

Piloting REACH on Downstream Use
and Communication in Europe

Final Report

January 2006
Main Text

PRODUCE
Final Report

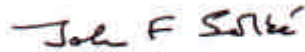
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FACILITATOR'S NOTE

This report is the result of the productive collaboration of groups of people who will have key parts to play when the REACH Proposal becomes part of EU legislation.

All participants, whether at working or management level of the project, and including the Commission and Member States, have done their utmost to achieve the objectives of PRODUCE within a very tight time-frame. This friendly co-operation has been of the greatest assistance to the Facilitator and he expresses his sincere gratitude.



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To assist the reader, in the main text lessons learned are given in *bold italics*.
Recommendations are placed in blue borders.

---Recommendations---

If further explanatory notes are required for either lessons learned or recommendations, these are given in *italics*.
Direct quotes from the proposed or existing legislation are placed in red borders.

---Legislation---

EXECUTIVE SUMMARY

PRODUCE (Piloting REACH On Downstream Use and Communication in Europe) is a Strategic Partnership set up to test and establish the workability of REACH, based on the Commission Proposal¹. The partners are three services of the European Commission, four Member States and Industry representatives. These include Manufacturers/Importers (M/I) (Suppliers) and Downstream Users (DU) of substances and preparations, among which are Formulators and non-formulators. Under the guidance of a multi-stakeholder Steering Group, and with additional input from observers such as Non-Governmental Organisations, the project had the aim of placing workability of REACH in a Downstream User context. Of necessity, the work had to proceed in the absence of technical guidance on REACH.

PRODUCE focused on one sub-set of downstream uses of substances: use of chemicals as ingredients in consumer products.

To test the workability of REACH for DU, three Working Groups (made up of Suppliers and Downstream Users) considered three typical and interesting examples of chemicals to which REACH would apply. These were

- a substance, made in the EU and to be used as a propellant gas in various applications;
- a complex preparation sourced both from within the EU and by importation, to be incorporated into other preparations;
- a substance imported into the EU by a company, solely for conversion into another chemical required by the importing company.

With these three substances and preparations, five cases could be examined, which sought to examine situations where uses had and had not been identified and to compare actions on substances with those on preparations.

Following six months of preliminary work the Project started on 22 June 2005 and was completed by 31 December 2005. The results will be made available in one or more suitable forms to all stakeholders and particularly to the Commission's REACH Implementation Projects, the European Parliament and Member States. A Workshop will be held under the Austrian Presidency to discuss the report with stakeholders, especially those involved with communication in the industrial and retail sectors downstream of the Manufacturers or Importers of chemicals.

More than 30 recommendations of specific interest for Downstream User Companies have been made in the report, addressed to the Commission, Companies, Trade Associations / Sector Groups. The most important recommendations are as follows.

- Companies must ensure full awareness of their roles and responsibilities under REACH and should start to get ready to meet their duties under REACH by accommodating their internal organisation, collecting the necessary information and proactively contacting their business partners as appropriate;

¹ Commission Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC on the classification, packaging and labelling of dangerous preparations and Regulation (EC) {on Persistent Organic Pollutants} from 29 October 2003. Brussels, 29.10.2003, COM(2003) 644 final.

- Trade Associations and Sector Groups should play a pivotal role in raising awareness of REACH;
- DU should be encouraged to add their own information to that of Registrants; for this and other reasons, guidance should further explore Confidential Business Information issues;
- It would be helpful if a convenient way could be found to identify registered substances on Safety Data Sheets by a single code which cannot be linked to the identity of the Supplier and which is globally relevant;
- There should be greater recognition of the different approaches to human-health and environmental exposure scenarios (and thus assessments). Targeted risk assessment should be strengthened in REACH: Risk assessment should only be required for a target if the substance is classified for hazards appropriate to that target.

The report pays particular attention to the various difficulties of preparing a Chemical Safety Assessment for preparations. For human health a Chemical Safety Assessment for preparations is extremely difficult but not impossible. For the environment it is even more difficult. Therefore it is recommended

- To develop guidance for preparations as well as appropriate and workable methodologies, requiring proportional resources.

More than 50 'lessons learned' have been listed in one of the extensive appendices to this report, which will be made available on CD. Other appendices cover inputs to the project in the form of compiled questions and answers that arose and were used as *modus operandi* during the project, Competent Authority notes, extended Safety Data Sheets, advice from a Trade Association and an informal note to help Downstream Users to prepare for REACH.

Is the REACH Proposal workable? Although it is very complex and still lacks the necessary guidance to test it fully, the conclusion is that REACH is extremely time-consuming and hard to grasp in its entirety but it is not un-workable. This emphasizes and confirms the strong need for guidance and tools, to be developed under the REACH Implementation Projects.

RECOMMENDATIONS

as agreed by the Steering Group

Preface

It should be noted that the roles of companies under REACH do not depend on the nature of the Company but rather on the nature of the substance and the activity and situation of the Company in relation to this substance. Throughout this report the words Receiving Company² will be used for a company receiving chemicals or preparations and using or selling them. A Receiving Company can have different roles under REACH such as Downstream User³, Distributor, Warehousing Company, Importer, Retailer and Professional User, alone or in combination.

Preliminary actions by Companies and their Organisations

- 1. Companies must check their roles and responsibilities under REACH for each substance used as such or in a preparation, i.e. as Manufacturer, Importer, Distributor or Downstream User as defined by REACH. [Section 5]**

With the proposed new framework under REACH for assessing the safety of chemicals in their production, supply and use, activities of a Company may fall under different roles and responsibilities for different chemicals. Consequently, one single company may have more than one role and it may not be immediately obvious where their roles apply.

- 2. Receiving Companies should analyse the REACH processes, understand their obligations for each link in the supply chain where they may be involved and assign tasks and duties relevant to each requirement.**

With complex preparations the upstream side may have a multiplicity of supply chains, from inside and outside the EU, with many chemicals involved in every preparation etc. The learning from this was that it takes far longer to establish company roles and responsibilities.

- 3. It is recommended that Companies having roles under REACH should establish and implement systems to enable themselves to assemble the information they will need to comply with REACH in an efficient manner. There is a necessity (as under current legislation) to keep an annual update on tonnage and origin of substances as such and as part of a preparation. [Section 5]**

Information will be needed from companies under REACH on volumes, new substances and preparations, new uses and Suppliers. As a Downstream User in REACH it is by monitoring the incoming Safety Data Sheets that obligations under REACH in this respect are triggered.

² When referring to a company purchasing substances without specifying whether this is from inside or outside the EU, the term “Receiving Company” will be used throughout the report. This Receiving Company can be either a Downstream User or an Importer, as per REACH definition.

³ As per REACH definition.

4. Non-EU manufacturers exporting into the EU are encouraged to consider the value of establishing an EU representative. Companies importing from outside the EU should contact their suppliers at an early stage to check if their supplier would like to nominate an EU representative and thus decide who will take on the role of Importer (Registrant). [Section 7.1]

5. It is recommended that Trade Associations should play a pivotal role in raising the awareness of REACH among their members and provide appropriate guidance, in particular for SMEs. [Section 5]

Trade Associations will need to maintain thorough awareness of the legislation and keep up to speed on the progress of the REACH Implementation Projects (RIP). They should provide their membership with guidance on an ongoing basis. (See, for example, Appendix D.)

6. Cross-industry initiatives (like HERA) or Sector Groups should be encouraged to think of themselves as one of the natural brokers (facilitators) of consortia formation and to organise their member companies to assist each other in preparing for and acting on the REACH legislation. [Section 7.2.1]

Upstream / Downstream Collaboration

7. Given the complexity and ever-changing detail of supply-chain management, companies should identify a person (function) or persons who can act as points of contact for the purposes of REACH, and communicate these up and down the Supply Chain, for example taking advantage of Sales-Force/Buyers liaison. [Section 5]

8. When purchasing from outside the EU (unless through a representative, see Recommendation 4), the Importer needs to be told the aggregate amounts of each substance sold to them, e.g. in all perfumes supplied by a non-EU Supplier, even if the exact formulations are not divulged. [Section 5]

This is recommended because when tonnages exceed one tonne per year there may be a need to register.

9. It is recommended that RIP Guidance should investigate different ways of handling Confidential Business Information. In doing so, one could take into account the experiences of HERA and ERASM on Upstream/Downstream companies working together and of PRODUCE. [Section 7.3]

The combined experience from three decades of collaboration in the surfactant industry has demonstrated the practical advantages (and the problems) of

upstream/downstream partnerships, developing the practicalities and science of delivering targeted risk assessments and publishing the lessons learned.

10. Currently, only Manufacturer/Importer may be members of Substance Information Exchange Fora (SIEFs), but DU Companies should also be allowed and encouraged to become members of SIEFs, if they can contribute data for Registration. [Section 7.4]

This will minimise any possible shortfall in the interpretation of data and risk due to lack of data or any special understanding of use known to the Downstream User. (The PRODUCE Team accepts the fact that there may be a considerable imbalance between the data-rich and data-poor companies and indeed the importance of a Receiving Company chemical to a Supplier. Some proportionality in the degree of representation on a consortium might therefore be needed.)

11. Downstream Users should be encouraged (as is their right) to identify and add their own data to those of registrant/s (Article 34(2)) and to help, for example, to model human exposure or environmental fate and reduce the need for further animal testing. A mechanism should be provided for Downstream Users to identify and contribute data to SIEFs. Besides, in the political agreement reached by the Council, there is an inconsistency between Articles 26.6 and 27.1 of REACH which needs to be resolved. [Section 7.4]

There is good precedent for collaborative work (e.g. the development of the environmental modelling system GREAT-ER) and Suppliers should continue to encourage this.

Registration

12. In order to complete the work for Registration the process should be automated as much as possible, as is done in many parts of the EU with the submission and calculation of Income Tax returns. [Sections 6.2 and 7.5.1]

The REACH proposal states that “A downstream user may provide information to assist in the preparation of a registration”. The Project Team are convinced, that Downstream Users in some cases will have to be far more involved than Article 34(1) would imply. Indeed, this is in everybody’s interests. The Project Team have identified possible cases where the producers might not be capable of carrying out a fully successful Registration. One DU Company looked at the question of ensuring that substances are correctly registered in such cases. The work needed could go beyond a simple ‘assistance’ because a DU Company in such a position might want to be involved in consortia, pay for tests and participate in decision making. Whilst it will be difficult for some DUs to participate beyond providing basic assistance, some might also want to participate to the same high degree in the Registration of substances imported (e.g. from China) by trading companies and brokers whose attempts at Registration within the REACH time-frame would otherwise fail.

13. For the sake of practicality (and to maintain competitiveness) in identifying substances once and for all, it is recommended that a system should be found and implemented to avoid the problem of continual modifications to Safety Data Sheets. [Section 5]

Several Registration numbers could be associated with one substance (even if the proposal for ‘One Substance, One Registration’ (OSOR) was adopted). These registration numbers may be specific to individual suppliers/registrants. If Registration numbers are on Safety Data Sheets for preparations, not only may confidential business information be disclosed (by linking the Registration numbers to individual Suppliers – see below) but also there would be a continual and unworkable need to modify Safety Data Sheets (SDS) of preparations to reflect changes in supply chain. A solution might be the use of composite Registration numbers with separate substance-related and supplier-related number strings, if the downstream preparation Safety Data Sheets should only be required to show the substance-related number strings. In addition, the use of CAS, EINECS, or ELINCS numbers would in many cases provide a workable solution if they can be linked in the REACH-IT system to the relevant Registration numbers, especially for global application and relevance.

14. It is recommended that Registration numbers that can be linked to individual suppliers should not be included in Safety Data Sheets for preparations. It is further recommended that this problem of maintaining confidentiality be addressed in the relevant RIP. [Sections 5 and 7.8.4]

In Article 116 on Confidentiality, part 1(a) states that a Trade Name is not confidential. However, part 2(d) in the same Article states that links between a Manufacturer/Importer and Downstream Users are confidential. In a Safety Data Sheet a Trade Name can be inserted, but this automatically permits the link to be made and the confidentiality to be lost. In the context of the Globally Harmonised System for Classification and Labelling of Chemicals (GHS), and the hoped-for opportunity to generate globally applicable Safety Data Sheets, CAS numbers may be preferred and registration numbers could be added to Section 15. This would ensure that there was no confidential business information in the Safety Data Sheets for preparations but would still enable Receiving Companies to identify Suppliers registering a substance, provided that they are given proper access to the relevant sections of REACH-IT.

[Note that Article 116(2) has been deleted in the Political Agreement text. In relation to preparations, Article 10(2)(3) still applies.]

15. In order to ensure sourcing flexibility now and in the future, Receiving Companies need to develop an awareness of Suppliers’ intentions to register / pre-register a substance. [Sections 5 and 7.2.4]

Receiving Companies should be aware that, because of choices made by Suppliers under REACH, they may have to find new Suppliers for some of their chemicals. Therefore they need to contact their existing Suppliers as soon as possible to assess the situation. Downstream Users who are entitled to become members of a SIEF will be able to check whether their substances have been Pre-Registered. If they have not, they can take the appropriate action to ensure continuity of supply.

16. Downstream Users should be encouraged to contact their Suppliers to ensure that all information they (DUs) have is used in the CSR. [Section 7.6.1]

Receiving Companies may wish to access substance CSRs in order to check that the risks associated with their use have been adequately considered.

17. The part of the proposal (Annex 1, Section 7) which sets out the format of the Chemical Safety Report should be revised so that the data entries appear in logical order. [Section 7.5.3]

The current version mixes up a whole series of subjects e.g. the environmental fate properties are misplaced.

Safety Data Sheets

18. To enable the new Extended Safety Data Sheets to be easily translated into the different languages of the Community the standard phrases that have been developed for the Dangerous Substances and Preparations Directives need to be extended to cater for the requirements of REACH. Trade Associations could lead a sector approach in standardisation of phraseology to facilitate this work. [Section 7.5.8] In addition, consistency with GHS should be pursued [but note that the extended part of the SDS is not a part of GHS].

Automated software is available to prepare Safety Data Sheets in the different languages of the Community. The new requirements to include Exposure Scenarios (which will generally require free text) in Safety Data Sheets and Risk Management Measures do not lend themselves to this sort of approach. Any means of minimising the variety of the phrasing would be welcomed.

19. To identify and summarise the Registration, Restriction or Authorisation status of a substance or substances in a preparation would be made easier by the use of standard phrasing, probably in Section 15 in the substance Safety Data Sheets. It is recommended that this should be investigated further. [Section 7.8.4]

This would limit the number of times the Safety Data Sheets would need to be modified and also keep the data sheet more in line with current and future texts on SDS; it could help if the REACH Registration numbers were also given in Section 15 of the substance Safety Data Sheets.

20. In order to distinguish whether the absence of data in the Safety Data Sheets against a heading was due to a gap in knowledge or to the existence of information rendering the entry valueless, it would be worthwhile if a full list of properties was provided in the Safety Data Sheets, with “not applicable” (“N/A”) written against any item where such a phrase was valid. [Section 7.8.4]

Section 9 of the Safety Data Sheets deals with physical and chemical properties. Many of the properties stated may be irrelevant to many substances or preparations.

21. When designing and compiling template documents for Pre-Registration and Registration, care should be taken to avoid inflexible, repetitious processes. [Section 7.5]

Chemical Safety Report and Exposure Scenarios

22. Companies should distinguish their roles in relation to environmental risk assessments. Companies should make an environmental assessment, both at the local and regional scale, of the volume they put on the market. The authorities may then perform a local and/or regional assessment of the total volume of the substance under “Substance Evaluation”. [Section 7.7]

In order to facilitate regional environmental risk assessments, it is important to know the total tonnage of a substance used but this is not the responsibility of the Downstream Users or anyone else in the Supply Chain. Where this tonnage is made up of various sources, including imports of substances and preparations the contributions from each source must be known. It is the responsibility of the Competent Authority performing substance evaluation to assemble the aggregated volume and make the total assessment. (Production volumes cannot be disclosed.)

23. Where required, Chemical Safety Assessments prepared by Receiving Companies should address all their own relevant uses and associated Exposure Scenarios. [Section 7.5.2]

A Supplier may indicate a maximum level of a substance or preparation for use in a consumer product e.g. that use of a classified substance, x, is safe for use in skin cream at 1%. If a DU uses x at >1% they will need to assess this new ES (to consumers) as it is not covered by the Supplier and may pose higher risks to the consumer. However, the higher inclusion level may not affect the environmental ES if the route of disposal is the same as assessed by the Supplier. Receiving Companies still have a responsibility to check that environmental aspects are not affected by modifying the health aspects of the CSA and vice versa where for example a secondary source of human exposure may arise from contamination of the environment.)

24. Different approaches may be necessary for environmental and human health Exposure Scenarios (ESs). [Section 7.5.2]

Human health ESs would typically be based on the percentage of a chemical in a product and may need to be more detailed to account for an individual's exposure to a substance whereas an environmental ES would be based on tonnages and needs to take a broad view to account for the many possible facets of environmental exposure and the need to safeguard populations rather than individuals.

25. In order for the option to conduct a preparation CSA within REACH to be workable, especially for SME companies, there will be a need to develop acceptable methods that will have to be simple as well as meaningful, considering the vast number of preparations placed on the EU market. Resources channelled into this activity must be proportionate. [Section 7.7.2]

The PRODUCE Team struggled to find a scientifically justifiable approach to developing Chemical Safety Assessments (CSAs) for Preparations. It should be recognised that one methodology may not be appropriate for all product sectors and that an approach designed specifically for a particular sector may be more

appropriate to the relevant workability, human health and environmental issues associated with the products within that sector.

26. Individual Sector Groups should be encouraged to compile data-bases on descriptions of uses throughout the Supply Chain. [Section 7.5.2]

27. Sector Groups may usefully provide a standard framework for the development of Exposure Scenarios relevant to their own sector. [Section 7.5.2]

(Note similar recommendation from RIP 3.5.)

