The REACH Proposal
Process description

The REACH Proposal

Process description

This document is a result of the Reach Implementation Project 1 (RIP 1)

This document describes the main processes and procedures set out in the 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[1].

It is for information purposes only and does not contain any legal interpretation of the text.

In event of any inconsistency with the text of the REACH proposal,
the proposal alone shall be decisive.

June 2004

---

[1] COM(2003) 644, 29 October 2003 (http://www.europa.eu.int/comm/enterprise/ or http://www.europa.eu.int/comm/environment/

CONTENTS

1. INTRODUCTION **5**

1.1. AIM OF THIS DOCUMENT 5
1.2. STRUCTURE OF THIS DOCUMENT 5

2. REACH OVERVIEW **7**

2.1. THE REACH PROPOSAL 7
2.1.1. Titles I to V: Registration and Data Sharing *7*
2.1.2. Title VI: Evaluation *10*
2.1.3. Titles VII and VIII: Authorisation and Restrictions *10*
2.1.4. Title IX: Chemicals Agency *11*
2.1.5. Titles X to XV, Directive amending Council Directive 67/548/EEC *12*
2.1.6. Annexes *12*
2.2. MAIN STAKEHOLDER ROLES AND DUTIES - AT A GLANCE 13
2.2.1. Industry *13*
2.2.2. Member States *17*
2.2.3. Agency *17*
2.2.4. Commission *18*
2.2.5. All stakeholders, including industry groups/associations, NGOs, and the public *18*

3. REGISTRATION (ART. 5, 19) **18**

3.1. DEFINING A COMPANY'S ROLE AND ITS OBLIGATIONS 19
3.2. SCOPE AND EXEMPTIONS (ART. 2, 4, 7, 8, 22) 20
3.3. INFORMATION REQUIREMENTS FOR ISOLATED INTERMEDIATES (ART. 15 AND 16) 23
3.4. INFORMATION REQUIREMENTS FOR ALL OTHER SUBSTANCES SUBJECT TO REGISTRATION 23
3.4.1. Technical Dossier (Art. 9, 11, 12 and Annexes IV to X) *25*
3.4.2. Chemical Safety Report (Art. 13, Annex I) *26*
3.4.2.1. Hazard Assessment 27
3.4.2.2. Exposure Assessment and Risk Characterisation 28
3.4.3. Documentation of the assessment in the chemical safety report *31*
3.4.4. Implementation or recommendation of risk management measures (Art. 13 (6)) *31*
3.5. TIMING (ART. 19, 21) 32
3.6. DATA –SHARING TO PREPARE THE TECHNICAL DOSSIER 32
3.6.1. Identifying information needs *32*
3.6.2. Data sharing (Art. 23 to 28) *34*
3.6.2.1. Data sharing for non-phase-in substances (Art. 24 and 25) 35
3.6.2.2. Data sharing for phase-in substances (Art. 26 to 28) 36
3.7. PREPARATION OF A REGISTRATION DOSSIER AS A MEMBER OF A CONSORTIUM 38
3.8. REGISTRATION PROCEDURE 38
3.8.1. Submission of the registration dossier and completeness check (Art. 18) *38*
3.8.2. Start of manufacture or import (Art. 19) *39*
3.9. REGISTRANTS' OBLIGATIONS TO UPDATE THE REGISTRATIONS (ART. 11 (2), 20) 39
3.10. REGISTRATION OF SUBSTANCES IN ARTICLES (ART. 6) 40
3.10.1. Obligation to register substances in articles (Art. 6 (1)) *40*
3.10.2. Obligation to notify substances in articles (Art. 6 (2) and (3)) *43*
3.10.3. Obligation to register notified substances in articles (Art. 6 (4)) *43*

4. INFORMATION IN THE SUPPLY CHAIN (ART. 29 TO 33) **43**

4.1. INFORMATION DOWN THE SUPPLY CHAIN 43
4.1.1. Safety Data sheets (SDS) for dangerous substances (Art. 29) *43*
4.1.2. Information for non classified substances (Art. 30) *45*
4.2. INFORMATION UP THE SUPPLY CHAIN (ART. 31) 45
4.3. INFORMATION FOR WORKERS AND OBLIGATION TO KEEP AND MAKE AVAILABLE INFORMATION (ART. 32, 33) 45

5. DOWNSTREAM USERS 46

5.1. DOWNSTREAM USER OBLIGATIONS 46
5.2. PERFORMING THE DOWNSTREAM USER CHEMICAL SAFETY ASSESSMENT 49
5.3. REPORTING OF INFORMATION 49
5.4. INFORMATION THROUGH THE SUPPLY CHAIN 50

6. EVALUATION 50

6.1. DOSSIER EVALUATION (ART. 38 TO 43) 52
6.1.1. Competent Authority and its tasks (Art. 38, 39, 40) 52
6.1.2. Examination of testing proposals (Art. 39) 52
6.1.3. Compliance check (Art. 40) 53
6.2. SUBSTANCE EVALUATION (ART. 43 A TO 46) 53
6.2.1. Competent Authority and its tasks (Art. 43 a, 43 a bis, 44) 53
6.2.1.1. Conditions (Art. 43 a, 43 a bis) 54
6.2.1.2. Procedure to develop Rolling Plans (Art. 43 a bis) 54
6.3. PERFORMANCE OF SUBSTANCE EVALUATION AND REQUEST FOR FURTHER INFORMATION (ART. 44) 56
6.4. PROCEDURE TO TAKE DECISIONS REQUIRING (FURTHER) INFORMATION (ART. 48, 49) 56
6.5. FOLLOW UP FOR REGISTRANTS (ART. 39, 40, 44, 20) 58
6.6. FOLLOW UP FOR AUTHORITIES (ART. 41 AND 46) 58
6.7. EVALUATION OF POLYMERS (ART. 37) AND OF ON SITE ISOLATED INTERMEDIATES (ART. 47) 59

7. AUTHORISATION (ART. 52 TO 63) 59

7.1. SUBSTANCES SUBJECT TO AUTHORISATION (ART. 54) 60
7.2. PROCEDURE TO INCLUDE SUBSTANCES INTO THE AUTHORISATION SYSTEM 60
7.2.1. Identification of substances of very high concern (Art. 56) 60
7.2.1.1. Prioritisation of substances with identified properties of very high concern (Art. 55 (3) and (4)) 63
7.2.2. Inclusion in Annex XIII (Art. 55 (1) and (2)) 63
7.2.3. Relationship between authorisation and restrictions (Art. 55 (5) and (6)) 64
7.3. THE AUTHORISATION REQUIREMENT FOR USES OF SUBSTANCES INCLUDED IN ANNEX XIII (ART. 53) 64
7.3.1. General Rule 64
7.3.2. Exemptions 64
7.4. APPLICATION FOR AUTHORISATIONS (ART. 59) 65
7.5. GRANTING OF AUTHORISATIONS (ART. 57) 66
7.5.1. Competent authority (Art. 57 (1)) 66
7.5.2. Conditions for granting of authorisations (Art. 57 (2) and (3)) 66
7.5.3. Procedure (Art. 61) 67
7.5.4. Authorisation Decisions (Art. 57 (7)) 68
7.6. OBLIGATIONS FOR HOLDERS OF AUTHORISATIONS (ART. 57 (8), 62) 70
7.7. REVIEW OF AUTHORISATION DECISIONS (ART. 58) 70

8. RESTRICTIONS (ART. 64 TO 70) 70

8.1. PROCEDURE TO AMEND CURRENT RESTRICTIONS AND TO INTRODUCE NEW RESTRICTIONS 71
8.1.1. The Accelerated Restrictions Procedure (Art. 65 ff) 71
8.1.1.1. Initiating the procedure (Art. 66, Annex XIV) 71
8.1.1.2. Procedure within the Agency for dossiers submitted by Member States 74
8.1.1.3. Restrictions procedure for all dossiers conforming to Annex XIV 74
8.1.2. Procedure to restrict consumer use of CMR substances and the manufacture, use and placing on the market of POP substances 75
8.2. TRANSITIONAL PROVISIONS FOR PROPOSALS DEVELOPED UNDER THE CURRENT RESTRICTION PROCESS 76

9. CLASSIFICATION AND LABELLING INVENTORY (ART 109-113) 76

9.1. INTRODUCTION 76
9.2. REQUIREMENTS AND PROCEDURES 78

10. RELATIONSHIP TO WORKPLACE LEGISLATION 78

11. ANNEX I: ABBREVIATIONS AND DEFINITIONS 80

12. ANNEX II: INFORMATION REQUIREMENTS 84

The REACH Proposal

Process description

1. INTRODUCTION

1.1. Aim of this document

This document explains the processes and procedures set out in the Commission's 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[2]. It has been developed in the context of the Commission Interim Strategy on Implementation of REACH (RIP-1) and aims at helping industry, authorities and policy makers to better understand the REACH proposal. Detailed guidance documents supporting industry and authorities to applying REACH once it enters into force are also under development under the RIP-3 and RIP-4 projects[3] of the Interim Strategy and will be published at a later stage.

1.2. Structure of this document

This document consists of flowcharts and supplementary text explanation.

Chapter 2 provides an overview of the main procedures under REACH and of the main stakeholder roles and duties – at a glance.

The following Chapters explain in more detail the processes under the Titles Registration, Information through the Supply Chain, Downstream users, Evaluation, Authorisation, Restrictions and the Classification and Labelling Inventory. Finally Chapter 10 explains the relationship to the workplace legislation.

Annex I to this document lists common abbreviations used in this document and terms which are defined in Art. 3 of the REACH proposal, and Annex II sums up the information requirements set out in Annexes V to VIII to the REACH proposal.

The shapes, symbols, colours that are used in the flowcharts are explained in Figure 1.

---

2 COM(2003) 644, 29 October 2003 (http://www.europa.eu.int/comm/enterprise/ or http://www.europa.eu.int/comm/environment/

3 RIP 3 for industry and RIP 4 for authorities

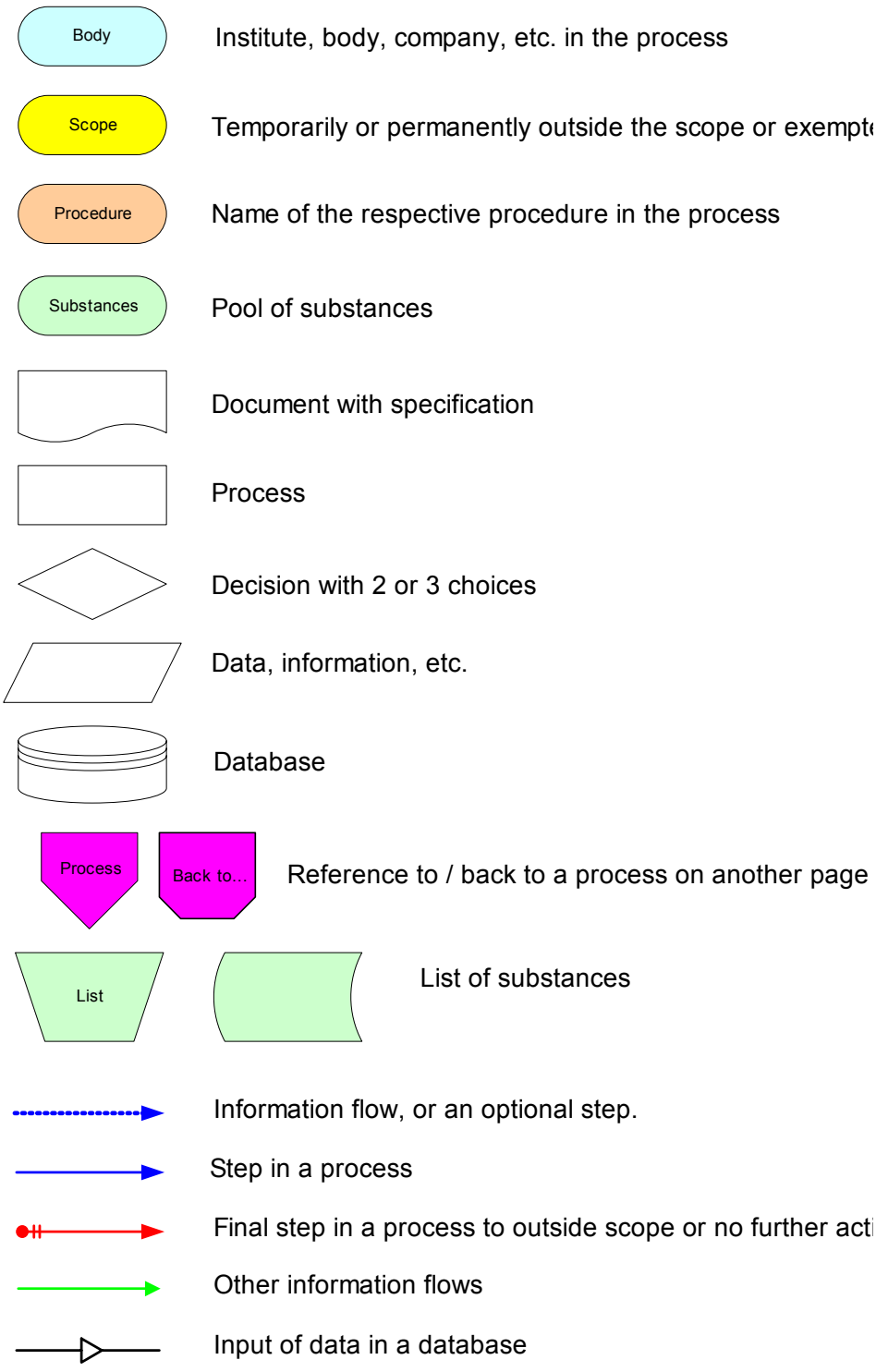

Figure 1: Explanation of the used shapes, symbols, colours etc. in the flowcharts.

2. REACH OVERVIEW

The REACH proposal replaces the current ineffective and inefficient system of about 40 existing Community Directives and Regulations on chemicals with different rules for existing and new substances, by a single regulation with one consistent approach to controlling risks from both existing and new substances.

It aims at maintaining and enhancing the competitiveness of the EU chemicals industry as well as at the protection of human health and the environment. It contains rules about chemical substances on their own, in preparations and in articles.

To adequately control the risks arising from the manufacture, import, placing on the market and use of substances, the REACH proposal reverses the burden of proof from the authorities to industry for gathering information on chemical substances and using this information to assess the safety of chemicals and select appropriate risk management measures. To reflect this new approach, the Regulation states in Art. 1 (3) that it is based on the principle that it is up to manufacturers, importers and downstream users of substances to ensure that they manufacture, place on the market or import or use such substances in a way that does not adversely affect human health or the environment.

The first part of the overview sums up the different obligations set out in the different Titles of the REACH proposal (2.1) while the second part glances at the roles and duties under the whole REACH proposal from the viewpoint of the different stakeholders (2.2).

2.1. The REACH proposal

The REACH proposal is divided into different titles. A general overview of these titles and how they are linked is given in Figure 2.

2.1.1. Titles I to V: Registration and Data Sharing

Titles I to V place the requirements to collect information, and to develop risk management measures, on industry and set out, in general terms, the following **obligations**:

(1) For manufacturers and importers of substances in quantities of 1 tonne or more per year

- to collect and share existing, and to generate and propose to generate new, information on properties of substances,
- to use this information to draw conclusions to classify and label the substances and to notify the classification to the Agency to be included in the classification and labelling inventory,
- for dangerous substances in quantities of 10 tonnes or more per year to assess the exposure and characterise the risks with the aim to identify appropriate risk management measures for specific, **identified uses** in a chemical safety assessment (CSA) and to document this assessment in the chemical safety report (CSR),

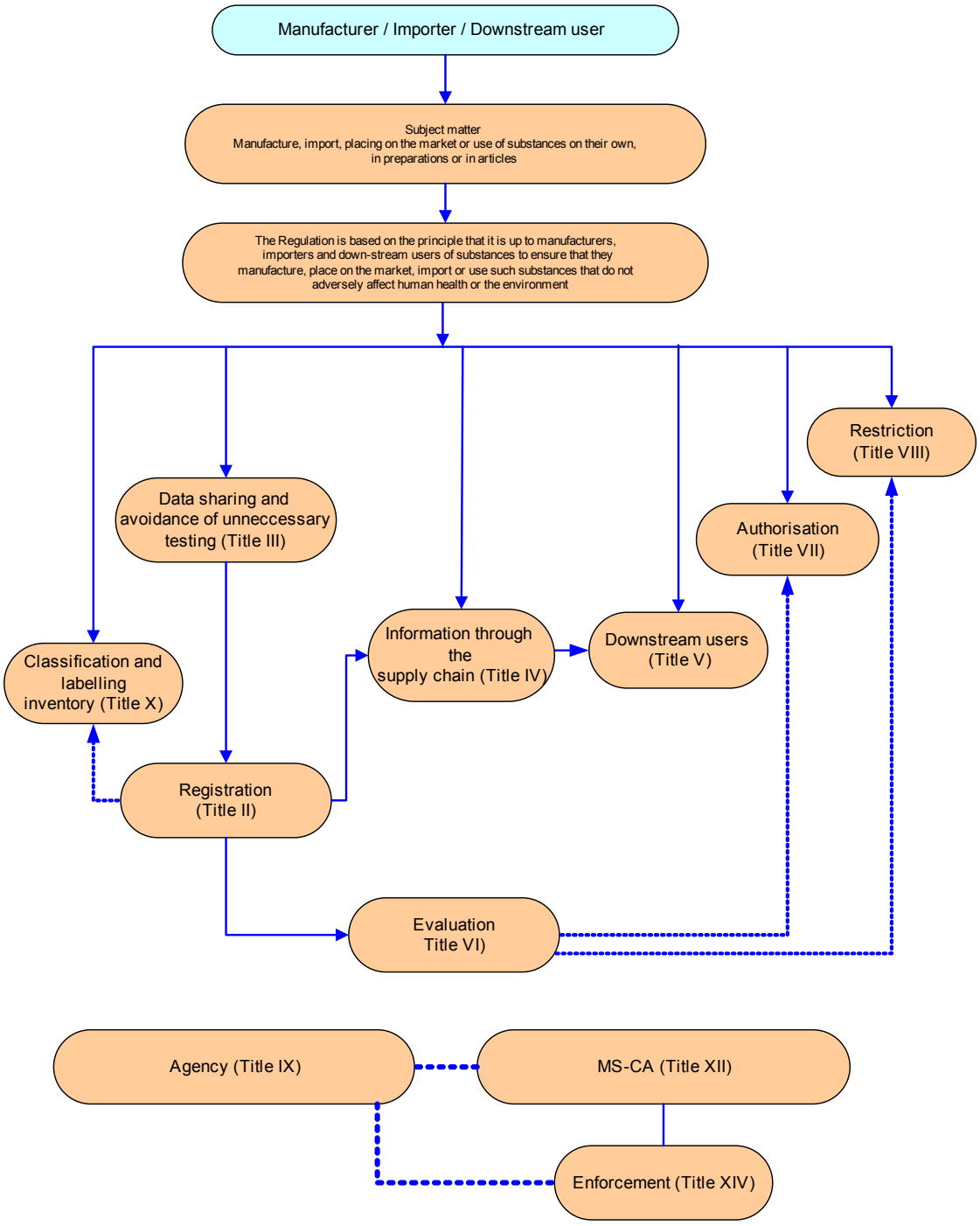

Figure 2: The structure of the REACH legislation

- to apply the identified risk management measures to own uses and to recommend them to customers together with other information, in a safety data sheet,
- to submit documentation of the above to the newly created European Chemicals Agency (the **REGISTRATION,** consisting in general of the **technical dossier** and for substances in quantities of 10 tonnes or more per year of the **CSR)**.

The extent of the obligations depends upon the quantity of the substances manufactured or imported (see Chapter 3).

Note that REACH proposal in its current state relies on the existing provisions on classification and labelling in Directives 67/548/EEC[4] (substances) and 1999/45/EC[5] (preparations). However, the Commission plans to replace them and implement the Globally Harmonised System for the classification and labelling of chemicals (GHS) with the aim that the new provisions will enter into force at the same time as REACH.

(2) For all manufacturers and importers of substances:

- for dangerous substances: prepare and supply information on these substances in safety data sheets to downstream users and distributors,
- for non-dangerous (non-classified) substances: prepare and supply information on these substances to downstream users and distributors,
- keep information available for a period of at least ten years.

(3) For the Chemicals Agency:

- to perform a completeness check of all registrations submitted,
- to pass on the result of the completeness check to the competent authorities of the Member States to enable any necessary follow up action to be taken.

(4) For Downstream Users (DUs):

- for DUs of dangerous substances to either:
  - inform their suppliers of their or their customers' use(s) so the supplier can prepare exposure scenarios for that use, including the identification of appropriate risk management measures, or
  - keep the uses confidential and prepare the exposure scenarios and identify appropriate risk management measures for these uses themselves (downstream user chemical safety assessment), and
  - to apply as a minimum the identified risk management measures for their own uses and to recommend the identified risk management measures to their customers together with other information in the safety data sheet for the substance,
  - to report their uses to the Agency if they use substances in quantities of 1 tonne or more per year **outside the conditions of an exposure scenario** supplied to them in the safety data sheet, including, if necessary, any proposals for testing.
- for DUs of non-dangerous (non-classified) substances: prepare and supply information on these substances to further downstream users and distributors.

---

4 Council Directive (EC) 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ P 196, 16.08.1967, p.1

5 DIRECTIVE 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations, OJ L 200, 30.07.1999, p. 1

- for all DUs: to provide feedback to their suppliers if they do not agree with information supplied to them.
- keep information available for a period of at least ten years.

2.1.2. Title VI: Evaluation

This title VI sets out **obligations for**

(1) Member States' competent authorities:

- to evaluate testing proposals submitted for tests contained in annexes VII and VIII and to check compliance of information submitted to the Agency in the registration dossiers with the requirements of the Regulation for selected registration dossiers, independently of the tonnage (**dossier evaluation**),
- to further evaluate substances in case of a suspicion that the substance presents a risk to human health or the environment (**substance evaluation**),
- to draft decisions requesting tests to be performed and further necessary information to be submitted by registrants and, in rare cases, by downstream users.

(2) the Agency:

- to set priorities and manage the decision making process,
- to take decisions requesting further information or to pass on the draft to the Commission for decision.

The information obtained may be used for Community wide risk management measures in the form of the inclusion of substance into the authorisation system or in the form of restrictions. It may also be referred to those authorities managing other Community legislation.

2.1.3. Titles VII and VIII: Authorisation and Restrictions

Titles VII and VIII set out a framework for Community wide general and specific risk management decisions:

(1) The authorisation system

The authorisation system addresses substances of very high concern:

- Substances meeting the criteria for classification as carcinogenic category 1 or 2, mutagenic category 1 or 2 and toxic for reproduction category 1 or 2 (**CMR** substances),
- Substances which are persistent, bioaccumulative and toxic (**PBT** substances) and very persistent and very bioaccumulative (**vPvB** substances), and
- Substances of an equivalent concern to the above, having serious and irreversible effects to human health and the environment.

For substances with PBT, vPvB properties (criteria in Annex XII) and equivalent serious and irreversible effects a procedure has been set up to agree on the identification of this very high concern.

All substances of very high concern will be prioritised by the Agency and may be included in Annex XIII to the proposal by the Commission in decisions taken under the regulatory comitology procedure.

Once a substance is included in the Annex, its uses and its placing on the market need to be authorised by the Commission.

Authorisations will be granted when the risk to human health or the environment from the use of the substance arising from the intrinsic properties specified in Annex XIII is adequately controlled. If that cannot be demonstrated by the applicants, authorisations may be granted if it is shown that the socio economic benefits outweigh the risks to human health or the environment and if there are no suitable alternative substances or technologies.

(2) Restrictions

The placing on the market and use of a number of specific substances have already been restricted within the Community by Directive 76/769/EEC[6] for many years. Annex XVI of the proposed REACH Regulation takes over these restrictions in a consolidated version into the Regulation.

In addition, the REACH proposal sets up a procedure for adding further restrictions of the manufacture, placing on the market and use of substances by amending the Annex. Member States, or the Agency on behalf of the Commission, may prepare dossiers and propose such new restrictions; a decision on them will be taken by the Commission following the regulatory comitology procedure after consultation of the stakeholders and on the basis of opinions by the Agency on the risk assessment and socio-economic analysis of any proposed restrictions.

