/import reaches 1 tonne or more per year.

(b) **Registration** under REACH applies to substances manufactured or imported, on their own, in preparations or intentionally released from articles. Other substances in articles are potentially subject to a notification scheme or a full registration on a case-by-case basis. Registration requirements depend on the quantity manufactured or imported a substance by a company per legal entity. This step of the regulation's obligation consists of a technical dossier (the content of the technical dossier is dependent on tonnages) and a Chemical Safety Report (for substances above 10 t/year), submitted to the newly created European Chemicals Agency (Agency).

(c) **Evaluation** is conducted *via* Agency and Member State Competent Authority reviews of the technical registration dossiers; it is separated into 'dossier evaluation' and 'substance evaluation'.

(d) **Authorisation** is applied in several stages, including (i) the issuing of a 'Candidate List', containing substances liable for Authorisation, (ii) Prioritisation of certain substances for Annex XIV, (iii) inclusion of a substance into Annex XIV which are banned unless company-specific authorisation is issued. Authorisation can be obtained (i) if the use of a substance is adequately controlled (*i.e.* if the substance is contained to achieve an exposure level below a given threshold), (ii) if no substitutes are available and if economic and social benefits outweigh the risks, in the case of substances for which no safety threshold applies (*e.g.* PBTs or vPvBs).

Exemptions of substances from REACH apply, if any of the following criteria apply to the substance in question:

- used in human/veterinary medicinal products,
- used in food/feed,
- used in biocides/pesticides (NOTE: inert (non-active) substances must be registered),
- non-isolated intermediates
- listed in Annexes IV and V (NOTE: exempt from registration only).

There are specific requirements for polymers; although polymers are exempt from registration, the monomers and other reactants used to produce the polymer need to be registered even if it is only the final polymer that is imported. The rules for defining polymers and establishing requirements require detailed analysis.

There are reduced requirements for isolated and transported isolated substances if only used under strictly controlled conditions. There are also particular exceptions for R&D and a special notification procedure for uses of substances for Product and Process-Orientated R&D (PPORD).

Substances used in cosmetics are not exempt from registration, but Chemical Safety Reports on these substances do not require information on direct risks to human health from final product use. Other effects from the ingredients and the actual product, such as occupational health and human health *via* the environment must be included as part of a registration.

Substances used in medical devices are not exempt from registration and may trigger a re-assessment of risks addressed by specific legislation. Uses of substances in medical devices are not subject to the Authorisation procedure under REACH, but could be subject to restrictions.

2.1. Masterclass: Nanomaterials under REACH

In October 2006 the Environment Committee of the European Parliament proposed an amendment to subject 'nanoparticles' to authorisation irrespective of their properties. This proposal was voted down, so that the final version of the REACH regulation, adopted in December 2006 by the European Parliament and the Council of Ministers does not contain the specific requirement. Nanomaterials are therefore subject to the same requirements as all other substances (*i.e.* Registration, Evaluation, Restrictions and Authorisation):

(a) Registration will consider nanomaterials as 'phase-in', if substances are listed on EINECS (European Inventory of Existing Commercial Chemical Substances) (*cf.* decision of Member States Competent Authorities), are considered as No-Longer Polymers or have been manufactured in the EU but not placed on the market between 1st June 1992 and 2007. Once pre-registered, a company can benefit from delayed registration deadlines depending on tonnage tonnages if they are pre-registered by each company manufacturing or importing them; the size of particles and other specifics must be mentioned in actual registration data submission.

(b) Although registration applies to substances in articles if the nanomaterials are released intentionally, above 1 tonne/year and if no one else registered the substance for the same use; this is not required if the substance has already been registered for that specific use. This is particularly important in the case of imported goods. If the nanomaterial is a known SVHC (included in the 'candidate list') and exceeds 0.1% in an article, a notification is required if above 1 tonne per year and not already registered; the nanomaterial must be

notified to the Agency (if no one else registered it for the specific use) and persons placing the article on the market must inform the recipients of the presence of the nanomaterial. in such a case, information must be transmitted in the supply chain regardless of tonnage. Consumer requests for information on the content of 'Candidate List' SVHC substances in articles above 0.1% w/w must be responded to within 45 days.

(c) Autorisation may be necessary, if the nanomaterials are composed of known SVHCs. A process of Restrictions can also apply.

3. Masterclass: Implementation of REACH

3.1. Masterclass: Timeline for the implementation of REACH

The Workshop introduced the described timeline of the REACH Regulation, illustrated in Figure 2.