Risk Assessments

28. Risk assessments should not be required for human health and the environment unless the substance is classified for hazards appropriate to that target.⁴ [Section 7.5.4]

Comprehensive Risk Assessments are not part of the REACH Proposal but Targeted Risk Assessments are, and are considered by the PRODUCE Team to be useful in relation to issues (ES) of concern. PRODUCE tested a comprehensive approach just to see how difficult and time-consuming it could be. REACH is clear that classification of a substance leads to production of a Chemical Safety Assessment and Exposure Scenario. Non-classified substances require only a statement of hazard assessment. There is, however, a likelihood that a substance will be classified based on one aspect of its intrinsic properties (say toxicological) and not on others such as environmental.

Communication

29. Further work is recommended to address the needs for appropriate communication beyond the Downstream Users in the distribution chain as specified in REACH. For warehousing, transporting (not in REACH) and retailing, as well as for personal use of products containing the chemical and for waste disposal operations, further work is needed on targeted communication in addition to that specified in REACH. [Section 7.8.5]

The REACH Proposal encourages communication but is limited in its scope. Since 2003 there have been developments which have expressed the need for wider communication to enable REACH to achieve its ends. The PRODUCE Team discussed with Retailers the kind of safety communication they would find useful. The Safety Data Sheet was regarded as something to which they might have access in an emergency but what they really needed was a simple set of safety instructions based on the Safety Data Sheet.

⁴ This problem has been addressed and solved in the political agreement on REACH.

Guidance

30. The Chemicals Agency should facilitate the development of a glossary of terms targeted at Receiving Companies and presented in all official EU languages. [Section 7.1]

It could be very helpful to provide guidance on terminology, especially for the SMEs. REACH definitions and especially the definitions of different Receiving Company roles as per RIP 3.5 would be welcomed.

31. It is recommended that guidance should highlight those responsibilities which are continuing from previous legislation and those which are new responsibilities under REACH. [Section 5]

RIP 3.5 could consider this by adding further clarification, highlighting the new and continuing aspects of legislation.

32. In the case where a Downstream User may have a large amount of data and experience which it wishes to share with its Suppliers to assist in consortia discussions and to facilitate data-sharing, we recommend that Downstream Users be allowed and encouraged to participate effectively in the process using the relevant technical tools. [Section 7.3]

In the case described above, the Receiving Company would need access to IUCLID 5 / REACH IT systems so that it could contribute in the appropriate technical language. A Downstream User will be able to examine the Pre-Registration list of substances. Downstream Users can then enter a SIEF if they have relevant data. To this extent they should be given access to the same tools and training (IUCLID 5 and REACH-IT) as that available to Suppliers.

33. Guidance is needed to determine the sufficient level of justification if standard information requirements are adapted in a registration dossier. [Section 7.6.1]

34. Guidance is needed on how to use existing information such as historical human data. [Section 7.6.1]

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1. INTRODUCTION

PRODUCE (Piloting REACH on Downstream Use and Communication in Europe) is a Strategic Partnership between the European Commission, a number of Member States and Industry to study the workability of REACH. REACH is the process for Registration, Evaluation and Authorisation of chemicals in the EU. The process is outlined in the proposal from the European Commission COM (2003) 644, of 29 October 2003⁵ and it is this proposal which is the principal basis for the work of PRODUCE. Two Strategic Partnerships have been formed as an element of the Interim Strategy of the Commission, which also includes drafting the necessary guidance documents, software tools and infrastructure through a number of REACH Implementation Projects (RIPs).

SPORT (Strategic Partnership On REACH Testing), managed by Cefic (the European Chemical Industry Council) was a partnership between three Commission Services, nine Member States and a broad industry coalition. It has used information on eight substances or substance groupings, particularly to examine workability at the upstream end of the Supply Chain. SPORT delivered its final report in July 2005.

PRODUCE (Piloting REACH On Downstream Users of Chemicals in Europe) started its work on 22 June 2005 (but benefited from a considerable amount of preliminary work by the partners initiated in January 2005). The partners in this Strategic Partnerships were four Member States, three Commission Services and six companies inside and outside the EU. PRODUCE has examined the workability of certain aspects of the Commission proposal *via* three sub-Projects where the implications of REACH have been pilot-tested on selected substances and preparations, examining five types of situation. The focus has been very much on downstream aspects of the proposed legislation but to place these in context a wider view was needed (further upstream within REACH and further downstream, outside REACH). The work was to be completed at the end of 2005.

In the cases of both SPORT and PRODUCE, it is important to note that these Strategic Partnerships did not have the benefit of guidance documents, since these are still being drafted within the RIPs. Indeed, the two partnerships are feeding information to aid the development of REACH Guidance. It should also be noted that the PRODUCE Team experiences are likely to be very specific and may not be representative of the whole area of Downstream Users.

⁵ Commission Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC on the classification, packaging and labelling of dangerous preparations and Regulation (EC) {on Persistent Organic Pollutants} from 29 October 2003. Brussels, 29.10.2003, COM(2003) 644 final.

2. OBJECTIVES OF PRODUCE

The following objectives were agreed by the Steering Group.

- To learn what the Commission proposal for REACH means for a Downstream User of chemicals and to gain hands-on experience within the general working environment of a Receiving Company and its Suppliers, that can be shared with Industry partners and in particular with SMEs;
- To test the communication system along the supply chain (upstream and downstream);
- To develop procedures for the formation of partnerships between Manufacturers / Importers and Downstream Users for the former to develop Registration dossiers with their immediate customers, and for both to maximise synergy⁶ between themselves and amongst all stakeholders, and to improve the understanding of practicalities of REACH⁷;
- To test and to establish the workability of the Pre-registration and Registration steps in REACH, including the organisational set-up and requirements;
- Where the REACH proposal does not specify how certain parts of REACH work or have to be carried out in practice, to make assumptions and test these;
- To advise the European Commission on aspects of the REACH process which, based on case studies, could create workability problems;
- To provide input to (and use results of) REACH Implementation Projects, and to identify additional requirements for guidance, guidelines, tools, methodologies and approaches beyond those already incorporated in the Commission's Interim Strategy work plan.

⁶ ...while recognising the competitive aspects arising from any legislation applied to commerce.

⁷ PRODUCE may in particular identify the value of generic scenarios covering the use of household cleaning chemicals and preparations.

3. ORGANISATION AND *MODUS OPERANDI*

PRODUCE was organized in a similar manner to SPORT, whose organisation had proved effective. The highest decision-making body was the multi-stakeholder Steering Group, setting directions, while day-to-day management was in the hands of a single Project Manager, who reported to the Steering Group and was a member of a small 'hands-on' Contact Group, set up to ensure continuity of communication between the Sub-Project Working Groups and the Steering Group. Further details of the roles and composition of these groups are given in Appendix A.

The Project was facilitated by a consultant, who had the responsibility, among other matters, to act as Technical Secretary to the Steering Group and to draft the interim and final reports of PRODUCE.

PRODUCE used the experience of three Sub-Project Working Groups which had each studied one of the chosen three substances / preparations. These Sub-Projects are described below but not as individual Sub-Project reports. Instead, parts of their specific outputs, for example, considerations of Article 13 (Chemical Safety Report) or an analysis of work required by Downstream Users under Article 34, may be found in this document.

3.1 *Rules of PRODUCE*

In a Project of the nature of a Strategic Partnership, with many interests involved, from all aspects of European industry, government and public representation, rules of procedure, if not essential, are very valuable. The following rules were agreed at the first meeting of the Steering Group, on 22 June 2005.

- (i) PRODUCE will examine the workability of the proposed REACH process, not the risk profile of the substances chosen as examples.
- (ii) Members will respect the confidentiality of any material provided to them and described as 'In Confidence' and will not disclose it outside the PRODUCE Team (Steering Group, Contact Group, Sub-Project Working Groups).
- (iii) Given the above, and adhering absolutely to Competition Law, the principles of transparency will be followed within the PRODUCE Team.
- (iv) Conflicts will be resolved at the lowest possible level in the PRODUCE Team. The Facilitator may be asked to intervene and seek a resolution.
- (v) A Deputy of a voting member may attend meetings of the Steering Group when the absence of the member is unavoidable. Observers may be accompanied by an additional representative of their organisation.
- (vi) The draft results of the Project will not be modified for any purpose that diminishes their value as a study of workability or impairs the credibility of the Steering Group.
- (vii) Publications arising from the Strategic Partnership must be authorised in advance by the Steering Group.

4. DESCRIPTION OF SUB-PROJECTS

in order to explore aspects of workability

4.1 The Sub-Project Working Groups

Table 4.1 identifies the sub-projects and participants. The term ‘Receiving Company’ is introduced to avoid assumptions that a company is acting as only a DU Company in REACH terminology or only as an Importer. (A further note on this subject is provided in Appendix E.) Nevertheless ‘Supplier’ does mean Manufacturer/Importer throughout. It may be noted that two Suppliers had headquarters outside the EU. The Member States had different roles in the Sub-Projects, as described under section 4.2 (a) to (c) below. The membership of the Sub-Project Working Groups is given in Appendix A.

Table 4.1 Summary of involvement in Sub-Projects of PRODUCE

Substance or Preparation	Receiving Companies	Roles of Receiving Companies	Supplier	Member State	Commission involvement
A propellant gas (LPG)	Unilever	DU	BP	Greece	DG JRC*** DG ENTR
	McBride/APL*	DU			
	BAMA**	Trade assoc			
A perfume preparation	Unilever	Importer	Firmenich (CH)	Netherlands	JRC
	Unilever	DU			
	Carrefour	Distributor			
Linear alkylbenzene	Unilever	Importer	ISU (Korea)	Hungary	JRC DG ENV

* APL (Aerosol Products Ltd is part of McBride)

** BAMA (British Aerosol Manufacturers’ Association)

*** JRC: Joint Research Centre playing the role of the Agency and performing completeness check

4.2 Details of the Sub-Projects

Each Sub-Project is outlined to a single format:

- specification;
- uses;
- role of MSCA / JRC-ECB;
- information available to or generated by PRODUCE⁸; aspects of particular interest to PRODUCE.

a) Spray-can propellant gas from EU

(i) *Specification of substance/s used in PRODUCE*

⁸ A selection of this material will be provided for each case in the Appendices.

The LPG (CAS number: 68476-85-7) is assumed to have a single specification for European use, i.e. 40 psi arising from a controlled composition of *n*-butane, isobutane, propane and pentane.

(ii) Uses of the substance/s

REACH does not provide enough detail to define specific exposures for each generic type of exposure for the various possible uses available. The PRODUCE Team therefore prepared its own detail. (Future work by RIP 3.5.1 should address this need for guidance.)

Propellants are used within Unilever Home & Personal Care, Europe as in the table below. A similar situation applies in McBride/APL, although they do have additional applications such as air fresheners (included) and insecticides (not evaluated here).

Percentage substance in product	
Higher Group (30-100%)	Lower Group (1-10%)
deodorant	hair-mousse
anti-perspirant	shower mousse
hairspray	shaving foam
	household care

(iii) Role of MSCA and JRC

The JRC was asked to carry out a completeness check of the Registration dossier. The Greek CA was asked to focus on key aspects of the Chemical Safety Report. This would include:

- a compliance check (v data requirements for >1000 tpa);
- check of classification and risk management phrases;
- the approaches taken on data gaps;
- a chemical class approach;
- use of alternative data, e.g. human volunteer data;
- the influence of physico/chemical properties on risk management decisions.

(iv) Information available to, or generated by the Sub-Project Working Group
Available

- Guidance from BAMA and BP on material specification requirements for propellants;

Generated

- Chemical Safety Report: LPG as a hydrocarbon propellant (Appendix H2);
- Pre-Registration document;
- Registration document;
- PRODUCE (as distinct from REACH) Risk Assessment (i.e. on downstream products – aerosols using LPG propellant);
- Extended SDS (Appendix H1);
- Extended SDS for an air-freshener containing LPG (Appendix J).

(i) Aspects of particular interest to the Sub-Project Working Group and PRODUCE

Completion of a dossier for this high-volume chemical (>1,000 tonnes) including CSA/CSR: refinement of human exposure assessment, accounting for diverse LPG content and use scenarios;

Consideration of the requirement for testing proposals to be added to the dossier;

Discussion of specific points of evaluation:

- UVCB material (Unknown Variable Composition or Biological origin):
- Differences from a well-defined organic material;
- LPG as a very simple example of an UVCB mixture;
- Grouping approach: the representativeness of the dataset for a larger chemical class comprising different CAS numbers;
- The value and acceptability of non-GLP data :

The notes on scoping RIP 3.3 on the use of non-GLP data were considered.

- The use of human data for filling data gaps (for example volunteer studies from the 1970s; data from accidents and studies of solvent abuse);
- Physical / chemical data, risks of fire and explosion;
- Reasons/justification for providing waiving statements and read-across (inferences drawn from related data).

The LPG extended SDS was prepared for workers and Downstream Users; the extended formulation SDS, was intended to be used to communicate through distributors, for example including risk management information for both. The useful BAMA guidance on tanker operations (factory handling and process safety) was noted.

Consequences for communication to consumers were to be considered.

The BAMA Retail Liaison Group was involved as distributors, in addition to the downstream involvement of McBride / APL.

b) Perfume preparation/s from EU and non-EU sources

(i) Specification of substance/s used in PRODUCE

The perfume preparations considered in PRODUCE are fictional (complex proprietary mixtures) but bear a close resemblance to typical formulations applied to the household cleaning area.

(ii) Uses of the substance/s

The preparations were concentrated aromatic raw materials, not for personal use in this form or concentration but for manufacturing use only as a (perfume) preparation to be used in a more complex (finished product) formulation. More than one dozen types of product were exemplified, typically with maxima of 1-2% (w/w) of perfume preparation in the formulated product.

(iii) Role of MSCA and JRC

Review of preparation and finished product SDSs by The Netherlands CA, who were especially helpful in interpreting the REACH proposal

(iv) Information generated by the Sub-Project Working Group

- SDS on three formulated perfume preparations (Appendices M1-3) and one formulated household cleaner according to Directive 2001/58/EC;
- Extended Safety Data Sheet for one formulated household cleaner , following one strict interpretation of the REACH requirements (Appendix K1);
- Extended Safety Data Sheet for one formulated household cleaner with level of information tailored to distributors (Appendix K2);
- Extended Safety Data Sheet for aerosol mousse bathroom cleaner (Appendix L);
- A note on Chemical Safety Assessments for preparations (Appendix N).

(v) *Aspects of particular interest to the Sub-Project Working Group*

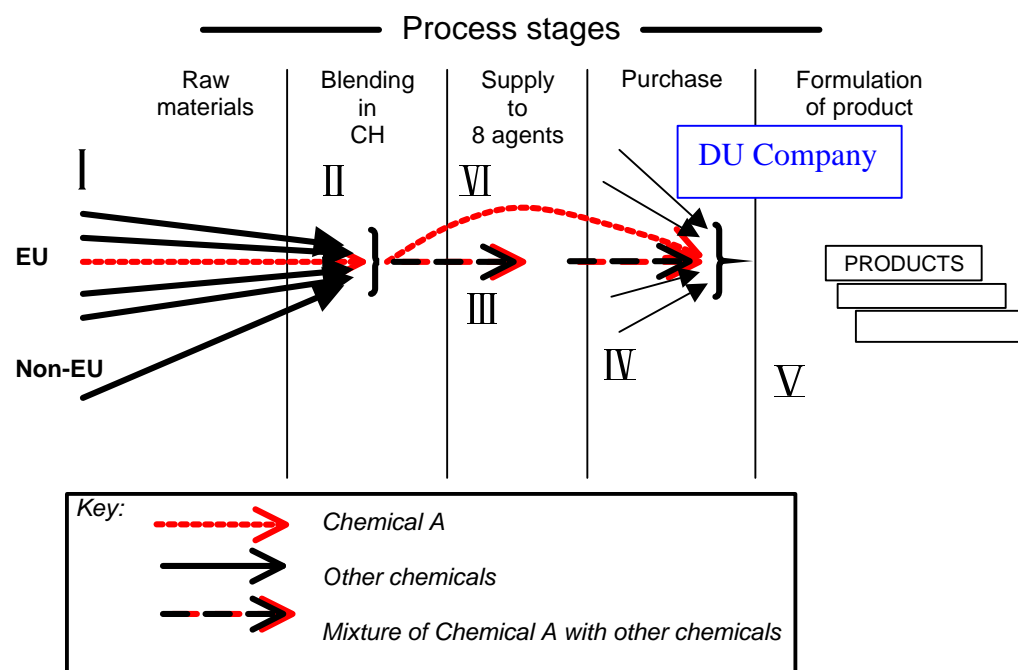
Consideration of a complex, proprietary perfume preparation;

The use of the preparation in a formulated household cleaning product;

Aspects of interest: (Roman numerals refer to points in Figure 4.1):

- multiple manufacturing sites of raw materials; (I)
- multiple routes to an EU Downstream User; (III & VI)
- multiple routes of final use and exposure; (V)
- data from a non-EU country;
- confidentiality of data which define the proprietary nature of the preparation.

Figure 4.1 (See text)



Possible additional scenarios to be explored included:

- a product which contained no classified ingredients;
- a product which did contain one or more classified ingredients but which, as a formulation, did not classify under the Dangerous Preparations Directive 1999/45/EC (DPD);
- a product which did classify due to the content of its classified ingredients;
- a product whose uses lay outside the normal uses expected.

This experience was to be used to improve understanding of how Receiving Companies are to deal with purchased preparations in general (i.e. also non-perfume).

c) Linear Alkyl Benzene from outside EU

(i) Specification of substance/s used in PRODUCE

Liquid, 86-99% pure linear alkyl benzene

EINECS number: 267-051-0

CAS number: 67774-74-7

(ii) Uses of the substance/s

Linear alkyl benzene (LAB) is used by Unilever solely in the manufacture of linear alkyl benzene sulphonates (LAS). The substance is imported into Europe at

Rotterdam and transported as LAB to a number of Unilever sites, which may or may not be different legal entities, where it is sulphonated to form Linear Alkylbenzene Sulfonate. LAS is used as a surfactant in a variety of Unilever products with a variety of use scenarios.