Restrictions implementing the international Stockholm Convention and United Nations Economic Convention for Europe (UN-ECE) on Persistent Organic Pollutants (POPs) are found in Annex XVII.

2.1.4. Title IX: Chemicals Agency

Title IX sets up the **Chemicals Agency,** which is composed of a Management Board, an executive Director, a Committee for Risk Assessment, a Committee for Socio-economic Analysis, a Member State Committee, a Forum for Exchange of Information on Enforcement, a Secretariat and a Board of Appeal.

In particular, the Agency will receive all registrations and check their completeness, decide on the requirement to register substances released unintentionally from articles, impose conditions in case of time-limited exemptions for product and process orientated research and development (PPORD), and extend exemptions for that

[6] Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, OJ L 262, 27.09.1976, p. 201

purpose. Furthermore, it will be involved in the data sharing process, it will set priorities for evaluation and coordinate the work by Member States' competent Authorities, it will take decisions on requests for access to information and on the confidentiality of information, it will recommend priorities for substances which need to be authorised, and it will through its Committees for Risk Assessment and Socio-Economic Analysis provide scientific opinions for Commission decisions to grant authorisations and to amend existing, and include new, restrictions into the Restrictions Annexes.

2.1.5. Titles X to XV, Directive amending Council Directive 67/548/EEC

Title X sets out provisions on the Classification and Labelling inventory which is a new tool to enable easy public access to industry's self-classification and which serves as the platform to strongly encourage industry to arrive at a harmonised classification and labelling.

Titles XI to XV finally set out rules on information, on competent authorities in the Member States, on enforcement and on review clauses, transitional and repeal provisions, in particular of Council Regulation (EEC) 793/93[7] and Directive 91/155/EEC[8].

A separate proposal for a Directive[9] amends and partly repeals Directive 67/548/EEC.

2.1.6. Annexes

The REACH proposal includes seventeen Annexes.

Annex I contains provisions on the chemical safety assessment for manufacturers and importers and sets out the format for the chemical safety report. *Annex XI* contains provisions for the downstream user chemical safety assessment and refers back to parts of Annex I.

Annex IA takes over Directive's 91/155/EEC Annex, the guide to the compilation of safety data sheets, *Annex IB* sets out a methodology for chemical safety assessments for preparations to be used optionally in case a safety data sheet is prepared for a preparation.

Annexes II and *III* list exemptions from the obligation to register.

Annex IV contains the general information requirements for registration, and *Annexes V* to *VIII* specify information that needs to be submitted for registration purposes depending on the quantities of substances manufactured or imported. *Annex IX* sets out general rules for adaptation of the testing regime set out in *Annexes V* to *VIII*. *Annex X* consolidates the testing methods of Directive 67/548/EEC.

---

7 Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances, OJ L 084 , 05.04.1993 p. 1

8 Commission Directive 91/155/EEC of 5 March 1991 defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Directive 88/379/EEC, OJ L 076, 22.03.1991, p. 35

9 Proposal for a Directive of the European Parliament and of the Council amending Council Directive 67/548/EEC in order to adapt it to Regulation (EC) of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals

Annex XII specifies the criteria for the identification of persistent, bioaccumulative and toxic substances, and very persistent and very bioaccumulative substances and *Annex XIII* will be the list of substances which are subject to authorisation.

Annex XIV sets out requirements for Dossiers prepared by Member States or the Agency to propose harmonised classification and labelling, identify substances of very high concern to be included in the authorisation system and to prepare restrictions.

Annex XV provides guidance on how to prepare a socio-economic analysis.

Annex XVI lists restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles, and *Annex XVII* lists restrictions on the manufacture, placing on the market and use of Persistent Organic Pollutants (POPs).

2.2. Main stakeholder roles and duties - at a glance

This section provides an overview of the main roles and duties under the whole REACH proposal for each stakeholder addressed:

2.2.1. Industry

A first glance at *currently* existing duties, which will continue after REACH enters into force

Manufacturers/importers/downstream users need to:

- comply with any restrictions on marketing and use of substances and preparations (restrictions as set out in directive 76/769/EEC will be taken over by REACH in Annex XVI);
- classify and label substances and preparations that are placed on the market according to Directive 67/548/EEC and Directive 1999/45/EC;
- prepare safety data sheets (SDS) for substances and preparations (requirements in Directive 91/155/EEC will be taken over by REACH in Art. 29 and Annex IA);
- conduct risk assessments and reduce risks for any chemical agent occurring at the workplace (Directive 98/24/EC on chemical agents at work).

A glance at the duties *after* entry into force of REACH

(1) Manufacturers and importers of substances in quantities of less than 1 tonne per year need to:

- comply with any restrictions on manufacture, placing on the market and use of substances and preparations as set out in Annexes XVI and XVII;
- apply for authorisation for use(s) of substances listed in Annex XIII;
- classify and label substances and preparations that are placed on the market;

- notify classification of dangerous substances with the Agency for the classification and labelling (C&L) inventory for all substances placed on the market;
- prepare and supply safety data sheets for substances and preparations as required by Art. 29 and Annex IA to downstream users and distributors;
- prepare and supply information on non classified substances as required by Article 30 to downstream users and distributors;
- conduct risk assessments and reduce risks for any chemical agent occurring at the workplace (Directive 98/24/EC on chemical agents at work).

(2) Manufacturers of substances in quantities of 1 tonne or more per year need to:

- comply with any restrictions on manufacture, placing on the market and use of substances and preparations as set out in Annexes XVI and XVII;
- apply for authorisation for use(s) of substances listed in Annex XIII;
- collect and share existing, and generate and propose to generate new, information on properties of substances and prepare the technical dossier;
- prepare CSA, CSR including developing exposure scenarios (≥ 10 tonnes/year per manufacturer);
- implement appropriate risk management measures (RMM) for own manufacture and use;
- submit registration for substances (≥ 1 tonne/year per manufacturer);
- classify and label substances and preparations that are placed on the market;
- notify/register classification of dangerous substances with the Agency for the classification and labelling (C&L) inventory for all substances placed on the market;
- prepare and supply safety data sheets for substances and preparations as required by Art. 29 and Annex IA to downstream users and distributors;
- recommend appropriate risk management measures (RMM) in SDS;
- communicate exposure scenarios developed in CSA as Annex to SDS (≥ 10 tonnes/year per manufacturer);
- prepare and supply information on non classified substances as required by Article 30 to downstream users and distributors;
- conduct risk assessments and reduce risks for any chemical agent occurring at the workplace (Directive 98/24/EC on chemical agents at work);
- respond to any decision requiring further information as a result of the evaluation process.

(3) Importers of substances and preparations in quantities of 1 tonne or more per year:

- comply with any restrictions on manufacture, placing on the market and use of substances and preparations as set out in Annexes XVI and XVII;
- apply for authorisation for use(s) of substances listed in Annex XIII;
- collect and share existing, and generate and propose to generate new, information on properties of substances and prepare the technical dossier;
- prepare CSA, CSR developing exposure scenarios (≥ 10 tonnes/year per importer);
- implement appropriate risk management measures (RMM) for own use;
- submit registration for substances, on their own or in preparations (≥ 1 tonne/year per importer)
- classify and label substances and preparations;
- notify/register classification of dangerous substances with the Agency for the classification and labelling (C&L) inventory;
- prepare and supply safety data sheets for substances and preparations as required by Art. 29 and Annex IA to downstream users and distributors;
- recommend appropriate risk management measures (RMM) in SDS;
- communicate exposure scenarios developed in CSA as Annex to SDS (≥ 10 tonnes/year per importer)
- prepare and supply information on non classified substances as required by Article 30 to downstream users and distributors;
- respond to any decision requiring further information as a result of the evaluation process.

(4) Producers of articles:

- comply with any restrictions on manufacture, placing on the market and use of substances and preparations as set out in Annexes XVI and XVII;
- use substances authorised for incorporation into the articles as set out in the authorisation or apply for authorisation for use(s) of substances listed in Annex XIII;
- implement RMM as set out in SDS for dangerous substances and preparations which are incorporated into the articles;
- when receiving SDS with exposure scenarios (ES) annexed for dangerous substances and preparations to be incorporated into the articles:
  - if the use is covered by the ES, implement RMM as set out in ES ; or
  - if the use is not covered by the SDS annex, inform supplier of the use (i.e. make use known with the aim to make it an identified use) and await new SDS with updated ES(s) or conduct own chemical safety assessment and (if DU tonnage ≥ 1 tonne/year) notify the Agency;

- under some circumstances register substances in articles (tonnage trigger ≥ 1 tonne/year per producer and per article type);
- under some circumstances notify substances in articles (tonnage trigger ≥ 1 tonne/year per producer and per article type);
- conduct risk assessments and reduce risks for any chemical agent occurring at the workplace (Directive 98/24/EC on chemical agents at work);
- respond to any decision requiring further information as a result of the evaluation process (only relevant for registered substances).

(5) Importers of articles:

- comply with any restrictions on manufacture, placing on the market and use of substances and preparations as set out in Annexes XVI and XVII;
- apply for authorisation for use(s) of substances listed in Annex XIII;
- under some circumstances register substances in articles (tonnage trigger ≥ 1 tonne/year per importer and per article type);
- under some circumstances notify substances in articles (tonnage trigger ≥ 1 tonne/year per importer and per article type);
- respond to any decision requiring further information as a result of the evaluation process (only relevant for registered substances).

(6) Downstream Users:

- Comply with any restrictions on manufacture, placing on the market and use of substances and preparations as set out in Annexes XVI and XVII;
- respond to any decision requiring further information as a result of the evaluation process (only relevant for registered substances);
- Use authorised substances as set out in the authorisation (this info should be found in the suppliers' SDS) or apply for authorisation for use(s) of substances listed in Annex XIII;
- implement RMM as set out in SDS;
- when receiving SDS with exposure scenarios (ES) annexed:
  - if DU use is covered by the ES, implement RMM as set out in ES annexes to SDS ; or
  - If DU use is not covered by the SDS annex, inform supplier of the use (i.e. make use known with the aim to make it an identified use) and await new SDS with updated ES(s) or conduct own chemical safety assessment and (if DU tonnage ≥ 1 tonne/year) notify the Agency;
- prepare and supply SDS(s) and recommend appropriate risk management measures (RMM) in them and annex ES(s) for further downstream use;
- prepare and supply information on non-classified substances as required by Article 30 to further downstream users and distributors;
- pass on new information directly to their suppliers on the hazard of the substance and information that might call into question the risk management measures identified in the SDS for identified uses;

- conduct risk assessments and reduce risks for any chemical agent occurring at the workplace (Directive 98/24/EC on chemical agents at work);
- respond to any decision requiring further information as a result of the evaluation of testing proposals in downstream user reports.

2.2.2. Member States

- provide advice to manufacturers, importers, downstream users and other interested parties on their respective responsibilities and obligations under REACH (competent authorities' help desks);
- provide adequate scientific and technical resources to the members of the Committees that they have nominated;
- conduct dossier evaluation of registrations including testing proposals and other selected registrations and conduct substance evaluation of prioritised substances; prepare draft decisions;
- suggest harmonised C&L for CMRs and respiratory sensitisers;
- identify substances of very high concern for authorisation;
- suggest restrictions;
- nominate candidates to membership of Agency committees on risk assessment and socio-economic analysis;
- appoint member for “member state committee” to resolve divergences of opinion on decisions following evaluation, consider proposals for harmonised classification and labelling, and identify substances for authorisation;
- appoint member to the “forum” and meet to discuss enforcement matters;
- enforce REACH.

2.2.3. Agency

- day to day management of technical, scientific and administrative aspects of REACH;

Responsibilities:

- provide technical and scientific guidance and tools for the operation of REACH in particular to assist the development of chemical safety reports by industry and especially by Small and Medium Sized Enterprises (SMEs);
- provide technical and scientific guidance on the operation of REACH for Member State competent authorities and providing support to the competent authorities' help desks;
- receive and check requests for research and development (PPORD) exemptions;
- pre-registration – receive information and grant access to all manufacturers and importers who have submitted information on one substance;
- operate the rules on data-sharing for non phase-in substances;
- registration: check completeness, require completion of registration and reject incomplete registrations;

- evaluation: ensure a harmonised approach; set priorities and take decisions;
- substances in articles: take decisions on notifications;
- authorisation/restrictions: manage the process and provide opinions; suggest priorities;
- secretariat for forum and committees;
- take decisions on access to submitted data;
- publish certain specified data on a publicly accessible database;
- deal with appeals - registration, R&D, evaluation, confidentiality.

2.2.4. Commission

- take decisions on further information needs under the evaluation process where there is no unanimous agreement by Member States;
- include substances into the authorisation system;
- take decisions on granting or rejecting authorisations;
- take decisions on restrictions.

2.2.5. All stakeholders including industry groups/associations, NGOs, and the public

Note: The following are possibilities for stakeholders

- access to non-confidential information via the Agency web-site;
- request access to information;
- authorisation:
  - provide comments on substances which the Agency has proposed to be prioritised and on uses which are to be exempted from the authorisation requirement;
  - provide information on possible alternatives;
- restrictions:
  - provide comments on restriction proposals;
  - provide socio-economic analysis for suggested restrictions, or information to contribute to one;
  - provide comments on draft opinions from Agency's Committee for Risk Assessment and Committee for Socio-economic Analysis.

3. REGISTRATION (ART. 5, 19)

The main purpose of the registration requirement and data sharing provisions of REACH is to establish a transparent, predictable and balanced framework within which industry exercises the responsibility for the safety of their products. This framework requires industry to collect sufficient information and to use this information to determine appropriate risk management measures to be implemented

by manufacturers and importers and recommend the appropriate measures to downstream users. The main tool used by industry to document that this responsibility is fulfilled is the registration dossier, which includes, for substances above 10 tonnes, a chemical safety report.

Substances shall not be manufactured or imported in quantities of 1 tonne or more per year, unless their manufacturers or importers[10] have submitted a complete registration for the substances to the Agency.

The registration is the **documentation** by manufacturers or importers of substances

- of information obtained about their substances and their uses (technical dossier), and,

- for substances in quantities of 10 tonnes or more per year, of the analysis of the information in the technical dossier. For dangerous substances and PBTs and vPvBs, the analysis needs to demonstrate that risks arising from identified use(s) of the substances can be adequately controlled by them and their downstream users (the chemical safety report).

3.1. Defining a company's role and its obligations

REACH sets out different obligations for manufacturers and importers of substances on the one hand and downstream users of substances on the other hand.

A *manufacturer* is any natural or legal person established within the Community who manufactures a substance within the Community and an *importer* is any natural or legal person established within the Community who is responsible for import.

A *downstream user* is any natural or legal person established within the Community, *other than the manufacturer or the importer*, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. *Use* means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation.

Therefore, for each substance a company has to define its role under REACH. Here are a few examples:

- A *manufacturer or importer of a substance* who *uses* the manufactured or imported substance himself is a **manufacturer or importer** under REACH. He has a duty to register each substance manufactured or imported in quantities of 1 tonne or more per year and will have to include information on *his own use(s)* in his registration.

- An *importer of a preparation* has to register those substances which are present in the imported preparation in quantities of 1 tonne or more per year. He will have to include information in his registration on the use for the substance in the

[10] non-EU manufacturers can choose an only representative in accordance with Art. 6a who fulfils the duties of an importer, customers further down the supply chain will then be downstream users

preparation. There is no obligation for importers of preparations to register the preparations. Note, however, where an importer prepares a safety data sheet for a preparation, he and his customers may find it useful if he followed the methodology set out as an option in Annex IB to prepare a chemical safety assessment for the preparation as a basis for the safety data sheet, instead of for the substance contained in the preparation.

- Any person who is using substances which he has **not** manufactured or imported himself, is a downstream user and has no obligation to register these substances - see Chapter 5 for downstream user obligations.

- A downstream user who incorporates substances into an article, thus a producer of an article, will have to assess whether – in addition to possible downstream user obligations - he is required to register or notify any substances in the article according to Art. 6 (see Chapter 3.10).

- An importer of an article will need to find out whether he is required to register or notify any substances in the article according to Art. 6 (see Chapter 3.10).

3.2. Scope and exemptions (Art. 2, 4, 7, 8, 22)

Figure 3 provides an overview of the scope of the registration Title of REACH. Each manufacturer or importer of a substance in quantities of 1 tonne or more per year needs to submit a registration to the Agency for any substance within the scope of the REACH Regulation and its registration title which is not exempted from the obligation to register.

Radioactive substances, *non-isolated intermediates*[11] and substances, which are subject to *customs supervision* under certain conditions (Art. 2 (1) (b)) are outside the scope of the REACH Regulation and therefore do not have to be registered.

There is also no obligation to register to the extent that a substance is used:

- *in medicinal products for human or veterinary use*,
- *as a food additive in foodstuffs,*
- *as a flavouring in foodstuffs*,
- *as an additive in feedingstuffs*,
- *in animal nutrition*.

within the scope of the respective Community Regulations or Directives (see Art. 4).

[11] see definition in Annex I

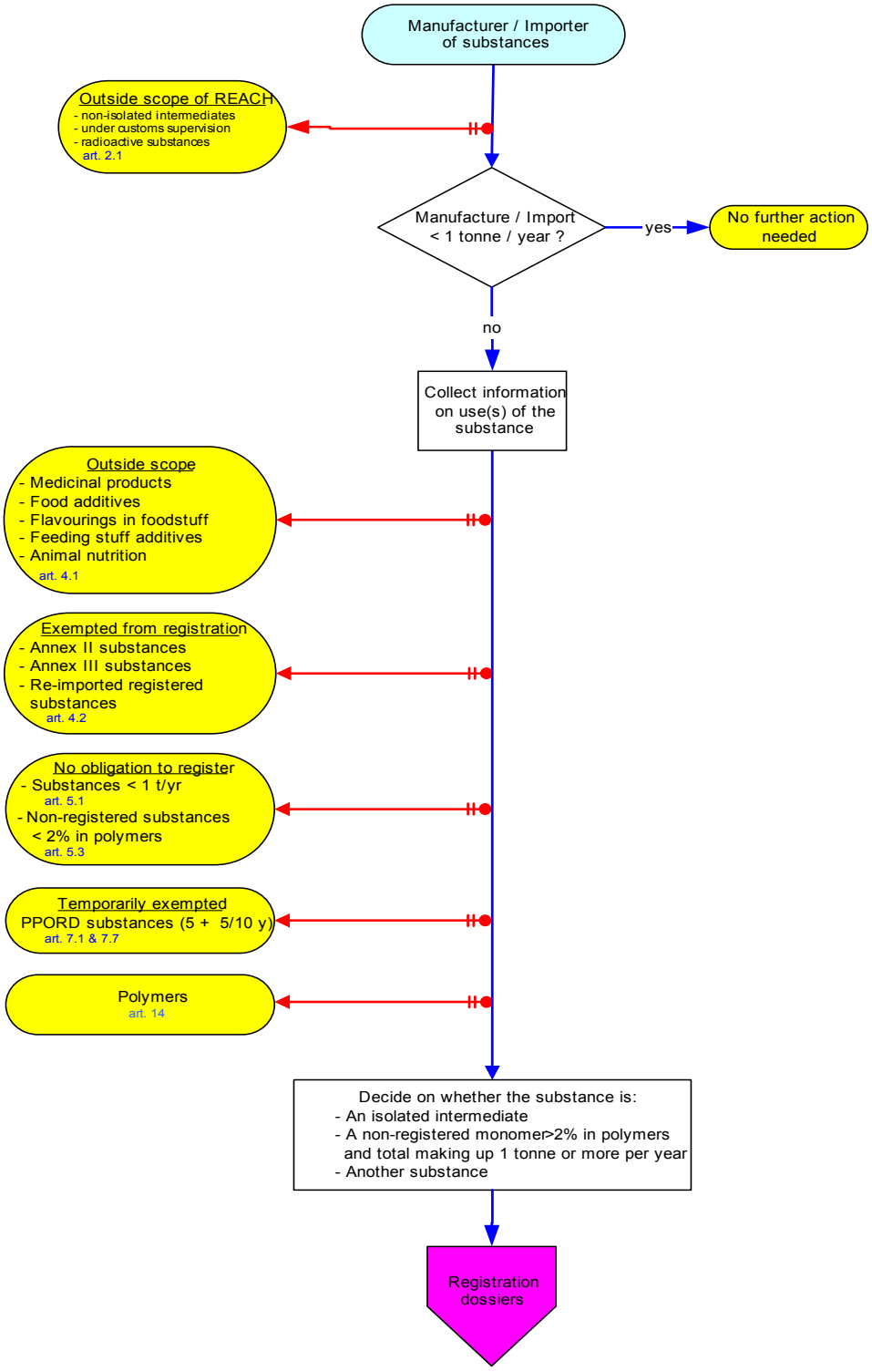

Figure 3: An overview of the scope of registration

If a substance is manufactured or imported solely for any of the above listed use(s), there is no obligation to register that substance.

If the substance is manufactured or imported for the above listed uses as well as for other uses, the quantity foreseen for the listed uses need not to be considered for the

determination of the information requirements which depend upon tonnage and information on the above listed uses need not be included in the registration dossier.

Active ingredients in pesticides and biocides are considered as registered for that use. Therefore, no registration has to be submitted for substances which are only used for that purpose. The essential difference to the exempted substances is that the information submitted under the procedure of the biocides or pesticides legislation will be included in the database by the Agency.

Substances which were *notified* under Directive 67/548/EEC as new substances are regarded as registered, independent of the uses. However, if the next REACH tonnage threshold is reached, missing information needs to be submitted.

Furthermore, there is an exemption from the obligation to register substances included in *Annex II*, which are considered as not being of concern, and those substances which are covered by *Annex III* (substances which are not intentionally manufactured or occurring in nature, subject to specific conditions).

Polymers[12] are exempted from registration[13] but non-registered *monomers,* or other substances, in polymers do need to be registered if the total quantity of the substances makes up 1 tonne or more per year or if the polymer consists of 2% weight by weight (w/w) or more of such substances.

A *re-importer* of a substance has no obligation to register when he is able to show that:

- the substance he re-imports is the same as a previously exported substance which was already registered within his supply chain by the exporter of the substance from the Community and,
- he has been provided with the information required by Articles 29 and 30 for that substance.

Substances used in *scientific research and development* by definition[14] will be used in quantities of less than 1 tonne per year and therefore will not be required to be registered.

To promote innovation, for substances which are manufactured or imported for product and process orientated research and development (***PPORD***)[15] in quantities of 1 tonne or more per year, with a number of listed customers, are exempted for 5 years from the duty to register, provided information on the identity of the manufacturer or importer and the substance, its classification, estimated quantity, the list of customers and the research and development programme has been notified to the Agency. The Agency is given 4 weeks – during which the applicant may not manufacture or import the substance for that use - to check the information and to impose conditions after consultation of the competent authority of the Member State(s) where the PPORD takes place. On request, the Agency may extend this exemption for up to another five years, or ten years for the development of medicinal products.

---

12 see definition in Annex I

13 see however possibility for review of this provision in Art. 133 (2)

14 see definition in Annex I

15 see definition in Annex I

3.3. Information requirements for isolated intermediates (Art. 15 and 16)

Information requirements for a registration depend upon, first of all, whether the substance is used only as an isolated intermediate, as the REACH proposal provides rules for reduced information requirements for isolated intermediates[16] (see Figure 4).

For isolated intermediates *used on site*, information is required about the identity of the manufacturer or importer, about the identity of the substance, its classification, and all available existing information on physicochemical, human health or environmental properties needs to be submitted.

For isolated intermediates *transported* to other sites, the above mentioned information is required, provided the intermediate is transported under strictly controlled conditions (set out in Art. 16 (4)) - otherwise the information requirements are the same as for all other substances (see 3.4). For transported isolated intermediates under strictly controlled conditions in quantities of 1000 tonnes or more, information specified in Annex V to the Regulation is required in addition.

The lighter registration requirements for intermediates do not apply to monomers which are used as intermediates. This is necessary because the potential risk to human health or the environment is normally from the monomers, which can be toxic, used in the manufacture of polymers. Moreover, polymers themselves do not have to be registered.