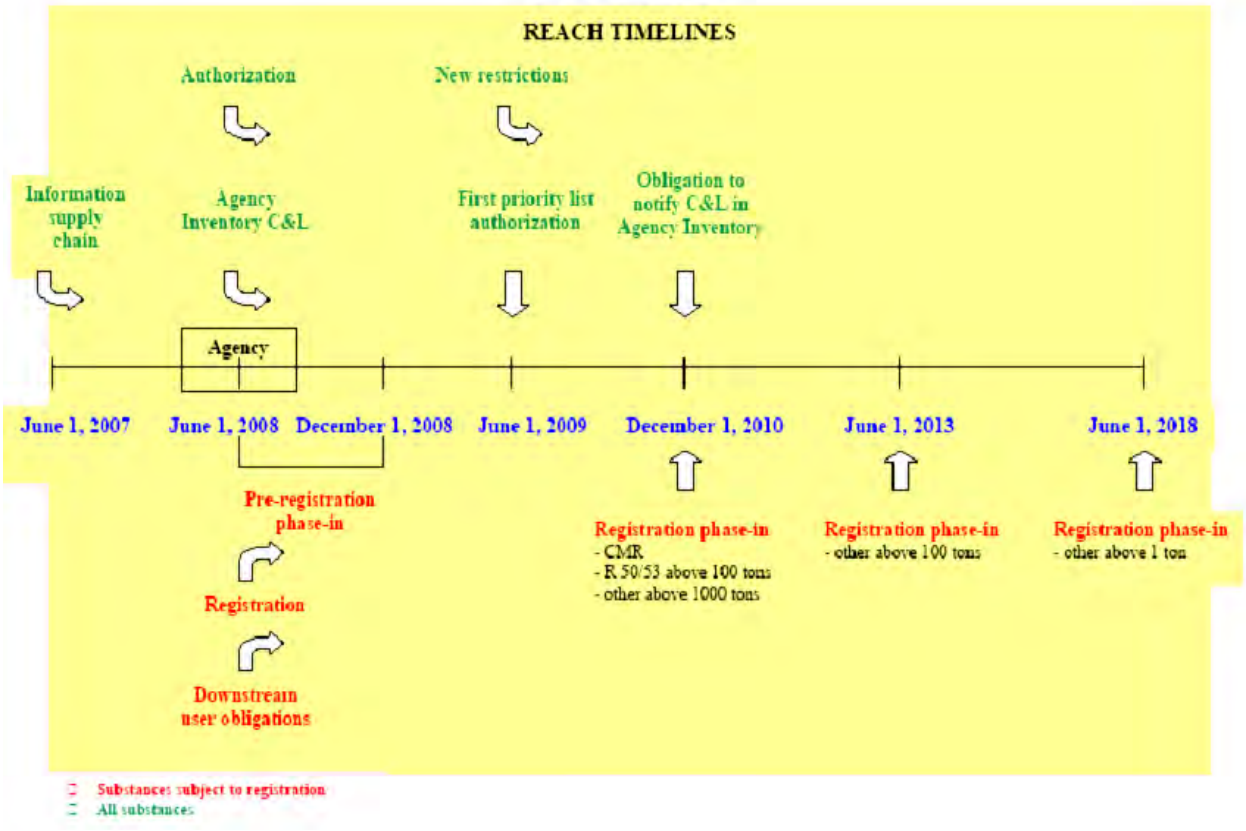

Figure 2: Schematic illustrating the timeline of the REACH regulation implementation (courtesy of Ruxandra Cana, McKenna Long & Aldridge).

3.2. Masterclass: REACH Implementation Projects (RIPs)

The implementation of the REACH regulation is conducted within the framework of so called REACH Implementation Projects (RIPs); these are 7 projects (and a number of sub-projects) that cover the main processes and requirements of REACH:

- RIP 1: REACH Process Description & Overall Guidance
- RIP 2: REACH-IT
- RIP 3: Guidance for Industry*
- RIP 4: Guidance for Regulatory Authorities*
- RIP 5 & 6: Setting-up the European Chemicals Agency
- RIP 7: Commission preparation for REACH

(* RIP 3 relates to technical guidance for industry and RIP 4 to technical guidance for authorities.)

3.2a Masterclass: RIP 2 - The IT system supporting REACH implementation

Figure 3 displays a flow-chart, illustrating the implementation support provided by the online IT system.