(iii) Role of MSCA and JRC

The JRC was asked to carry out a completeness check of the Registration dossier. The role of the Hungarian CA was to assess the compliance of the dossier, taking note of the fact that this substance has already been the subject of an EU risk assessment but that other data may have become available since this time.

(iv) Information generated by the Sub-Project Working Group

- SDS;
- Pre-Registration Form (Technical Dossier);
- Chemical Safety Report – Parts A, B and C (Appendices G1-3);;
- Robust Study Summaries;
- Comments by Unilever Safety and Environmental Assurance Centre on ISU documentation and inclusion of complementary information;
- Comments by the Hungarian CA, given in full in Appendix G4.

(v) Aspects of particular interest to the Sub-Project Working Group and PRODUCE

- To gain an understanding of the role which a company, familiar with a downstream role, must play when they import a substance and thus take on the role of Manufacturer/Importer;
- To establish whether Unilever and ISU jointly have all the information needed for proper REACH Registration;
- To identify the nature of any gaps in knowledge and how these can be filled in joint work between EU and non-European companies;
- To determine where communication responsibilities end for the importing of a transported isolated intermediate and not passed down the Supply chain outside the importing company;
- To establish the relevance of a European Harmonised Risk Assessment for REACH;
- To test the quality of communication.

5. PREPARATORY ACTIONS BY DOWNSTREAM USERS *before* entering the REACH process

5.1 General Considerations

The REACH proposal as published in October 2003 should not be taken as assuming that Downstream Users or other Receiving Companies will be able to enter the process with little or no preparatory work. In fact they may have to do a considerable amount of preparation if they are fully to contribute to those REACH processes requiring their involvement.

Defining the role and obligations of any company who could have a responsibility in REACH, for example under Article 4(1) and Article 5 has to be a first step for any company in the Downstream User industries. The Company must be clear about its position. Is it only a Downstream User or does it act as a Supplier to one or more other downstream companies? Is it both a Downstream User and at the same time a Manufacturer / Importer, as Unilever discovered itself to be? The roles and responsibilities are clearly different in each case and it is the *substance* and its circumstances which dictate the role of a company, not the historic role of the company or the dominating balance between the roles of Upstream or Downstream as which the company is used to thinking of itself.

5.2 Roles and contacts

The most important part of the preliminary work is the identification and quantification of all the substances used per product type by the Receiving Company so that each Supplier can be approached in a fashion relevant to the degree of collaboration required. This subject is covered in the subsequent paragraphs but first of all there are clearly some lessons to be learned from PRODUCE for Receiving Companies concerning the roles they may play under REACH.

There was also confusion about the definition of a Downstream User of chemicals. A company may think of itself as a downstream user of chemicals (because they purchase a substance which they do not chemically modify and use it to formulate in preparations), but may in fact be an Importer in the first place (according to the definitions in REACH). In this case they have an obligation to register the imported substance(s) and cover their own use(s).

In order to more fully understand and explore the duties of 'downstream user' companies the term '(Receiving) Company' will be used in Table 5.1 (introduced later) and in some of the text below.

Lessons learned:

- (i) ***Companies must get to know REACH so that they properly understand their role/s.***

This may be easier said than done. For SMEs it may be particularly difficult because they may not be familiar with the potential new roles arising for them under REACH. They need the right level of guidance in the right format. Misinterpretations are all too easily made, even by very large companies, partly because they do not think of themselves as simultaneously having several roles in the Supply Chain according to REACH but only the role of Downstream Users.

- (ii) ***It takes time and effort to identify the right people to establish the links between a DU Company and its Suppliers.***

Of course the first point of contact between a Receiving Company and its Suppliers is through the buying/sales relationship. However, it is true to say that it might not be easy to make the link between the right people in charge of REACH-related matters in both Receiving Company and Supplier companies (if they exist). Also, the Receiving Company should think of who to contact if it wants to be a member of a consortium, or wants to be part of a SIEF, because it has animal data (subject to REACH amendments), or if it wants to make sure a substance is available from a Supplier for a certain application, well before buying it (e.g. from a Company Supplier Liaison person or the R&D environment). Who to contact is the question. It would be good if every company had a designated REACH person or a REACH mailbox for such purposes.

- (iii) ***A Receiving Company can expect to find a variety of degrees of commitment to REACH among its Suppliers, partly dependent upon their experience and their geographic location.***

It should not be assumed however that a non-EU company will not show a high level of commitment to the developing European policy on chemicals.

Recommendations

From the lessons learned above, the following recommendations were derived.

Companies must check their roles and responsibilities under REACH for each substance used as such or in a preparation, i.e. as Manufacturer, Importer, Distributor or Downstream User as defined by REACH. [Recommendation 1]

With the proposed new framework under REACH for assessing the safety of chemicals in their production, supply and use, activities of a Company may fall under different roles and responsibilities for different chemicals. Consequently, one single company may have more than one role and it may not be immediately obvious where their roles apply.

There is also the issue of recognising the continuation of current legislative duties and the new duties under REACH.

It is recommended that guidance should highlight those responsibilities which are continuing from previous legislation and those which are new responsibilities under REACH. [Recommendation 3]

RIP 3.5 could consider this by adding further clarification, highlighting the new and continuing aspects of legislation.

Given the complexity and ever-changing detail of supply-chain management, companies should identify a person (function) or persons who can act as points of contact for the purposes of REACH, and communicate these up and down the Supply Chain, for example taking advantage of Sales-Force/Buyers liaison. [Recommendation 7]

It is recommended that Trade Associations should play a pivotal role in raising the awareness of REACH among their members and provide appropriate guidance, in particular for SMEs. [Recommendation 5]

Trade Associations will need to maintain thorough awareness of the legislation and keep up to speed on the progress of the REACH Implementation Projects (RIP). They should provide their membership with guidance on an ongoing basis. (See, for example, Appendix D.)

N.B. Not all Trade Associations are equipped to do this and not all companies are represented by Trade Associations or Sector Groups. Trade Associations also have a potentially valuable role in handling data which would otherwise give problems of the confidentiality of business information.

Trade Associations are well-placed to develop an understanding of the parts of REACH which are particularly relevant for their part of industry or commerce.

5.3 Substances and the Supply Chain

The identification of chemical substances used within a Receiving Company may be a simple matter in a small company, or one with a limited range of products. For many companies however the situation may be far more complex. Each company will have to adopt its own procedures to identify and fulfill their obligations under REACH. One example follows (Figure 5.1). Systems and data-bases must be suitably linked to provide the Receiving Company with the information it is going to need to ensure satisfactory communication with its Suppliers.

A further complexity lies in the Supply Chain itself: it may be a simple two-step process (one original Supplier selling to the Receiving Company) but in most cases a Receiving Company is at the end of a long chain of supply steps, some of which may be outside the EU. The chemical or preparation reaching the Receiving Company may of course be the result of many manufacturing steps in a wide variety of companies, each being a Manufacturer (inside or outside the EU) or an Importer (See Figure 5.1).

Lesson Learned

(iv) Supply chains can be extremely complex

This aspect took PRODUCE participants a lot of time and effort to sort out.

Flexibility in Supply Chains is a concern for Receiving Companies especially when it can mean changing between EU and non-EU Suppliers. It was initially unclear that Receiving Companies could rely on their Suppliers to register all substances where, in the case of imported perfume ingredients for example, the preparation is made outside the EU but supplied *via* an EU agent.

Recommendation

In order to ensure sourcing flexibility now and in the future, Receiving Companies need to develop an awareness of Suppliers' intentions to register / pre-register a substance. [Recommendation 15]

Receiving Companies should be aware that, because of choices made by Suppliers under REACH, they may have to find new Suppliers for some of their chemicals.

Therefore they need to contact their existing Suppliers as soon as possible to assess the situation. Downstream Users who are entitled to become members of a SIEF will be able to check whether their substances have been Pre-Registered. If they have not, they can take the appropriate action to ensure continuity of supply.

5.4 Determining Identified Use

Observations

One aspect considered (and giving rise to recommendations) but not exhaustively tested in PRODUCE was the process by which a Receiving Company checks that the Supplier has registered the appropriate use. This should appear from the (extended) SDS as Registration numbers are mandatory here. However, this may raise a problem. If Registration numbers are on Safety Data Sheets for finished products confidential business information may be disclosed if the Registration number can be linked to an individual Supplier. To be clear, this refers to substance Safety Data Sheets from Suppliers or about finished product Safety Data Sheets from Receiving Companies. In the case of substance Safety Data Sheets from Suppliers it is clear that Registration numbers should be on the Safety Data Sheet: there is no secret to be disclosed.

Lesson Learned

- (v) ***In the case of a finished product the Safety Data Sheet could disclose business-sensitive information if the Registration numbers can be linked to an individual company.***

In practice, a Receiving Company cannot put its product development processes on hold until a number of Suppliers have registered a particular substance for a particular downstream use in Safety Data Sheets of registered chemicals. They may therefore have to have contacts with hundreds of Suppliers for all their substances. A practicable solution to these problems has to be developed.

Several Registration numbers could be associated with one substance (even if the proposal for 'One Substance, One Registration' (OSOR) was adopted). These registration numbers may be specific to individual suppliers/registrants. If Registration numbers are on Safety Data Sheets for preparations, not only may confidential business information be disclosed (by linking the Registration numbers to individual Suppliers – see below) but also there would be a continual and unworkable need to modify Safety Data Sheets (SDS) of preparations to reflect changes in supply chain. A solution might be the use of composite Registration numbers with separate substance-related and supplier-related number strings, if the downstream preparation Safety Data Sheets should only be required to show the substance-related number strings. In addition, the use of CAS, EINECS, or ELINCS numbers would in many cases provide a workable solution if they can be linked in the REACH-IT system to the relevant Registration numbers, especially for global application and relevance.

Recommendation

For the sake of practicality (and to maintain competitiveness) in identifying substances once and for all, it is recommended that a system should be found and implemented to avoid the problem of continual modifications to Safety Data Sheets. [Recommendation 13]

Figure 5.1 indicates a work-flow to allow a Receiving Company to assemble the distribution among its products of a single substance and to assign all the relevant exposure scenarios to that substance (per tonnage too if required, to check if tonnage exceeds 1t p.a.). A system such as this would assist Receiving Companies to develop the information they will need for REACH.

Lesson Learned

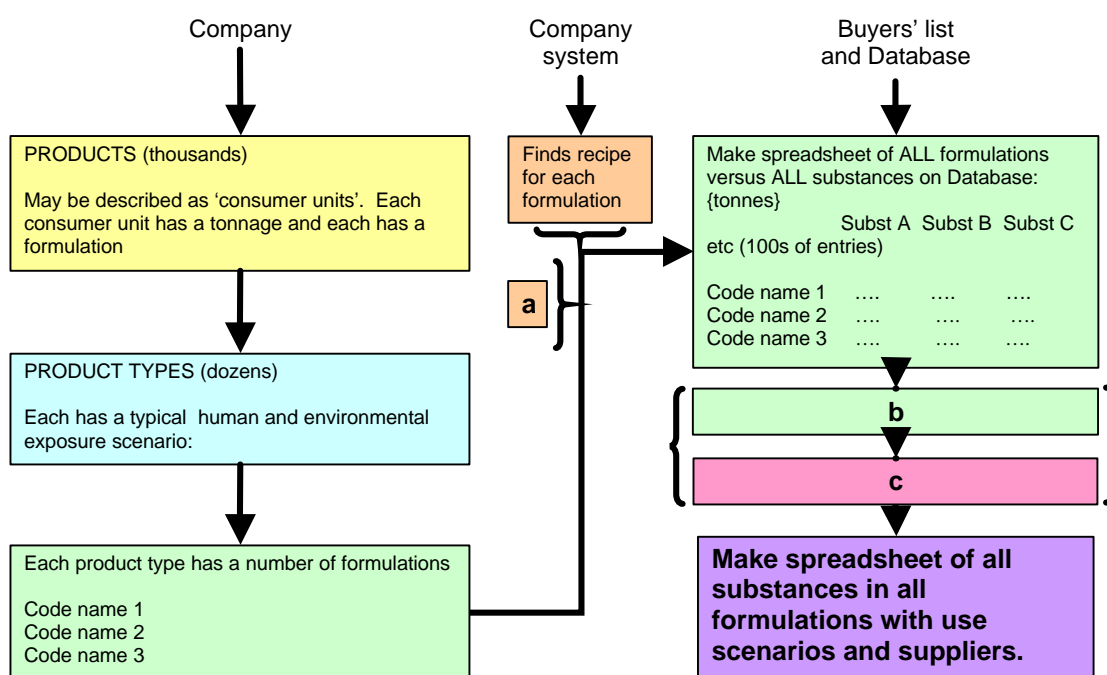
- (vi) *Although this sort of information is vital to an ability to work within the REACH processes it may not be easy to get, at least it was not in one large multinational and especially would not be in an SME which does not necessarily have the resources (in quantity and/or quality) for gathering it.*
- (vii) *Company systems may exist for sales and buying purposes but are not necessarily in line with the needs of REACH.*

Recommendation

It is recommended that Companies having roles under REACH should establish and implement systems to enable themselves to assemble the information they will need to comply with REACH in an efficient manner. There is a necessity (as under current legislation) to keep an annual update on tonnage and origin of substances as such and as part of a preparation. [Recommendation 3]

Information will be needed from companies under REACH on volumes, new substances and preparations, new uses and Suppliers. As a Downstream User in REACH it is by monitoring the incoming Safety Data Sheets that obligations under REACH in this respect are triggered.

Figure 5.1 An example of preliminary work required of a Downstream User (Receiving Company), for example under Article 34



Notes:

A Company may decide to add extra steps to this flow, in relation to tonnages. The three lettered boxes would then contain work similar to that outlined in (a)-(c) below. Tonnages may be needed per substance and per supplier, as well as tonnages per use if not covered by a Supplier.

- a Company system finds tonnage by adding up all tonnages with this formulation, making a distinction between substances imported by the Company and substances supplied from European Manufacturers/Importers.
- b Buyers' list and database used to include tonnages in a spreadsheet.
- c System sums up total tonnage of e.g. Substance A with a split over formulations in previous table (b) and adds up columns for different kinds of Substance A sources etc.

5.5 Aggregated tonnages

In Figure 4.1, a possible example was given of a supply chain situation in which a number of EU agents are involved in the supply of a complex preparation. In this case, the Receiving Company may not know the composition of the mixture e.g. if it is a perfume preparation, such information being of critical commercial value to the Supplier (as this is linked to the exclusive and proprietary know-how of the Supplier). How does the Receiving Company in its role as Importer then know how much of a substance it is importing if sourced from non-EU suppliers? This suggests the need for the following recommendation.

When purchasing from outside the EU (unless through a Representative – see Recommendation 4) the Importer needs to be told the aggregate amounts of each substance sold to them, e.g. in all perfumes supplied by a non-EU Supplier, even if the exact formulations are not divulged. [Recommendation 8]

This is recommended because when tonnages exceed one tonne per year there may be a need to register

Observation

In order to facilitate regional environmental risk assessments, it is important to know the total tonnage of a substance used but this is not the responsibility of the Downstream Users or anyone else in the Supply Chain. Where this tonnage is made up of various sources, including imports of substances and preparations the contributions from each source must be known. It is the responsibility of the authority performing substance evaluation to assemble the aggregated volume and make the total assessment. (Production volumes cannot be disclosed.)

Lesson learned

- (viii) The only way to complete a regional environmental risk assessment, taking the total volume into account, is at the Substance Evaluation stage when all the data are in. The Authority performing substance evaluation will accept that it is their responsibility to complete risk assessments for total tonnages at a regional scale and Registrants are not expected to do so. (At a local scale other legislation such as IPPC and discharge consent conditions will apply.)*

5.5 Initial rationale for choice of substances under PRODUCE

In addition to the prime motivation of PRODUCE, to understand and explore the workability issues relating to the REACH Proposal, there were three themes it was considered worth pursuing:

- the relative responsibilities of a Receiving Company acting as an Importer, for which Linear Alkylbenzene was the chosen example;
- the handling of a simple mixture, potentially containing highly hazardous minor components using Liquefied Petroleum Gas;
- and any issues surrounding the use of a highly complex mixture containing known and unknown substances, in this case Perfume Preparations.

This rationale evolved further once the project had started and each aspect is discussed later in this document.

6. APPLICATION OF REACH TO FIVE SUPPLY CHAIN SITUATIONS

The following is a summary of the Sub-Projects. A complete listing of those REACH steps relevant to PRODUCE is given later.

6.1 Synopsis

There are various ways of approaching the choice of overall scenario to be covered in a Strategic Partnership such as PRODUCE. For the present exercise it was considered suitable to examine aspects of the origin of supply (inside or outside the EU), the differences which might be needed when focusing on a preparation rather than a substance ('articles' were deliberately excluded from PRODUCE) and whether or not the use of the material had been 'identified'. Of these subjects there are certainly various combinations of scenario (as in Figure 6.1) but the choice in PRODUCE was restricted to five. The possibilities not examined in PRODUCE are those shown as shaded, while the letters (a) to (e) refer to the cases examined.

Figure 6.1 Possible scenarios of interest to Companies

? Supplier	Unilever role	Substance in ES*?		All substances in Preparation within Supplier's ES?	
		Yes	No	Yes	No
EU*	DU*	a	Not tested	d	c
Non-EU	Importer	b		e	

*DU: Downstream User; ES: exposure scenario; EU: European Union

In other words the chosen cases for PRODUCE were:

- a) Company buys substance from EU Supplier for identified use(s).⁹
- b) Company imports substance from non-EU Supplier (and is therefore an Importer) for own use(s) and must therefore register.
- c) Company buys a preparation from EU Supplier for use(s) outside preparation ES.
- d) Company buys preparation from EU Supplier for identified use(s).
- e) Company imports preparation from non-EU Supplier (and is therefore an importer of all substances in the preparation) for own use(s) and must therefore register all substances >1 tonne per year.

To assist comparison, the five cases are set out below (and in more detail later).