To share and facilitate the work, manufacturers and importers can form a consortium for the purposes of registration (Art. 17). In case of a consortium, registrants need to submit information about their identity and the identity of their intermediate separately. However, the classification of the intermediate, the available information on physicochemical, human health or environmental properties and, if necessary, information in accordance with Annex V will need to be submitted by one member of the consortium acting on behalf of the others, whom will refer to the lead registration in their dossiers.

3.4. Information requirements for all other substances subject to registration

Information requirements for all other substances subject to registration depend upon the quantity in which the substance is manufactured or imported. The reason for this is that, generally, the higher the quantity of a substance manufactured or imported, the higher the potential exposure to the substance to humans or the environment, and thus the higher the potential risk. Higher quantities therefore justify a greater amount of both data and a comprehensiveness of assessments that need to be submitted.

[16] see definition in Annex I

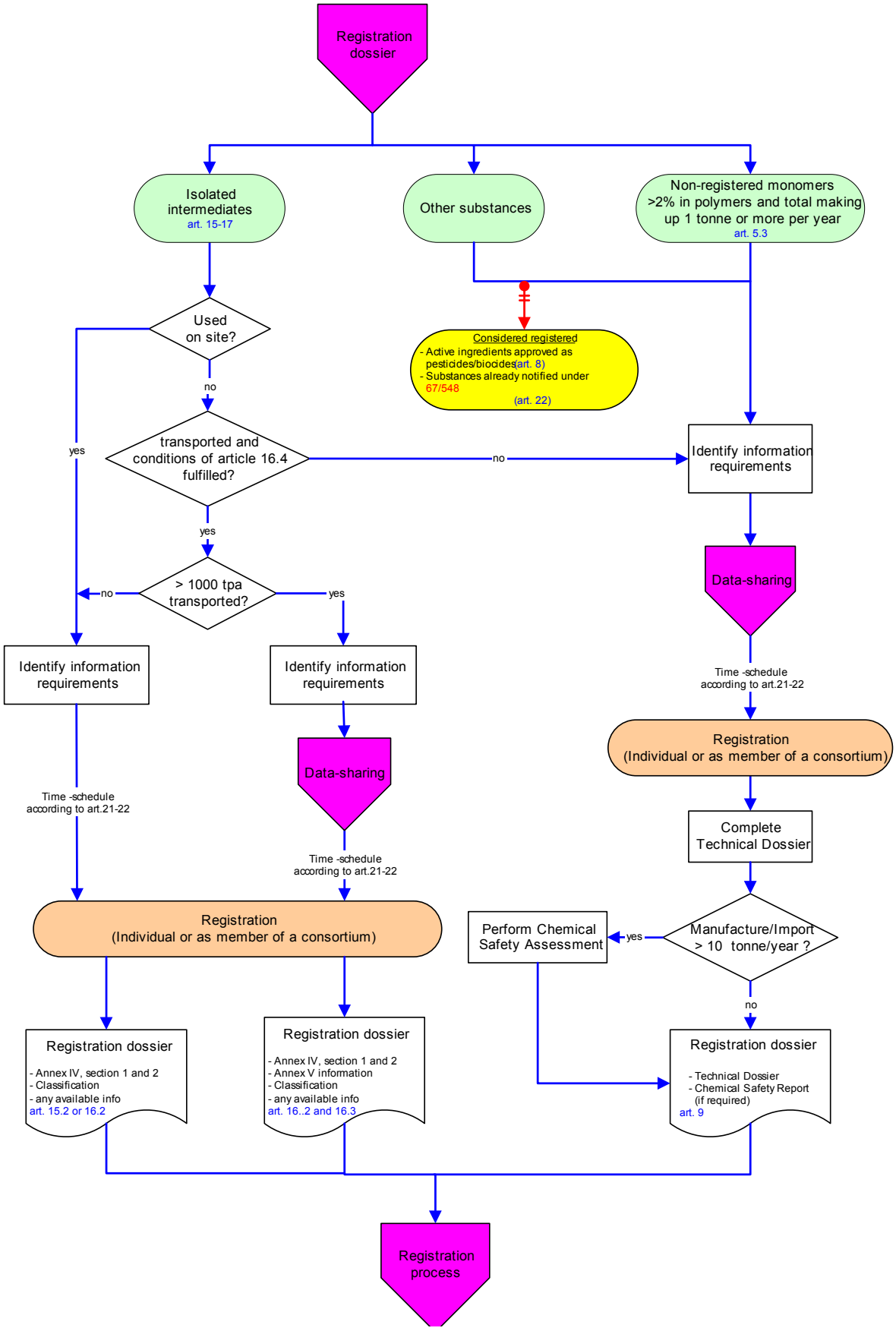

Figure 4: An overview of the different types of registration dossiers

For each substance a *technical dossier* is required whose content depends on the quantity of the substance manufactured or imported per year, the levels are set at 1, 10, 100 and 1000 tonnes.

In addition, a *chemical safety report* is required for all substances which are manufactured or imported in quantities of 10 tonnes or more per year.

3.4.1. Technical Dossier (Art. 9, 11, 12 and Annexes IV to X)

The technical dossier specifies the identity of the substance and its manufacturer or importer, the quantity manufactured or imported, information on the identified uses, the classification and labelling of the substance and guidance on safe use (Annex IV).

Further information requirements for substances, also to be included in the technical dossier, are specified in the Annexes V to VIII to the Regulation. The Annexes apply cumulative, i.e. the higher the quantities of the substances manufactured or imported per year, the more Annexes apply. To clarify, the information requirements (specified in the Annexes) are as follows:

- 1 tonne or more per year according to Annex V,
- 10 tonnes or more per year according to Annexes V and VI,
- 100 tonnes or more per year according to Annexes V, VI and VII,
- 1000 tonnes or more per year according to Annexes V, VI, VII and VIII.

Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall also be provided.

Annex II to this document summarises the information requirements of Annexes V to VIII in one table.

For information specified in Annexes V and VI generally only summaries of the relevant studies are required to be included in the technical dossier, unless the application of Annex I requires robust study summaries to be registered (see 3.4.2.1). If no relevant existing information is available for the information requirements set out in Annexes VII and VIII, only testing proposals need to be prepared. In some cases such tests can also be proposed to adapt testing requirements specified in Annexes V or VI. All testing proposals will be checked as part of the dossier evaluation (see 6.1.2) and only after the proposals have been confirmed by the authority as being warranted do the tests have to be performed. For phase-in substances[17] registrants shall take all reasonable steps to reach an agreement within their Substance Information Exchange Forum (SIEF) to propose one registrant who will carry out the test on behalf of the other participants of the SIEF who need this test for their registration (see Chapter 3.6.2.2).

The REACH proposal specifies that tests need to be performed, if existing information is not available, according to test methods laid down in Annex X and in compliance with the principles of good laboratory practice (GLP) provided for in Directive 87/18/EEC, unless the use of other test methods or of other means than tests

[17] see definition in Annex I

can be justified. Certain tests, or use of Annex X test methods, can be waived; rules for this can be found for specific tests in the Annexes V to VIII themselves or more general rules are found in Annex IX which can be applied to any testing requirement set out in the Annexes V to VIII. Exposure related waiving, however, is only possible for information requirements in Annexes VII and VIII.

If tests are required to be carried out, including those required through evaluation, they shall be carried out in accordance with the provisions of Directive 86/609/EEC[18].

For the hazard classification of substances and preparations, the REACH proposal refers to Directive 67/548/EEC (hazard classification of substances) and Directive 1999/45/EC (hazard classification of preparations).[19] An identified hazard (or classification) of a substance or preparation establishes requirements to label the substance (see Directive 67/548/EEC) or preparation (see 1999/45/EC), to supply downstream users with a safety data sheet (see Chapter 4.1.1) and to apply other sector specific legislation linked to the classification[20].

The technical dossier finally needs to include a declaration whether information has been generated by testing on vertebrate animals and whether the registrant would like to share information not involving tests on vertebrate animals. As the REACH data sharing requirements are only mandatory for vertebrate animal tests this provides a mechanism for companies to also share other tests.

3.4.2. Chemical Safety Report (Art. 13, Annex I)

A manufacturer or importer of a substance in quantities of 10 tonnes or more per year needs to prepare a chemical safety assessment (CSA) and needs to document this assessment in his chemical safety report (CSR) as part of his registration dossier.

Annex I sets out a methodology for assessing whether risks from the use of substances to human health and the environment are adequately controlled as well as the format for the chemical safety report.

In the *chemical safety report* the registrant needs to document how he derived his – positive or negative - hazard classification as "dangerous" according to Directive 67/548/EEC (hazard classification of substances) and his PBT and vPvB assessment of the substance. The assessment shall also include the identification of derived no-effect levels (DNELs) and predicted no-effect concentrations (PNECs) (see 3.4.2.1 hazard assessment).

To focus resources and priorities on substances of higher concern, the registrant only needs to document how he developed appropriate *risk management measures* (RMM)

---

18 Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes

19 It is planned however, to replace the current classification and labelling rules and implement the lobally harmonised system (GHS). This should enter into force at the same time a REACH.

20 These are listed in the document "Note on Downstream Consequences on Community Legislation from a Revision of Directive 67/548/EEC due to a Globally Harmonised System on Classification and Labelling of Dangerous Substances" (ECBI/31/99 Rev. 3) (5 February 2002). Available at: http://ecb.jrc.it/classification-labelling/

for those substances that are either classified as dangerous or identified as a PBT or vPvB. He does this, by documenting the relevant exposure assessments and the risk characterisations for these substances (see 3.4.2.2 exposure assessment and risk characterisation).

A CSA need not to be performed for a substance which is present in a preparation below any of the concentration limits defined in Art. 13 (2)[21]. For substances with similar properties, a group assessment can be performed.

Results of the chemical safety assessment shall also be used when compiling safety data sheets for information that will be passed down the supply chain, in particular the exposure scenarios developed shall be annexed to it (see Chapter 4.1.1).

Where a safety data sheet is prepared for a preparation, the supplier may carry out a Chemical Safety Assessment for the preparation, and ensure the SDS is consistent with that assessment, rather than with that for each substance. The methodology for this is set out in Annex IB and includes documenting his hazard classification according to Directive 1999/45/EC (hazard classification of preparations), deriving DNELs and PNECs for the preparation, and carrying out an exposure assessment.

3.4.2.1. Hazard Assessment

The hazard assessment comprises identification and evaluation of the physicochemical hazards, human health hazards and environmental hazards of a substance including the consideration of the data, a comparison with the criteria for hazard classification, a derivation of the dose, or concentration, that has no effect on human health or the environment, and a comparison with the PBT[22] and vPvB[23] criteria in Annex XII.

The hazard assessment will be based on all available data on the intrinsic properties of substances and all data which is shared under REACH or generated in accordance with Annexes V and VI. If at a later stage tests, which were proposed in the registration in accordance with Annexes VII or VIII (see 3.4.1), are conducted, or new information becomes available, the hazard assessment, and possibly the risk characterisation, will need to be refined.

Evaluation of hazard data

Hazard data need to be evaluated with respect to identifying hazardous properties and establishing quantitative dose (concentration) – response (effect) relationships for relevant endpoints.

---

21 No CSA is required if the concentration of the substance in the preparation is less than the lowest of any of the following: the applicable concentrations defined in the table of Art. 3(3) of Directive 1999/45/EC; the concentration limits given in Annex I to Directive 67/548/EEC; the concentration limits given in Part B of Annex II to Directive 1999/45/EC; the concentration limits given in Part B of Annex III to Directive 1999/45/EC; the concentration limits given in an agreed entry in the classification and labelling inventory as established and maintained by the Agency; 0.1%, if the substance meets the criteria for PBT or vPvB substances as given in Annex XII

22 see definition in Annex I

23 see definition in Annex I

If more studies are available addressing the same endpoint, the valid study giving rise to the highest level of concern shall be selected as the key study unless justifiable grounds exist for not selecting this study. In this case a Robust Study Summary[24] is required to be submitted with the technical dossier.

If whilst carrying out the CSA, with respect to the identified uses of the substance (see Chapter 3.4.2.2), it is assessed that further information is needed and that the information can only be obtained by a test described in Annexes VII or VIII - even if this is not required because of the volume manufactured or imported - a proposal for testing has to be developed. The proposal is submitted in the technical dossier as part of the registration of the substance and the reasons are given in the CSR. This proposal will be evaluated as part of the dossier evaluation. No testing shall be conducted before a decision is taken under evaluation. Until then the risk management measures put in place, taking into account the need for further information, should be recorded in the CSR.

Classification and labelling

The data on the intrinsic properties of the substance have to be compared with the criteria for classification and labelling as established in Directive 67/548/EEC and the appropriate classification and labelling shall be derived.

Derived no effect levels (DNELs) and predicted no effect concentrations (PNECs)

Based on the outcome of the evaluation of the hazard data, derived No-Effect-Level(s) reflecting the likely route(s), duration and frequency of exposure will need to be established for human health.

For environmental compartments, predicted No-Effect-Concentration(s) will need to be derived.

PBT and vPvB Assessment

The data on the intrinsic properties of the substance have to be evaluated to identify whether it possesses one or more of those properties described in Annex XII: persistent, bioaccumulative and toxic or very persistent and very bioaccumulative.

Those substances of very high concern will most likely be given priority for evaluation by the authorities, and PBT and vPvB substances, whose identification is agreed in the Agency's Member State Committee, may be prioritised to be subjected to authorisation (see Chapter 7.2.2 and 7.2.3).

3.4.2.2. Exposure Assessment and Risk Characterisation

REACH aims at targeted safety assessments compared to many of the comprehensive risk assessments conducted under Regulation 793/93, to make best use of the resources available.

[24] see definition in Annex I

For substances meeting the criteria for classification as dangerous according to Directive 67/548/EEC and for substances assessed to be PBT or vPvB substances, an exposure assessment for each identified use of the substance needs to be prepared.

Identified uses are uses of a substance on its own or in a preparation, or the use of a preparation, that the manufacturer or importer makes himself, uses that the manufacturer or importer intends to sell the substance for, and uses that are made known to him in writing by any of his downstream user-customers, which he includes in his chemical safety assessment. An identified use can also be the incorporation of a substance or a preparation into an article.

The exposure assessment shall take into account the effects of risk management measures already in place. Further effect assessment/testing for other endpoints can therefore be omitted, if the risk management measures that are put in place to adequately control the risk from the hazard of one identified endpoint of the substance (e.g. when a substance is classified as a category 1 carcinogen) would be sufficient to control other hazards or risks.

Moreover, if the emission patterns and the physical or chemical properties of a substance clearly show that, for example, it will not reach the soil environment, there is no need to assess the exposure and characterise the risk for that compartment. This would need to be justified in the Chemical Safety Report.

The final step, the *risk characterisation,* corresponds to the risk characterisation carried out under the current chemicals legislation. In particular, under REACH it will be an iterative process, where the hazard assessment (e.g. by obtaining more data and revision of the DNELs and/or the PNECs) and/or the exposure assessment (e.g. by introducing more risk management measures or by conducting better exposure measurements, i.e. a revision of the exposure levels) are improved until it is demonstrated that risks arising from the manufacture, import and uses of the substance are adequately controlled. This is an industry internal process of which only the end-result will need to be recorded in the CSR.

REACH requires the supplier to pass on exposure scenarios, for which the risk characterisation showed that the risks are adequately controlled, to downstream users as Annexes to their safety data sheets (see Chapter 4.1.1).

(a) Exposure assessment

The exposure assessment will comprise of two steps:

Development of exposure scenarios

An exposure scenario is the set of conditions that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends others to control, exposures of humans and the environment.

Exposure scenarios need to be developed for manufacture in the Community, and all manufacturer's and importer's identified uses, following the steps in the life cycle for each use of the substance. Each exposure scenario needs to include a description of the waste management measure implemented, or recommended, by the manufacturer or importer.

The exposure scenarios may be as wide-ranging or specific as necessary and may describe conditions how to control exposure from one or several uses. Generic exposure scenarios and/or exposure categories can be developed by manufacturers and importers where appropriate. Further specific guidance on how to develop exposure scenarios and how to communicate these down the supply chain will be developed under the Reach Implementation Projects (RIP-3).

Identified uses of substances can be the uses of substances on their own, in preparations or in articles.

Exposure estimation of a substance

The exposure has to be estimated for each exposure scenario developed and shall contain three elements:

(1) emission estimation: this needs to consider the emissions during all relevant parts of the life-cycle of the substance under the assumption that the risk management measures described in the exposure scenario have been implemented;

(2) evaluation of chemical fate and pathways: here, a characterisation of possible degradation, transformation, or reaction processes and an estimation of environmental distribution and fate shall be performed;

(3) estimation of exposure levels: this needs to be performed for all human populations (workers, consumers and humans liable to exposure indirectly via the environment) and all environmental spheres for which exposure to the substance is known or reasonably foreseeable. If monitoring data on exposure levels is available, interpretation of this data shall be given special consideration. Each relevant route of human exposure (inhalation, oral, dermal and combined through all relevant routes of exposure) has to be addressed. Such estimations shall take account of spatial and temporal variations in the exposure pattern.

(b) Risk characterisation

The risk characterisation needs to be carried out for each exposure scenario. It needs to consider the human populations (exposed as workers, consumers or indirectly via the environment and if relevant a combination thereof) and the environments for which exposure to the substance is known or reasonably foreseeable, under the assumption that the risk management measures described in the exposure scenarios have been implemented. In addition, the overall environmental risk caused by the substance need to be reviewed by integrating the results for all relevant environments and all relevant emission/release sources of the substance.

The assessment consists of:

- a comparison of the exposure of each human population known to be or likely to be exposed with the appropriate DNELs;
- a comparison of the predicted environmental concentrations (PECs) in each environmental compartment with the appropriate PNECs; and
- an assessment of the likelihood and severity of an event occurring due to the physicochemical properties of the substance.

For any exposure scenario, a risk can be considered to be adequately controlled, if:

- the exposure levels estimated do not exceed the appropriate DNEL or the PNEC, as determined in the hazard assessment, and;
- the likelihood and severity of an event occurring due to the physicochemical properties of the substance as determined in the hazard assessment is negligible.

For those human effects and those environments for which it was not possible to determine a DNEL or a PNEC, a qualitative assessment of the likelihood that effects are prevented when implementing the exposure scenario has to be carried out.

For PBT and vPvB substances, the manufacturer or importer shall implement, and recommend for downstream users, risk management measures that minimise exposure to humans and the environment.

This assessment needs to be repeated iteratively until the outcome of the risk characterisation which is recorded in the CSR shows that risks are adequately controlled.

3.4.3. Documentation of the assessment in the chemical safety report

The chemical safety report has to be prepared in a standard format set out in Section 7 of Annex I to the REACH Regulation. The Agency will determine which word processing programs may be used to complete the report with and make this known via it's web-site. To facilitate the work, the development of an automatic CSR generation tool is being considered, which can generate the basic elements of the chemical safety report from data that are entered into the database IUCLID 5 as part of the future REACH – IT system. Of course, no IT system can replace expert judgement and decisions which will always need to be justified and included into the report by the registrants.

Parts of this standard format will also be used by Member States for the preparation of dossiers demonstrating the need for introducing restrictions (Annex XIV).

3.4.4. Implementation or recommendation of risk management measures (Art. 13 (6))

After having defined the conditions under which the substance can be manufactured and used under adequate control, the use conditions and appropriate risk management measures shall be implemented on the manufacturer or importer's own site(s).

Furthermore, information on recommended risk management measures and the corresponding exposure scenarios have to be communicated together with substances or preparations to downstream users for any identified (downstream) use (see Chapter 4).

Part A of the Chemical Safety Report will contain a declaration by the manufacturer or Importer that they have implemented the relevant risk management measures, and they have been communicated to downstream users.

3.5. Timing (Art. 19, 21)

From 60 days after the entry into force of the regulation, substances will need to be registered under REACH before they are manufactured or imported in quantities of 1 tonne or more per year. After submission of the dossier, the registrant will have to wait for 3 weeks to allow the Agency to check that the dossier is complete (but see paragraph below). If there is no indication from the Agency that the dossier is not complete, the registrant may start his manufacture or import after these 3 weeks. In cases of mandatory data-sharing this period will be extended by four months if the previous registrants so requests (see Chapter 3.6.2.1). For the consequences of an incomplete dossier see Chapter 3.8.

It cannot be expected that companies will have their registration dossiers ready for all substances which they have been manufacturing or importing for the last 15 years and which they intend to manufacture or import after the entry into force of the registration provisions. Therefore, transitional provisions with different deadlines for Registration - without the need to interrupt the manufacture or import of these substances - are proposed. Thus those substances which will be "phased into" the REACH system are known as "*phase-in substances*".

A number of deadlines for the registration of phase–in substances have been set based on the volume manufactured or imported:

3 years: for substances in quantities of *1000 tonnes* or more per year and for *CMR* substances.

6 years: for substances in quantities of *100 tonnes* or more per year

11 years: for substances in quantities of *1 tonne* or more per year.

3.6. Data –sharing to prepare the technical dossier

Figure 5 provides an overview of the pre-registration and data-sharing processes.

3.6.1. Identifying information needs

Before conducting new tests on intrinsic properties of substances, as required by the Annexes, each manufacturer or importer shall identify the data gaps between the available data and the data required, and thus his information needs by:

- collecting and evaluating the applicability/validity of any existing data,
- considering the possibility of using qualitative or quantitative structure-activity relationships ((Q)SARs), read-across from data on structurally related substances, or other grouping considerations, and
- considering other possibilities for waiving of tests according to Annex IX and the waiving rules for specific tests in Annexes V to VIII.

Note: the technical dossier needs to contain justification for using information other than test data, test data gained by methods other than those set out in Annex X, or by non-GLP tests, or that no information is provided.

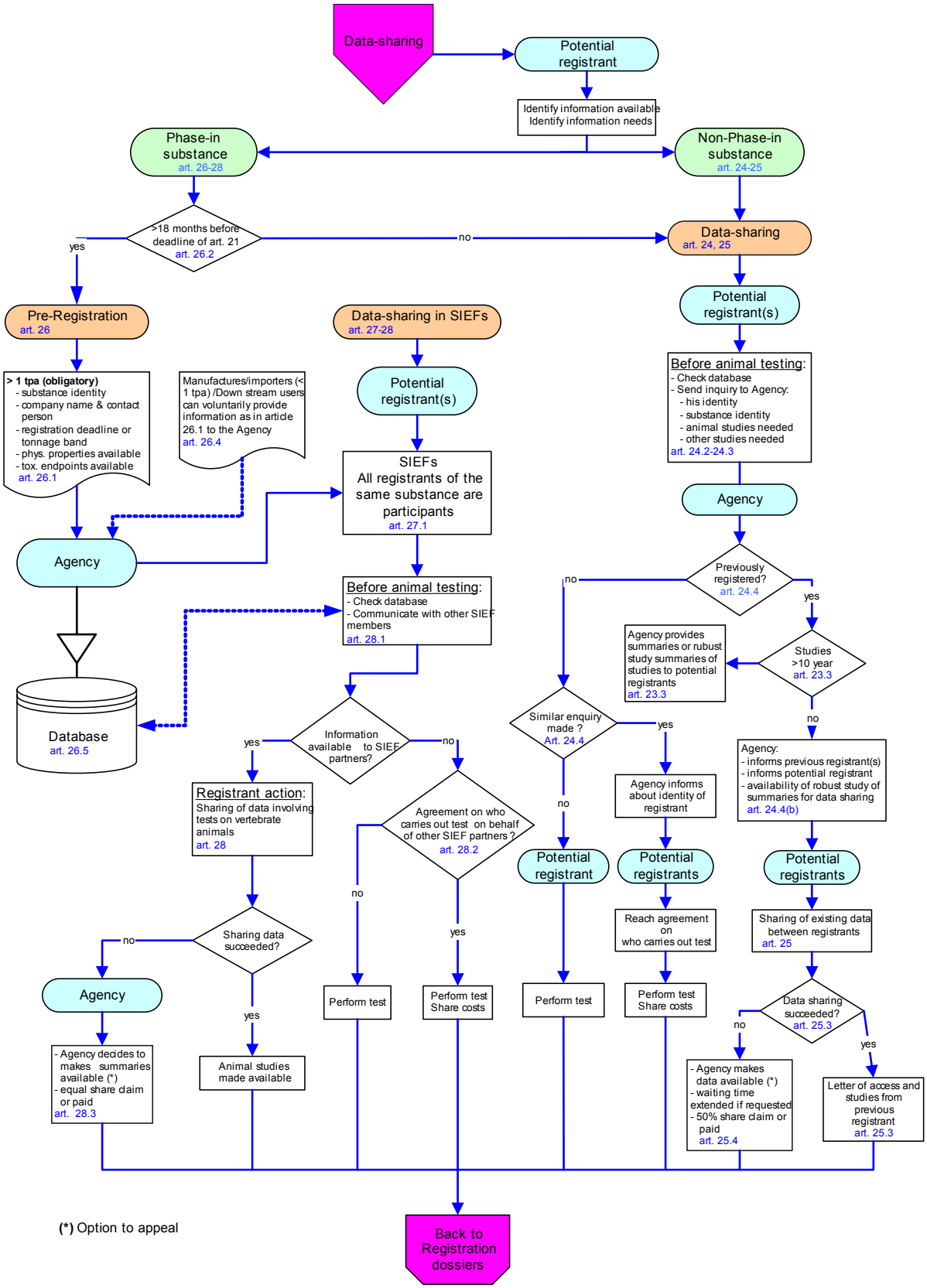

Figure 5: An overview of the data-sharing and pre-registration process.