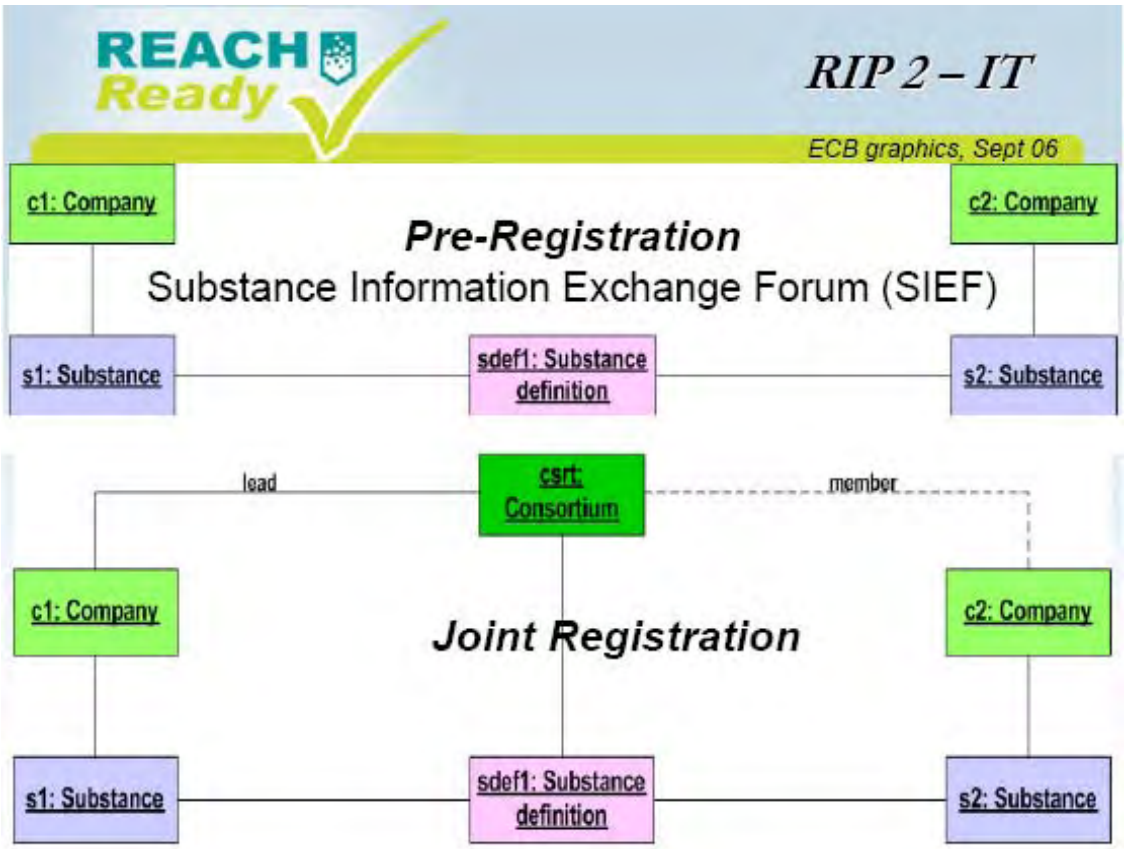

Figure 3: Illustration of the REACH Implementation Project 2 (RIP 2): the online IT-support provided (courtesy of Dr Steffen Erler, REACHReady).

3.2b Masterclass: RIP 3 – Guidance for Industry

Figure 4 displays a series of schematics, illustrating the complex structure of support provided through RIP 3 - Guidance for Industry. In particular, the Chemical Safety Report (CSR), required for substances at or above the 10 tonnes per year threshold, and the rules applying to substance identification are highlighted as fundamentally important for implementation.

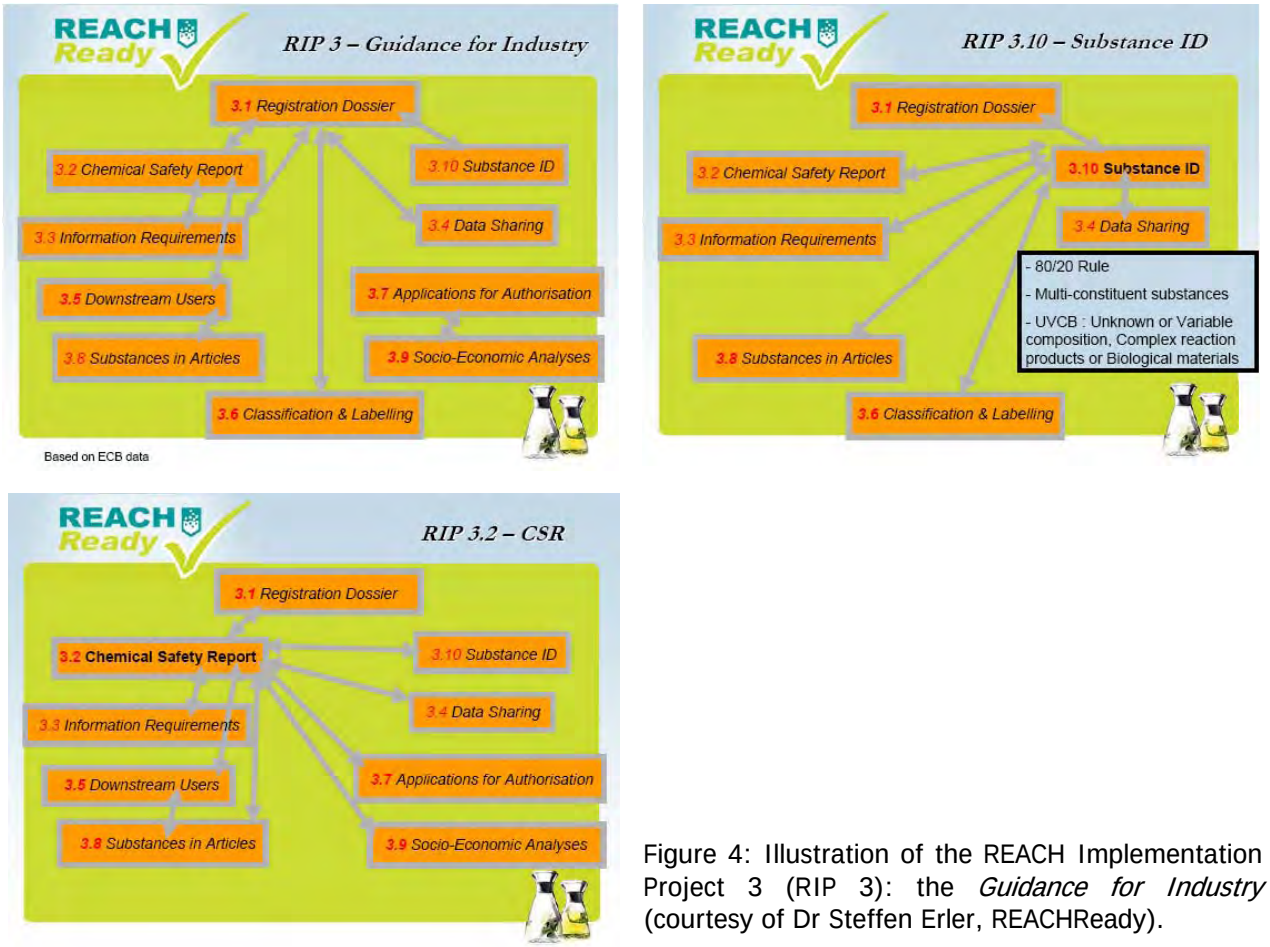

Figure 4: Illustration of the REACH Implementation Project 3 (RIP 3): the *Guidance for Industry* (courtesy of Dr Steffen Erler, REACHReady).