⁹ In this document 'identified use' (see Article 3(25)) means a use within the exposure scenario of the Supplier. The exposure term can depend on various matters, such as the percentage incorporation of the substance in the Receiving Company product, the route of disposal of the product etc. If the exposure is not mentioned or is not supported by the Supplier, the use is to be termed 'not identified'.

Case tested (a)		Details	
EU Supplier	Use within ES	Name: Liquid petroleum gas	Substance
Steps of REACH tested		Project specificities	
<ul style="list-style-type: none"> ▪ Typical DU situation as described in REACH: ▪ DU selects Supplier; ▪ Registration by Supplier ▪ Completeness check ▪ Dossier compliance check by MS CA ▪ DU acts to ensure that key Supplier covers DU scenario; ▪ DU provides information to expedite registration process; ▪ DU implements recommended risk management measures in Ext SDS provided by M/I or applies at least equivalent risk reduction measures; ▪ If DU is a Formulator or supplies substance further downstream, DU must recommend measures to control risks in Supplier's SDS or own CSA or extended SDS. 		<ul style="list-style-type: none"> ▪ Upstream and downstream communication by DU; ▪ Participation of a second DU; ▪ Handling confidential business information; ▪ Communication further down supply chain (involvement of retailers), extending to communication with consumers. 	

Case tested (b)		Details	
Non-EU Supplier	Use within ES	Name: Linear alkyl benzene	Substance
Steps of REACH tested		Project specificities	
<ul style="list-style-type: none"> ▪ Company buys a substance for its own use from outside EU. ▪ Company is thus a REACH Importer with duty to register and if required prepare an ES for own use. <i>(Not tested here but clarification left in for understanding.)</i> 		<ul style="list-style-type: none"> • Obligations for registering the imported material: LAB is transformed by Unilever wholly into surfactants (linear alkyl benzene sulphonates), making Unilever its own Downstream User. • Registration may include preparation of an extended SDS (Article 29) if required according to Article 13. (Article 16 examined to check if criteria met for a transported isolated intermediate.) • If the importer and the converter are the same legal entity, then Company has no further duties under REACH, but has to comply with Directive 96/71/EC on Worker Safety. 	

Case tested (c)		Details	
EU Supplier	Use outside ES	Name: Perfume preparation	Substance in a Perfume Preparation
Steps of REACH tested		Project specificities	
<ul style="list-style-type: none"> DU determines use is outside Supplier ES (Article 34(4)); DU decides not to inform Supplier of intended use (i.e. DU does not wish to disclose this information); DU prepares own CSA (Article 34 (4)) which does not have to be submitted to the Agency; DU prepares simple 'postcard notification' to Agency (Article 35(2)) (not tested here in practice); 		<ul style="list-style-type: none"> Preparation is being used at a concentration greater than specified by Supplier. (Supplier set specification to take into account one or more critical substances in terms of risk.) Will this include preparation of ESs? Steps for DU use outside the supplier-supported use are being tested too (but this will only have relevance if ESs are available). The additional user requirements for imported formulations, which do not have a REACH compliant SDS are being marked. 	

Case tested (d)		Details	
EU Supplier	Use within ES	Name: Perfume preparation	Preparation
Steps of REACH tested		Project specificities	
<ul style="list-style-type: none"> Registration duties always lie with the M/I. The DU receives SDS with preparation. DU use of this information for further downstream communication about formulations it makes and which contain this preparation, i.e. the DU Company must supply a product SDS to its customers (additional DU and/or distributors), as is required under the present legislation, but containing additional information required by REACH. 		<ul style="list-style-type: none"> Formulator must provide exposure scenarios covering further use downstream if required according to REACH, (Titles IV and V). DU either produces Ext SDS for communication downstream (classified preparation) or information appropriate to non-classified preparation. Testing option for a DU to produce a preparation CSA. 	

Case tested (e)		Details	
Non-EU Supplier	Use within ES	Name: Perfume preparation	Preparation
Steps of REACH tested		Project specificities	
<ul style="list-style-type: none"> Receiving Company is the Importer of a preparation. Register any <u>substance</u> greater than one tonne/year in the imported preparation. Check pre-registration for SIEF. 		<ul style="list-style-type: none"> The question addressed is how to obtain and use this information (because Suppliers may be reluctant to provide full disclosure). 	

A summary of the context of the five cases is set out in the process map below (Figure 6.1). Receiving Companies may find such a decision tree useful in identifying their obligations under REACH, where, instead of the five sub-project boxes there could be lists of every substance of interest to the company.

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Figure 6.1 Process for establishing the work for each Sub-Project in PRODUCE

6.2 REACH steps of interest to PRODUCE

The REACH process can be demonstrated in various ways. For understanding workflow the process map is unequalled. However, to demonstrate simply a list of activities for each step can be a useful introduction. Table 6.2 which originated in Cefic, and was translated into the PRODUCE Proposal, sets out the steps which may be of interest and relevance to a DU Company. Some aspects will be essential to their work; others may be desirable if they are fully to grasp the process as it can be applied for them. For each part of each step an indication is given of the PRODUCE substance/s examined and of sections in the report where a description may be found.

Table 6.2 Steps in REACH of particular interest to Receiving Companies, with indication of aspects relevant to the PRODUCE substances

Process steps	Substances	Section of report	Activities
Establishing uses	<ul style="list-style-type: none"> ▪ All ▪ Perf ▪ LPG ▪ Perf 	<ul style="list-style-type: none"> ▪ 7.2.1 ▪ 7.2.2 ▪ 7.2.3 ▪ 7.2.4 	<ul style="list-style-type: none"> ▪ Identify tonnage and use scenarios separating substances imported by the user from those acquired from EU M/Is. ▪ Cope with complex supply chains, when identifying potential players in consortia. ▪ Consider benefits of - or barriers for downstream user participation in consortia ▪ Identify barriers and establish solutions for efficient upstream and downstream communication regarding uses of substances.
Pre-registration	<ul style="list-style-type: none"> ▪ All ▪ LAB - LPG, Perf - 	<ul style="list-style-type: none"> ▪ 7.3.1 ▪ 7.3.2 ▪ 7.3.3 ▪ 7.3.4 ▪ 7.3.5 	<ul style="list-style-type: none"> ▪ Identifying whether substance is in/out of REACH. ▪ Identify requirements and timings for pre-registration. ▪ Identify issues around formation of Substance Information Exchange Forum (SIEF) ▪ Explore issues around the sharing of data. ▪ Achieving agreement on proposals for new animal testing, including cost-sharing.
Consortium formation	<ul style="list-style-type: none"> ▪ - ▪ - ▪ - ▪ - ▪ - 	<ul style="list-style-type: none"> ▪ 7.4.1 ▪ 7.4.2 ▪ 7.4.3 ▪ 7.4.4 ▪ 7.4.5 	<ul style="list-style-type: none"> ▪ Consider willingness to enter consortia. ▪ Identifying partners. ▪ Working agreements. ▪ Consider commercial, confidentiality issues and competition law. ▪ Handling differences of opinion on e.g. classification.
Pre-work for Registration-1: Chemical Safety Assessment	<ul style="list-style-type: none"> ▪ LAB, LPG ▪ All ▪ LAB, LPG ▪ Perf ▪ LPG ▪ All ▪ LAB, LPG ▪ LPG, Perf ▪ All 	<ul style="list-style-type: none"> ▪ 7.5.1 ▪ 7.5.2 ▪ 7.5.3 ▪ 7.5.4 ▪ 7.5.5 ▪ 7.5.6 ▪ 7.5.7 ▪ 7.5.8 ▪ 7.5.9 	<ul style="list-style-type: none"> ▪ Compatibility check of existing safety data; quality of existing SDSs; solve any discrepancies. ▪ Provision of exposure scenarios (ES). ▪ Developing a Chemical Safety Assessment for substances. ▪ Handling unclassified substances. ▪ Passing Downstream data on hazard up to Suppliers. ▪ Developing appropriate risk management measures. ▪ Transmission of worker safety information. ▪ Transmission of safety data down the supply chain. ▪ Individual or joint preparation of guidance on safe handling and end use, for each sector, such as domestic or industrial uses of the substance.

Pre-work for Registration-2: Technical Dossier	<ul style="list-style-type: none"> ▪ LAB, LPG 	<ul style="list-style-type: none"> ▪ 7.6.1 	<ul style="list-style-type: none"> ▪ Compile data as required by REACH guidelines.
CSA for preparations	<ul style="list-style-type: none"> ▪ Perf 	<ul style="list-style-type: none"> ▪ 7.7 ▪ 7.7.2 ▪ 7.7.3 	<ul style="list-style-type: none"> ▪ Developing CSA for preparations, <ul style="list-style-type: none"> ○ for the environment, ○ for human health
Generating Registration Dossier and Evaluation	<ul style="list-style-type: none"> ▪ LAB, LPG ▪ LAB, LPG ▪ LAB, LPG ▪ LAB, LPG ▪ - ▪ Perf 		<ul style="list-style-type: none"> ▪ Provision of use and exposure data. ▪ Completion of dossier. ▪ Writing Chemical Safety Report and developing agreement on it and the Chemical Safety Assessment. ▪ Completeness checking and dossier evaluation. ▪ Registration of substances in articles (where relevant). ▪ 'Postcard' notification.
Communication further down the supply chain	<ul style="list-style-type: none"> ▪ LPG, Perf ▪ LAB, LPG ▪ LPG, Perf ▪ LPG, Perf ▪ LPG, Perf 		<ul style="list-style-type: none"> ▪ Prepare SDS including ES for substances and preparations ▪ Check that RMMs are implemented at the workplace ▪ Take extended SDS as basis. ▪ Add other information as required by REACH. ▪ Steps / methods for passing safety information further down the supply chain, all the way to the end-user.

As PRODUCE is focused on downstream use, it may be asked why the work included Pre-registration and the Registration procedures. In fact the PRODUCE Team considered, and is now convinced, that Receiving Companies will have to be extensively involved in the process.

Lesson learned

- (ix) ***Possible cases have been identified (e.g. essential oils produced in France, Spain and Italy) where the producers (distillers) might not be capable of carrying out a successful registration.***

Firmenich will be a Downstream User in these cases as the substances are produced in the EU even though Firmenich is re-importing them. For this reason, Firmenich is looking at how they will be able to ensure that these substances are correctly registered. This goes beyond a simple ‘assistance’ because a company in such a position might want to be involved in the consortium, pay for the tests and participate in the decision making.

- (x) ***EU-based DU Companies might also want to participate to the same degree in the Registration of substances imported (e.g. from China) by trading companies and brokers.***

Their attempts at Registration within the REACH time-frame would otherwise fail.

Recommendation

The REACH proposal states that

“A downstream user may provide information to assist in the preparation of a registration”.

The PRODUCE Team is convinced, that Downstream Users in some cases will have to be far more involved than Article 34(1) would imply. A recommendation addressing this point may be found in Section 7.4. [Recommendation 11]

Indeed, this is in everybody’s interests. Possible cases have been identified where the producers might not be capable of carrying out a fully successful Registration. One Receiving Company looked at the question of ensuring that substances are correctly registered in such cases. Whilst it will be difficult for some Receiving Companies to participate beyond providing basic assistance, some might also want to participate to the same high degree in the Registration of substances imported (e.g. from China) by trading companies and brokers whose attempts at Registration within the REACH time-frame would otherwise fail.

If the new version of REACH incorporates highly detailed OSOR instructions, it may be even harder for Receiving Companies to participate at all.

In the following process map (Figure 6.2) the aspects covered by PRODUCE are shown in blue. The process has been taken from the RIP 1. Note that the top left part of the process seems to end ‘in limbo’. There is no clarification of the process to follow when the Supplier and Receiving Company have different views on the classification of a substance.

Observation

As described by RIP 1 this information is simply transmitted to the Agency (Article 35(4)) and there is no indication of the existence or form of a resolution procedure. In such cases the parties should take responsibility to come to a single view (Title XI).

If they cannot, there is a sequence to be followed. The Agency firstly tries to facilitate this harmonisation.

Finally the parties can 'agree to differ' concerning classification and labelling. However, this stage is the start to exposure scenario development and if it starts on different premises, this could lead to inconsistencies in Downstream Communication.

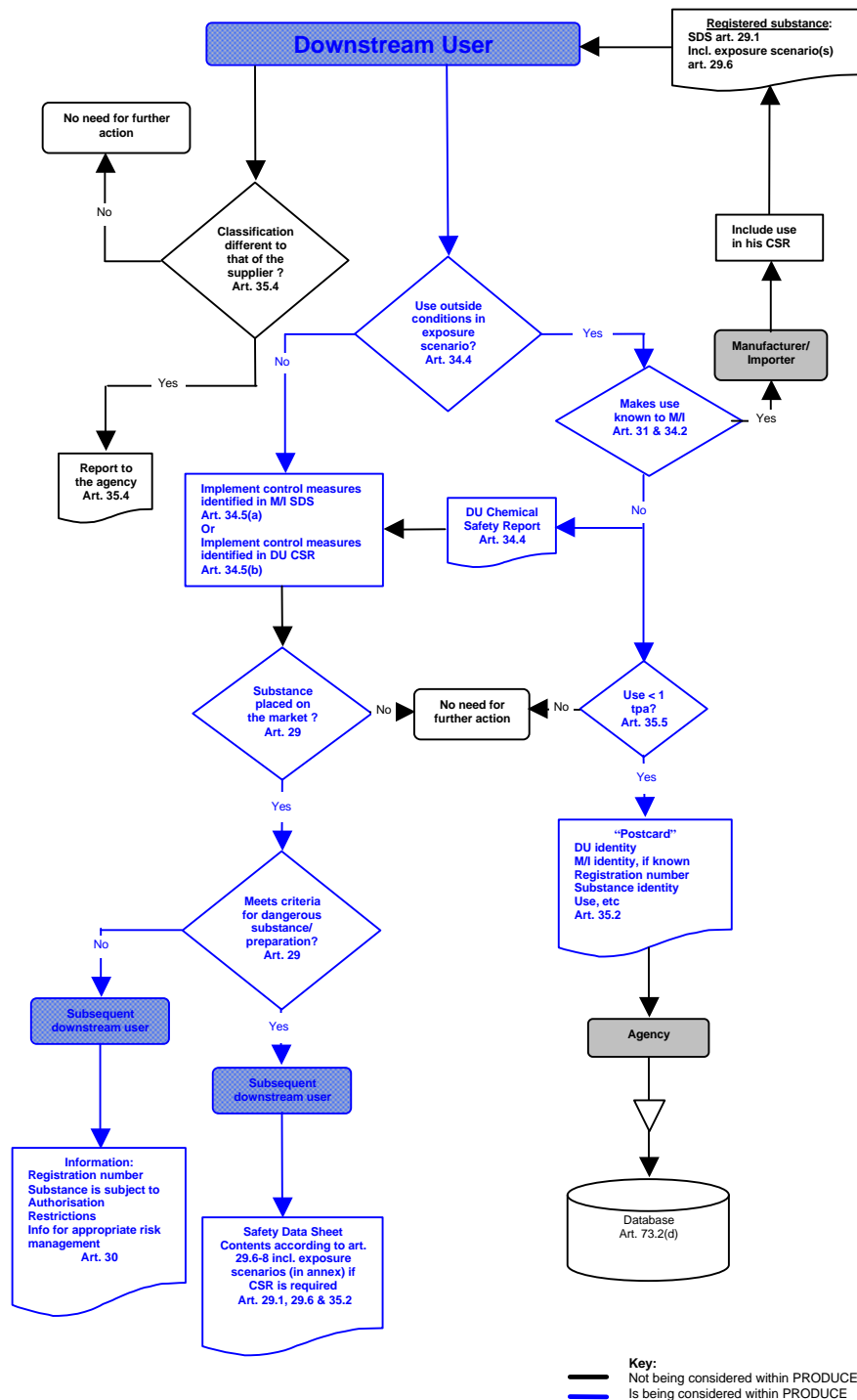


Figure 6.2 Process steps for a DU Company

7. THE FINDINGS OF PRODUCE & LESSONS LEARNED

In this section each topic listed in Table 6.2 is discussed in a relevant level of detail, according to a standard sequence:

The Process; Observations; Lessons learned; Recommendations.

There may not be entries under all of these headings in some cases. Under 'Observations' and 'Lessons Learned' there may be separate entries for each Sub-Project but the Recommendations, where made, bring together all the points which may have been identified in the topic. Similarly, as Table 6.2 shows, not all topics were relevant to all Sub-Projects.

7.1 Scope

a) **The Process**

All companies supplying or receiving chemicals need to establish whether each of their chemicals is inside or outside the scope of REACH. This is achieved by considering the steps described in Chapter 1 of Title II of the Proposal. This describes processes of including and exempting substances. In both cases substances could be chosen or rejected on the basis of (a) their nature (e.g. radioactive substances are outside REACH) or (b) their use/s (e.g. food additives are outside REACH). PRODUCE needed to check how each of the substances or preparations¹⁰ that it chose to study fell *vis à vis* the REACH Proposal and to establish how easy it was to come to these conclusions (workability).

b) **Observations**

General

From the substance viewpoint it must be admitted that there was a lack of clarity originally. The Unilever Team knew that, to check workability, it wanted to include an imported chemical in the project. One substance considered was talc, but this was found to be out of scope, being a natural mineral, unmodified chemically. (The sequence of considerations for including Liquefied Petroleum Gas is given below.)

Linear Alkylbenzene

It took some discussions to define LAB correctly in REACH terms. It was clearly in scope due its use and its tonnage but how should it be described? It arrives in the EU from its Korean manufacturer and is imported by Unilever. It is then transported to a number of Unilever sites around the EU, which may or may not be separate legal entities, where it is fully transformed into Linear Alkylbenzene Sulphonates for Unilever formulations only. Once Unilever's role was clarified (see *Lessons Learned*, below) the regulatory expertise and technical depth of the Company's Safety and Environmental Assurance Centre (SEAC) and their equivalents in the Korean supplier (ISU) found no difficulty in understanding the data available and the means of putting REACH into practice.