3.6.2. Data sharing (Art. 23 to 28)

One of the objectives of REACH is to limit vertebrate animal testing as far as possible, while balancing that with the generation of necessary information to identify the hazard of substances. Therefore duplicate animal testing has to be avoided and tests on vertebrate animals for the purposes of REACH shall only be undertaken as a last resort.

Before new tests are conducted to comply with the identified information needs (3.3), and thus with the information requirements, potential registrants have to take part in the data sharing mechanisms set up for tests on vertebrate animals. They may use those mechanisms for other tests not involving vertebrate animals to save time and money.

As a first step, summaries and robust study summaries of tests will only be protected for ten years from their Registration, after this time period the Agency will make them freely available to all potential registrants asking for them.

For other tests, the mechanisms set up shall encourage manufacturers and importers of substances to come to an agreement on the sharing of tests and costs. Forced sharing of tests involving vertebrate animals is a last resort.

Taking account of the different situations for phase-in and non-phase-in substances different mechanisms will be used:

- For *phase-in substances*, it is expected that test data are available for many of them. In addition, there are likely to be several potential registrants preparing their registrations for the same substance at the same time, heading for the same registration deadlines while hardly any information will be available at the Agency at this stage which could be shared.

  Therefore, for *phase-in substances*, potential registrants shall *pre-register* information to the Agency with the aim of identifying other potential registrants of the same substance and the available information. All potential registrants of the same substance will be participants of a **S**ubstance **I**nformation **E**xchange **F**orum (***SIEF***). Within a SIEF all reasonable steps shall be undertaken to reach agreements on the sharing of available information and on who will perform new test on behalf of other SIEF participants. Manufacturers and importers have to take part in the *pre-registration* of phase-in substances to be able to benefit from the phase-in deadlines for registration, thus to continue with their manufacture or import while they are preparing their registration.

- For *non-phase-in substances*, there will be fewer registrants for the same substance and their registrations will normally be expected sequentially, rather than at the same time. Hence, after the first registration information will be available in the Agency which the Agency can make available to later registrants if they fail to reach an agreement on the sharing of the information with previous registrants.

3.6.2.1. Data sharing for non-phase-in substances (Art. 24 and 25)

Before testing on vertebrate animals is carried out, the potential registrant will need to check whether the same substance has already been registered, or whether another potential registrant is making an inquiry to register the same substance at the same time. This is done by looking in the Agency's database, and by submitting information to the Agency about himself, his substance and which information requirements would require new studies on vertebrate animals and other new studies to be carried out by him.

The Agency will check the chemical identity of the substance and whether the substance has already been registered or been the subject of an inquiry. It will inform the potential registrant of the result:

- If the substance has not previously been registered and is not the subject of another inquiry, the potential registrant may conduct tests involving vertebrate animals for the preparation of his registration.

- If the substance has been registered more than ten years ago, the Agency will provide the potential registrant with any available summary or robust study summary requested by him.

- If the substance has been registered less than 10 years before the inquiry by the potential registrant, the Agency will inform the potential registrant of the name and address of the previous registrant(s) as well as the availability of requested robust study summaries or summaries of vertebrate animal studies. In case the previous registrant has indicated in his registration that he wants to share other studies, not involving vertebrate animals, the Agency will inform the potential registrant accordingly as well. Furthermore, the Agency will inform the previous registrant(s) about the identity of the potential registrant. This will allow the contact between the potential registrant and the previous registrant(s). A repeat of available studies is not allowed and the potential registrant would be open to sanctions if he duplicated them.

  Potential and previous registrants shall take all reasonable steps to reach an agreement on the sharing and making available of the studies, and on the sharing of the costs. If they succeed, the previous registrant shall grant a "*letter of access*" to the potential registrant for each of the studies concerned within 2 weeks of receipt of payment. The potential registrant can then make reference to the studies, and submit the letter of access, as part of his registration.

  If they fail to reach an agreement, within 1 month of receipt from the Agency of the identity of the previous registrant(s), the potential registrant may inform the Agency and the previous registrant(s) about this failure. In this case, the Agency will make available any requested summary or robust study summary, to the potential registrant on proof of payment of 50% of the costs incurred by the previous registrant. If the previous registrant fails to inform the Agency and the potential registrant about his incurred costs, the Agency will make available any requested summary, or robust study summary, to the potential registrant. The previous registrant will have a claim against the potential registrant for 50% of the costs incurred, which is enforceable in the national courts.

If requested by the previous registrant, the waiting period for the (potential) registrant after submission of the registration (see 3.8.2) will be extended by four months.

- If another potential registrant has made an inquiry about the same substance, but not yet submitted his registration, the Agency will inform both potential registrants of the name and address of the one another as well as those studies involving vertebrate animals that both potential registrants requested for preparing their registration dossiers. They shall take all reasonable steps to reach an agreement on who performs the test on behalf of both of them and on the sharing of the costs.

When submitting the registration, registrants may point out that they are willing to share also tests not involving vertebrate animals on a voluntary basis. In this case the Agency will inform a potential registrant when a request by him and an offer by a previous registrant match up.

3.6.2.2. Data sharing for phase-in substances (Art. 26 to 28)

Pre-Registration

To enable manufacturers and importers of the same substance to find partners for data sharing, two deadlines are foreseen for the pre-registration of information:

- 1.5 years for phase-in substances in quantities of 1000 tonnes or more per year and for CMR substances, and

- 4.5 years for all phase-in substance in quantities of 1 tonne or more per year, unless required to be pre-registered above.

These deadlines strike a balance between distributing and planning the work in line with the deadlines set for submitting the registrations (3, 6 and 11 years) and the need to collect existing information on substances as early as possible to enable efficient sharing. This will save animal lives and costs, in particular for small and medium-sized companies.

For each phase-in substance, each potential registrant has to submit information on the identity of the substance, his identity, his envisaged deadline for registration, and/or the tonnage band, and an indication of the physicochemical, toxicological and eco-toxicological endpoints for which he has relevant studies or available information. He must also indicate if the studies include tests on vertebrate animals and if not, if he will be willing to voluntarily share their summaries and robust study summaries.

Manufacturers and importers of phase-in substances who do not pre-register on time will be in breach of both the duty to pre-register and the duty to register a substance before manufacturing or importing it. This latter breach is because they are only allowed to benefit from the phase-in deadlines for registration (3, 6 or 11 years) if they take part in the pre-registration.

Downstream users and manufacturers and importers of substances in quantities of less than 1 tonne per year may, on a voluntary basis, contribute to the pool of available

studies by submitting information corresponding to that required from manufacturers or importers, to the Agency. This will contribute to the saving of animal lives and enable downstream users and small companies to get back parts of the costs incurred. There are no obligations for the downstream users, however, if the sharing does not succeed.

Substance Information Exchange Fora (SIEF)

For each phase-in substance, a Substance Information Exchange Forum (SIEF) is set up consisting of all manufacturers and importers who have pre-registered the same substance. To facilitate this, the Agency will record the information submitted in the pre-registrations and grant access to this information to those manufacturers and importers, who have pre-registered the same substance. By checking this database each potential registrant will then be able to identify which studies are already available within the SIEF.

Each SIEF establishes the following duties to communicate for its participants:

If a participant needs any of the available studies for his registration, he shall request this study within two months from the end of his deadline for pre-registration. Within two weeks, the owner of the study shall provide proof of his costs incurred.

They shall take all reasonable steps to reach an agreement on making available the study and on sharing the costs – otherwise they shall share the costs equally. The owner should provide the study within 2 weeks of payment.

If the owner of the study refuses to provide the study or proof of the costs, the other participants shall proceed as if no relevant study was available within the SIEF. However, if the owner of the study has already submitted his registration containing the study, the Agency shall make the study summary or the robust study summary available to the other participant(s). The study owner shall then have a claim on the other participants for an equal share of the costs. The owner who refused to provide the study or the proof costs is in breach of the Regulation and subject to sanctions.

If a relevant study is not available within a SIEF, the participants who need it shall take all reasonable steps to agree who carries out the study on behalf of them, and

- arrange for the test to be carried out in relation to tests specified in Annexes V and VI or,

- to develop proposals for tests specified in Annexes VII and VIII including the arrangements taken by the participant who intends to carry out the test on behalf of the other participants after evaluation when a decision is taken requesting to perform the test.

If downstream users or manufacturers and importers of substances in quantities of less than 1 tonne have made available information on tests, participants of SIEFs may contact them. However, these manufacturers, importers or downstream users who do not have a duty to register will not be granted access to all information in the SIEF.

3.7. Preparation of a registration dossier as a member of a consortium

Manufacturers and importers working together in a SIEF can facilitate the formation of a consortium for the purposes of registration. Also for new substances consortia can be formed to facilitate and share the work.

Nevertheless, each manufacturer or importer needs to prepare his own registration dossier for his substance, even if he is member of a consortium, because commercially sensitive information may not be shared.

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

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

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

3.8. Registration procedure

Only registered substances are allowed to be manufactured or imported.

An overview of the registration procedure is provided in Figure 6.

3.8.1. Submission of the registration dossier and completeness check (Art. 18)

Each manufacturer or importer of a substance shall submit his registration dossier for the substance to the Agency, accompanied by a fee. As a consortium member he only has to pay one third of the registration fee.

The registration dossiers submitted to the Agency will be handled electronically to facilitate the management of the expected amount of registrations that will be submitted. The Agency assigns a registration number and a registration date to each registration dossier received and immediately communicates this information to the registrant.

Within 3 weeks of the registration date, the Agency performs an automated completeness check of the dossier to ascertain that all elements required for the registration are included. If the registration is incomplete, the Agency will inform the registrant within these 3 weeks from the registration date about which further information is needed and will set a deadline for completion of the dossier.

For phase-in substances, a considerable number of registrations are expected to arrive just before the deadlines for the registrations. Therefore, the Agency is given 3 months from each registration deadline to check the completeness of those

registrations that have been submitted within 2 months of the deadlines. However, the Agency will have to check the completeness of registrations submitted more than 2 months before the deadlines, within 3 weeks of receipt.

The registrant needs to submit the requested missing information in an updated dossier to the Agency within the set deadline. The Agency then confirms the submission date of this information and makes a further completeness check within 3 weeks of receipt of the updated dossier.

If the registrant fails to complete his registration within the set deadline, the registration will be rejected by the Agency and the manufacturer or importer is not allowed to start or continue manufacture or import of the substance.

The Agency will forward the registration dossier, the registration number and date, and the result of the completeness check to the authorities of the Member States in which the manufacturers and importers are established to enable enforcement action, if necessary. Also the further information that is submitted for completion of the dossier will be forwarded to the competent authority together with the result of the second completeness check.

The Agency does not explicitly accept registrations because registration is not an approval system and responsibility remains with the registrant.

The Agency will make non-confidential information (as defined in Art. 116) submitted in registrations available on its webpage.

3.8.2. Start of manufacture or import (Art. 19)

Registrants *of non-phase-in substances* have to wait for 3 weeks – the time given to the Agency to check the completeness of the registration - before they are allowed to start manufacturing or importing the substance, provided there is no indication to the contrary from the Agency by a request for missing information.

After having submitted requested information, the registrant has to wait for another three weeks – for a second completeness check by the Agency - before he is allowed to start manufacturing or importing the substance in quantities of 1 tonne or more per year, provided the registration is not rejected because it is still incomplete.

In case of forced data sharing, the waiting period is extended by four months on request of the previous registrant(s) (see Chapter 3.6.2.1).

Registrants *of phase-in substances*, who register before the end of the registration deadlines set for the registration of the respective quantity of the substances, are allowed to continue their manufacture or import, unless their registration is rejected by the Agency.

Registrants who are members of a consortium will have to liaise closely with the member who is acting on their behalf, as all members are only allowed to start manufacture or import of the substance, if there is no indication to the contrary from the Agency with regard to both the registration submitted by the consortium member acting on behalf of them and the parts of the Registration they submitted separately.

3.9. Registrants' obligations to update the registrations (Art. 11 (2), 20)

The information submitted in the registration to the Agency will have to be kept up-to-date. Registrants are required to inform the Agency about any change in his identity, in the composition of the substance, any significant changes in the annual or

total quantities manufactured or imported, new uses of the substance, significant new knowledge of the risks of the substance for human health and/or the environment, any change in the classification and labelling of the substance, and any update or amendment of the Chemical Safety Report.

As soon as a registered substance is manufactured or imported in a quantity for which an additional Annex for the generation of information applies, i.e. at 10, at 100 and at 1000 tonnes, an updated registration has to be submitted. If the update of the registration dossier requires one or more tests on vertebrate animals, the registrant will have to consult the database of the Agency to find out whether these tests have already been carried out under previous registrations as described in section 3.6.2. Any new information shall be submitted by updating the original registration dossier and resubmitting the updated version.

3.10. Registration of substances in articles (Art. 6)

Producers or importers of articles will need to register or notify those substances in their articles which meet the criteria for classification as dangerous, are present in a quantity of more than 1 tonne per producer or importer per year per article type and are either intentionally or unintentionally released (see Figure 7). The obligation will apply from 11 years and three months after the entry into force of the Regulation.

A producer of articles does not have an obligation to register or notify a dangerous substance, if a supplier further up the supply chain, has already registered the substance for that use.

3.10.1. Obligation to register substances in articles (Art. 6 (1))

Substances in articles meeting the criteria for classification as dangerous will need to be registered only, if they are *intended to be released* under normal and reasonably foreseeable conditions of use and if they are present in the articles in a quantity of more than 1 tonne per year per producer or importer and per article type.

If these conditions are fulfilled, a registration has to be prepared and submitted according to the general requirements (see Chapter 3.3 to 3.6), including the information requirements according to the tonnage levels for the substance manufactured or imported and per article type.

However, with regard to preparing the technical dossier, after 11 years and three months, much of the information required will already be available in the Agency's database. Summaries and robust study summaries that have been submitted ten years or more ago may be requested free of charge from the Agency. For other information, the data sharing mechanisms (Chapter 3.6.2.1) will need to be used.

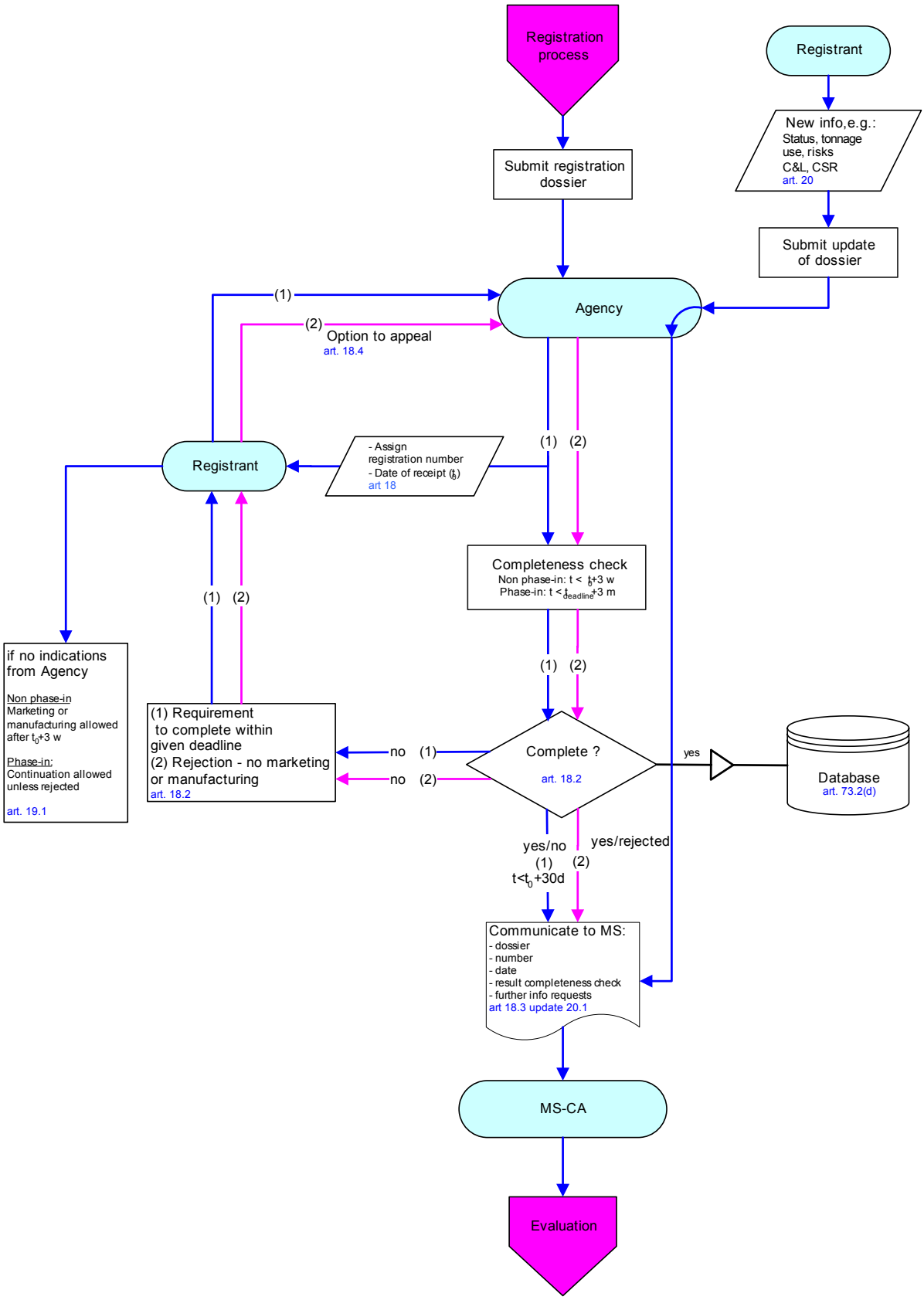

Figure 6: An overview of the registration process.

In the chemical safety report, exposure scenarios for the use of the substance in the articles will be developed. As with all exposure scenarios, they may be specific or generic as appropriate.

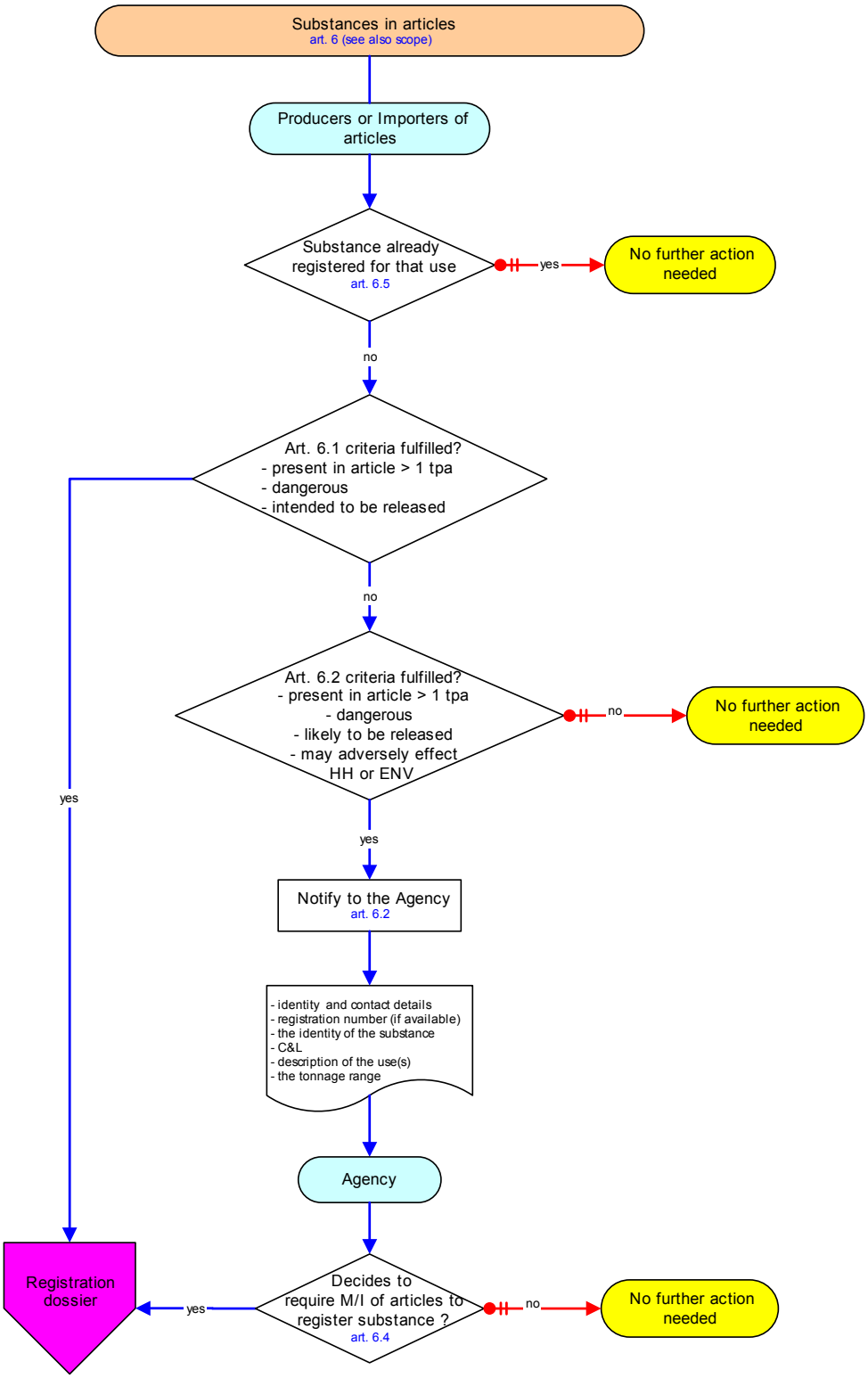

Figure 7: Registration of substances in articles.

3.10.2. Obligation to notify substances in articles (Art. 6 (2) and (3))

Substances in articles meeting the criteria for classification as dangerous, will have to be notified to the Agency if they are not intended to be released but for which the producer or importer knows or is made known that the substance is likely to be released under normal and reasonably foreseeable conditions of use. Further conditions for the obligations to notify are that the quantity released may adversely affect human health or the environment, and that the substance is present in a quantity of more than 1 tonne per producer or importer per year per article type.

The notification only needs to include the producer's or importer's identity, the identity of the substance, its classification, the tonnage range of the substance, and a brief description of the use(s) of the article, and, if available, any registration numbers for the substance.

3.10.3. Obligation to register notified substances in articles (Art. 6 (4))

The Agency may take decisions requiring producers or importers of articles to register any notified substances. The requested registrations will then have to be prepared and submitted according to the general rules (see Chapter 3.3 to 3.7).

4. INFORMATION IN THE SUPPLY CHAIN (ART. 29 TO 33)

The main purpose of the information through the supply chain provisions of REACH is to establish a comprehensive and transparent framework within which industry can transmit information on hazards and risks down the supply chain to ensure appropriate risk management measures are implemented by downstream users. The main tool used by industry is the Safety Data Sheet (SDS). These will be improved over today's situations due to more information being available and the requirements to do CSRs in certain circumstances.

Suppliers of chemicals are required to inform their downstream users or distributors about hazards and measures to adequately control the risks of the substances they supply. With regard to obligations to pass on information down the supply chain, a distinction has to be drawn between dangerous and non dangerous substances (see Figure 8).