3.3 Masterclass: Data Sharing and use of SIEFs

REACH recommends extensive Data Sharing and use of Substance Information Exchange Forms (SIEFs); in the case of necessary vertebrate animal test, Data Sharing is mandatory, but it is highly commended that the provided Data Sharing mechanisms are also adopted for other tests.

In January 2009, the Agency will publish a list of pre-registered substances on its website (no company names will be given). Before this time, possibly on a first-come-first serve basis, the Agency is expected to inform all pre-registrants of what it views as potentially the same substance of the identity of the other companies. Company anonymity can be protected through the use of a third party or only representative. It is currently understood that upon pre-registration, all pre-registrants automatically become members of a possible substance-specific SIEFs. However, the Agency will not verify substance identity and it is therefore up to companies to confirm whether their substance definitions are the same, and to form the final SIEF.

After the publication of the list of pre-registered substances on the Agency's website, other parties may become members of the SIEF in question (*i.e.* companies manufacturing/importing below 1 tonne, downstream users, third parties holding information on substances, non-EU companies not active in the EU, etc.). Late entrants on the market may benefit from prolonged registration deadlines if they pre-register within 6 months of first manufacturing or importing and no later than 12 months before the relevant registration deadline (3, 6 or 11 years); in this case, they become members of the respective SIEF.

The main aim for SIEFs is to (a) facilitate exchange of information and avoid duplication of studies, and (b) agree classification and labelling of the substance.

Each SIEF will be operational until June 2018; it can form the basis of a consortium for Registration of substances (above 1,000 tonnes and SVHC) and 2013 (above 100 tonnes) and subsequent response to Evaluation. A SIEF may also form the platform for consortia formation to cover the 'Authorisation' discussions (*i.e.* defence of 'Candidate' or 'Priority' substances) and the Restrictions procedure.

Companies are encouraged to organise themselves within SIEFs; neither the Agency nor the Commission is planning to get involved in the management and organization of SIEFs. The cooperation within SIEFs may continue beyond 2018 on the basis of an agreement, even if the SIEF is formally dismantled. New entrants may need access to data submitted earlier than 12 years ago, in which case the older SIEF members would be compensated. Within the SIEFs, agreements covering all participants are not mandatory, but anti-trust memorandum and agreements to maintain discussions and information exchanged confidential are recommended at a minimum.

Data Sharing will be conducted within the existing SIEFs; formally, the first step will be taken by the first SIEF participant who needs to conduct a study for his registration dossier. In practice, however, companies are expected to start discussions before the pre-registration, in order to agree on issues such as substance identity. Figure 5 illustrates the anticipated Data Sharing process for a 'phase-in' case.