Liquefied Petroleum Gas

With LPG, PRODUCE had the benefit of a REACH-aware Supplier, who had also been deeply involved with the work of the industry organisation CONCAWE. Thus questions concerning the allocation of a single CAS number to a liquefied gas made up of several constituents, each of which also had a CAS number, were swiftly

¹⁰ For convenience, in the general text of this report the term substance or substances will be taken to include preparations. Where an explicit definition is needed the individual terms will be used.

answered. LPG was therefore to be addressed as a substance, not a preparation. Whether the ‘substance’ was in or out of the scope of REACH is addressed under *Lessons Learned* below.

Perfume Preparations

Perfume Preparations are complex, containing many ingredients of natural and synthetic origin. Natural substances can vary seasonally or as a result of processing modifications. The preparations are often imported and may be exported and re-imported giving rise to questions about responsibilities. Perfumes are also proprietary and disclosure of the ingredients under some circumstances could seriously jeopardise the commercial value of the preparation.

c) Lessons Learned

General

- (xi) *Downstream Users need access to expertise to understand definitions as used in REACH.*

Linear Alkylbenzene

After discussions with the Commission Services, LAB was judged to be a ‘transported isolated intermediate’, so that Article 16 of REACH applies (reduced Registration requirements if handled in certain conditions). However, for the purpose and Lessons Learned of PRODUCE it is considered to be an imported substance. The difficulties over the status of LAB under REACH were more to do with the frame of mind of the company which had for decades been much more a DU Company than a Manufacturer/Importer. Under REACH they now found themselves to be Importer with all the registration duties set out in Article 16.

Liquefied Petroleum Gas

LPG was found to be in scope, as argued next. The REACH proposal contains three headings (6, 8 and 9) in Annex III (‘Exemptions from the obligation to register...’) that can be considered when deciding if the propellant is excluded from Registration.

Heading 6. By-products, unless they are imported or placed on the market themselves;

Heading 8¹¹. Minerals, ores, or substances occurring in nature if they are not chemically modified during their manufacturing, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC on Dangerous Substances;

Heading 9. Natural gas, crude oil, coal.

Taking these headings in turn –

Heading 6: The propellant is a by-product from natural gas production. However the by-product is placed on the market – it is thus not excluded from Registration on the basis of Heading 6.

Heading 8: The propellant is ‘substance[s] occurring in nature... not chemically modified during manufacture’...BUT it will be classified as dangerous according to Directive 67/548/EEC on Dangerous Substances – ‘Extremely Flammable’. Thus it will not be excluded from Registration on the basis of Heading 8. *The PRODUCE*

¹¹ Headings 8 and 9 have been subject to changes since PRODUCE began its work. The observations may no longer be valid in the future. In fact modifications to Heading 8 in the Political Agreement Text mean that LPG will be outside the Scope of REACH.

Team was aware, of course, that, in a purification process the content of undesirable components is reduced to meet Supplier specifications (to “levels as low as reasonably practicable”).

Heading 9: Whatever ‘Natural gas’ is (either from the ground (crude) or as delivered to the consumer (methane) or both), the propellant is unlikely to be considered as Natural Gas within the meaning of Heading 9 and thus not excluded from Registration on the basis of Heading 9.

This leads to the view that Liquefied Petroleum Gas (the substances in it) will NOT be exempt from the obligation to Register [but see the footnote¹¹ on previous page].

Perfume Preparations

In terms of scope, the Perfume Preparations represented a number of challenges, but these were sorted out by the PRODUCE Team after an initial intervention by the experts in the Steering Group. (It was established that essential oils are in scope.) Some problems which arose from the need to disclose the composition of imported preparations could be overcome by changing the Supply Chain arrangements so that the Perfume House established an EU Agent in order that the Receiving Company did not have the responsibilities of an Importer but was a Downstream User under REACH.

d) Recommendations

The Chemicals Agency should facilitate the development of a glossary of terms targeted at Receiving Companies and presented in all official EU languages. [Recommendation 30]

It could be very helpful to provide guidance on terminology, especially for the SMEs. REACH definitions and especially the definitions of different Receiving Company roles as per RIP 3.5 would be welcomed.

Non-EU manufacturers exporting into the EU are encouraged to consider the value of establishing an EU representative. Companies importing from outside the EU should contact their suppliers at an early stage to check if their supplier would like to nominate an EU representative and thus decide who will take on the role of Importer (Registrant). [Recommendation 4]

7.2 Establishing uses

7.2.1 Identifying tonnage

a) The Process

Company systems were relied upon to define the origins (EU v non-EU) and tonnages of all the PRODUCE examples. The system has already been set out in Figure 5.1.

b) Observations

General

It is important that many parts of the Company are fully aware of REACH: it is not just a regulatory matter: it includes Manufacturing, Supply, IT, Safety, R&D etc as well as Regulatory.

Linear Alkylbenzene and Liquefied Petroleum Gas

LAB tonnage and uses were easily defined because there is only one use, totally under Unlever's control.

For LAB and LPG the supply chains were not complex, at least concerning supply to the Downstream Users (or Importer in the case of LAB). However, once the substances are transformed or formulated, exported, re-imported and used in a wide variety of products, the chains become much more complex. Nevertheless, the first step in the chain was straightforward.

Perfume Preparations

With the Perfume Preparations, things were much more complex at the outset, because the upstream side had a multiplicity of supply chains, from inside and outside the EU, with many chemicals involved in every preparation etc.

c) Lessons Learned

- (xii) *If a company system is not designed to answer questions concerning the intricacies of substances used, in which products and at what tonnage for complex supply chains it is often inefficient to work the process manually.*

7.2.2 Cope with complex supply chains

a) The Process

See the list of questions prepared to assist Receiving Companies in defining their role/s under (c) below.

b) Observations

In some cases it took far longer than expected to establish company roles and responsibilities concerning the case of Perfume Preparations.

c) Lessons Learned

- (xiii) *What does a Company typically in a Downstream User mode but finding itself in Manufacturer/Importer mode need to do? A list of questions to address:*

1: Are you importing the substance into the EU? Does the substance ultimately originate from within the EU (i.e. a re-imported substance)? If you are the importer, you are an M/I with all the duties of an M/I under REACH. If you are re-importing, you are not an M/I but a Downstream User.

2: Do you understand your duties if you find yourself to be a Manufacturer or Importer? (eg Article 19 and Article 20)

3: Are you sure you are covering Registration appropriately either with your Suppliers or yourself?

d) Recommendations

With complex preparations the upstream side may have a multiplicity of supply chains, from inside and outside the EU, with many chemicals involved in every preparation etc. The learning from this was that it takes far longer to establish company roles and responsibilities.

Receiving Companies should analyse the REACH processes, understand their obligations for each link in the supply chain where they may be involved and assign tasks and duties relevant to each requirement. [Recommendation 2]

7.2.3 Consider benefits of, or barriers for Downstream User participation in consortia

b) Observations

The LPG project benefited from the inclusion of other Downstream Users and a Trade Association, to refine exposure scenarios and bring in more data to improve risk assessments for consumers. It is for debate whether Receiving Companies should be formal members of a SIEF or should participate more informally on a consultative basis.

c) Lessons Learned

- (xiv) There must be good two-way discussions. It is conceivable that there can be disagreements concerning data among partners in a consortium. These may be matters of differences in test methods, interpretation, test material etc. In PRODUCE such issues were not encountered. On the contrary there was at least one case where new data brought in by a Receiving Company supported those of the Supplier.*
- (xv) It is important to note that (even having no registration duties under REACH) Receiving Companies in some sectors may have considerable amounts of data on the intrinsic properties of chemicals, as well as an understanding of exposure scenarios.*
- (xvi) Receiving Companies, within the PRODUCE team, were very willing to contribute data and experience to allow the best information to be used in the REACH procedures.*

d) Recommendation

Cross-industry initiatives (like HERA) or Sector Groups should be encouraged to think of themselves as one of the natural brokers (facilitators) of consortia formation and to organise their member companies to assist each other in preparing for and acting on the REACH legislation. [Recommendation 6]

7.2.4 Identify barriers and establish solutions for efficient upstream and downstream communication regarding uses of substances

Two situations are discussed here: uses identified by the Registrant and non-identified uses.

a) The Process

Uses identified

Liquefied Petroleum Gas

Discussion was certainly needed between Supplier and Receiving Companies to reach common understanding: BP needed to include various scenarios (i.e. to support various uses) in the SDS and was aware of its liability if Receiving Companies were not appropriately informed. Details in the possession of Receiving Companies and BAMA were required for full calculations of exposure.

Perfume Preparation

In some respects this was a special case, but surely one which will recur for many industries. Supplier and the Receiving Company had to discuss the required use of the Perfume Preparation in detail so that the Perfume House can formulate exactly in line with the identified use.

Uses not identified

Liquefied Petroleum Gas

All uses were supported by the Supplier but the Receiving Companies did need to tell the Supplier of some uses, which were subsequently supported.

b) Observations

Uses identified

This step was easily accomplished in the simple situation of LAB where there is one Importer Company who is also the Receiving Company with one use for this raw material i.e. it is a transported isolated intermediate for conversion solely to another substance, linear alkylbenzene sulphonates by the same Receiving Company. With the other two Sub-Projects the lessons learned, set out below, imply a greater complexity, although all uses were covered as a result of the long-term collaboration between the Receiving Company and Manufacturer/Importer.

Uses not identified

It was quite clear that in this industry Suppliers were keen to work with DU Companies to refine exposure scenarios and risk assessments. Whether this good experience would also be seen where the downstream player was a much smaller company is a moot point.

c) Lessons Learned

- (xvii) *The Receiving Companies can and should take an initiative to check that Registrants not only support their use but do so with the best data available. This should include not only today's uses but those foreseen by the R&D of the Receiving Companies.*
- (xviii) *Barriers to communication may originate in over-stretched resource, lack of well-informed staff etc.*
- (xix) *The Supplier did not have a responsibility if the Receiving Company chose to use the substance outside the exposure scenarios described to the Supplier. The Receiving Company will write its own CSA.*
- (xx) *The Sub-Project on LPG pointed to the need for good dialogue between Receiving Companies and Manufacturer/Importer and also to the need for a Confidentiality Disclosure Agreement. This was the case because there were more players involved and it was a tripartite situation, with Unilever, McBride/APL and BP working together. The discussions were helped by having BAMA involved.*

- (xxi) *In the type of preparation-within-a-preparation typified by the uses of Perfume Preparations it can be vital to establish a degree of flexibility in the supply chain to cope with formulation changes driven by the market and indeed by Supplier changes.*
- (xxii) *Other complexities arose with the Perfume Preparations because*
- a) this was a complex preparation;*
 - b) it was put to a variety of uses by Receiving Companies;*
 - c) the supply chain itself was far from straightforward and*
 - d) of the commercial sensitivity of the detailed formulations but the need for restricted disclosure of formulation.*
- (Tonnage levels of some major ingredients in Perfume Preparations need to be made visible in the event of a trigger level being exceeded. Allergens and classified substances force disclosure of elements of any preparation.)*
- (xxiii) *The Perfume Preparations Sub-Project brought to the surface some internal communication issues. For example a Safety Department may be well aware of the complexity of the situation but not a Manufacturing Department in the same Receiving Company.*

d) Recommendation

See **Recommendation 15**, already made under Section 5, concerning the need for Receiving Companies to check continuity of supply and ensure sourcing flexibility now and in the future.

7.3 Pre-registration

a) The Process

In this section the five bullet points given under 7.3 in Table 5.2 have been merged. The process for checking the completeness of data input went smoothly, utilising check-lists of data requirements. The aim of the check was to identify gaps in the dossier. It was not intended as a quality check of the submitted information or a check of the relevance to a given endpoint. The JRC performed the completeness checks and regarded the dossiers as being mostly complete apart from minor omissions and corrections¹².

b) Observations

It was very valuable that LAB had been the subject of an Existing Substances Regulation risk assessment and that this will be accepted under REACH, with little additional work required.

Within PRODUCE there have been examples of the useful sharing of data. This depended on levels of trust and on legal systems to enable the necessary exchanges. However, there are general concerns about the lack of encouragement for DU Companies to participate in consortia.

Consideration of the practicalities of data input led recommendations (this section and 7.5) concerning formatting and the need for development of appropriate IT skills.

The commercial value of data was not explored. A consequence for Receiving Companies may be an increase in the cost of substances.

c) Lessons Learned

(xxiv) It is usually true that if Receiving Companies are in doubt the first thing they should do is ask their Suppliers for help.

(xxv) It is important for Receiving Companies to realise that even though they never needed to register in the past, because they have not been Manufacturers, under REACH they may become Importers and therefore need to register. They may not have much data to support this registration. They might then have to form partnerships with data-rich Suppliers and this may be very costly in terms of both administration and acquisition of data. Alternative approaches are (i) to persuade a Supplier from outside EU to establish and EU-only representative or (ii) switch Supplier to an EU Company.

(xxvi) In the period between the entry into force of the regulation and the deadline for the pre-registration phase, Receiving Companies have an opportunity to ensure that their Supplier supports their use or to locate alternative Suppliers who will do so. If no Supplier intends to support their use, Receiving Companies have the option to prepare their own CSA for their uses of the substance and notify the Agency via a postcard registration.

(xxvii) Confidentiality Disclosure Agreements had to be signed before work could start on real data, and this took weeks to achieve, even with an informal partnership such as PRODUCE. Previous work, such as in HERA (HERA, 2005) and ERASM have paved the way to confidence in Upstream and Downstream working together.

(xxviii) If a Receiving Company has a large amount of data or experience and wishes to support their Supplier in consortium discussions, they would need access to and the ability to use the IUCLID 5 / REACH IT systems so that they could contribute in the appropriate technical language.

¹² The completeness check was as close as possible to a real-life situation under REACH. Note that the check is conducted under the following conditions and assumptions:

1. The completeness check under REACH is an automated procedure with the aim of identifying gaps in the dossier. Thus, it is not a quality check of the submitted information or a check of the relevance to a given endpoint. This will be done under the *compliance check* conducted by the MS.
2. A completeness check facility will probably be available so that the Registrant before submission can check if the submitted dossier is complete.
3. The completeness check in PRODUCE accepts any study result, a reference or letter of access to a study result, a justification for adaptation of the information required, a testing proposal or any indication that no data are required (according to the right hand side column in Annex V-VIII). IUCLID 5 will probably be more interactive, e.g. by accepting empty fields where data are not logic and by having specific fields for justifications for waiving, letter of access and testing proposals. But here in PRODUCE any text string has been accepted in the completeness without further checking of the validity of the documentation or statements.

d) Recommendations

It is recommended that RIP Guidance should investigate different ways of handling Confidential Business Information. In doing so, one could take into account the experiences of HERA and ERASM on Upstream/Downstream companies working together and of PRODUCE. [Recommendation 9]

This combined experience from three decades of collaboration in the surfactant industry has demonstrated the practical advantages (and the problems) of upstream/downstream partnerships, developing the practicalities and science of delivering targeted risk assessments and publishing the lessons learned.

In the case described below, the Receiving Company would need access to IUCLID 5 / REACH IT systems so that it could contribute in the appropriate technical language. A Downstream User will be able to examine the Pre-Registration list of substances. Downstream Users can then enter a SIEF if they have relevant data. To this extent they should be given access to the same tools and training (IUCLID 5 and REACH-IT) as that available to Suppliers.

In the case where a Downstream User may have a large amount of data and experience which it wishes to share with its Suppliers to assist in consortia discussions and to facilitate data-sharing, we recommend that Downstream Users be allowed and encouraged to participate effectively in the process using the relevant technical tools. [Recommendation 32]

7.4 Consortium formation

a) The Process

Under PRODUCE, a Receiving Company could participate in a consortium either as an equal partner in which data and expertise would be brought to the table or as a partner with minimal data but possibly expertise (or *vice versa*). Again there is a situation where a Company in a Downstream User industry may become an Importer under REACH and be under the regulation a Manufacturer / Importer.

b) Observations

Larger Receiving Companies may be more interested and able to contribute than smaller companies. They may have a considerable amount of data, on intrinsic properties, exposure scenarios, consumer science studies and risk assessments.

c) Lessons Learned

(xxix) The Sub-Projects kept clear of competition law minefields but discussed ways to overcome divulging commercially sensitive information. The use of ranges rather than absolute values was found useful.

(xxx) One of the benefits of pre-work by Trade Associations, Sector Groups and their member companies is to assemble and agree on sets of data such as classifications for the important chemicals in their area. This can include, and has included the preparation of risk assessments.

d) Recommendations

Downstream Users should be encouraged (as is their right) to identify and add their own data to those of registrant/s (Article 34(2)) and to help, for example, to model human exposure or environmental fate and reduce the need for further animal testing. A mechanism should be provided for Downstream Users to identify and contribute data to SIEFs. Besides, in the political agreement reached by the Council, there is an inconsistency between Articles 26.6 and 27.1 of REACH which needs to be resolved. [Recommendation 11]

There is good precedent for this collaborative work (e.g. the development of the environmental modelling system GREAT-ER) and Suppliers should continue to encourage this.

Currently, only Manufacturer/Importer may be members of Substance Information Exchange Fora (SIEFs), but DU Companies should also be allowed and encouraged to become members of SIEFs, if they can contribute data for Registration. [Recommendation 10]

This will minimise any possible shortfall in the interpretation of data and risk due to lack of data or any special understanding of use known to the Downstream User. (The PRODUCE Team accepts the fact that there may be a considerable imbalance between the data-rich and data-poor companies and indeed the importance of a Receiving Company chemical to a Supplier. Some proportionality in the degree of representation on a consortium might therefore be needed.)

7.5 Work for Registration

7.5.1 Compatibility check of existing safety data

a) The Process

Unilever sent ISU the relevant pro-formas and later checked the ISU submission on LAB for its scientific content – template for Registration, Robust Study Summaries and Chemical Safety Reports. Comments were sent to ISU. ISU had done a good job and were able to take advantage of the Existing Substances Regulation (ESR). The JRC carried out the completeness check¹² and Hungary made the compliance check.

b) Observations

Under the LPG Sub-Project it was found that the pro-formas would benefit from thoughtful editing to avoid unnecessary repetition and a suitable degree of flexibility. An even better option would be an interactive IT application (like tax return software) leading the registrant to relevant sections only.