Obligations to pass on information up and down the supply chain apply regardless of the quantity of a substance that is manufactured, imported or used.

4.1. Information down the supply chain

4.1.1. Safety Data sheets (SDS) for dangerous substances (Art. 29)

Manufacturers, importers, downstream users and distributors supplying substances or preparations meeting the criteria for classification as dangerous, further down the supply chain to other downstream users or distributors, are already today required to compile and supply a safety data sheet at the first delivery of a substance or preparation.

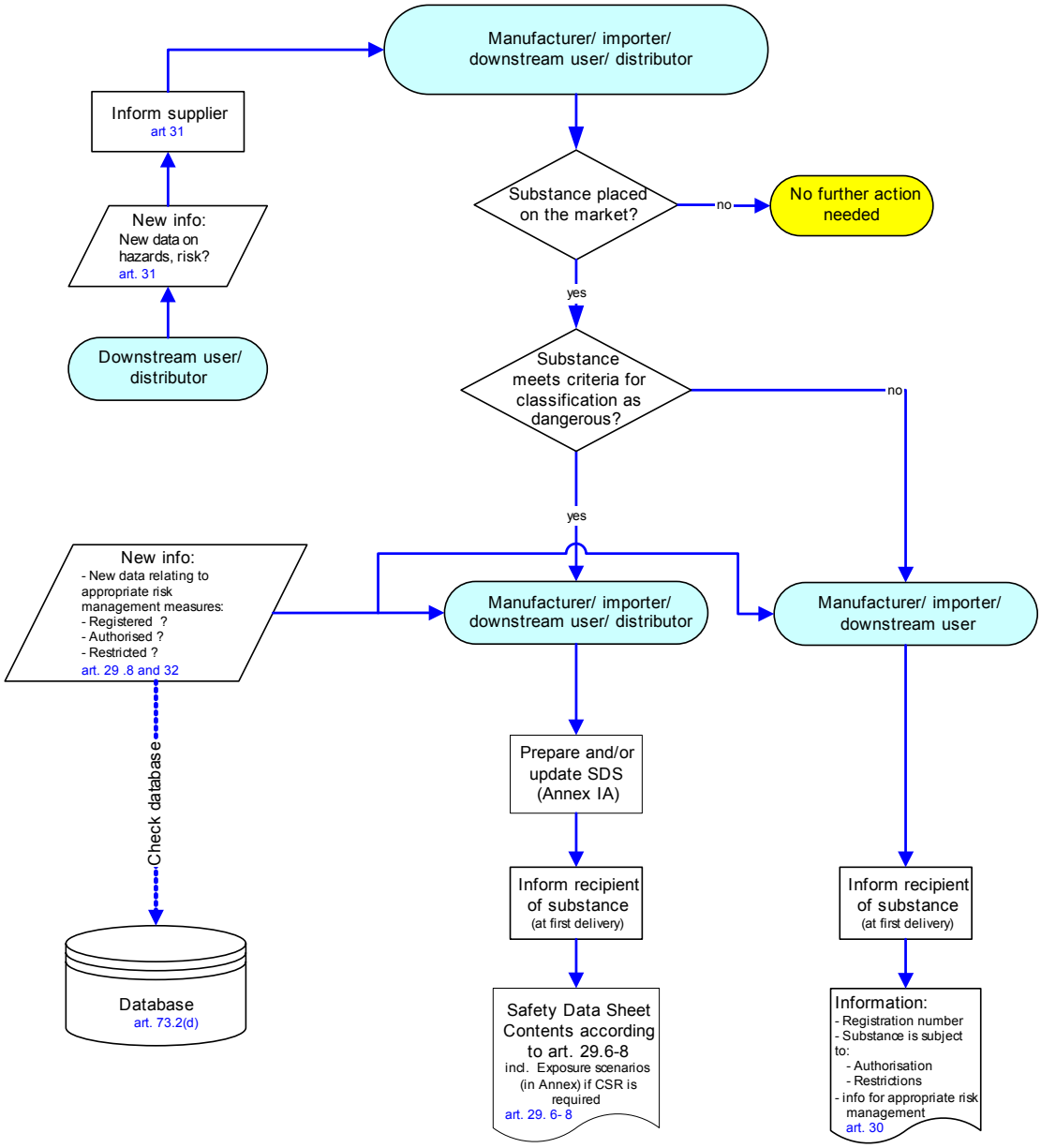

Fig. 8. Information through the supply chain

REACH takes over this existing duty in its Art. 29 and Annex IA - the guide to the compilation of safety data sheets. Safety data sheets will continue to contain information on the hazards of the substance, or the preparation, as well as information on the recommended risk management measures to adequately control any risks to health and environment. The 16 headings, the content of which is explained in Annex IA, will have to be used.

In addition, for all those substances for which a chemical safety assessment (CSA) is required, the information in the SDS must be consistent with the CSA and the relevant exposure scenarios for the recipient shall be annexed to the SDS.

This obligation to annex exposure scenarios to the SDS has to be fulfilled by:

- *manufacturers or importers:* for registered substances on their own, or in a preparation, manufactured or imported in quantities of 10 tonnes or more per year,
- *downstream users:* for substances on their own, or in preparations, supplied to them, that are manufactured or imported in quantities of 10 tonnes or more per year, for uses which the downstream user did not identified to their suppliers (see Chapter 5), as well as the relevant exposure scenarios from their suppliers
- *distributors:* if they have received such information and it is relevant for their customers.

All these actors in the supply chain need to make sure that they use the information derived in the CSA to compile the SDS and that the SDS is thus consistent with the CSA.

In case of preparations, Art. 29 (2) allows the option of developing a CSA for the preparation as a whole instead of for all substances in the preparation to make it easier to derive DNELs and PNECs and better reflect the hazards and control measures for the preparation itself. The method for performing a CSA for preparations is set out in Annex IB. Annex IB has specifically been developed for cases where the preparation consists of many dangerous components that all lead to a classification of the preparation. If only a few components cause the preparation to be classified, it may be easier to ensure that the information in the safety data sheet is consistent with the CSAs for the relevant substances.

4.1.2. Information for non classified substances (Art. 30)

For substances which do not meet the criteria for classification as dangerous, manufacturers, importers and downstream users will have to pass down the supply chain some basic information: the registration number(s), whether the substance is subject to authorisation or restrictions, guidance on safe use and other information which is necessary to enable appropriate risk management measures to be taken.

4.2. Information up the supply chain (Art. 31)

Downstream users and distributors will need to inform their suppliers directly of new information on the hazard of the substance. This information will need to be passed up the supply chain until the manufacturer or importer of the substance receives the information. For identified uses they will have to inform their suppliers of information leading them to consider any communicated risk management measures as not being appropriate.

Information on the appropriateness of risk management measures will need to be passed on up the supply chain until the supplier who developed the recommended measures receives the information.

4.3. Information for workers and obligation to keep and make available information (Art. 32, 33)

Workers and their representatives shall be granted access to all information that is passed down the supply chain (see Chapter 4.1), for substances they use or may be exposed to during the course of their work.

All information that will have been generated to fulfil any obligation under REACH will need to be kept for at least ten years after the last manufacture, import or use of the substance. The Agency and competent authorities of the Member State of any actor in the supply chain may request to make this information available, in addition to any requests made under the registration or evaluation procedures.

5. DOWNSTREAM USERS

5.1. Downstream user obligations

Downstream users will need to apply appropriate measures to adequately control the risks arising from their use of substances meeting the criteria for classification as dangerous (see Figure 9). REACH requires them to identify and apply appropriate measures to adequately control the risk identified in any safety data sheet supplied to them. In addition to REACH, other law on chemicals, such as Directive 98/24/EC on chemical agents requires assessment and control of substances.

If the substance was registered in their supply chain by a manufacturer or importer in quantities of 10 tonnes or more per year then their use of the substance will need to have been assessed in a CSA to ensure it can be adequately controlled. Two possibilities are foreseen in REACH for the generation of a CSA, to give downstream users a choice:

(1) Downstream users will have to develop their own appropriate risk management measures in a chemical safety assessment in accordance with Annex XI, if they use a substance *outside the conditions described in an exposure scenario* communicated to them in a safety data sheet annex. This will particularly be the case if the downstream users want to use a substance for uses which are not foreseen or not even thought of by their suppliers, and the downstream users prefer to keep these uses confidential. In this case they will have to report certain information to the Agency (see Chapter 5.3).

However, there is no obligation for the downstream users to perform a CSA, if they do not receive a safety data sheet with exposure scenarios in the Annex, for one of the following reasons:

- the manufacturer or importer who supplies them with the substance registered less than 10 tonnes per year, and therefore did not need to perform a CSA, or

- the substance is not dangerous so that there is no obligation to compile a SDS.

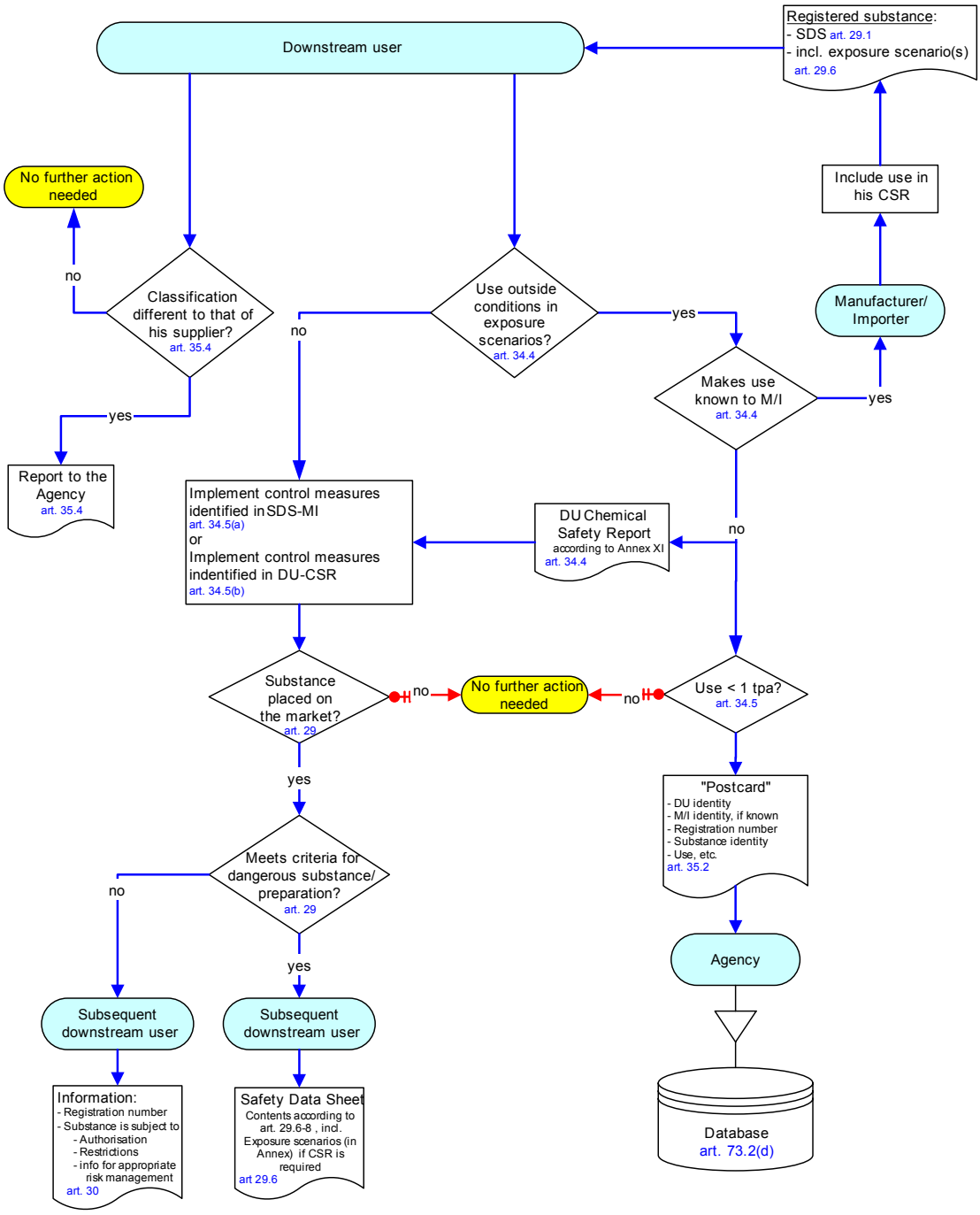

Fig. 9. Overview of downstream user obligations

(2) Downstream users do not need to perform their own chemical safety assessments, if they use substances *within the conditions described in exposure scenarios* communicated to them in a safety data sheet. In this case, they will have to apply the risk management measures communicated to them and therefore, they need to make sure that the safety data sheets in fact contain information that is appropriate to adequately control the risks arising from their uses. If he does not agree that the identified risk management measures are appropriate, he will need to inform his supplier (see Chapter 4.2) and will

have to resolve the matter with him or carry out a chemical safety assessment himself.

If a supplier has intended to manufacture or import a substance for the use to which the downstream user intends to put it, he will have developed exposure scenarios for this use as part of his registration and will have communicated them in the safety data sheet to the downstream user. In this case, the downstream user will only have to check whether he agrees with the information supplied to him with the substance and then to apply the risk management measures foreseen. If he does not agree that the identified risk management measures are appropriate, he will need to inform his supplier (see Chapter 4.2) and reach agreement on how to resolve the matter.

If supplier's exposure scenario(s) do not specifically cover the downstream users use(s) of a substance, downstream users may still not need to perform their own chemical safety assessments. They do not have to perform a CSA if they use the substance within the conditions of an exposure scenario communicated to them, and they implement, as a minimum, the conditions described in the exposure scenario, even if the use(s) for which the exposure scenario was developed are different to that of the downstream user.

E.g. a downstream user can implement or recommend conditions which were developed in an exposure scenario for a specific use of the substance for another use, if the conditions described in the exposure scenario are appropriate.

A downstream user may also apply stricter risk management measures for a use than those described as conditions in the exposure scenario developed for the use of the substance without calling into question the appropriateness of the communicated measures.

This might for instance be the case because stricter risk management facilities are already in place or they might be necessary to control risks arising from other substances used at the same time whose risks did not need to be included in the communicated exposure scenario.

If the conditions described in the exposure scenario provided by the supplier do not cover the downstream use(s), or the downstream user is a new customer, and in both cases he wishes his supplier to provide him with exposure scenarios for his uses, he has to inform his supplier in writing about this and include sufficient information for his supplier to develop exposure scenarios for his use(s). If the supplier includes the uses in his CSA and SDS, they become identified uses.

If a supplier accepts the use made known by the downstream user as an identified use for him and to include it in this CSA, he will have to provide the information to the downstream user within one month or before he next supplies him with the substance, whichever is the later. For phase-in substances the information shall be supplied in line with the registration deadlines, providing the downstream user makes the request within 12 months of the relevant deadline.

If the supplier does not accept the use then he may no longer supply the downstream user with that substance for that use.

If the supplier is not a manufacturer or importer, he may identify the use up the supply chain to his supplier.

If downstream users supply those substances on their own or in dangerous preparations to other downstream users, or distributors, further down the chain, they will also need to pass on information on recommended risk management measures for the further downstream uses in a safety data sheet.

5.2. Performing the downstream user chemical safety assessment

If a downstream user uses a dangerous substance outside the conditions described in an exposure scenario communicated to him in a safety data sheet, he has to conduct his own chemical safety assessment and has to develop exposure scenarios with appropriate risk management measures for adequately controlling risks to human health and the environment. The rules are laid down in Annex XI, which partly refers back to the methodology set out in Annex I.

The downstream users will have to develop exposure scenarios, perform the exposure assessment and characterise the risks arising from the uses. They only need to refine the outcome of the hazard assessment which they find in the safety data sheet supplied to them, if necessary for the risk characterisation. If they consider that additional information is needed for this, they need to obtain this information. However, if they consider tests involving vertebrate animals are necessary for this, they shall include a testing proposal in their report to the Agency. They need to also record in their CSR, the risk management measures put in place while awaiting an evaluation decision in respect of the testing proposals.

The format for the downstream user's CSR shall be the format set out in Section 7 of Annex I in part C, heading 5 and 6.

Downstream users have 12 months from receipt of the safety data sheet to perform the CSA.

5.3. Reporting of information

If downstream users use dangerous substances outside the conditions described in exposure scenarios communicated to them in a safety data sheet annex, they will have to report to the Agency a brief general description of these use(s) together with information on the identity of the substance, on their identity, and if known, the identity of the manufacturer or importer of the substance, the registration number, if available, and if considered necessary in the chemical safety report, a proposal for testing involving vertebrate animals.

Whenever a downstream user classifies a substance differently than his supplier, he also shall report this to the Agency.

Reporting is not required for uses of substances of quantities of less than 1 tonne per year.

The information required to be reported to the Agency is limited to minimise the burden on downstream users. If necessary, authorities will request further information from registrants under evaluation, may take enforcement action or may propose restricting certain uses of substances.

Downstream users have 6 months from receipt of the safety data to comply with the reporting requirements.

5.4. Information through the supply chain

Downstream users who place on the market their substances to downstream users or distributors further down the supply chain need to supply them with information about the substances, on their own or in preparations (see Chapter 4).

6. EVALUATION

The evaluation process has three purposes: The first purpose is for authorities to evaluate the testing proposals made by industry to ensure the safety of their products and thereby ensuring that animal testing is kept to a minimum. The second purpose is to check compliance with the requirements of the regulation. The third purpose is to examine any suspicion of risks to human health and the environment arising from substances.

Evaluation provides a means for the authorities to require registrants, and in very limited cases downstream users, to provide further information.

There are two types of evaluation: dossier evaluation and substance evaluation:

Dossier evaluation is conducted by authorities to examine proposals for testing to ensure that unnecessary animal tests and costs are avoided, and to check the compliance of registration dossier with the registration requirements.

Substance evaluation is performed by authorities when there is a reason to suspect that a substance presents a risk to human health or the environment (e.g. because of its structural similarity to another substance). Therefore, all registration dossiers submitted for a substance are examined together and any other available information is taken into account.

An overview of the dossier and substance evaluation processes is given in Figure 10.

Evaluation decisions may be addressed to any registrant, or in the case of examining testing proposals under dossier evaluation to a downstream user, of a substance who has not informed the Agency that he stopped manufacture or import of that substance. In the latter case he shall generally no longer be responsible for generating additional information. A decision to stop manufacture or import of a substance can still be taken after receipt of a draft decision requiring further information. However, if there is a potential long-term risk to man or the environment and the exposure to that substance contributes significantly to that risk, the registrant shall remain responsible for providing additional information, even if they ceased manufacture, import or use of the substance.

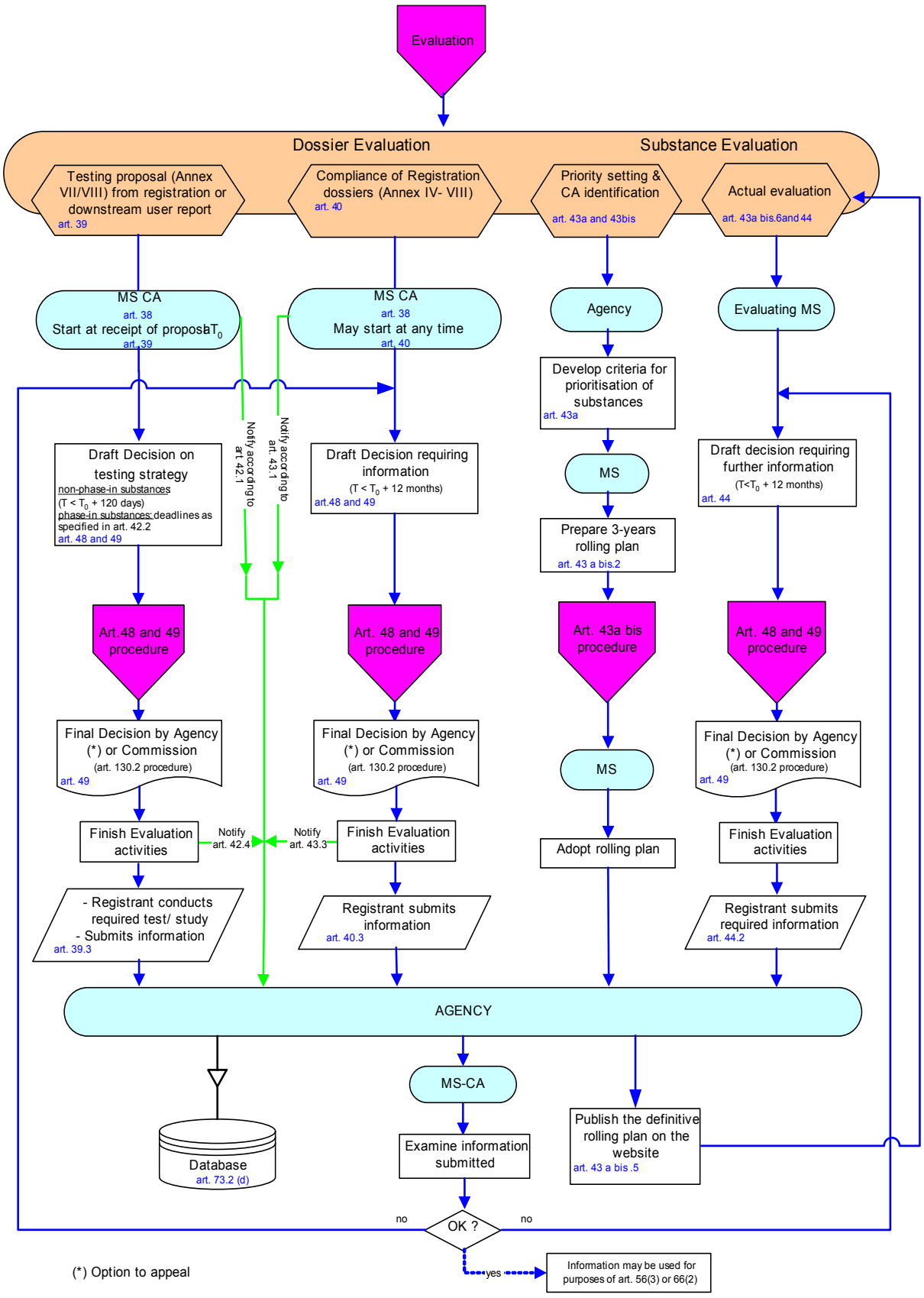

Fig. 10. Overview of the evaluation processes

6.1. Dossier Evaluation (Art. 38 to 43)

6.1.1. Competent Authority and its tasks (Art. 38, 39, 40)

The competent authority of a dossier evaluation, shall be the competent authority of the Member State in which the manufacture takes place or where the importer is established. This will help to avoid language and communication problems. Where a consortium has been formed for the purpose of registration (see Chapter 3.7), the competent authority shall be the competent authority in the Member State in which the member of the consortium submitting data to the Agency on behalf of the others is established.

The competent authority shall check all dossiers containing testing proposals (thus, usually dossiers for substances in quantities of 100 tonnes or more per year) and may check the compliance of any technical dossier with the requirements of the Regulation and shall draft decisions requesting information from registrants and, rarely, from downstream users in case of evaluation of testing proposals. These decisions will be taken either by the Agency or by the Commission (see Chapter 6.3).

6.1.2. Examination of testing proposals (Art. 39)

All proposals for tests specified in Annexes VII and VIII, which will be submitted as part of registrations, or occasionally in downstream user reports[25] (see Chapter 5.3), will have to be examined in dossier evaluation. Annexes VII and VIII contain the most costly tests and require the greatest number of vertebrate animals to be used, therefore unnecessary tests must be avoided, and such tests that need to be performed are done so under conditions which are not called into question afterwards.

As a result of the examination, the competent authority drafts one of the following decisions:

a) a decision requiring the concerned registrant(s) or DU(s) to carry out the proposed test(s) and to submit a summary of their results or a robust study summary, if required by Annex I, within a set deadline;

b) a decision similar to a) but requiring that the proposed test shall be carried out under modified conditions; or

c) a decision rejecting the testing proposal.

The final decision will be taken following the procedure described in Chapter 6.3.

For new substances the authorities shall draft their decisions within 120 days of receipt of the dossier.