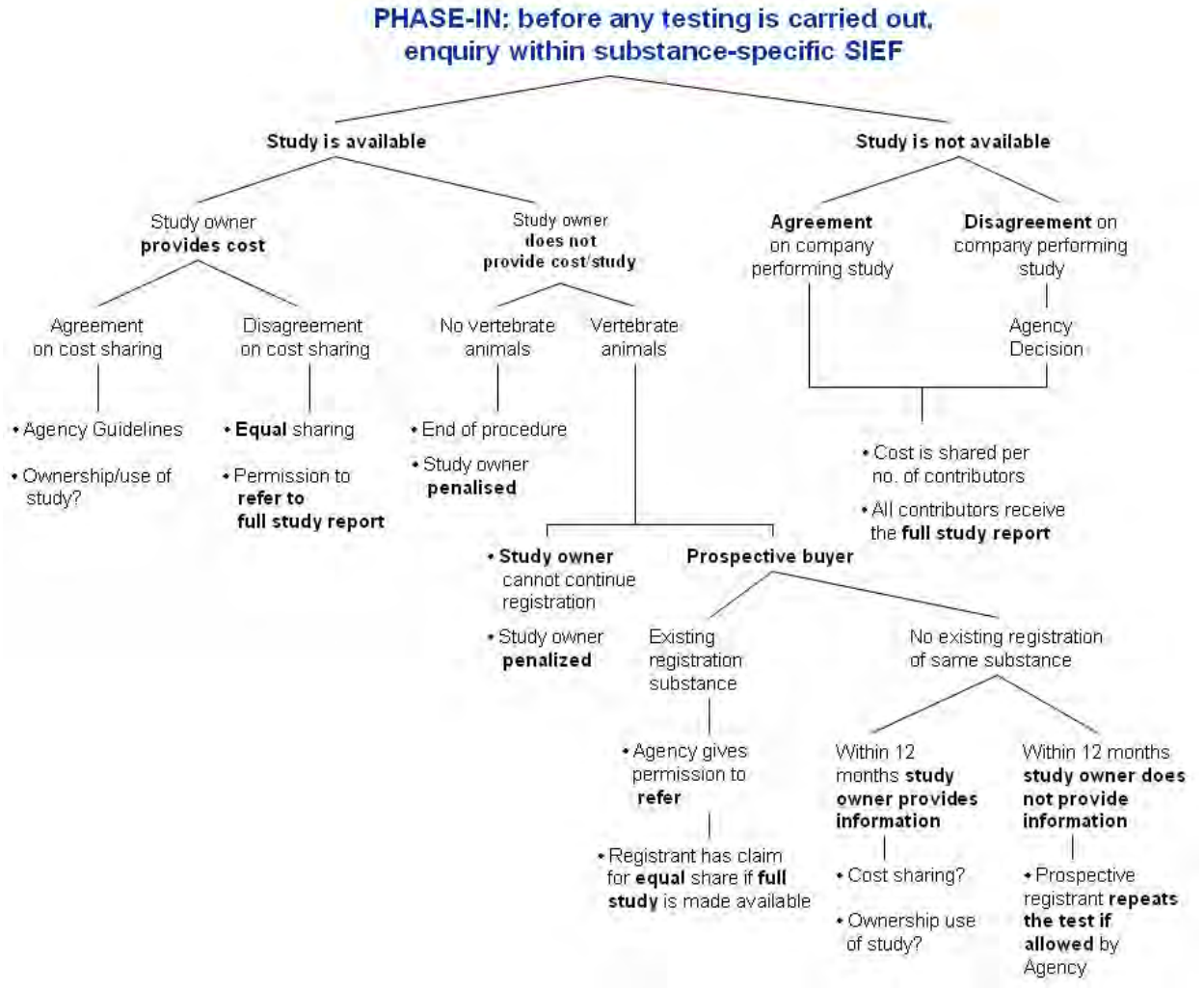

Figure 5: Illustration of a 'phase-in' Data Sharing process (courtesy of Ruxandra Cana, McKenna Long & Aldridge).

For the purpose of Registration, the following information is expected to be submitted jointly (*i.e.* by lead registrant):

- classification & labelling,
- study summaries & robust study summaries (per specific tonnage band), with proof of ownership or access, and
- testing proposal (not for Annexes VI and VII – tests to be conducted before registration).

Information expected to be submitted individually includes:
- identity of registrant & substance, and
- specific information on manufacture and uses.

Other information can be submitted jointly or separately, such as:
- guidance on safe use,
- chemical safety report (CSR), and
- information about completed reviews by assessors.

Companies may opt out of joint registration if:
- joint submission is disproportionately costly,
- disclosure of commercially sensitive information is likely to cause substantial commercial detriment, or
- there is disagreement with the lead registrant on the selection of information.

Figure 6 illustrates the anticipated Data Sharing process in case of a 'non phase-in' registration.