Just because there is an ESR assessment, it does not mean that the future requirements under REACH are met.

c) Lessons Learned

(xxxi) A good quality risk assessment from whatever source, with its supporting information, will lighten the burden of REACH.

(xxxi) Downstream Users don't have to register substances in the formulations they purchase from an EU perfume house (PH). The PH that supplies a perfume should already have registered the substance, and if necessary have developed the Chemical Safety Assessment for the use, in the appropriate volume bands that he imports or makes himself (M/I).

(xxxiii) If the PH (M/I) total volume of a particular substance is below one tonne the PH does not have to register at all.

(xxxiv) It does not matter if, in aggregate, a Receiving Company brings more than one tonne of such a substance to market, by buying perfumes from different PHs (unless the Receiving Company imports them in volumes over one tonne).

d) Recommendations

In order to complete the work for Registration the process should be automated as much as possible, as is done in many parts of the EU with the submission and calculation of Income Tax returns. [Recommendation 12]

When designing and compiling template documents for Pre-Registration and Registration, care should be taken to avoid inflexible, repetitious processes. [Recommendation 21]

7.5.2 Provision of exposure scenarios (ES)

Environmental v Human Health Exposure Scenarios

a) The Process

One issue of significant discussion with the Perfume Preparations Sub-Project was the definition of Exposure Scenarios, as communicated within the annex of an Extended Safety Data Sheet, and their relationship to an identified use, provided in section 1.2 of an Extended SDS. For “Whizzo APC” (all-purpose cleaner), created for and investigated within this project, Firmenich supplied Unilever with an extended SDS for the fragrance preparation. This extended SDS contained a number of intended uses for the fragrance along with maximum inclusion levels (e.g. *within Laundry powder detergents up to 1.0%*).

There was a more-or-less equal contribution from Upstream and Downstream in the risk assessment of the Perfume Preparations. Firmenich supplied a very specific Exposure Scenario, as necessary for Human health. This level of detail might not be needed for the environment. Environmental assessment needs a much broader approach to Exposure Scenario setting. With the LPG Sub-Project another approach was needed. A generic approach was worked out, then refined for specific uses: a combination of measured values and models was used for calculating exposure. A model provided by the British Aerosol Manufacturers Association (BAMA) (but not published with this report) was very useful.

In the LPG case, the DU Companies played a leading role in calculating consumer exposure for the Supplier. Hence the Downstream Users were fulfilling their obligations under REACH under Article 34(2): when a DU makes a use known to his supplier, he should provide sufficient information for the Supplier to prepare the ES.

b) Observations

PRODUCE lacked guidance on what Exposure Scenarios will look like and the relationship between an ES and an identified use. (N.B.: RIP 3.2 i.a. is addressing this area.) An identified use is just part of the story. It is necessary to assess the relevant human health exposure scenarios but note that a variety of uses (e.g. most uses of down-the-drain chemicals in the home), may lead to the same type of environmental exposure. Downstream Users are only responsible for assessing the Exposure Scenarios relevant to their own downstream uses. (Aggregation at a higher level would be done by the authority performing substance evaluation.)

On review, the identified use of Whizzo APC was considered appropriate to account for human exposure of the fragrance, but too specific to account for the environmental exposure. For example, it is conceivable that Unilever would want to use this fragrance within a product format that is not specified in section 1.2 for the fragrance SDS, but which the environmental exposure would be the same (i.e. 100% disposal down the drain).

c) Lessons Learned

(xxv) In order for a DU to be able to assess whether a CSA would be required for this unidentified use the description of the ES in the substance extended SDS needs to be sufficiently detailed.

(xxvi) In addition, the Perfume Preparations Sub-Project included a situation in which Unilever would use the fragrance within Whizzo APC at a

concentration greater than that included within the relevant identified use given in the fragrance extended SDS. It was clear that this situation would result in Unilever having to conduct a CSA for the use of the relevant substances within the fragrance as the use was outside the conditions specified by the supplier. But, it would seem appropriate that only a human health CSA would be required as the environmental exposure scenario of using the fragrance within the same product format at >1% instead of <1% would be the same.

(xxxvii) The Perfume Preparations Sub-Project Working Group concluded that it may be problematic to combine Exposure Scenarios for both the environment and for human health and these need to be considered separately when deciding whether a Chemical Safety Assessment for the use of a substance outside the use conditions communicated by the suppliers needs to be conducted. For example, inclusion levels within specific product formats may be suitable for human health purposes, but would be too specific for an environmental Exposure Scenario.

(xxxviii) There should be careful consideration of the Exposure Scenarios for human health and the environment (as these could be distinctly different).

(xxxix) Sometimes Receiving Companies are better placed to understand exposure resulting from the use of the substance in their products.

(xl) The knowledge brought to the Exposure Scenarios discussions by DU Companies and Trade Associations/Sector Groups demonstrated the value of involving them where possible.

d) Recommendations

Where required, Chemical Safety Assessments prepared by Receiving Companies should address all their own relevant uses and thus Exposure Scenarios. [Recommendation 23]

For example, use outside a consumer Exposure Scenario might not indicate use outside an environmental scenario.

A Supplier may indicate a maximum level of a substance or preparation for use in a consumer product e.g. that use of a classified substance, x, is safe for use in skin cream at 1%. If a DU uses x at >1% they will need to assess this new ES (to consumers) as it is not covered by the Supplier and may pose higher risks to the consumer. However, the higher inclusion level may not affect the environmental ES if the route of disposal is the same as assessed by the Supplier. Receiving Companies still have a responsibility to check that environmental aspects are not affected by modifying the health aspects of the CSA and vice versa where for example a secondary source of human exposure may arise from contamination of the environment.)

Different approaches may be necessary for environmental and human health Exposure Scenarios (ESs). [Recommendation 24]

Human health ESs would typically be based on the percentage of a chemical in a product and may need to be more detailed to account for an individual's exposure to a substance whereas an environmental ES would be based on tonnages and needs to take a broad view to account for the many possible facets of environmental exposure and the need to safeguard populations rather than individuals.

Sector Groups may usefully provide a standard framework for the development of Exposure Scenarios relevant to their own sector. [Recommendation 27]

(Note similar recommendation from RIP 3.5).

Individual Sector Groups should be encouraged to compile data-bases on descriptions of uses throughout the Supply Chain. [Recommendation 26]

7.5.3 Developing a Chemical Safety Assessment for substances

This was not the prime focus of the project, except with LAB. However, some comments are offered. A special sub-section, **7.5.3.1**, discusses the substance CSA when the use is not identified by the Supplier.

b) Observations

In this project the LPG Chemical Safety Report did not contain a fully comprehensive data set and explanation of risk assessment. However, for the purposes of PRODUCE it was adequate to carry forward to the extended substance SDS.

The advantage of having existing assessments has been mentioned above. This would not normally be a task for Downstream Users unless the DU had useful data to contribute or if the DU uses a substance outside the Supplier's Exposure Scenario. (See below.)

Annex 1 section 7 of the Proposal sets out the information required in the CSR and indicates a format for doing so. Since exposure scenarios and risk assessments are only required for substances classified as dangerous, it is understood that collation of hazard data is required as an initial and separate step in the report, (even though this may not be the most convenient way of following a subsequent risk assessment). However, it seems logical to include the information on environmental fate properties, currently in part B of the CSR, in part C as a section between section 3 (environmental hazard assessment) and section 4 (PBT and vPvB assessment).

d) Recommendations

The part of the Proposal (Annex 1, Section 7) which sets out the format of the Chemical Safety Report should be re-drawn so that the data entries appear in logical order. [Recommendation 17]

The current version mixes up a whole series of subjects e.g. the environmental fate properties are misplaced.

7.5.3.1 Substance CSA when used outside scope of suppliers ES

a) The Process

The workability of the REACH requirements for a Receiving Company using a substance outside the scope of a Supplier's exposure scenario was investigated within the Perfume Preparations Sub-Project. Specifically, the requirements investigated were:

Article 34(4) states that a "... *DU of a substance on its own or in a preparation shall prepare a chemical safety report in accordance with Annex XI for any use outside the conditions described in an exposure scenario communicated to him in a safety data sheet*".

Article 35(1) states "... *any downstream user shall report to the Agency the information specified in paragraph 2 of this Article, if a safety data sheet is communicated to him that includes an exposure scenario and the downstream user is using the substance outside the conditions described in that exposure scenario*".

The requirements for a Downstream User to conduct CSAs under REACH, as tested within the Perfume sub-project, can be illustrated as in Figure 7.2. In this situation the incorporation of a preparation into a formulation is illustrated too.

When conducting a CSA for the use of a substance outside the Supplier's exposure scenario, the requirements given in Article 13(2) to (7) apply.

b) Observations

Comments, questions and the interpretation from the Perfume Sub-Project Working Group on these requirements are given in Table 7.1 following the figure.

Figure 7.2 Requirements for action by a DU Company considering identified and non-identified uses in a preparation

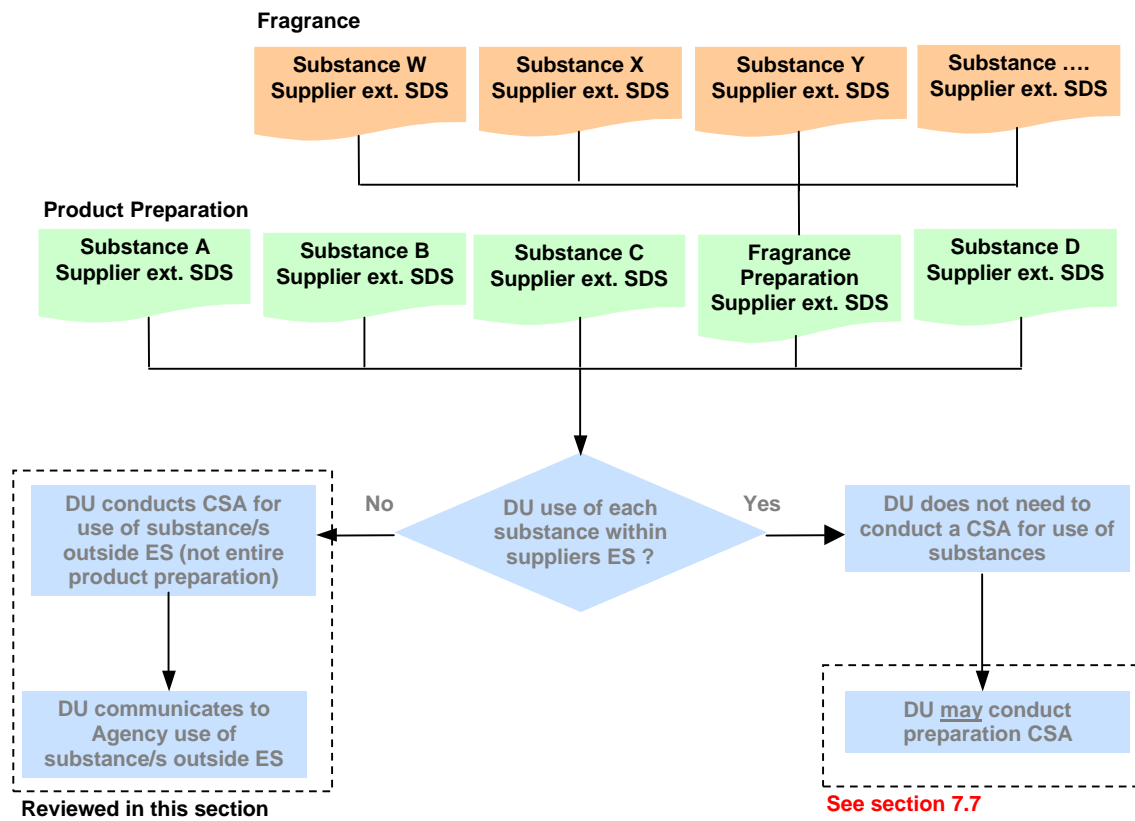


Table 7.1 Consideration of aspects of Article 13 on the Chemical Safety Report

Article 13 para	Requirement	Comments / Questions / Interpretation when DU uses substance outside Supplier's ES
2	Includes concentration limits below which a substance does not need to be considered when present in a preparation	Assuming the substance which is used outside the Supplier's ES is below the relevant concentration limits, no CSA is required to be performed by the DU
3	Includes the steps that must be taken for all substances that require a CSA to be performed (i.e. hazard assessments)	Assuming the substance is used above the concentration limit specified in 13(2), these hazard assessments are required. The information necessary in conducting such an assessment will be available on the Supplier's extended SDS
4	If, based on the hazard assessment required under para 3, the substance meets the criteria for classification as dangerous under Directive 67/548/EEC on Dangerous Substances, or is a PBT or vPvB, an exposure and risk characterisation step is required	<p>1. It is not clearly specified in the Commission proposal whether the steps required under this paragraph are required for all endpoints or only those which are classified as dangerous under Directive 67/548/EEC on Dangerous Substances. For example, if a substance is classified as dangerous to human health or based on physico-chemical properties only (i.e. not classified as environmentally hazardous) is an environmental exposure assessment and risk characterisation required? Using the principles on which para 4 is based, it would only seem necessary to conduct an environmental exposure assessment and risk characterisation for substances classified as environmentally hazardous. This argument also applies to the human health exposure assessment and risk characterisation for substances that do not represent a danger to human health.</p> <p>2. Article 13 requirements also apply to M/I of substances higher in the supply chain. An interpretation of these requirements from a M/I standpoint concludes that, as the development of exposure scenarios is an activity conducted within the exposure assessment step of the CSA, only those substances which are classified as dangerous under Directive 67/548/EEC will be assigned exposure scenarios. Therefore, as no ES will be assigned for non-classified substances, the DU would not be required to conduct a CSA. In other words, the DU duty to perform DU CSAs are triggered by receiving an ES from their supplier. Similar to point 1 above, it is not currently clear if environmental ESs, for example, will be assigned to substances which are classified according to Directive 67/548/EEC on Dangerous Substances, but not for environmental hazard.</p>

7.5.4 Handling unclassified substances

a) The Process

Classification can be based on any intrinsic property: physical/chemical toxicological or ecotoxicological. Any classification triggers a series of actions, regardless of the relevance of the classification. For example, if a substance is not classified for the environment, it is still necessary to conduct an environmental exposure and risk assessment.

b) Observations

Comprehensive Risk Assessments are not part of the REACH Proposal but Targeted Risk Assessments *are*, and are considered by the PRODUCE Team to be useful in relation to issues (ES) of concern. PRODUCE tested a comprehensive approach just to see how difficult and time-consuming it could be. REACH is clear that classification of a substance leads to production of a Chemical Safety Assessment and Exposure Scenario. Non-classified substances require only a statement of hazard assessment. There is, however, a likelihood that a substance will classify based on one aspect of its intrinsic properties (say toxicological) and not on others such as environmental. The following recommendation caters for this situation.

c) Lessons Learned

- (xli) *If a substance is unclassified there is no requirement to include in the CSA or CSR a risk assessment or an Exposure Scenario. (There is still a need for a CSA or CSR.)*

d) Recommendations

Risk assessments should not be required for human health and the environment unless the substance is classified for hazards appropriate to that target.¹³
[Recommendation 28]

Comprehensive Risk Assessments are not part of the REACH Proposal but Targeted Risk Assessments are, and are considered by the PRODUCE Team to be useful in relation to issues (ES) of concern. PRODUCE tested a comprehensive approach just to see how difficult and time-consuming it could be. REACH is clear that classification of a substance leads to production of a Chemical Safety Assessment and Exposure Scenario. Non-classified substances require only a statement of hazard assessment. There is, however, a likelihood that a substance will be classified based on one aspect of its intrinsic properties (say toxicological) and not on others such as environmental.

7.5.7 Developing appropriate risk management measures

a) The Process

For worker safety, risk management measures (RMM) were needed for LAB and LPG; for LPG there was an additional need for RMM for uses further down the supply chain: retailers and consumers.

b) Observations

No difficulty was found in linking the SDS with RMM. With the Perfume Preparations the issue was more to do with how specific the RMM needed to be (e.g. the material from which gloves were made). Of course this was not necessarily a direct REACH issue.

7.5.8 Transmission of worker safety information

b) Observations

Use of the Safety Data Sheets was considered with LAB, although the Health and Safety Framework Directive 89/391/EC and subsequent daughter Directives cover this adequately for Worker Safety. Unilever must comply with its own internal Worker Safety requirements and may want its own SDS for this reason. (Unilever is importing and supplying to a plant which has a different legal entity.)

7.5.9 Transmission of safety data down the supply chain

a) The Process

The Receiving Companies should get sufficient information in the Safety Data Sheets to make their own assessments, establish their risk management measures and inform their customers in a relevant manner.

b) Observations

No problems were encountered in working with the SDS format set out in Annex 1a.

c) Lessons Learned

(xlii) Phrases must still be translated before production of Safety Data Sheets can be automated.

(xliii) The new requirements to include Exposure Scenarios (which will generally require free text) in Safety Data Sheets will make translation very difficult.

(xliv) The translation of Safety Data Sheets is not just a recent issue but translation of Exposure Scenarios is. Any means of minimising the variety of the phrasing in these would be welcomed. For example, a suggestion from the Commission was to begin with translation of the S-Phrases and develop from there.

d) Recommendations

To enable the new Extended Safety Data Sheets to be easily translated into the different languages of the Community the standard phrases that have been developed for the Dangerous Substances and Preparations Directives need to be extended to cater for the requirements of REACH. Trade Associations could lead a sector approach in standardisation of phraseology to facilitate this work. In addition, consistency with GHS should be pursued [but note that the extended part of the SDS is not a part of GHS]. [Recommendation 18]

Automated software is available to prepare Safety Data Sheets in the different languages of the Community. The new requirements to include Exposure Scenarios (which will generally require free text) in Safety Data Sheets and Risk Management

Measures do not lend themselves to this sort of approach. Any means of minimising the variety of the phrasing would be welcomed.