For phase-in substances the authorities shall draft their decisions regarding proposals in registration dossiers for substances,

[25] A downstream user might need to propose a test if his use is not an identified use and he considers this test necessary to complete his CSA, see above

in quantities of 1000 tonnes or more per year:	within 5 years of the entry into force of the Regulation,
in quantities of 100 tonnes or more per year:	within 9 years of the entry into force of the Regulation,
for other proposals:	after the deadlines after nine years

The competent authority shall notify the start and end of the examination of the testing proposals to the Agency.

If no decision is drafted within the deadlines set in the proposal, the Commission may start infringement proceedings against the Member States concerned.

6.1.3. Compliance check (Art. 40)

At the same time as testing proposals are examined or completely independent from this examination, the competent authorities may also check that the information in any technical dossier is in compliance with the requirements of the regulation, i.e. that

(a) the information in the technical dossier(s) complies with the requirements of Art. 9, 11 and 12 and with Annexes IV to VIII;

(b) the adaptations of the standard information requirements and the related justifications submitted in the technical dossier(s) comply with the rules governing such adaptations set out in Annexes V to VIII and with the general rules set out in Annex IX.

If the information in the technical dossier does not comply with the requirements, the authority will draft a decision requiring the registrant to submit any information necessary to bring the registration into compliance with the requirements within a set deadline.

The final decision will be taken following the procedure described in Chapter 6.3.

6.2. Substance evaluation (Art. 43 a to 46)

6.2.1. Competent Authority and its tasks (Art. 43 a, 43 a bis, 44)

Substance evaluation aims at clarifying whether a suspicion of a risk to human health or the environment is justified. Substance evaluation may be carried out on any registered substance. All registration dossiers submitted for that particular substance, and any other available information, need to be examined. Therefore, the work will need to be divided between the competent authorities of the Member States on a substance by substance basis.

Each Member State will have to include substances which it proposes to evaluate in a draft rolling plan. The draft rolling plan shall cover a 3 year period and shall be updated annually. The procedure for the final adoption of these plans is described below under Chapter 6.2.1.2. The competent authority shall be the competent authority of the Member State that has included the substance in its definitive rolling plan.

Each Member State competent authority will have to evaluate all substances which are included in its definitive rolling plan within 12 months from the date fixed in the plan and draft any decisions requesting further information needed to clarify the suspicion of risks within this time.

6.2.1.1. Conditions (Art. 43 a, 43 a bis)

Member States are only allowed to select a substance for evaluation and to include it in its draft rolling plan, if they have reasons for suspecting that the substance presents a risk to health or the environment. This may arise because of a structural similarity of the substance with known substances of concern or with substances which are persistent and liable to bio-accumulate, that suggests that the substance under suspicion, or one or more of its transformation products, has properties of concern or is persistent and liable to bio-accumulate. The suspicion may also arise from aggregated tonnage from the registrations submitted by several registrants.

Member States selecting substances to be included in the draft rolling plans, will have to apply the criteria for prioritisation developed by the Agency. These criteria will be risk-based and take into account the available information on hazard, tonnage and potential exposure.

6.2.1.2. Procedure to develop Rolling Plans (Art. 43 a bis)

A specific allocation mechanism is foreseen where more than one Member State plans to evaluate the same substance. This is to avoid duplication of work and to encourage swifter evaluation of the substance concerned.

This allocation mechanism will work as follows (see also Figure 11):

a. *Each Member State submits its draft rolling plan to the Agency and the other Member States by 28 February each year. The Agency may comment on it and Member States may send their comments to the Agency or express their interest in evaluating a substance included in a draft rolling plan of another Member State by 31 March of each year.*

b. *When no comments are received or no other Member State has expressed an interest in any of the substances it wants to evaluate, the Member State adopts this rolling plan as its definitive rolling plan.*

c. *When two or more Member States have included the same substance in their draft rolling plans or, after submission of the rolling plans, have expressed an interest in evaluating the same substance, the Agency shall refer the matter to the Member State Committee, to agree which shall be the competent authority. In its discussion the Committee will take into account the principle that the allocation of substances among Member States shall reflect their proportion of the total Community gross domestic product. For efficiency reasons, priority needs to be given to Member States that have already performed dossier evaluations of the substance in question.*

d. *If, within 60 days of the referral, the Member State Committee reaches unanimous agreement, the Member States concerned adopt their definitive rolling plans accordingly.*

e. *If the Committee fails to reach a unanimous agreement, the Agency submits the conflicting opinions to the Commission, which shall decide which authority shall be the competent authority, in accordance with the regulatory comitology procedure referred to in Art. 130 (3). The Member States shall adopt their definitive rolling plans accordingly.*

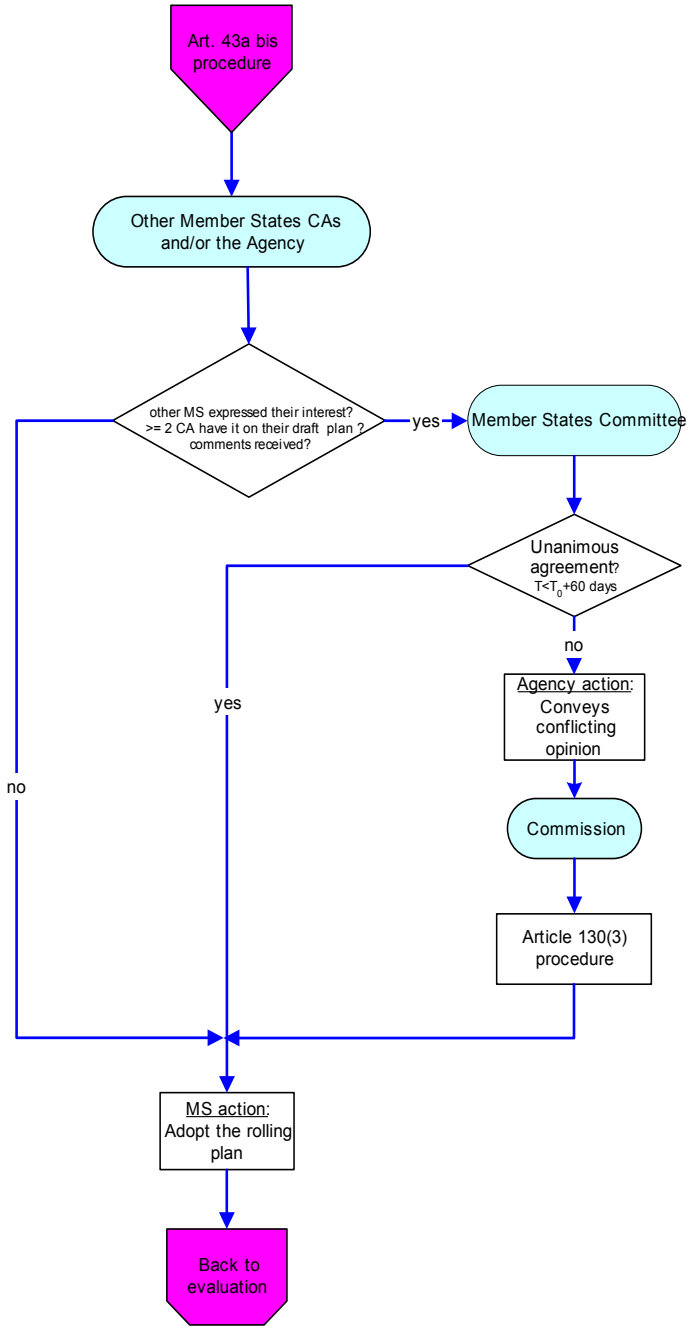

Fig. 11. Decision procedure for adoption of MS rolling plans

The competent authority shall be the competent authority of the Member State that has included the substance in its definitive rolling plan. The Agency will publish the

definitive rolling plans on its website as well as information on the progress made with substance evaluations[26].

6.3. Performance of Substance evaluation and request for further information (Art. 44)

Substance evaluation is the means to ask registrants in justified circumstances for further information which is needed to clarify a suspicion of risk to health or the environment. The request for information may be related to any aspect of the technical dossiers and/or the chemical safety reports of the dossiers registered for that substance.

Substance evaluations shall be based on any previous dossier or substance evaluations performed under REACH. Any decision requiring further information may therefore be justified only by a change of circumstances or acquired knowledge. Each draft decision needs to state the reasons for its request for information.

The draft decision will be taken following the procedure described in Chapter 6.3.

Any draft decision needs to be prepared within 12 months of the publication of the rolling plan on the Agency's website.

To ensure a harmonised approach to requests for further information, the Agency has the task to monitor draft decisions taken by the competent authorities and shall develop criteria and priorities.

6.4. Procedure to take decisions requiring (further) information (Art. 48, 49)

After having given the registrants or downstream users concerned the opportunity to comment on the draft decision, the decision-taking procedure under evaluation starts with a written procedure involving the Agency and all Member States so that in case of an agreement the decision can be taken quickly. In case of disagreement, the Agency's Member State Committee provides a technical forum to resolve differences. Only in cases where disagreements cannot be solved in this Agency Committee, the matter is referred to the Commission to take a decision in the comitology procedure. Figure 12 provides an overview of the decision procedures for evaluation.

In more detail, the procedure is as follows:

a. *A Member State competent authority prepares the draft decision on the testing proposal, requiring information necessary for compliance of the registration with the Regulation or requiring further information to clarify a suspicion of risks and communicates it to the registrant, or the DU, allowing him 30 days to provide comments. The authority examines all comments by the registrants or DUs and, if appropriate, amends the draft decision accordingly.*

[26] Art. 73 (2) (e)

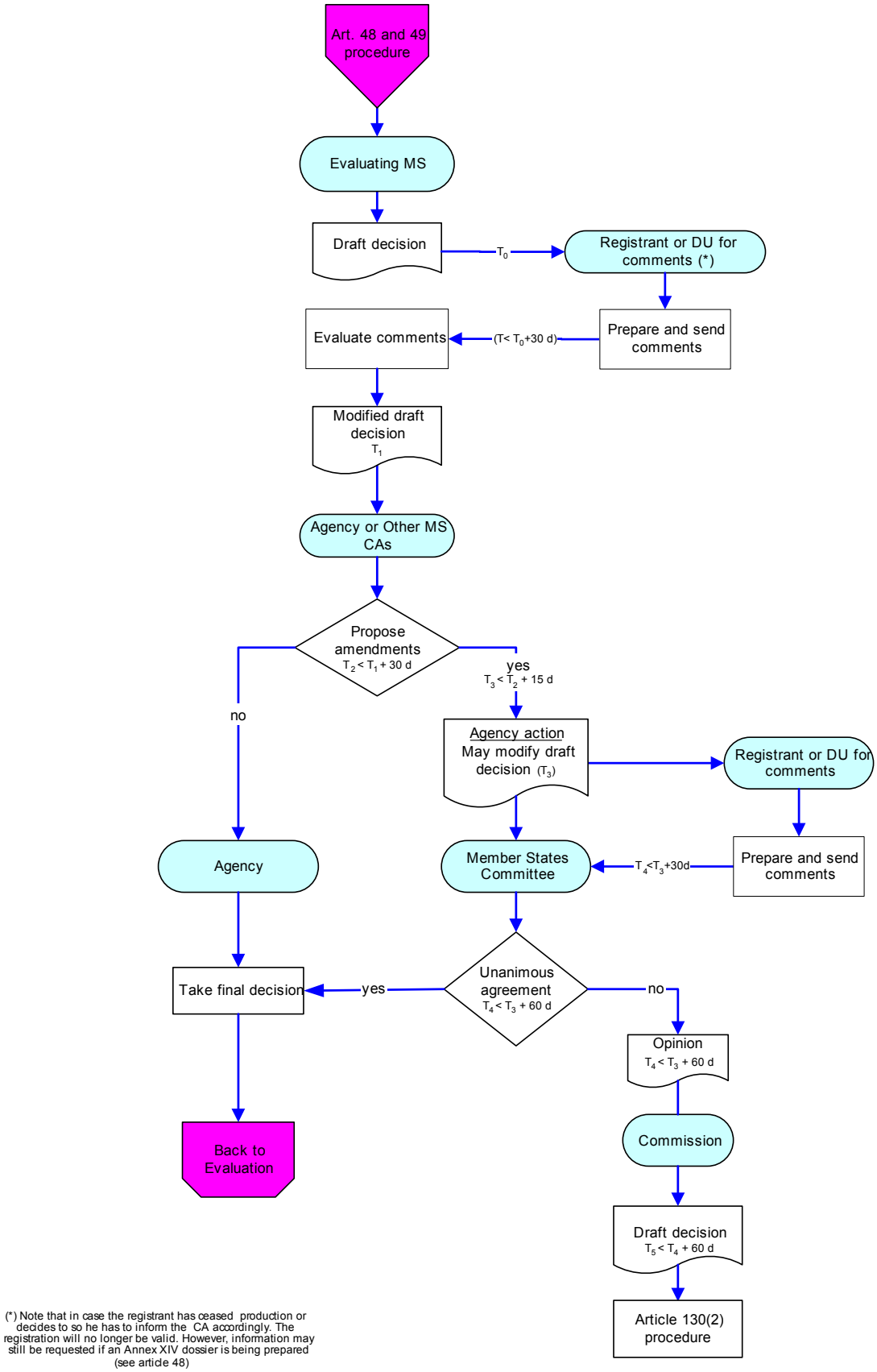

Fig. 12. Decision procedures for evaluation

b. The competent authority then notifies its draft decision together with any comments and a specification how these have been taken into account, to the Agency, which circulates it all to the other Member State Competent Authorities.

c. Member States' competent authorities as well as the Agency may propose amendments to the draft decision within 30 days. In case no one provides any comments, the Agency takes the decision as drafted by the Competent Authority and communicates it to the registrant or downstream user addressed.

d. If the Agency receives a proposal for amendment or has made such a proposal itself, it may modify the draft decision. In particular in respect of tests required to be performed according to testing proposals, this step in the procedure enables the competent authorities and the Agency to avoid duplicate testing by co-ordinating the selection of one registrant to perform a test on behalf of other registrants for the same substance, if no common testing proposal was submitted. If comments have been received, the Agency refers the matter to the Member State Committee within 15 days from the end of the period for comments. In addition, the Agency communicates any proposal for amendments of the draft decision to the registrant(s) or DU allowing them to comment within 30 days. The MS Committee shall take into account any comments received within that deadline.

e. If within 60 days from the referral the MS Committee reaches a unanimous agreement on the draft decision, the Agency takes the decision accordingly and communicates it to the registrants or the DU concerned.

f. In case no unanimous agreement is reached within 60 days in the MS Committee, the Agency sends the conflicting opinion of the Committee to the Commission who then within 60 days of receipt of this opinion prepares a draft decision to be taken in accordance with the advisory procedure referred to in Art. 130 (2).

6.5. Follow up for registrants (Art. 39, 40, 44, 20)

After the final decision has been taken by the Agency or the Commission, the registrants shall perform the additional testing or gather the necessary information and submit this to the Agency within the deadline specified in the decision. For IT-purposes, this would need to be in the form of an updated registration dossier.

Further testing and generation of information may lead to a change in the hazard assessment (e.g. different DNELs, PNECs and/or Classification and Labelling) of the substance and therefore also the C&L and Chemical Safety Report may need to be adapted and the registration or notification to the C&L inventory updated.

If a registrant or downstream user performs a test on behalf of others, he shall provide each of the others concerned with a copy of the test. All registrants shall share the cost of that study equally.

6.6. Follow up for authorities (Art. 41 and 46)

The competent authority that drafted the decision shall examine the submitted information and if necessary draft a further decision requiring further information.

Evaluation may lead authorities to the conclusion that action needs to be taken under the restrictions or authorisation procedures in REACH, or that information needs to be passed to those authorities managing other Community legislation.

6.7. Evaluation of polymers (Art. 37) and of on site isolated intermediates (Art. 47)

Polymers are exempted from the evaluation procedure as all other substances for which there is no obligation to register. However, the provision on polymers might be reviewed in future (Art. 133 (2)).

For on-site isolated intermediates a risk equivalent to the level of concern arising from the use of substances that may be subjected to authorisation needs to be demonstrated (see Chapter 7.1), to justify a request for further information related to that risk. The CA of the Member State on which territory the site is located, shall examine all submitted information and may decide to take any appropriate risk reduction measures to address the risk.

7. AUTHORISATION (ART. 52 TO 63)

The REACH proposal sets up a system under which the use of substances with properties of very high concern and their placing on the market can be made subject to an authorisation requirement.

This authorisation requirement ensures that risks from the use of such substances are either adequately controlled or justified by socio-economic grounds, having taken into account the available information on alternative substances or processes.

The substances selected for the authorisation system have hazardous properties of such very high concern that the Community needs to decide about the adequacy of the control of risks arising from their uses or about the socio-economic benefits of the uses of such substances that justify risks arising from their use:

Category 1 and 2 CMR substances have effects on humans which are generally so serious and cannot normally be reversed, and PBT and vPvB substances accumulate in living organisms, which cannot normally be reversed, either. To provide a security net, other substances with serious and irreversible effects of an equivalent level of concern as the CMR, PBT and vPvB substances, can be identified on a case-by-case basis. This could for example be endocrine disrupters which are not already covered by the CMR criteria.

The authorisation provisions require those using or making available substances with properties of very high concern which are included into the system to apply for an authorisation for each use, regardless of the quantity of the substance used, within deadlines set by the Commission.

The burden of proof is placed on the applicant to demonstrate that the risk from the use is adequately controlled or that the socio-economic benefits outweigh the risks. In the latter case, applicants need to submit a substitution plan along with a socio-economic analysis.

The Agency, via its Committees for Risk Assessment and Socio-economic Analysis provides opinions on the applications, which the Commission will use for its decisions on applications.

In particular the Authorisation process ensures that:

- the burden of proof to demonstrate that the risk from the use is adequately controlled or that the socio-economic benefits outweigh the risks are placed on the applicants for authorisation.
- the Commission and the MS authorities can monitor the progress;
- the Commission, the MS authorities and industry can focus their resources by starting with those substances that are considered to pose the greatest current risk and to deliver the 'Highest Expected Regulatory Outcome' (Hero).

7.1. Substances subject to authorisation (Art. 54)

Substances of very high concern which may be included in the Annex XIII, and for which thereby the authorisation requirement will be established, are substances with the following properties:

(a) substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction (categories 1 or 2) according to the criteria of Directive 67/548/EEC;

(b) substances which are persistent, bioaccumulative and toxic (PBT) or which are very persistent and very bioaccumulative (vPvB) in accordance with the criteria of Annex XII;

(c) substances, such as those having endocrine disrupting properties, or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of Annex XII but which are identified as causing serious and irreversible effects to humans or the environment which are equivalent to those of other substances listed under (a) or (b) on a case-by-case basis.

Persistent organic pollutants (POPs) are vPvB-substances and are therefore substances that would be subjected to authorisation. However, the Stockholm Convention and the United Nations Economic Committee for Europe (UNECE) Protocol have banned the manufacture, use and placing on the market of a list of these substances (with only a few exemptions). These banned substances will not be made subject to the authorisation system as an authorisation would never be granted for the use of these substances and exemptions allowed under the Convention/Protocol are only for a limited time. The international rules are therefore implemented under the restrictions in Annex XVII.

7.2. Procedure to include substances into the authorisation system

The procedure to include substances into the authorisation system consists of three steps: the identification of the properties of the substances, the prioritisation of substances with identified properties and their inclusion in Annex XIII (see Figure 13 for an overview of these processes).

7.2.1. Identification of substances of very high concern (Art. 56)

The criteria to identify category 1 and 2 CMR substances are set out in Annex VI of Directive 67/548.

For PBT substances and vPvB substances no classification and labelling rules exist. Annex XII defines criteria for these substances for the first time in Community legislation. Therefore, for these substances, as well as for other substances with serious and irreversible effects, unanimous agreement has to be reached in the Agency's Member State Committee before they may be prioritised for inclusion in Annex XIII.

This identification procedure consists of the following steps:

1. *A Member State or the Agency, on request by the Commission, prepares a dossier in which it provides the argumentation why a substance is a PBT or a vPvB or why it causes serious and irreversible effects to human health or the environment which are of equivalent concern as category 1 and 2 CMR or the PBT and vPvB substances. This dossier needs to follow the format in Annex XIV, and Member States need to send it to the Agency.*
2. *The Agency distributes the dossier to the other Member States.*
3. *Within 30 days of the date of circulation the other Member States can send their comments on the identification of the substance in the dossier to the Agency; the Agency may also provide comments.*
4. *If no comments are received, the Agency may include the substance in its recommendations on priority substances to the Commission for inclusion into Annex XIII (see 7.2.3.).*
5. *If (other) Member States send in comments, the Agency will forward the dossier to the Member States Committee within 15 days after expiry of the 30 days commenting period. The Agency may also decide on its own initiative to send the dossier to this committee within the same deadline.*
6. *If the Member State Committee reaches unanimous agreement within 30 days, the Agency may include the substance in its recommendations on priority substances to the Commission for inclusion into Annex XIII.*
7. *When the Member State Committee does not reach unanimous agreement, it will adopt an opinion on the issue within 30 days.*
8. *The Agency submits this opinion including information on any minority view to the Commission.*

All substances identified in this procedure will form a group of substances, together with the category 1 and 2 CMR substances, from which the Agency will select priority substances for inclusion into the authorisation system.

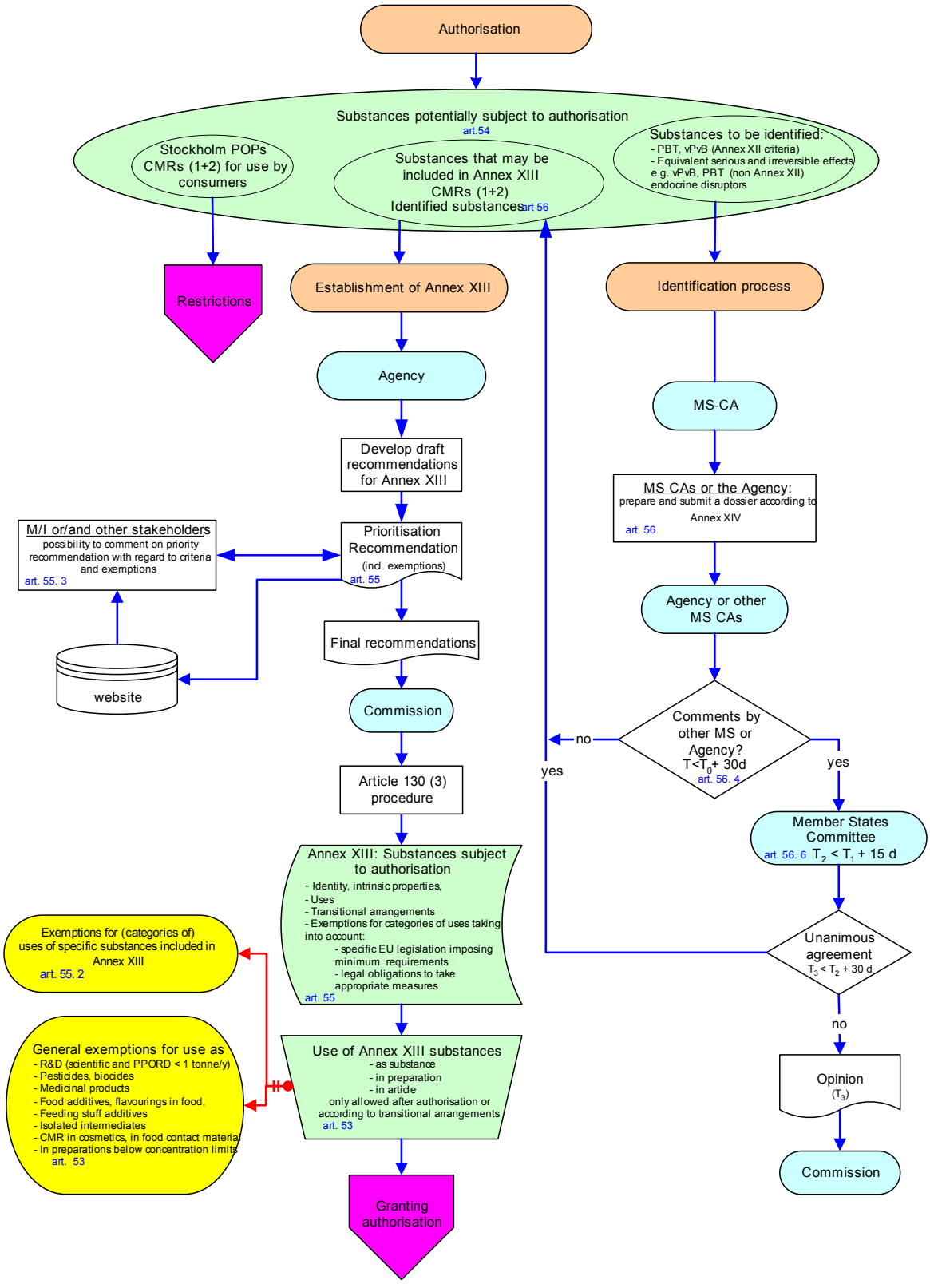

Fig. 13. Substance identification and establishment of Annex XIII

7.2.1.1. Prioritisation of substances with identified properties of very high concern (Art. 55 (3) and (4))

As the number of substances with identified defined properties is expected to be quite high, it is necessary to prioritise the progressive inclusion of identified substances into the system, to avoid overloading it.