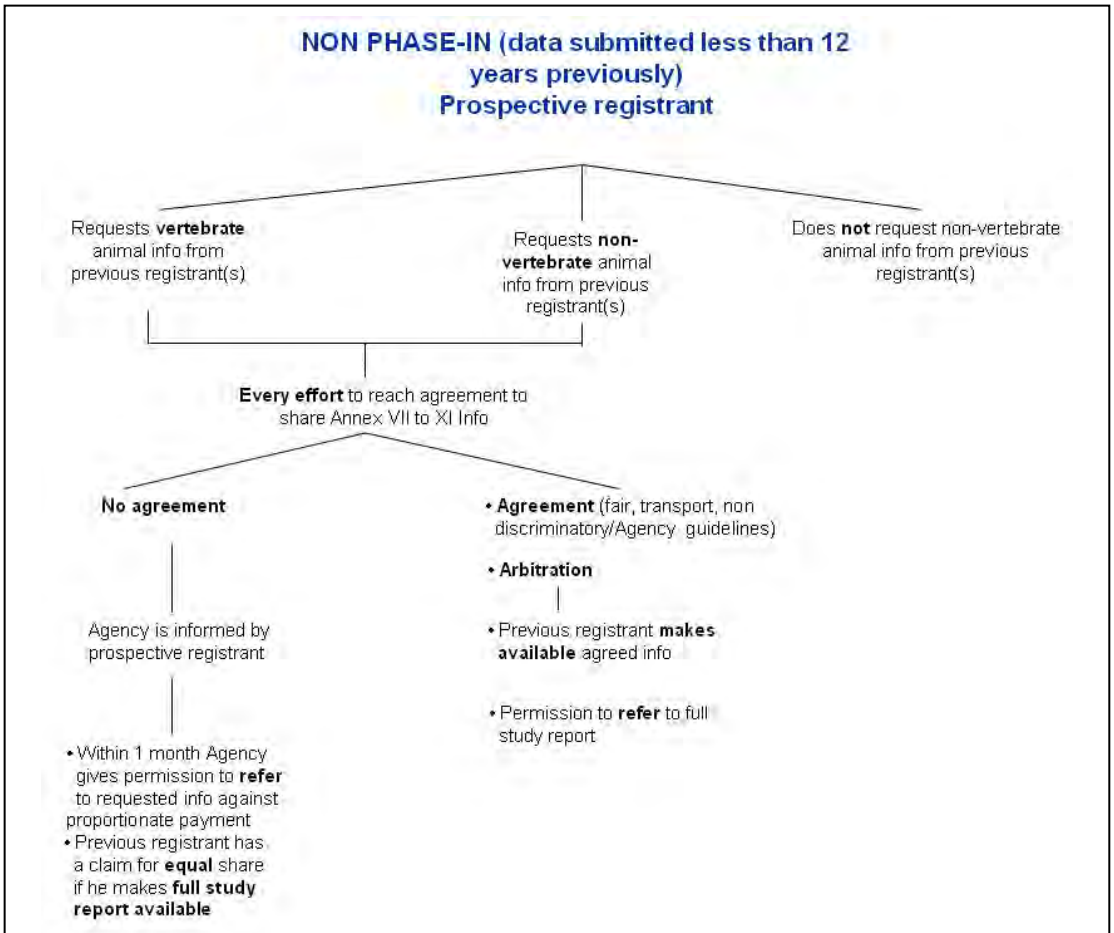

Figure 6: Illustration of a 'non phase-in' Data Sharing process (courtesy of Ruxandra Cana, McKenna Long & Aldridge).

Individual data requirements depend on the use and exposure categories of the substance in question (*i.e.* professional, industrial or consumer uses); the exposure categories are dependant on the routes of exposure, routes of emission into the environment and duration and frequency of exposure. Figure 7 illustrates the determination process of some data and communication requirements as a function of general use and exposure categories.

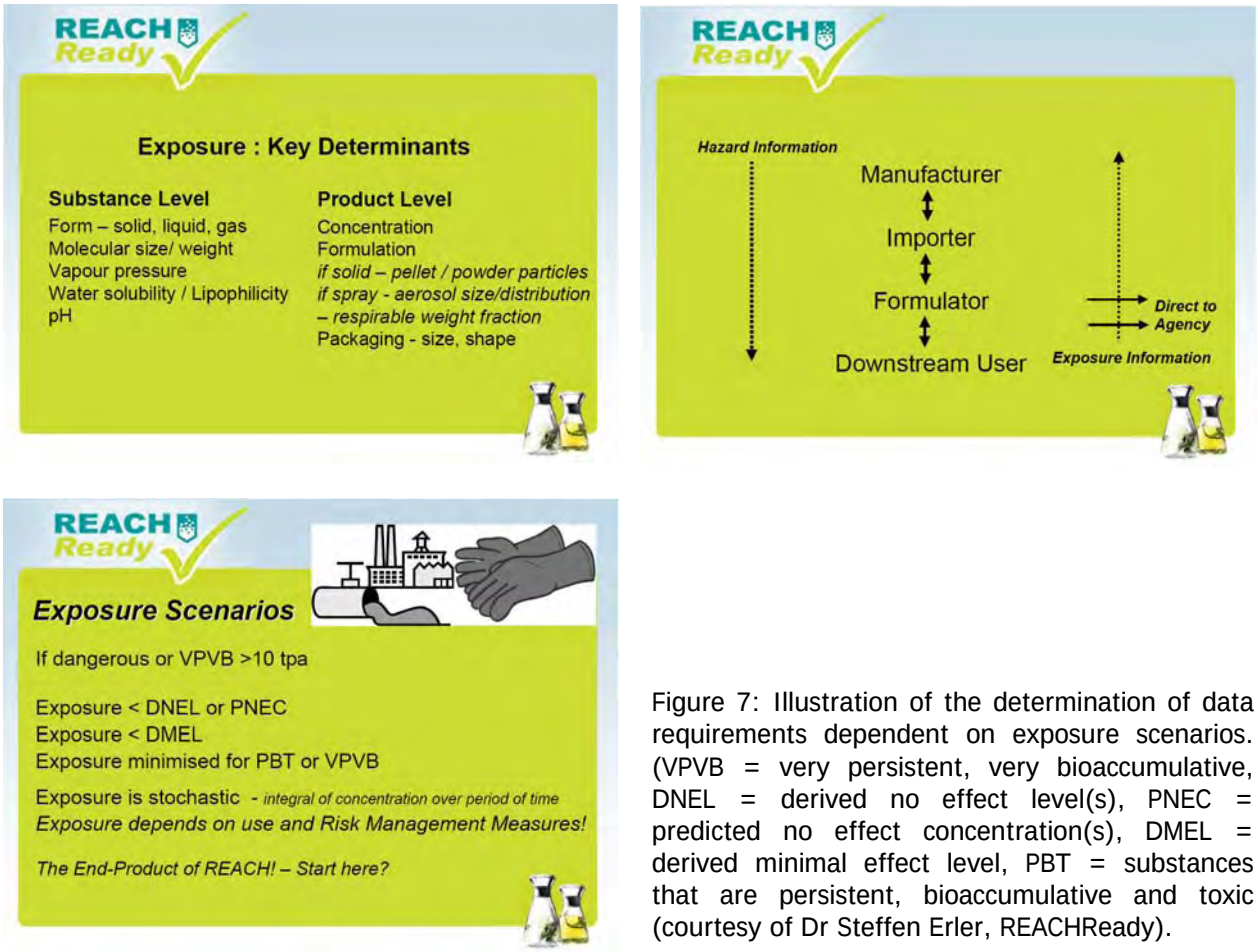

Figure 7: Illustration of the determination of data requirements dependent on exposure scenarios. (VPVB = very persistent, very bioaccumulative, DNEL = derived no effect level(s), PNEC = predicted no effect concentration(s), DMEL = derived minimal effect level, PBT = substances that are persistent, bioaccumulative and toxic (courtesy of Dr Steffen Erler, REACHReady).