7.5.10 Individual or joint preparation of guidance on safe handling and end-use

for each downstream use

Chemical Safety Assessments

a) The Process

In the LPG case there was specific advice given separately to consumers and to professional users, *via* the SDS rather than the CSA (as the CSA is not intended to be passed down the supply chain). The rest of this sub-section refers to the preparation of a Chemical Safety Assessment.

Linear Alkylbenzene

In this case, which would not be the typical situation once REACH is implemented (although it might still be very helpful to a non-EU Supplier), the Receiving Company sent the non-EU Supplier the relevant forms for completion.

Liquefied Petroleum Gas

BP made use of pro-formas (for outcome, see Appendix H2); the Receiving Companies and BAMA added further information. BP checked the quality of the data.

b) Observations

Data-richness and quality can be expected to be very variable.

For substances which have not been the subject of the Existing Substances Regulation there are other pieces of work which can help the Supplier: the output of the Project HERA, a joint study by A.I.S.E and Cefic on the Human & Environmental Risk Assessment of chemicals used in household cleaning products www.heraproject.com, the initiatives of the International Council of Chemical Associations (ICCA), the OECD HPV chemicals process, the work and databases of the IPCS and the chemical-specific monographs of ECETOC can be a very considerable help.

c) Lessons Learned

(xlv) Trade Association archives can be very useful in enquiries on intrinsic properties, exposure scenarios and risk assessments.

Existing assessments may not be fully up-to-date, and care should be taken when referring across: (the science may have developed and sometimes existing assessments only provide hazard-based information, while REACH is about risk assessment). BAMA, for example, was particularly helpful concerning exposure scenarios and the specific properties of aerosols, but national associations covering a broad sector could not expect to have quite the same level of detail.

- (xlvi) *ISU, as a non-EU Manufacturer, quickly gained an understanding of the requirements for the Supplier's duties under REACH.*
- (xlvii) *It took the Perfume Preparations Sub-Project time to realise that for complex mixtures such as Perfume Preparations it was necessary for the registrant to identify and quantify the individual components of the mixture and to register single substances.*
- (xlviii) *Untangling tonnages in complex proprietary preparations and complex supply chains in order to define who is responsible for Registration and then to deliver these is a lengthy process.*

Technical Dossier

b) Observations

Linear Alkylbenzene

Compilation was found to be straightforward, partly due to the dataset assembled for the Existing Substances Regulation. The Supplier had no problems completing forms to a good standard. It was certainly valuable for the Receiving Company to have internal safety / regulatory teams available to assess the material provided by a non-EU Supplier.

Liquefied Petroleum Gas

There were more data gaps than with LAB, therefore more discussions were needed. It cannot be taken for granted that liaison with Suppliers will always be so positive.

c) Lessons Learned

- (xlix) *The informal LPG 'consortium' established with Supplier and Downstream Users in PRODUCE was found to be very positive and useful. There were no conflicts needing solution. There were good approaches to discussions on gap-filling.*

7.6 Preparing Registration Dossier

7.6.1 Compile data as required by REACH guidelines

a) The Process

Member States assessment of registration dossiers for LAB and LPG.

Linear Alkylbenzene

Hungarian CA comments on the LAB Sub-Project.

1) Method of working by the CA

The Hungarian Competent Authority took a step by step examination of the REACH process to find any problematic points. The exact part of REACH and its position within the proposal were indicated in a table along with explanatory comments. For ease of presentation in this report, only the steps in REACH where comments were made are reported here but a full report may be found in Appendix G4.

2) Reviewed documents

- Chemical Safety Report A,B,C of LAB
- Robust Safety Report of LAB
- Technical Dossier of LAB
- Summary Risk Assessment Report of LAB

- the whole text of the REACH Proposal and its Annexes of 29 October 2003

3) General Opinion of the CA

The CA followed the possible process and way of registration for LAB. The REACH system appears a well-working system. The comments can be considered more as questions, sometimes to the Commission, than proposals or recommendations. They may be subjects of further considerations. The comments are given in full in Appendix G4. Only those which gave rise to special comments or Recommendations are described in the following abstract (Table 7.2).

Table 7.2 Abstract of Hungarian CA comments for Linear Alkylbenzene

STEP IN REACH	CA COMMENT	COMMENT
REACH PROPOSAL (2003) <i>Article 5</i> General obligation to register substances on their own or in preparations	<p>Note that these questions largely confirm the need for guidance to be developed under RIPs.</p> <p>Missing information: The circumstances of submitting the dossier to ECB / Agency (company, date, etc.)</p> <p>Should the MSCA-s have a special form filled in by the Agency with data of submission of the dossier?</p>	<p>This information will be available from REACH IT as it has to be filled in IUCLID 5</p>
ANNEX V STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 1 TONNE OR MORE	<p>How can this paragraph [on permitted adaptations] be controlled?</p> <p>What are the rules of acceptance of the mentioned statements [on acceptability of adaptations]?</p>	<p>Guidance is needed to determine the sufficient level of justification if standard information requirements are adapted in a registration dossier. [Recommendation 33]</p>
9. METHODS OF DETECTION AND ANALYSIS	<p>How will the Agency (if it is the Agency) decide which method should be described? Which board (of the Agency) will accept the description?</p>	
Annex IX 1.1.3. Historical human data	<p>May some kind of directives help the Agency/CA-s to consider human health data?</p>	<p>Guidance is needed on how to use existing information such as historical human data [Recommendation 34]</p>
1.2. Weight of evidence	<p>May some kind of directives help the Agency/CA-s to make a proper decision?</p>	<p>Subject for preparation of RIP guidance.</p>
<p>(ix) proposals for testing where required by the (x) a declaration as to whether he agrees to share information</p>	<p>How can “payment” be regulated? If summaries or robust study can be subject of payment, how can the ownership of these data be legally regulated?</p>	

STEP IN REACH	CA COMMENT	COMMENT
ANNEX X INTRODUCTION The Annex sets out test methods for the determination of physicochemical, toxicological and ecotoxicological properties listed in Annexes A-D	How can the notifier's data of impurities can be protected? (Number of ways of production of a substance may exist. List and type of impurities or additives can help to find out what a way of production is used by a notifier. Agency or CA-s have the right to know all information, but is protection of data from other companies regulated?)	M/Is will have ways to prevent this information being disclosed if it is commercially sensitive (Art.115). This may be an area where guidance could be required.
2. The completeness check	What way will the Agency inform the registrant? Via e-mail, via mail, via courier?	It is foreseen, to the extent possible, that communication will be electronic

Observations/Lessons learned

- (l) *The overall positive comments from the MSCA suggest that the data submitted in the registration dossier was reasonably adequate (at least for the purposes of PRODUCE) and that the stepwise approach through REACH was workable for the MSCA. Few workability issues were identified, most of which should be resolved when guidance is issued.*

Several comments were made on the lack of a SDS for LAB in the registration dossier. Annex IV of REACH (information referred to in Article 9(1) (A) (I) to (V) sets out the information needed. Section 5 indicates that guidance on safe use shall be consistent with the SDS but inclusion of a SDS in the registration dossier is not a requirement, presumably since the key data are reported via the CSR. In PRODUCE the question of the responsibility of the importing company for preparing its own SDS for LAB (for internal communication within the company) was discussed.

Comments on the further testing requirements were not pursued since the focus of the project was not on the comprehensive evaluation of an LAB dossier. It can be assumed that such issues would be resolved through dialogue with the relevant CA and/or the Agency.

Liquefied Petroleum Gas

Greek CA comments on the LPG Sub-Project

The following minor comments were made by the CA:

Technical dossier

In part 2.3 the CAS numbers of ethane and propane are still missing: (CAS No 74-84-0 for ethane, 74-98-6 for propane).

In part 5.6 instructions for workers should be incorporate as described in Part A 1.1. of the CSR (RMM for aerosol manufacturing).

Risk assessment

1.3 Hazard classification

Petroleum products like LPG are assigned Note H which makes mandatory the classification of the product for other endpoints if this is known to the producer. (See

exact wording of Note H in the 28th ATP of the Directive 67/548/EEC). It is recommended that this paragraph should be re-phrased.

Further testing on reproductive toxicity is accepted.
Scenario C is an excellent idea.

Chemical Safety Report

In points 1.9.1 & 1.9.2. it should be added " Further studies in progress".

b) / c) Observations/Learnings

In general, the CA considered the dossier to be of a good standard. No major limitations were identified.

d) Recommendations

It is recommended that Registration numbers that can be linked to individual suppliers should not be included in Safety Data Sheets for preparations. It is further recommended that this problem of maintaining confidentiality be addressed in the relevant RIP. [Recommendation 14]

In Article 116 on Confidentiality, part 1(a) states that a Trade Name is not confidential. However, part 2(d) in the same Article states that links between a Manufacturer/Importer and Downstream Users are confidential. In a Safety Data Sheet a Trade Name can be inserted, but this automatically permits the link to be made and the confidentiality to be lost. In the context of the Globally Harmonised System for Classification and Labelling of Chemicals (GHS), and the hoped-for opportunity to generate globally applicable Safety Data Sheets, CAS numbers may be preferred and registration numbers could be added to Section 15. This would ensure that there was no confidential business information in the Safety Data Sheets for preparations but would still enable Receiving Companies to identify Suppliers registering a substance, provided that they are given proper access to the relevant sections of REACH-IT.

Downstream Users should be encouraged to contact their Suppliers to ensure that all information they (DUs) have is used in the CSR. [Recommendation 16]

Receiving Companies may wish to access substance CSRs in order to check that the risks associated with their use have been adequately considered.

7.7 Preparing a Chemical Safety Assessment for Preparations

7.7.1 Introduction

The issues and workability of conducting a CSA for a preparation were investigated within the PRODUCE Perfume sub-group. The sub-group discussed the context of the preparation CSA and the value of conducting such an assessment while considering certain limitations and workability issues.

It is worth noting that preparations can vary dramatically in their complexity and structural diversity. For example, some preparations are very simple mixes of two or three substances which are all structurally similar. In contrast, the majority of preparations placed on the market will contain a greater number of substances which are likely to be structurally diverse. It is with these more complex/diverse preparations that a greater number of limitations and workability issues manifest themselves. Within the REACH proposal the requirement for a DU to conduct a CSA for a preparation is optional. CSAs for preparations are permitted by Article 29(2) and the methodology is given in Annex Ib. Article 29(2) states:

*“If the safety data sheet is developed for a preparation, the actor in the supply chain **may** prepare a chemical safety assessment for the preparation in accordance with Annex Ib. In that case, it is sufficient if the information in the safety data sheet is consistent with the chemical safety report for the preparation instead of with the chemical safety report for each substance in the preparation”.*

The role that a preparation CSA can play within the REACH process is elaborated further in the explanatory preamble to the REACH proposal. Here, it is recognised that it may be a complicated exercise to prepare a SDS for a preparation containing many registered components. The resulting SDS may need to contain a great deal of detailed information on each component (e.g. on physical and chemical properties in section 9, toxicological information in section 11 and ecological information in section 12) which could make the writing of the SDS resource intensive with consequent workability issues. Therefore, REACH provides the option of preparing a SDS which reflects a preparation CSA rather than the CSAs for all registered components.

7.7.2 Analysis of the Issue

A summary of the sub-group analysis is provided below while a more complete account is provided in Appendix N.

a) The Process

REACH Annex Ib does not provide detail on the methodology that should be used in order to conduct a preparation CSA. However, in order that this option within REACH may be taken up, especially by SME companies, the methodology must be simple, yet meaningful, and require proportionate resources considering the vast number of preparations placed on the EU market. With this in mind the Perfume sub-project team identified a number of options that could be followed in order to conduct a preparation CSA. These options were discussed within the context of the preparation CSA environmental and human health assessments.

b) Observations

(i) Preparation CSA – Environmental context of assessment

The context and principles of a preparation CSA within the total REACH process were discussed. It was recognised that conducting an environmental CSA for the volume of a substance in a preparation will provide an incomplete indication of environmental safety. Any comprehensive environmental risk assessment should be conducted on the total amount of a substance entering the environment. That is, the sum of all downstream uses supplied by all EU manufacturers and importers. This is illustrated within the figure below.

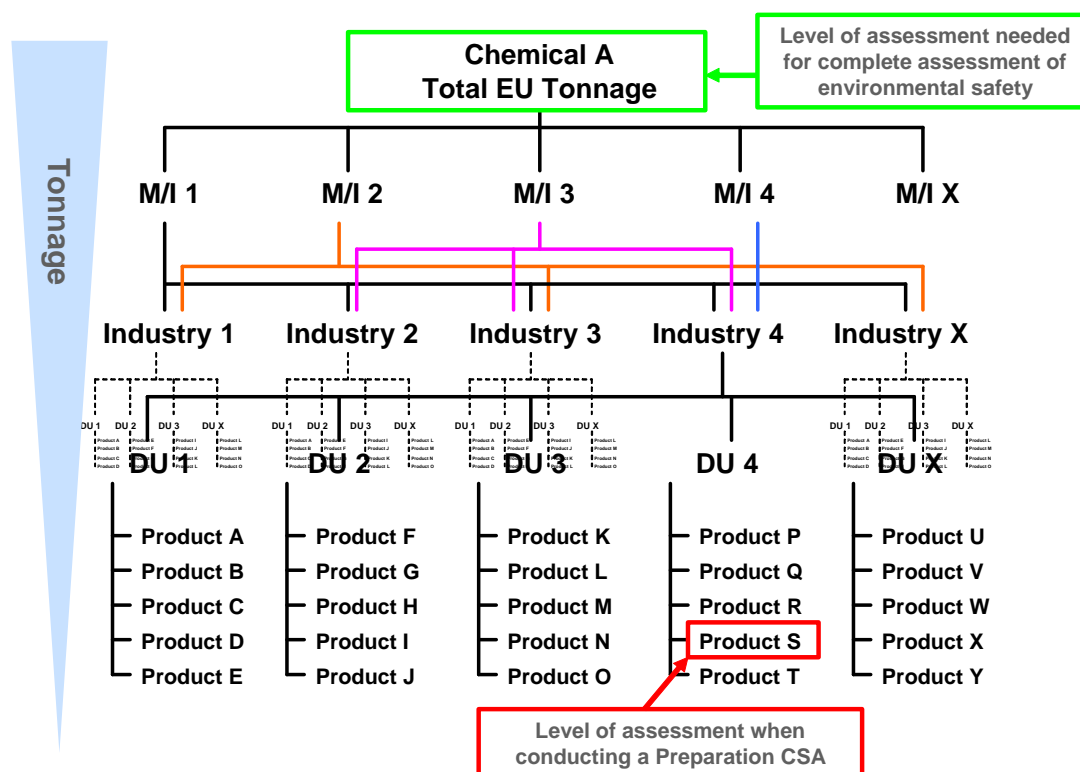


Figure 7.3 Environmental assessment at the preparations level

Despite the incomplete nature of the environmental assessment of substances within a preparation CSA, the principles of REACH require individual companies to be responsible only for the safety of each substance within their uses, not those of other companies. Therefore, within this context a preparation environmental CSA can be conducted assuming the intention is to derive summary information on environmental parameters that will be included within a preparation SDS.

(ii) Preparation CSA – Human health context of assessment

The context of a human health preparation CSA is somewhat different to that for the environment. Individuals can be exposed to complex preparations containing many substances because there is not immediate fragmentation into individual substances as seen during environmental discharge. Although this means that it may be appropriate to assess a preparation, there remains limitations to this. Each human may be exposed to the same substance at a variety of different levels from a number of different preparations, with different uses. This is analogous to the need to assess all sources of exposure to the environment (i.e. the total aggregated tonnage level). For humans the equivalent level is to assess all exposure to products containing the same

substance. There are a large number of human health endpoints for which there can be multiple potential effects that need to be considered in any assessment.

7.7.3 Options considered for conducting a CSA for preparations

The sub-group considered 3 options for conducting a CSA for preparations and the observations on these are summarised below. Further detail is provided in Appendix N.

Option 1 – Consider the preparation as a single entity

Environmental comments: This is not an appropriate option as preparations do not normally exist as a single entity once discharged to the environment.

Human health comments: A preparation can sometimes be considered as a single entity from a human health point of view. This is due to the fact that a preparation can exist for some time as the mixture and humans could be exposed to this mixture at the point of use. However, absorption and bioavailability of each component will vary depending on the physico-chemical properties of each individual substance and the route of exposure and therefore, once absorbed the preparation should not be considered as a single entity in the body.

Option 2 – Consider each substance within the preparation separately

General comments: This approach raises a number of workability issues that are applicable for both the environmental and human health assessments. For example, issues relating to the large number of substances that would need to be considered, especially for more complex preparations, and the availability of the information required for each substance, especially for those substances that will be registered later in the REACH process.

Human health comments: In addition, to the general comments a number of specific comments regarding the derivation of appropriate DNELs are detailed in Appendix N.