Priority shall be given to substances with PBT or vPvB properties, wide dispersive use or high volumes.

The Agency shall prepare a recommendation for a list of priority substances for inclusion on Annex XIII. This list needs to specify the details that will be included in Annex XIII. It will specify the resource implications for the Agency to handle the applications for authorisation after the inclusion of the substances in the Annex. The list will be the technical basis for the decision to include substances in the Annex.

The Agency will make its recommendations available on its website and will invite all interested parties to submit comments within 3 months from publication, in particular on whether the substances have PBT, vPvB properties or cause other serious and irreversible effects to human health or the environment of equivalent concern (Art. 54 (d), (e) and (f)) and on uses to be exempted from the authorisation requirement in Annex XIII when the substance is included in the system. See further details on exemptions in Chapter 7.2.2.

The Agency will update its recommendations to take into account the comments and then send them to the Commission.

7.2.2. Inclusion in Annex XIII (Art. 55 (1) and (2))

The decision to include substances in Annex XIII is taken by the Commission in the regulatory comitology procedure in Article 130(3). The decision needs to take into account the resources available for considering applications for authorisation.

For each substance, it will be specified in the Annex:

a) the identity of the substance

b) the identified properties which make the substance subject to the authorisation

c) transitional arrangements for substances which are already being used or placed on the market:

   - "the sunset date", i.e. the date from which the placing on the market and the uses of the substance are prohibited without an authorisation,

   - an application date, at least 18 months before the sunset date: uses of the substances applied for until this date will be allowed to be continued until a decision will be taken, even after the sunset date.

d) review periods, if appropriate;

e) exemptions of uses or categories of uses and conditions for these exemptions, if necessary. For these exemptions account shall be taken of existing specific Community legislation imposing minimum requirements relating to the protection of health or the environment such as binding occupational exposure limits or emission limits, and of existing legal obligations to take appropriate technical and management measures.

This allows the authorisation process to concentrate on the uses of substances that are likely to pose the greatest risk rather than devoting resources to considering uses that are known to be adequately controlled and corresponds to the principle of proportionality. If as a result of information gained under REACH, or of developing Community legislation, further uses are justified to be exempt from the authorisation requirement, such exempted uses can be added to Annex XIII at a later stage following the regulatory comitology procedure according to Article 130 (3) of the Regulation.

7.2.3. Relationship between authorisation and restrictions (Art. 55 (5) and (6))

Prior to being placed on Annex XIII, any substance subject to authorisation may be subject to the restrictions process as there may be risks that need to be addressed at Community level in advance of any decision to include a substance into the authorisation system.

Once a substance is included in Annex XIII, it may not be restricted by inclusion in Annex XVI or XVII covering the risks to human health and the environment from the use of the substance arising from the properties specified in Annex XIII. However, restrictions of uses because of risks to human health and the environment from other properties can be included in the restriction Annexes. These restrictions will then prevent that an authorisation for that restricted use is granted by the Commission.

Substances for which all uses are prohibited, as well as consumer use of CMR substances, shall be banned through the restrictions process.

7.3. The authorisation requirement for uses of substances included in Annex XIII (Art. 53)

7.3.1. General Rule

Substances which are included in Annex XIII shall not be used or placed on the market by any manufacturer, importer or downstream user for any use of the substance on its own, in a preparation or the incorporation into an article if this use has not been authorised.

7.3.2. Exemptions

This general rule does not apply to

- the use of substances in preparations, if they are present in the preparation
  - below the concentration limits in Directive 1999/45/EC, so that the preparation would not have to be classified as dangerous; and
  - below 0,1 % for all substances for which classification rules do not apply;
- specific uses of the substances which are exempted from the authorisation requirement in Annex XIII itself (Art. 55 (2));
- the use of substances in scientific research and development or in product and process-orientated research and development in quantities up to 1 tonne per year;
- the use of a substance by a downstream user if an authorisation was granted for this use to his supplier;

- uses of substances which are generally exempted from the authorisation requirement in Art. 53 (5):
  - uses in plant protection products[27];
  - uses in biocidal products[28];
  - uses as medicinal products for human or veterinary use[29];
  - uses as food additives[30];
  - uses as additives in animal feeding stuffs[31];
  - uses as flavourings in foodstuffs[32];
  - uses as an on site isolated intermediate or as a transported isolated intermediate;
  - use as motor fuels[33];
  - uses as fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems.
  - uses in cosmetic products[34] and in food contact materials[35] for CMR substances, as the risks to human health are already regulated under sector specific Community legislation. However, if a PBT, vPvB substance or a substance of equivalent concern is included in Annex XIII, its use in cosmetic products or in food contact material, needs to be authorised as risks to the environment are not regulated in the specific legislation.

7.4. Application for authorisations (Art. 59)

Applicants need to submit their application dossiers to the Agency for the use(s) of substances which are included in Annex XIII. To make the process as efficient as possible and to allow the burden sharing between a number of applicants, applications may be made by one or more applicants, for one or more substances (the grouping of substances needs to be justified in the application), and for one or more uses of each of the substances. The uses applied for can be for the applicants' own uses and uses by their downstream users.

The application dossier needs to include the identity of the substance(s) and of the applicants, the request for authorisation, specifying for which use(s) the authorisation is sought (including the use of the substance in formulating preparations and/or the incorporation of the substance in articles, where this is relevant) and a chemical safety

---

27 within the scope of Council Directive 91/414/EEC , OJ L 230, 19.08.1991, p.1

28 within the scope of Directive 98/8/EC of the European Parliament and of the Council OJ L 123, 24.04.1998, p. 1

29 within the scope of Council Regulation 2309/93 (OJ L 214, 24.08.1993, p. 1), Directives 2001/82 (OJ L 311 , 28.11.2001, p. 1) and 2001/83 (OJ L 311, 28.11.2001), p. 67 of the European Parliament and of the Council

30 within the scope of Council Directive 89/107/EEC (OJ L 040, 11.02.1989, p. 27)

31 within the scope of Council Directive 70/524/EEC (OJ L 270, 14.12.1970, p. 1)

32 within the scope of Commission Decision 1999/217/EC

33 covered by Directive 98/70/EC

34 OJ L 262 , 27.09.1976, p. 169

35 Council Directive 89/109/EEC

report in accordance with Annex I, unless it has already been submitted as part of the registration for a registered substance in quantities of 10 tonnes or more per year. The chemical safety assessment for an authorisation only needs to address the properties that led to an authorisation being required as specified in Annex XIII: CMR, PBT, vPvB or other and the risks arising from the use of the substance due to these properties.

In cases where the applicant cannot demonstrate, or is not confident that he will succeed in demonstrating, to the Commission that the risks of the use of the substance are adequately controlled, he may decide to include also a socio-economic analysis, conducted in accordance with Annex XV. He may also include an analysis of the alternatives considering their risks and the technical and economic feasibility of substitution, where appropriate accompanied by a substitution plan, including research and development and a timetable for proposed actions.

The application for an authorisation needs to be accompanied by the fee as set by the Agency.

The application shall not address risks to human health and/or the environment of emissions of the substance from an installation for which a permit was granted in accordance with the IPPC Directive[36] or from a point source governed by requirement for prior regulation under the Water Framework Directive[37] or arising from the use in a medical device[38]. These emissions are adequately controlled under other Community instruments which are applied by the Member States' authorities. Interference with these Member State competences must be avoided as well as duplicate work by examining an impact twice.

If an application has already been made for a use, a subsequent applicant does not have to provide all information as described above again. He may refer to the chemical safety report, the socio-economic analysis and/or the analysis of the alternatives, which were submitted by the previous applicant, provided the subsequent applicant can show a letter of access granted to him by the previous applicant. The same applies in case of an authorisation which has already been granted, if the holder of the authorisation grants a letter of access to a subsequent applicant (Art. 60).

7.5. Granting of Authorisations (Art. 57)

7.5.1. Competent authority (Art. 57 (1))

The Commission will be responsible for granting or denying authorisations.

7.5.2. Conditions for granting of authorisations (Art. 57 (2) and (3))

The Commission shall grant an authorisation for a use if the applicant demonstrates that the risks to human health and the environment arising from the use of the substance are adequately controlled.

The Commission may grant an authorisation if the applicant cannot demonstrate that the risks are adequately controlled but the socio-economic benefits outweigh the risks

36 Directive 96/61/EC

37 Directive 2000/60/EC

38 Council Directive 90/385/EEC, Council Directive 93/42/EEC or Directive 98/79/EC of the European Parliament and of the Council

to human health and the environment after having taken into account alternative substances or technologies. In this case alternatives will be carefully analysed. If the use poses a high risk and a suitable alternative (taking into account cost, availability, and efficacy and risks of the alternative) is available, this will be a key consideration for the authorisation decision and unless there are other considerations, it is unlikely an authorisation will be granted.

An authorisation can never be granted for a use which is not allowed under the restrictions in Annexes XVI and XVII. An example is if consumer use of a CMR substance is restricted in Annex XVI, and this substance is included in Annex XIII, an authorisation for consumer use of this substance will always be refused.

7.5.3. Procedure (Art. 61)

Applications for authorisation will be examined by the Agency who will provide an opinion on the risks arising from the use of the substance and, if relevant, on the socio-economic factors associated with this use. The Agency's opinion(s) will form the scientific basis for the Commission's decision as to whether to grant or deny the authorisation.

The procedure is summarised in Figure 14 and will consist of the following steps:

1. *On receipt of the application dossier, the Agency communicates the date of receipt to the applicant.*
2. *The Agency will place the non-confidential information on the identity of the substance and the use(s) applied for on its website. This is done to enable other interested parties within a set deadline to make the Agency aware of alternative substances or processes that may be less harmful to human health and the environment.*
3. *The Agency's Committees for Risk Assessment and Socio-Economic Analysis will check whether the application dossier contains all required information and if necessary will ask the applicant for additional information.*
4. *The Committee on Risk Assessment and, in case a socio-economic analysis is provided, the Committee on Socio-economic Assessment, will prepare a draft opinion. This draft opinion shall take account of the information submitted by the applicant as well as any other available information.*
5. *Within 10 months of the date of receipt of the dossier, the Agency will send the draft opinion(s) to the applicant.*
6. *Within 1 month of receipt to the draft opinion(s)[39], the applicant may inform the Agency in writing that he wishes to comment on the draft opinion.*
7. *If the applicant wishes to comment, he shall send these comments to the Agency within 2 months of receipt of the draft opinion(s).*
8. *If the applicant does not comment or informs the Agency that he does not intend to comment, the Agency adopt its opinion(s) and sends them to the Commission, the Member States and the applicant within 15 days after the deadline for commenting or after receipt of the notice of the applicant that he does not intend to comment.*

[39] *deemed to have occurred 7 days after the Agency has sent it*

9. *When comments are received, the Committees of the Agency shall consider these and shall adopt their final opinion within 2 months of receipt of the comments. The adopted opinion(s), with the comments from the applicant attached, will be sent to the Commission, the Member States and the applicant within a further 15 days.*
10. *The Agency will make the non-confidential parts of its opinions and any attachments thereto publicly available on its website.*
11. *Within 3 months of receipt of the Agency's opinions, the Commission shall prepare a draft authorisation decision. The Commission takes the decision granting or refusing the authorisation in the advisory committee procedure according to Art. 130 (2).*
12. *The Agency will make publicly available on its website the summaries of the final Commission decisions, including the authorisation numbers, as published in the Official Journal.*

7.5.4. Authorisation Decisions (Art. 57 (7))

Any authorisation decision shall specify the person(s) to whom the authorisation is granted, the identity of the substance(s), the use(s) for which the authorisation is granted and its conditions. This is important for the holder of the authorisation and also for their downstream users as they all have to apply these conditions set out in the authorisation.

Authorisations may also specify review period and/or monitoring arrangements. Authorisations granted for socio-economic reasons shall normally be time-limited. Thus, if such an authorisation is granted for an unlimited time, this has to be justified.

It is important to note that authorisation decisions are taken after consideration of the risks, from the use(s) of a substance, to human health and the environment, from the hazardous properties that lead to the substance being included in Annex XIII.

In its decision the Commission shall not consider the risks to human health and the environment of emissions of the substance from an installation for which a permit was granted according to the IPPC Directive[40] and the risks to and via the aquatic environment of discharges of the substance from a point source for which is a priory regulated under the Water framework Directive[41] and the risks to human health arising from the use of the substance in a medical device[42] as the risks are examined and managed by Member State authorities under specific Community legislation.

40 Directive 96/61/EC
41 Directive 2000/60/EC
42 Directives 90/385, 93/42, 98/79

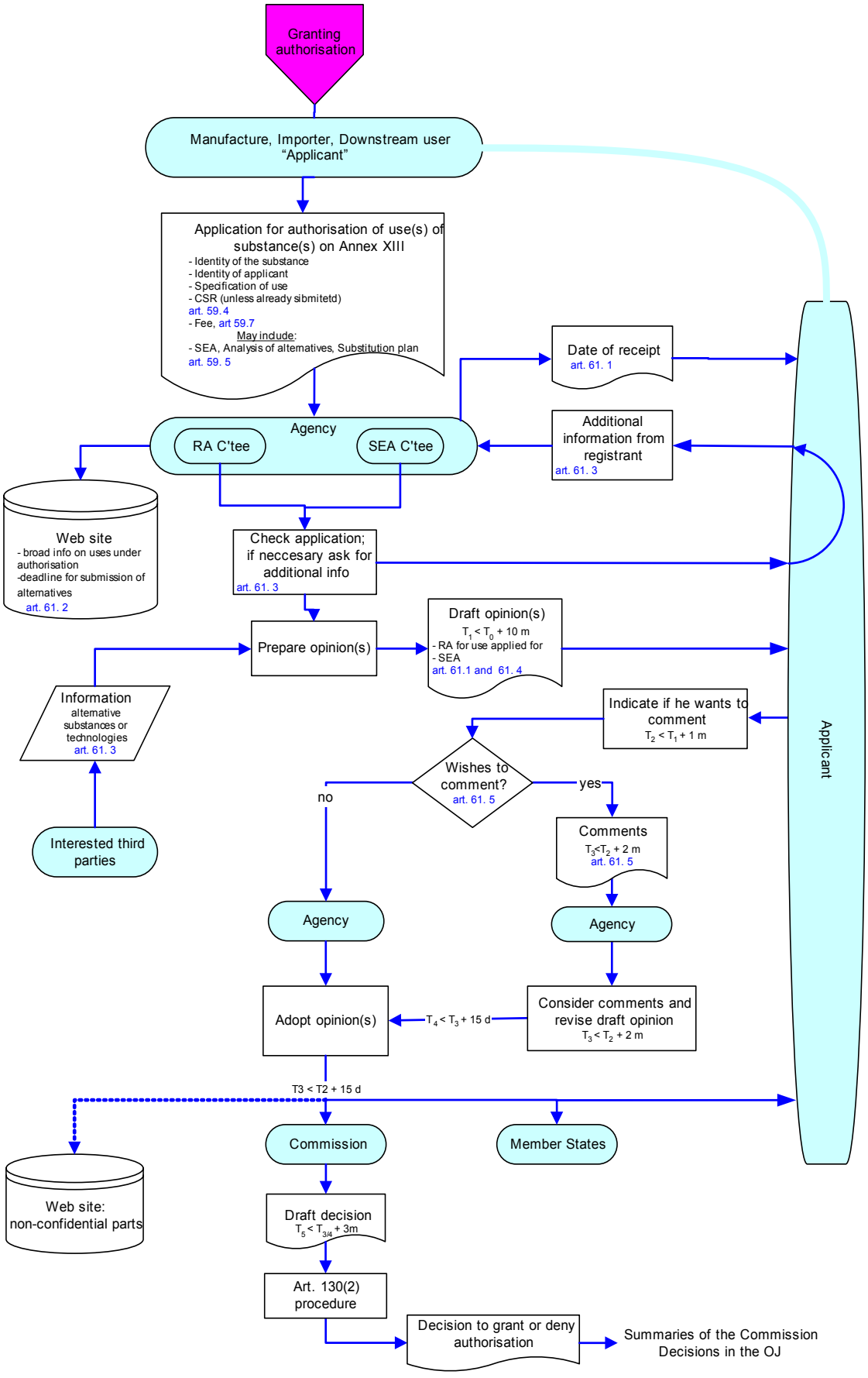

Fig. 14. Granting of authorisations

7.6. Obligations for holders of authorisations (Art. 57 (8), 62)

Notwithstanding the conditions of an authorisation, the holder of the authorisation shall ensure that the level of exposure is reduced to as low as is technically possible.

The holder of an authorisation shall include the authorisation number on the label before he places the substance on the market.

7.7. Review of authorisation decisions (Art. 58)

A time-limited authorisation expires without further decision by the Commission at the end of the time limit, unless the holder of the authorisation has submitted a new application 18 months before the end of the time-limit.

Other decisions may be reviewed at any time if the circumstances under which they were granted have changed. Such a change of circumstances may be for example a change in the scientific basis for an authorisation decision or that environmental quality objectives as defined under the IPPC Directive or Water Framework Directive are not met because of diffuse emissions to water or the air.

As a result of a review, subject to the setting of deadlines for the holder of the authorisation to update his case, authorisation decisions may be amended or if the use of the substance is subsequently prohibited in annex XVII, even withdrawn.

8. RESTRICTIONS (ART. 64 TO 70)

The restrictions procedure is a safety net for substances posing an unacceptable risk to human health or the environment arising from its manufacture, use or placing on the market, which need to be addressed on a Community wide basis.

The basis of the demonstration of the unacceptable risk to human health or the environment on a Community wide basis, will be a risk assessment. This will be different from the CSR of the individual dossiers as they usually won't deal with regional 'exposure', aggregate volumes, and multiple exposures

A restriction of a substance is any condition for, or prohibition of, its manufacture, use or placing on the market. Restrictions enable risk management measures beyond those already implemented by manufacturers, importers and downstream users, to be introduced across the Community where they are shown to be necessary. Restrictions can also impose a harmonised level of risk management measures. Restrictions apply to all manufacturers, importers, downstream users and distributors of a substance if the manufacture, use or placing on the market (activity) of this substance is included in Annex XVI or XVII.

The REACH proposal distinguishes two Annexes containing the restrictions: Annex XVII contains all restrictions for persistent organic pollutants agreed internationally in the Stockholm Convention and the UNECE Protocol and Annex XVI contains all other restrictions including a consolidation of the restrictions contained in Directive 76/769/EC.

Activities with the substances not included in the Annexes are allowed, provided there is no restriction in other, sector specific Community legislation, and the substance is not subject to authorisation.

All substances on their own, in preparations or in articles may be subject to restrictions, regardless of any duty to register the substance. Restrictions apply to activities regardless of the quantity, unless the annex specifies thresholds. However, use of a restricted substance in scientific research and development, as well as product and process oriented research and development activities in quantities below 1 tonne per year, is exempted. Specifically for POPs, only laboratory scale research and the use of the substance as a reference standard are exempted.

The restrictions also do not apply to substances that are waste being treated in a waste treatment installation within the conditions of a permit.

8.1. Procedure to amend current restrictions and to introduce new restrictions

New restrictions will be based on targeted risk assessments and decisions will be taken within strict deadlines and using streamlined procedures (Chapter 8.1.1.) but restrictions for consumer use of CMR substances and the manufacture, use and placing on the market of POP substances will be subject to even quicker decisions (Chapter 8.1.2). The restriction procedures have been summarised in Figure 15.

8.1.1. The Accelerated Restrictions Procedure (Art. 65 ff)

Restrictions of the manufacture, specific use(s) or their placing on the market under this process will need to be justified by an Annex XIV dossier that will normally include a targeted risk assessment, using parts of the same format as for the CSR (Annex I).

This procedure will be applied from 18 months after the entry into force of REACH.

8.1.1.1. Initiating the procedure (Art. 66, Annex XIV)

The Commission may ask the Agency to prepare a dossier in accordance with Annex XIV to propose restrictions of manufacture, use(s) and the placing on the market of a substance on its own, in a preparation or in an article. Member States may also propose restrictions by preparing such an Annex XIV dossier.

The Commission or the Member State has to demonstrate that the manufacture, placing on the market or use of a substance on its own, in a preparation or in an article poses a risk to human health or the environment that is unacceptable and that the risk needs to be addressed at Community level.

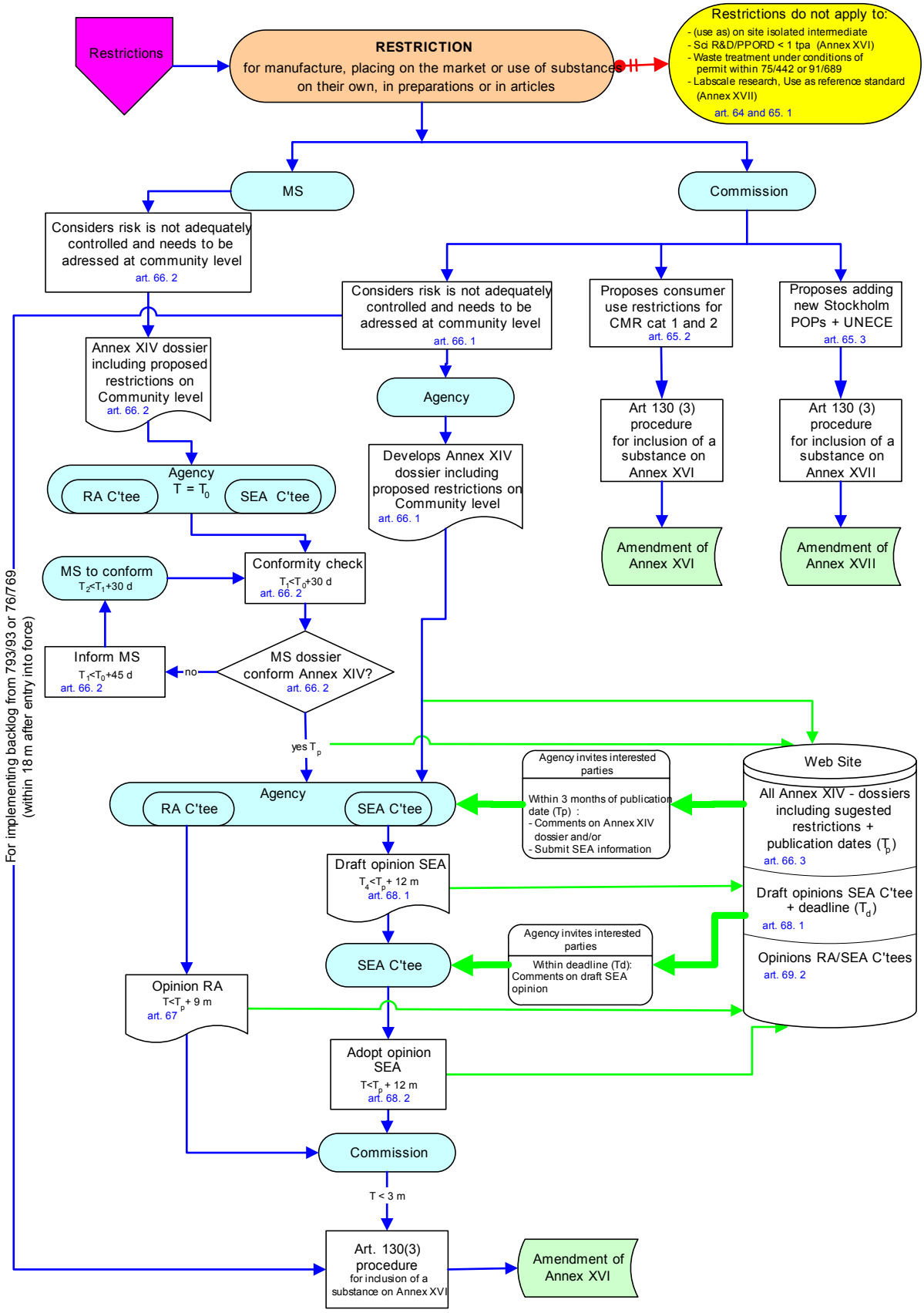

Fig. 15. Overview of the restriction process

Examples when a procedure may be initiated:

- manufacturers', importers' and downstream users' chemical safety reports recommend different risk management measures for the same activity and an acceptable standard for risk management measures needs to be identified.