Sharing the information relating to uses/exposure will be necessary to (a) devise testing strategies, and (b) agree on data waivers. A Chemical Safety Report must also be completed for dangerous or vPvB substances manufactured or imported above 10 tonnes per year. These substances must then have Exposure Scenarios developed that detail Risk Management Measures to ensure safe use. Relevant Exposure Scenarios must then be communicated through the supply chain as an Annex to Safety Data Sheets.

The sharing of information relating to uses/exposure could potentially be considered anti-competitive. In order to avoid such concerns, however, all information on uses may be transmitted to an independent third party, who would keep it confidential. The independent third party may then divide responsibilities to companies defending the same uses without disclosing the details.

3.4 Masterclass: Consortium Formation

Manufacturers and importers working together in a SIEF, or working with a new substance, are encouraged to form a consortium for the purposes of submitting a joint registration. Through the formation of consortia, companies are brought in line within the REACH provision to share data, and scientific inconsistencies are avoided. Other advantages include the reduction of costs for individual companies and the requirements of fewer company resources, as well as a strengthened position in front of the Agency.

On the other hand, it could be argued that the registration through consortia may take longer, due to a more complex underlying decision-making process. Individual companies could furthermore loose control of the conduct of studies, while their individual needs could be badly served by studies that have been selected on the basis of mean common dividers between all partners. Another major disadvantage of registration through consortia is the potential competitiveness regarding data sharing and data use.

Consortia usually are 'Task Forces' or 'Joint Ventures' without separate legal entities, and limited in scope and time. Following a more rigid model, companies may alternatively form a separate legal entity with its own legal personality.

Within the consortium, each manufacturer or importer needs to prepare his/her own registration dossier for his substance, even if he/she is member of a consortium, because commercially sensitive information may not be shared.[‡] The following competition law applies (Articles 81 (concerted practices) and 82 EC Treaty (abuse of dominant position)):

- Foreclosure may exist through joint exploitation of R&D results,
- Tying (R&D activities must be limited to developing data for REACH),
- No exchange of commercial information (markets, prices, etc.),
- Membership conditions must be fair, and
- Collective dominant position/definition of market.

The basic competition law criteria includes 'No discussions or exchange of sensitive information, such as (a) pricing or customer policies, (b) production, distribution or marketing plans, (c) production costs, capacity, sales volume, and (d) information about raw materials suppliers.'

'The REACH Proposal Process Description' explains: *If a consortium has been formed, one member will be selected to act on behalf of the other members. He will prepare and submit information on classification and labelling, summaries and robust study summaries of the required test data, any testing proposals required, and a declaration whether the consortium agrees that their summaries and robust study summaries of data concerning tests not involving vertebrate animal studies may be shared with subsequent registrants. This consortium member will also need to specify on whose behalf he is submitting the information.*

Each member of the consortium has to submit separately information about his identity, the identity of the consortium member who is acting on his behalf, the identity of

[‡] 'The REACH Proposal Process Description', European Commission, June 2004; obtainable from http://ecb.jrc.it/reach/rip/.

the substance, about manufacture and identified use(s) of the substance and a statement whether vertebrate animals have been used for testing. For the information that will be prepared and submitted by the chosen consortium member, the other members will only need to refer to it in their registrations.

The consortium members may choose whether to prepare and submit guidance on safe use as required by Annex IV as well as the chemical safety report, if required, separately or by one member on behalf of the others.

The consortium agreement is a contract; all participating parties have the discretion to decide about the underlying rules, provided these comply with (a) the Competition law, and (b) the REACH rules.

At a minimum, operating rules must be clear, transparent, proportionate and non-discriminatory. A case-by-case analysis may be warranted, unless a 'worst case' scenario is assumed in all cases.

It is important to note that all actions related to consortia are under continuous scrutiny from a competition law perspective, that at no time can a company's behaviour in the consortia be intended to result or result in the development of market barriers , and at no time can a company modify market behaviour based on information received or exchange confidential information within the consortium.

Figure 8 summarises the recommended managing preparations outlined above.

Figure 8: Summary of the recommended Managing Preparations for REACH (courtesy of Dr Steffen Erler, REACHReady).

4. Workshop: Nanomaterials under REACH

In the second half of the event, the Workshop examined scenarios and outlooks based on an inclusion of nanomaterials within the REACH Regulation; the audience considered the impact of REACH on nanomaterials within their own companies.

The Workshop explored whether and how conclusions under REACH could influence the scientific and legal assessment under other pieces of EU legislation, such as cosmetics and medical devices/medicines, where currently many nanomaterials are used.

4.1. Workshop: Pre-Registration of Nanomaterials

Section 2.1 outlines the history background of the debated inclusion of 'nanoparticles' into the authorisation-step of REACH, irrespective of the particles' properties. This proposal was voted down, and nanomaterials are therefore subject to the same requirements as all other substances (*i.e.* Registration, Notifications, Classification & Labelling Inventory, Communication of 'Candidate List' substances in articles, Restrictions and Authorisation).

Two Pre-Registration and Registration scenarios can be distinguished:

(a) Pre-Registration into different SIEFs:
- substances could be pre-registered and/or registered in a defined method to exclude 'nanoform', or
- alternatively, substances could be pre-registered and registered in 'nanoform' only.