Option 3 – Consider selected substances within the preparation

Within the RIP 3.2-1 project a number of proposed practical solutions to the workability issues identified in conducting a preparation CSA were reviewed. These practical solutions promote the consideration of selected substances within the preparation to a greater or lesser extent. The aim of such an approach is to reduce the bureaucracy and resources required in conducting an assessment. These proposals were briefly reviewed by the Perfume sub-project and comments are provided in Appendix N. The RIP 3.2-1 proposal most favoured by the sub-group was the “Key Critical Component” approach. This methodology leads to the identification of a key substance within the formulation (e.g. substance of highest concern) on which the CSA is based. The approach recognises that, in order to reduce the resources required to undertake a preparation CSA, that the number of individual substances and/or endpoints of concerns included within the assessment should be reduced to only include those that are of most concern.

c) Lessons learned

- (li) *The PRODUCE team recognises the importance of developing a workable preparation SDS that contains information that is focussed on the needs of the intended audience within REACH. This focus reflects the changing information requirements throughout the supply chain and is discussed elsewhere in this report (see, e.g. Table 7.3).*
- (lii) *Guidance is currently lacking on the methodology that should be used in order to conduct a preparation CSA. However, in order that this option within REACH is workable, especially for SME companies, the methodology must be simple, yet meaningful, and require proportionate resources considering the vast number of preparations placed on the EU market.*
- (liii) *The correct context of an environmental CSA for a preparation must be kept in mind. The objective is to provide an assessment of the environmental safety of the use of the substances within that product only. This assessment can then be used to derive summary information for inclusion within a preparation SDS.*
- (liv) *Considering a preparation as a single entity would not be appropriate for the environmental assessment and may have certain scientific limitations from a human health point of view.*
- (lv) *From a workability standpoint, the project team believes that considering selected substances within the preparation (e.g. those classified as dangerous for the specific endpoint of concern) is a suitable approach for conducting a preparation CSA.*
- (lvi) *From the RIP 3.2-1 proposals reviewed by the project team, the Key Critical Component method is currently thought to offer the greatest opportunity for conducting a CSA for a preparation. There are still workability issues for using this method for human health endpoints, even if these issues may be specific to a particular type of preparation from a particular industry sector. For certain industry sectors and endpoints, the methodology could be appropriate.*

d) Recommendations

Companies should distinguish their roles in relation to environmental risk assessments. Companies should make an environmental assessment, both at the local and regional scale, of the volume they put on the market. The authorities may then perform a local and/or regional assessment of the total volume of the substance under “Substance Evaluation”. [Recommendation 22]

In order to facilitate regional environmental risk assessments, it is important to know the total tonnage of a substance used but this is not the responsibility of the Downstream Users or anyone else in the Supply Chain. Where this tonnage is made up of various sources, including imports of substances and preparations the contributions from each source must be known. It is the responsibility of the Agency

to assemble the aggregated volume and make the total assessment. (Production volumes cannot be disclosed.)

In order for the option to conduct a preparation CSA within REACH to be workable, especially for SME companies, there will be a need to develop acceptable methods that will have to be simple as well as meaningful, considering the vast number of preparations placed on the EU market. Resources channelled into this activity must be proportionate. [Recommendation 25]

The PRODUCE Team struggled to find a scientifically justifiable approach to developing Chemical Safety Assessments (CSAs) for Preparations. It should be recognised that one methodology may not be appropriate for all product sectors and that an approach designed specifically for a particular sector may be more appropriate to the relevant workability, human health and environmental issues associated with the products within that sector.

7.8 Communication

7.8.1 Communication up and downstream

The issue of communication is one of great interest to the PRODUCE Team, because REACH will significantly increase communication within the supply chain. Besides it seemed to the team that the needs of the main users of chemicals, the EU public, have not yet been considered in REACH. (Amendments in the European Parliament's opinion in the First Reading are now addressing this need.) The public uses millions of tonnes of chemicals, including fuels, paints, adhesives, solvents, household chemicals every year. This section therefore not only considers communication within the chemical industry but also further down the supply chain as in Table 7.3.

Table 7.3 Information flow under REACH and *beyond REACH*

Actor in the supply chain	Indicative (only) information requirements to achieve safety in use of chemicals
Manufacturer / Importer	Data on intrinsic properties and exposure scenarios* to allow assembly of Chemical Safety Assessment, Chemical Safety Report
Downstream User	Safety Data Sheets
<i>Distributor</i>	Extended Safety Data Sheets, as required to be delivered to the Downstream Users, if applicable, tailor-made according to the needs of the Downstream Users or other Receiving Companies.
<i>Warehousing Professional user</i>	Summary of key data for storage / emergency action Extended Safety Data Sheets
<i>Retailer</i>	Safety information on the product, written in an understandable style to assist retailer in event of accidents, but the retailer must feel confident that the summary information is based on a full data set which is accessible to medical and other professionals.
<i>Domestic user</i>	Instructions for safety in use of the product and for correct disposal.

*Data on both intrinsic properties and exposure scenarios may be available from Downstream Users.

Receiving Companies, who are also formulators of products, from the chemicals with which they are supplied may hold a large volume of data. This large volume consists not only of the Manufacturer's data on intrinsic properties and occupational safety aspects but also of the plethora of scenarios describing eventual downstream use, whether in an industrial / institutional setting or in the home. At the same time, the nature of the information changes as the data are passed on in the form of instructions and advice on safe handling and use. Not all Receiving Companies will hold the same amount of data on intrinsic properties, or have the same level of detail on exposure scenarios as that from which PRODUCE has benefited. It may even be that some Supplier Companies have very little idea at all of the products into which their chemicals are incorporated by their customers, the Receiving Companies.

It is important to recognise that the focus of PRODUCE is mostly lower down the supply chain than was the focus of SPORT. This leads to a variety of problems and challenges in assessing workability of REACH.

7.8.2 Supplier's Safety Data Sheets

There are two types of customer for the SDS: one who uses SDS for preparation SDS and the other is the end-user. The needs of both are considered below.

b) Observations

General

The variable quality and quantity of data provided for construction of SDS and the shortage of experienced people to prepare material, compliant with REACH and fit for the purposes of Receiving Companies, may be a cause for serious concern. Any problem will be exacerbated when preparation Safety Data Sheets are needed.

Chemicals whose properties and use scenarios are less familiar than those chosen for PRODUCE may be far more difficult to address, because they may have features

which could be missed or misinterpreted. Assumed worst-case scenarios may mislead.

Liquefied Petroleum Gas

With the CSR in hand the preparation of the extended SDS was found to be reasonably straightforward. See Annex dated 20/09/2005, extended Safety Data Sheet on LPG. The document received from the Supplier was found to be highly satisfactory and could be used by people relatively unfamiliar with the area.

Perfume Preparations

The supplier provided Safety Data Sheets for a number of perfume preparations to be used by the Receiving Company in consumer products. The information was rather straightforward to use as long as the downstream applications were within the exposure scenarios and concentration limits given by the Supplier. When the Receiving Company decided to work outside these boundaries, there appeared to be difficulties in obtaining information for constructing a CSA by the Receiving Company.

c) Lessons Learned

(lvii) The need to generate so many Safety Data Sheets without standard text was and will be a problem.

(lviii) Supplier experience in compiling Safety Data Sheets was that there was a need for efficient formatting.

7.8.3 Worker safety

The legal requirement to conduct an assessment concerning the safety of workers makes use of the Safety Data Sheets from Suppliers. Examples may be found in the Appendices to this report.

7.8.4 SDS for further downstream use

The following sub-sections are detailed in the Appendices. The Process, Observations etc conclusions that follow refer to all these sub-sections.

Subject	Appendix
7.8.4.1 Aerosol Air Freshener with Perfume Formula A	J - Extended Safety Data Sheet
7.8.4.2 All-Purpose Cleaner with 0.15% fragrance A	K1 - Extended Safety Data Sheet K2 - Product Information Sheet for bulk transport, handling and storage
7.8.4.3 Bathroom Mousse	L - Extended Safety Data Sheet

a) The Process

The preparation of Safety Data Sheets is covered in Title IV (Information in the Supply Chain) of the REACH proposal, i.e. Articles 29-33 inclusive. These Articles are supported by explanatory memoranda and Annex 1a, which gives guidance on the compilation of Safety Data Sheets. Other supporting texts the PRODUCE team used in the generation of the SDS were:

- Directive 67/548/EEC on Dangerous Substances;
- Directive 1999/45/EC on Dangerous Preparations.

The Globally Harmonised System of Classification and Labelling of Chemicals (GHS) was borne in mind, as it is quoted in the explanatory memorandum.

To generate the Safety Data Sheets the following steps were taken:

1. Representative yet fictional formulations were identified from current trade press which contain the two substances under review in PRODUCE. These were “Whizzo All Purpose Cleaner” (APC) and Aerosol Air Freshener.
2. Raw Material Safety Data Sheets were obtained for all materials used in these preparations.
3. The classification of the finished products was derived. To do this the formulations were assessed according to the conventional method laid out in Directive 1999/45/EC on Dangerous Preparations and the relevant risk and safety phrases were assigned.
4. Two different approaches were then taken in order to generate the Safety Data Sheets under REACH.
 - 4a. For Whizzo APC, an automated/software system was used to generate the Safety Data Sheet of the finished product. This system is one commonly used by companies to generate the large volume of data sheets currently required by law (Directive 91/155/EC and Directive 2001/58/EC) and to keep them updated in a timely fashion. This was then supplemented by additional information required by REACH.
 - 4b. For the Air Freshener the supplier extended SDS were taken and the necessary text reworded to generate the SDS for distributing along the supply chain.
5. The ‘REACH’ data sheets were then shared with the next actor in the supply chain, the retailer.

b) Observations

- (i) The explanatory memorandum relating to Article 29 states that

“The 16 headings required for SDS are consistent with those agreed in the Globally Harmonised System for the Classification and Labelling of Dangerous Chemicals (GHS)”.

(See (c) (i) below.)

- (ii) Generation of the Whizzo APC data sheet very quickly highlighted the fact that for an 11-year period, the data sheet would likely be in a constant state of “semi-compliance” since substances would continue to be registered over this period. This would generate a lot of re-working of data sheets.

- (iii) Regarding Section 3, composition information, it became clear that the information could be interpreted in more than one way, leading to uncertainty in Section 2. Being more specific, companies may choose to assign broad ranges to the composition of ingredients in order to protect their formulation details. However, this can lead to questions over the accuracy of the final product classification if a substance with a particular classification is quoted as being present above the cut-off limits in Directive 1999/45/EC on Dangerous Preparations. (See recommendation below.)

(iv) Section 9 of the data sheet deals with physical and chemical properties. Many of the properties stated may be irrelevant to many substances or preparations.

(v) The information required in Section 11 (toxicological information) is extensive, particularly when dealing with preparations that contain many substances (which is very common). It is also above and beyond what is required from the GHS leading to a lack of harmonisation. The additional data provided for Whizzo APC extended the sheet by 3 pages. This is also the case for Section 12, ecotoxicological information. Together they formed the data sheet into a booklet. *The usefulness of this i.e. provision of detailed scientific information is questionable, particularly when a substance/preparation is in its final form and won't be modified, or re-worked in any way.*

(vi) It will be very difficult, with so much free text, to be able to generate data sheets translated into the official languages and pass them along the supply chain promptly. It is therefore recommended that these sections are limited to short standard text which is meaningful and translatable.

(vii) A further issue of resource was highlighted. It is current practice amongst many companies to generate SDS through computer software packages, set up by trained staff (toxicologists, ecotoxicologists, occupational health specialists etc.). The day-to-day task is then undertaken by administrative staff. To generate data sheets in the way completed for the Air Freshener, required a degree of expert knowledge and perhaps it always will. It will be impossible to find the physical resource able and more importantly willing to undertake this task.

c) Lessons Learned

(lix) *There are slight differences between the content of GHS and the text of Annex 1a of the REACH proposal. Specifically the GHS asks for CAS numbers and other unique identifiers. Annex 1a of the REACH proposal specifies EINECS or ELINCS shall be given and that CAS and IUPAC (if available) may be helpful.*

(lx) *In order not to disclose the exact formulation of a preparation, ranges of concentrations of ingredients are provided in Section 2 of the Safety Data Sheets. This is in accordance with the requirements of the Directive on Safety Data Sheets and with Article 29 of REACH. The issue is that there are various sets of concentration limits in existing legislation which will still apply, so a blanket set of ranges would be difficult to assign. This can give rise to questions over the accuracy of the final product classification, if a substance with a particular classification is quoted as being present above the cut-off limits in the Directive 1999/45/EC on Dangerous Preparations. To avoid the potential confusion caused by the variety of concentration limits to be found in existing and proposed legislation the ranges should be specified in Section 3 of the Safety Data Sheets.*

A statement may also be required in Section 2 and Section 15 to highlight the fact that classification of the preparation is based on actual concentrations, not the maximum of the range given in Section 3 of the Safety Data Sheet.

- (lxi) *The doubtful value of so complex a Safety Data Sheet was borne out by retailers/distributors who asked for a more focused safety data sheet. An example of what this may look like was generated for Whizzo APC.*

d) Recommendations

It would be helpful if the REACH and GHS texts were consistent. It would also be helpful if one unique substance identifier were required, although the difficulties of this are appreciated. [Recommendation 18 – part]

To identify and summarise the Registration, Restriction or Authorisation status of a substance or substances in a preparation would be made easier by the use of standard phrasing, probably in Section 15 in the substance Safety Data Sheets. It is recommended that this should be investigated further. [Recommendation 19]

This would limit the number of times the Safety Data Sheets would need to be modified and also keep the data sheet more in line with current and future texts on SDS; it could help if the REACH Registration numbers were also given in Section 15 of the substance Safety Data Sheets.

Section 9 of the Safety Data Sheets deals with physical and chemical properties. Many of the properties stated may be irrelevant to many substances or preparations.

In order to distinguish whether the absence of data in the Safety Data Sheets against a heading was due to a gap in knowledge or to the existence of information rendering the entry valueless, it would be worthwhile if a full list of properties was provided in the Safety Data Sheets, with “not applicable” (“N/A”) written against any item where such a phrase was valid. [Recommendation 20]

7.8.5 Further communication (e.g. to consumers)

The subject of communication downstream from the Downstream Users as defined in REACH is not part of the Commission Proposal but certain amendments have subsequently been voted through in the European Parliament which recognised this important aspect.

c) Lessons Learned

- (lxii) *PRODUCE had no proposal to test but the PRODUCE Team was aware of the work of DG SANCO, for example, demonstrating the lack of comprehension of safety icons shown on existing packs and indeed the lack of attention of the public to icons, because they put their trust in the safety of the brands they buy. Project HERA explored communication with the public further, by utilising carefully constructed language to communicate risks, and created an interactive CD to demonstrate the process for household laundry and cleaning chemicals.*

- (lxi) *Discussions with Carrefour and note from The Boots Company and John Lewis (see Appendix F) emphasised the need of the retailer to have very simple focused information on packs and pallets. Detailed Safety Data Sheets were not required in everyday work but in any kind of an emergency the relevant staff needed to be sure that the simple instructions were backed up by detailed data.*

d) Recommendation

Further work is recommended to address the needs for appropriate communication beyond the Downstream Users in the distribution chain as specified in REACH. For warehousing, transporting (not in REACH) and retailing, as well as for personal use of products containing the chemical and for waste disposal operations, further work is needed on targeted communication in addition to that specified in REACH. [Recommendation 29]

The REACH Proposal encourages communication but is limited in its scope. Since 2003 there have been developments which have expressed the need for wider communication to enable REACH to achieve its ends.

The BAMA document (APPENDIX D) is a good example of a form of targeted communication, in this case concerning preparations for REACH among BAMA's members.

The PRODUCE Team discussed with Retailers the kind of safety communication they would find useful. (See Appendix F.) The SDS was regarded as something to which they might want to have access in an emergency but what they really needed was a simple set of safety instructions based on the SDS.



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G4	Linear Alkylbenzene: Comments of the Hungarian CA
H1	Liquefied Petroleum Gas: Extended Data Sheet
H2	Liquefied Petroleum Gas (LPG): Chemical Safety Report – LPG used as hydrocarbon propellant
J	Air Freshener: Extended Safety Data Sheet: Formula A
K1	All-Purpose Cleaner: Extended Safety Data Sheet
K2	All-Purpose Cleaner: Product Information Sheet for bulk transport, handling and storage
L	Aerosol Mousse Bathroom Cleaner: Extended Safety Data Sheet
M1	Fragrance Formula A: Safety Data Sheet
M2	Fragrance Formula B: Safety Data Sheet
M3	Fragrance Formula C: Safety Data Sheet
N	Preparing a Chemical Safety Assessment for Preparations

GLOSSARY

A.I.S.E	Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien
BAMA	British Aerosol Manufacturers Association
CAS	Chemical Abstract Services
Cefic	European Chemical Industry Council
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DNEL	Derived No-Effect Level
DPD	Dangerous Preparations Directive
DU	Downstream Users of chemicals
DUCC	Downstream Users of Chemicals Co-ordination
ECB	European Chemicals Bureau
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
EDANA	European Disposables and Nonwovens Association
EINECS	European Inventory of New and Existing Chemical Substances
ELINCS	European List of Notified Chemical Substances
ERASM	Environmental Risk Assessment of Surfactants Management Group
ES	Exposure Scenario
ESR	Existing Substances Regulation
ETUC	European Trades Union Confederation
FEA	Fédération Européenne des Aérosols
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
GREAT-ER	Geography-referenced Regional Exposure Assessment Tool for European Rivers
HERA	Human & Environmental Risk Assessment project
HPV	High Production Volume (chemicals)
IFRA	International Fragrance Association
IPCS	International Programme on Chemical Safety
IUCLID	International Union Chemical Information Database
IUPAC	International Union of Pure and Applied Chemistry
JRC	Joint Research Centre
LPG	Liquefied Petroleum Gas
M/I	Manufacturer/Importer
MSCA	Member State Competent Authority
OSOR	One Substance, One Registration
PEC	Predicted Environmental Concentration
PH	Perfume House
PNEC	Predicted No-Effect Concentration
RIFM	Research Institute for Fragrance Materials

RIP	REACH Implementation Projects <i>Indicative list of subjects; RIPs in bold of particular interest to DU</i>
RIP 1	Process Description (flowcharts and Q&As available on Commission DG ENTR and ENV websites)
RIP 2	Development of IT systems for REACH
RIP 3/4	Guidance Documents for industry / authorities
RIP 3.1	Preparing a Technical Dossier for Registration
RIP 3.2	Preparing a CSR scoping study ; TGD revision
RIP 3.3	Information requirements
RIP 3.5	Guidance Document for Downstream Users
RIP 3.6	Classification & Labelling under GHS
RIP 3.7	Preparing an application dossier for Authorisation
RIP 3.8	Requirements for Articles
RIP 3.9	Socio-economic analysis
RIP 4.1	Dossier evaluation
RIP 4.2	Substance evaluation
RIP 4.3	Inclusion of substances into Annex XIII (list of substances subject to Authorisation)
RIP 4.4	Preparation of Annex 14 dossier
RIP 4.5	Priority Setting for Evaluation
RIP 5	Preparation for start-up of Agency
RIP 6	Agency
RIP 7	Commission preparations
RIP10	Substance identity
RMM	Risk Management Measures
SDS	Safety Data Sheet
TGD	Technical Guidance Document

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