(b) Pre-Registration under the same SIEFs:
- possibly no mandatory data sharing for registration, because not all data are needed or different data are needed

It is possible to opt out of consortia, if the substance definition of nanomaterials is restricted; in this case, the registration of nanomaterials may be submitted separately from the joint registration. A final possibility is the creation of specific (separate) consortia for nanomaterials.

Alternatively, nanomaterials can be registered within the consortium of the same bulk substance, if some of the data is shared (this might be difficult), if the nanomaterials manufacturers / importers opt-out from the joint submission altogether or if the exposure and use assessments are submitted separately. In such situations, nanomaterial forms of substances would be registered as specific uses. However, it is important to note that the precise descriptions of 'use' are under debate and the level of information on 'use' for substances below 10 tonnes per year is under review.

4.2. Workshop: Potential Handling of Nanomaterials under REACH

The following specifics for nanomaterials could apply to the current REACH Regulation model:

(a) Potential different data requirements:
- potential separate SIEFs/consortia, or
- different status in common SIEF/consortia.

(b) Different exposure scenarios:
- opt-out from joint registration dossier,
- participate in joint registration dossier, submit exposure scenarios separately, or
- point registration dossier by nanotech companies only.

(c) Potential authorisation based on 'nanoform' only:
- dangerous precedent, may result in public concerns, or
- potential non-applicability of 'adequate control', only substitutes.

Nanomaterials could potentially be included within the REACH Regulation under one of the following scenarios, which are subsequently analysed according to their advantages and disadvantages:

(a) Case-by-case basis (substance- or company-specific):
- Advantages:
  - no industry cooperation, more streamlined approach
- Disadvantages:
  - test cases may result in worst-case scenarios

(b) Industry-wide approach:
- Advantages:
  - harmonised approach, stronger position vis-à-vis competitors and authorities
- Disadvantages:
  - more difficult to obtain consensus
  - potential confidentiality concerns

4.3. Workshop: Potential Implications in other regulatory Areas

In case the REACH Regulation is amended to include technical requirements specific for nanomaterial, these requirements are likely to apply to sector-specific legislation as well (*e.g.* medical devices, cosmetics), without consideration of specifics.

New nano-specific legislation could be implemented (a) horizontally (*i.e.* the regulation is applicable to all uses), or (b) vertically (*i.e.* product specific); horizontal regulation is difficult to envisage, as it implies too many differences per uses, while vertical regulation would be a time-consuming effort.

Alternatively, REACH requirements could be addressed in time ('phased-in'), with pending definition and agreement of test methods/risk assessment methodologies. The advantages of this approach would be its anchoring on a sound scientific basis, while the disadvantages include a pronounced public pressure for precautionary restrictive measures (justified by scientific uncertainty).

5. Workshop: Next Steps

Having laid out the history, facts and current situation, as well as possible future of REACH for nanomaterials, the expert team presented and summarised uncertainties, such as the issue of exposure data, which may substantially differ for nanomaterials, and which may therefore need to be addressed and justified accordingly.

Through the discussion of future scenarios, the audience gained an understanding of the potential impact of an inclusion of nanomaterials within REACH; the debate and review of these scenarios by participants helped to develop the cornerstones and structures to influence any future debate on this topic and provided individual companies with guidance and opportunities to influence its implementation.

The Workshop concluded with agreeing on the following list of 'Next Steps':

1. Analyse nano-specific REACH requirements and identify consequences,
2. Assess advantages/disadvantages of industry-wide *versus* company-specific approach,
3. Prepare for any communications with EU authorities and Member States,
4. Prepare for contact with EU authorities through Member State authorities,
5. Utilise the potential REACH compliance to devise a public communication strategy, and
6. Propose a scheme to pilot a sample registration under REACH.

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APPENDIX I

Abbreviations:

CSR	chemical safety report
EINECS	European Inventory of Existing Commercial Chemical Substances
DMEL	derived minimal effect level
DNEL	derived no effect level(s)
PBT	substances that are persistent, bioaccumulative and toxic
PNEC	predicted no effect concentration(s)
PP	Precautionary Principle
PPORD	product- and process- orientated research and development
REACH	Registration, Evaluation and Authorisation of Chemicals
SIEF	substance information exchange forum
SVHC	substances of very high concern
vPvB	substances that are very persistent, very bioaccumulative

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APPENDIX II

Speakers' Biographies:

Ruxandra Cana - Partner at McKenna Long & Aldridge LLP

Ruxandra Cana is a partner in the Brussels office of McKenna Long & Aldridge LLP, where she counsels multinational companies and industry associations on European regulatory compliance and product defence, including related litigation.

Her areas of expertise include the European chemicals regulations (REACH in particular) and EU rules related to cosmetics, food and consumer products, such as electronics, reaching across many corresponding industry sectors.

Ruxandra was involved in advising clients on the impact of the new REACH since 2003 and she followed actively the discussions in the European Parliament and the Council of the EU. She now counsels companies on their REACH implementation efforts, including consortia formation.

Steffen Erler - REACHReady Technical Manager

With a background in biochemistry and engineering, Steffen Erler developed a practical knowledge of regulation during work with Bayer, the OECD Existing Chemicals Programme and the European Commission Enterprise DG Chemicals Unit. Steffen recently finished a PhD on REACH

Over the past few years, Steffen has worked as a consultant for companies, investors and regulators preparing for REACH. In June 2006, Steffen joined REACHReady, an enterprise created to help companies with REACH.