- Evaluation of a substance (see Chapter 6.2) shows the need for action at Community level, e.g. when:

  - There is a significant difference in the hazard assessment made by the manufacturer/importer of a substance on its own, in preparations or in articles, concerning e.g. the selection of study of the highest concern, the classification and labelling, or the derived no-effect level.

  - There are multiple human exposure from different sources, e.g. simultaneous exposure via: inhalation of air, water intake, food consumption, handling of preparations and/or articles releasing the substance.

- Evidence of the use of a dangerous substance in high quantities with release into the environment and/or exposure to humans indirectly via the environment.

- Evidence that risk management measures already in place, or recommended by manufacturers, or importers to be implemented by downstream users, are not sufficient for protection of human health and the environment, provided it is a Community wide issue.

Annex XIV specifies the format for any proposal to ensure that all relevant information will be available for those taking the decision. This will help avoid unnecessary delays in the procedure. A dossier will comprise of four parts:

- a proposal for the restriction of a substance;
- its technical and scientific basis demonstrating the necessity of Community wide action beyond measures already in place (an assessment of the hazard or risk, using the methodology set out in Annex I as appropriate, and presented in the format set out in Part B of that Annex I. This is to ensure consistency between any Chemical Safety Reports and the Annex XIV dossier);
- a justification for action at community level; and
- other information.

In addition, the dossier for each proposal shall take into account any available information such as technical dossiers, chemical safety reports, other risk assessments submitted to the Agency under this Regulation or for the purposes of other Community legislation.

In developing the dossiers it is important that a dialogue with stakeholders is set up to secure the adequacy of the proposed technical solutions to the problems identified, including substitution and best available technology. Such consultations may even lead to voluntary substitution/risk reduction without initiating the restriction process.

8.1.1.2. Procedure within the Agency for dossiers submitted by Member States

Any MS dossier sent to the Agency will be checked whether it is in conformity with Annex XIV by the Risk Assessment Committee and the Socio-economic Assessment Committee.

The Agency will then inform the Member State proposing restrictions whether the dossier conforms to the requirements of Annex XIV within 30 days of receipt of the dossier. If the dossier does not conform, the reasons will be given to the Member State in writing within 45 days of receipt. The Member State then has a further 30 days to bring it into conformity otherwise the procedure will stop. The Member State may of course at any time prepare a new dossier and submit it again.

The Agency may ask Member States submitting a dossier to provide the Agency or the Commission with any or all information on which the dossier was based or to which reference is made in the dossier.

8.1.1.3. Restrictions procedure for all dossiers conforming to Annex XIV

Dossiers conforming to Annex XIV are either dossiers which the Agency has received and which the Committees have judged as conforming to Annex XIV or dossiers which the Agency itself on behalf of the Commission has prepared according to Annex XIV.

The procedure for all these dossiers conforming to Annex XIV will consist of the following steps:

1. *The Agency will without delay make the dossiers publicly available on its website, specifying the suggested restrictions and clearly indicating the date of publication. The Agency will invite all interested parties to submit individually or jointly within 3 months of that date comments on dossiers and the suggested restrictions, and a socio-economic analysis (SEA), or information which can contribute to one, of the suggested restrictions, examining the advantages and drawbacks of the proposed restrictions, in accordance with Annex XV.*

   This public consultation aims at gathering relevant information to help in the decision making process such as views on the proposed problem and solution, including information on substitution, best available technology, etc.

2. *The rapporteur of the Committee for risk assessment carries out the review of the risk assessment and prepares a draft opinion on the dossier taking into account the views of interested parties resulting from the internet consultation within nine month from the date of publication on the internet.*

3. *The rapporteur for the socio-economic analysis (SEA) Committee carries out the review of the socio-economic impact of the proposed restrictions and prepares a draft opinion on the dossier taking into account views of interested parties resulting from the internet consultation.*

4. *The Agency will publish the draft SEA Committee's opinion on its website without delay and will invite interested parties to give their comments on the draft opinion within a deadline set.*

5. *Within 12 month of the publication date of the first internet consultation the SEA committee will adopt a final opinion on the suggested restrictions - the deadline for the SEA committee to provide an opinion is longer than for the RA committee so it can take account of the opinion of the RA Committee.*

   Where the opinion of the Committee for Risk Assessment diverges significantly from the restrictions suggested by a Member State or the Agency on behalf of the Commission, the Agency may postpone the deadline for the opinion of the SEA Committee by a maximum of 90 days.

6. *The Agency will then submit the opinions of the RA and SEA committees to the Commission. If one or both of the Committees do not formulate an opinion by the deadline (12 months from the first publication on the internet, occasionally extended by 90 days), the Agency will inform the Commission accordingly, stating the reasons. The opinions of the 2 Committees will be published on its website without delay.*

7. *If there is an unacceptable risk to human health or the environment that needs to be addressed at Community level, the Commission will prepare a draft amendment to Annex XVI within 3 months of the receipt of the SEA Committee opinion. If requested by the Commission, the Agency will provide all documents and evidence submitted to, or considered by it. If the draft amendment is not in accordance with any of the opinions of the Agency, the Commission will give a detailed explanation of the reasons for any of the differences.*

8. *The Commission proposal on restricting the manufacture, marketing and/or use of a substance on its own, in a preparation or in an article, will be adopted in the regulatory comitology procedure specified in Article 130 (3).*

9. *All restrictions will be published in the Official Journal and the Agency will also publish them on its webpage.*

8.1.2. Procedure to restrict consumer use of CMR substances and the manufacture, use and placing on the market of POP substances

The restriction procedure will be more rapid for restrictions for consumer use of category 1 and 2 CMR substances and for restrictions of POPs, implementing international agreements of the Stockholm Convention and the UNECE protocol.

For these restrictions the Commission itself will initiate the procedure and draft a proposal to include these restrictions in Annex XVI or XVII. The decision will be taken by the Commission in the regulatory comitology procedure specified in Article 130 (3).

This procedure is justified because a substance meeting the criteria for classification as category 1 and 2 CMR substances is of very high concern for human health and shall not be used by consumers[43], as the risk is unacceptable as its use by consumers

[43] CMR substances category 1 or 2 can also be subjected to the authorisation procedure. Once such a substance is included in Annex XIII for other uses than for consumer use an authorisation will have to be sought

cannot be adequately controlled. Risks from Persistent Organic Pollutants (POPs) have already been scientifically identified and examined by the parties to the Stockholm Convention and the UNECE Protocol, and further examination is not required.

8.2. Transitional provisions for proposals developed under the current restriction process

Extensive work has already been performed under Directive 76/769/EC and Regulation (EEC) No 793/93. It is likely, however, that some of the restrictions identified under these pieces of legislation will not have been taken all the way through to a Commission Proposal before the REACH regulation comes into force. As both Directive 76/769/EC and Regulation 793/93 are repealed when REACH enters into force, transitional arrangements for such dossiers prepared under those pieces of legislation are necessary. For such proposals the Commission shall draft any appropriate amendment to Annex XVI within 18 months of the entry into force of the regulation, without involvement of the Agency and its Committees.

9. CLASSIFICATION AND LABELLING INVENTORY (ART 109-113)

The Classification and Labelling inventory is a new tool to enable easy public access to industry's self-classification and which serves as the platform to strongly encourage industry to arrive at a harmonised classification and labelling. An overview of the C&L inventory Title is provided in Figure 16.

9.1. Introduction

All suppliers of substances are obliged to classify and label them in accordance with Council Directive 67/548/EEC before they place them on the market. This obligation is independent of the quantity manufactured or imported. This classification needs to be done on the basis of their investigations about accessible and relevant data on the properties of their substance(s). This will include the information required under REACH - to gather and share existing and generate new information - and the information made available on the Agency's web page.

So far, the instrument to harmonise different self-classifications by industry was Annex I to Directive 67/548. REACH now provides an new tool, a forum for manufacturers and importers to harmonise themselves their classification of substances which are not yet included on Annex I: the classification and labelling inventory, which will be part of the Agency's website. Thus, it enables easy public access to industry's self-classification.

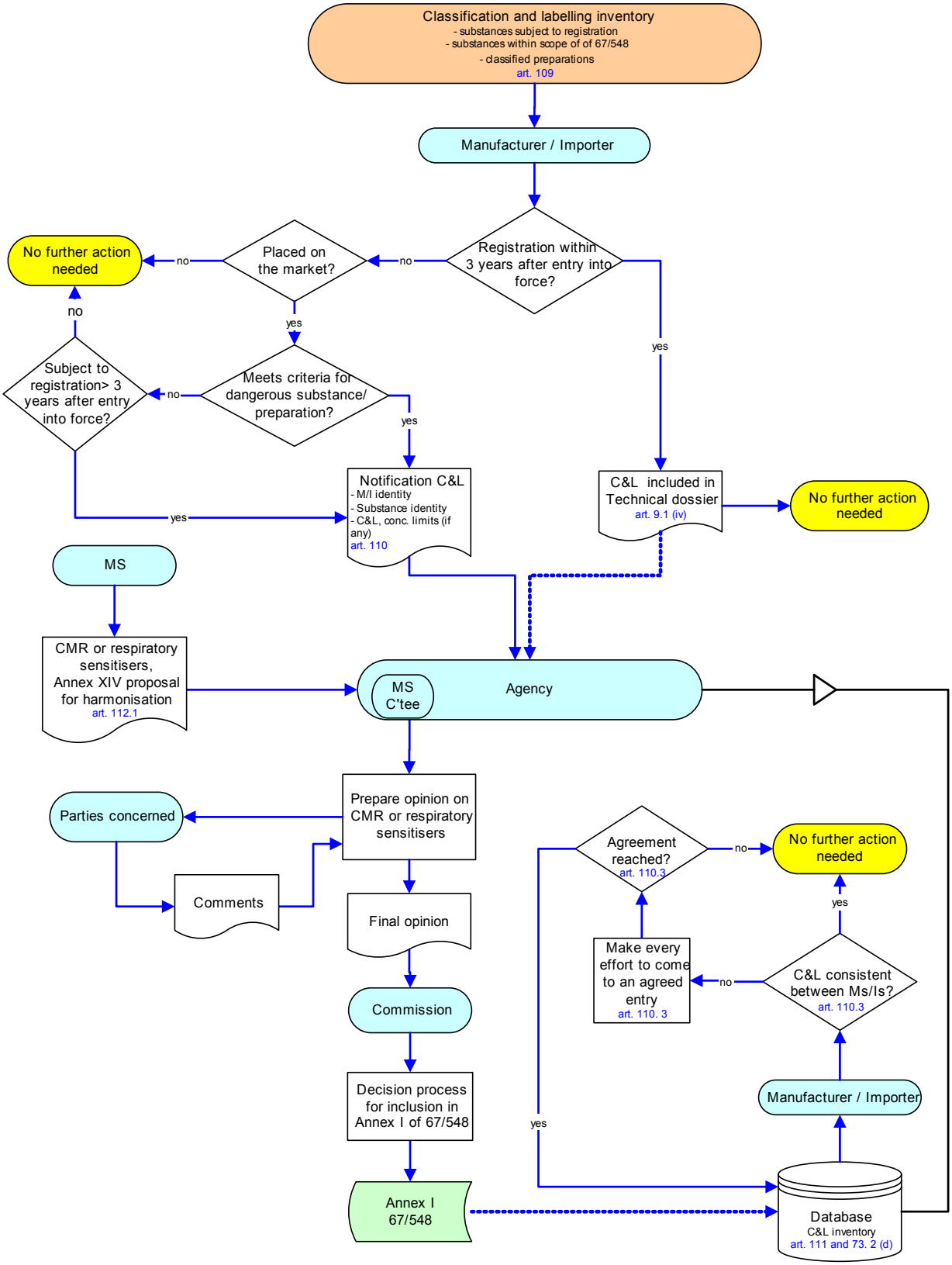

Fig. 16. The Classification and Labelling Inventory

9.2. Requirements and procedures

Manufacturers and importers are required, three years after the entry into force, to submit the classification and labelling of all their substances that are classified as being dangerous, and substances subject to Registration even if not classified, they place on the market to the Agency, independent of the quantity in which they place a substance on the market. For substances that are not classified but are subject to Registration then, submission will highlight if another manufacturer or importer has assessed that the substance is classified.

For phase-in substances which are registered before three years, the Agency will transfer the information to the database without requiring the registrants to submit it separately again.

The Agency will collate all this information on classification and labelling in a publicly available classification and labelling (C&L) inventory, together with the relevant registration number(s) if any, and whether classifications submitted by different registrants or notifiers differ.

In the latter case, registrants and notifiers of different classifications shall make every effort to come to an agreed classification ((the IT system to support the Regulation - REACH – IT - is designed so that the Agency will point this out to them). If they manage to agree on a classification, the registration(s) and/or notification(s) shall be updated accordingly and be resubmitted.

Under REACH, Annex I of Directive 67/548 shall only be used for the substances of the highest concern, i.e. CMRs and respiratory sensitisers, whereas it is industry's task to harmonise the classification for substances with other properties. Member States who think a harmonised classification is required shall prepare a dossier in accordance with Annex XIV to propose a harmonised classification. This will be discussed by the Member State committee and if agreed will be added to Annex I by the regulatory comitology procedure in Directive 67/548/EEC.

10. RELATIONSHIP TO WORKPLACE LEGISLATION

Together with safety data sheets, the chemical safety report under REACH will be a key tool for development of risk assessments under Directive 98/24/EC[44] on the protection of the health and safety of workers from the risks related to chemical agents at work.

Council Directive 98/24/EC requires employers to assess any risks to the safety and health of workers arising from the presence of any hazardous chemical agent[45] at the workplace. The employer must ensure as a general requirement that risks to health and safety shall be eliminated or reduced to a minimum. These requirements apply independently of the quantity of the chemical agents present in the workplace.

---

44 OJ L 131, 5.5.1998, p. 11

45 Essentially substances and preparations as occurring naturally or by any work activity

For risk assessments under Directive 98/24/EC all available information, including that gained under chemicals legislation, shall be used. REACH will therefore increase the amount of information that will be available for workplace risk assessments.

Moreover, Chemical Safety Assessments under REACH will include development of exposure scenarios for uses of substances at the workplace. The exposure scenarios will be communicated down the supply chain as annexes to the Safety Data Sheet and will help employers with their fulfilment of the requirements of Directive 98/24/EC.

On the other hand, the exposure assessment and risk characterisation under REACH will need to take account of occupational exposure limit values (OELs) and the level, type and duration of exposure during the manufacturing processes. It may take into account risk management measures already in place based on the risk assessment according to directive 98/24/EC. These can be improved based on the foreseen improved data availability under REACH.

In consultation with stakeholders, the Commission will investigate how the assessment requirements under Directive 98/24/EC and those of the REACH system can be made better compatible with respect to drafting guidance and developing software.

11. ANNEX I: ABBREVIATIONS AND DEFINITIONS

A. Abbreviations

C&L	classification and labelling
CMR	substances that are carcinogenic, mutagenic, toxic for reproduction
CSA	chemical safety assessment
CSR	chemical safety report
DNEL(s);	derived no effect level(s);
PNEC(s)	predicted no effect concentration(s)
DU	downstream user
GLP	good laboratory practice
PBT;	substances that are persistent, bioaccumulative and toxic
vPvB	substances that are very persistent, very bioaccumulative
POPs	persistent organic pollutants
RMM	risk management measures
SDS	safety data sheet
SIEF	substance information exchange forum

B. Definitions

For the purposes of REACH, the following definitions will apply:

1. *Substance* means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

2. *Preparation* means a mixture or solution composed of two or more substances;

3. *Article* means an object composed of one or more substances or preparations which during production is given a specific shape, surface or design determining its end use function to a greater degree than its chemical composition does;

4. *Polymer* means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are

primarily attributable to differences in the number of monomer units. A polymer comprises the following:

(a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;

(b) less than a simple weight majority of molecules of the same molecular weight.

In the context of this definition a 'monomer unit' means the reacted form of a monomer substance in a polymer;

5. *Registrant* means the manufacturer or the importer submitting a registration;

6. *Manufacturing* means production and extraction of substances in the natural state;

7. *Manufacturer* means any natural or legal person established within the Community who manufactures a substance within the Community;

8. *Import* means the physical introduction into the customs territory of the Community;

9. *Importer* means any natural or legal person established within the Community who is responsible for import;

10. *Placing on the market* means supplying or making available, whether in return for payment or free of charge, to a third party. Import into the customs territory of the Community shall be deemed to be placing on the market;

11. *Downstream user* means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 4(2)(c) shall be regarded as a downstream user;

12. *Use* means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation;

13. *Distributor* means any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties;

14. *Intermediate* means a substance that is solely manufactured for and consumed in or used for chemical processing to be transformed into another substance (hereinafter called *synthesis*):

(a) *non-isolated intermediate* means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipework for transfer from one vessel to another for the purpose of the next reaction step,

but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture;

(b) *on-site isolated intermediate* means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one more legal entities;

(c) *transported isolated intermediate* means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites;

15. *Site* means a single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared;

16. *Actors in the supply chain* means all manufacturers and/or importers and/or downstream users;

17. *Communicate down the supply chain* means that each actor in the supply chain communicates to the downstream user whom he supplies with a substance;

18. *Communicate up the supply chain* means that a downstream user communicates to the actor in the supply chain who has supplied him with a substance;

19. *Competent authority* means the authority or authorities or bodies established by the Member States to carry out the obligations arising from this Regulation;

20. *Phase-in substance* means a substance which, over the 15 years preceding the entry into force of this Regulation, meets at least one of the following criteria:

(a) it was manufactured in or imported into the Community, or the countries acceding to the European Union on 1 May 2004, by a manufacturer or importer and is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS);

(b) it was manufactured in the Community, or in the countries acceding to the European Union on 1 May 2004, but not placed on the market by the manufacturer or importer;

(c) it was placed on the market in the Community, or in the countries acceding to the European Union on 1 May 2004, and between 18 September 1981 and 31 October 1993 inclusive it was also placed on the market by the manufacturer or importer and was considered as having been notified in accordance with the first indent of Article 8 (1) of Directive 67/548/EEC, as amended by Directive 79/831/EEC[46], but does not meet the definition of a polymer set out in Directive 67/548/EEC, as amended by Directive 92/32/EEC[47];

provided the manufacturer or importer has documentary evidence of this.

---

46 OJ L 259, 15.10.1979, p. 10

47 OJ L 154, 5.6.1992, p. 1

21. *Notified substance* means a substance for which a notification has been submitted and which could be placed on the market in accordance with Directive 67/548/EEC;

22. *Product and process orientated research and development* means any scientific development related to product development, the further development of a substance in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance;

23. *Scientific research and development* means any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year;

24. *Registrant's own use* means an industrial or professional use by the registrant;

25. *Identified use* means a use of a substance on its own or in a preparation, or a use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user and that is covered in the safety data sheet communicated to the downstream user concerned;

26. *Undesirable use* means a use by downstream users which the registrant advises against;

27. *Robust study summary* means a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report;

28. *Per year* means per calendar year unless stated otherwise;

29. *Restriction* means any condition for or prohibition of the manufacture, use or placing on the market.

12. ANNEX II: INFORMATION REQUIREMENTS

5. information on the physicochemical properties of the substance

	1 tonne or more	10 tonnes or more	100 tonnes or more	1000 tonnes or more
5.1. State of the substance at 20o C and 101,3 kPa	Study shall be conducted			
5.2. Melting/freezing point	Study shall be conducted, however, the study does not need to be conducted for solids and liquids with a melting/freezing point below 0 °c.			
5.3. Boiling point	Study shall be conducted, however, the study does not need to be conducted: - for gases; or - for solids which either melt above 360 °C or decompose before boiling. In such cases the boiling point under reduced pressure may be estimated or measured; or - for substances which decompose before boiling (e.g. auto-oxidation, rearrangement, degradation, decomposition, etc.).			
5.4. Relative density	Study shall be conducted, however, the study does not need to be conducted if: - the substance is only stable in solution in a particular solvent and the solution density is similar to that of the solvent. In such cases, an indication of whether the solution density is higher or lower than the solvent density is sufficient; or - the substance is a gas. In this case, an estimation based on calculation shall be made from its molecular weight and the Ideal Gas Laws.			
5.5. Vapour pressure	Study shall be conducted, however, the study does not need to be conducted if: - a transition (change of physical state or decomposition) is observed. The following information should then be included: nature of the transition, temperature at which the transition occurs at atmospheric pressure, vapour pressure at 10 and 20 °C above this temperature (unless the transition is from solid to gas); or - the melting point is above 300 °C. If the melting point is between 200 °C and 300 °C, a limit value based on measurement or a recognised calculation method is sufficient.			
5.6. Surface tension	Study shall be conducted, however, the study does not need to be conducted if: - the water solubility is below 1 mg/l at 20 °C or - the substance forms micelles in the relevant concentration range for testing.			
5.7. Water solubility	Study shall be conducted, however, the study does not need to be conducted if: - the substance is hydrolytically unstable (half-life less than 12 hours); or - the substance is readily oxidisable in water. If the substance appears "insoluble" in water, a limit test up to the detection limit of the analytical method shall be performed.			
5.8. Partition coefficient n-octanol/water	Study shall be conducted, however, the study does not need to be conducted if the substance is inorganic. If the test cannot be performed (e.g. the substance decomposes, has a high surface activity, reacts violently during the performance of the test or does not dissolve in water or in octanol, or it is not possible to obtain a sufficiently pure substance), a calculated value for log P as well as details of the calculation method shall be provided.			
5.9. Flash-point	Study shall be conducted, however, the study does not need to be conducted if: - the substance is inorganic; or - the substance only contains volatile organic components with flash-points above 100 °C for aqueous solutions; or - the estimated flash-point is above 200 °C; or - the flash-point can be accurately predicted by interpolation from existing characterised materials.			
5.10. Flammability	Study shall be conducted, however, the study does not need to be conducted: - if the substance is a solid which possesses explosive or pyrophoric properties. These properties should always be considered before considering flammability; or - for gases, if the concentration of the flammable gas in a mixture with inert gases is so low that, when mixed with air, the concentration is all time below the lower limit; or - for substances which spontaneously ignite when in contact with air.			

	1 tonne or more	10 tonnes or more	100 tonnes or more	1000 tonnes or more
5.11. Explosive properties	Study shall be conducted, however, the study does not need to be conducted if: - there are no chemical groups associated with explosive properties present in the molecule; or - the substance contains chemical groups associated with explosive properties which include oxygen and the calculated oxygen balance is less than –200; or - the organic substance or a homogenous mixture of organic substances contains chemical groups associated with explosive properties, but the exothermic decomposition energy is less than 500 J/g and the onset of exothermic decomposition is below 500 ºC; or - for mixtures of inorganic oxidising substances (UN Division 5.1) with organic materials, the concentration of the inorganic oxidising substance is: ▪ less than 15%, by mass, if assigned to UN Packaging Group I (high hazard) or II (medium hazard) ▪ less than 30%, by mass, if assigned to UN Packaging Group III (low hazard). Note: Neither a test for propagation of detonation nor a test for sensitivity to detonative shock is required if the exothermic decomposition energy of organic materials is less than 800 J/g.			
5.12. Self-ignition temperature	Study shall be conducted, however, the study does not need to be conducted: - if the substance is explosive or ignites spontaneously with air at room temperature; or - for liquids non flammable in air, e.g. no flash point up to 200 °C; or - for gases having no flammable range; or - for solids, if the substance has a melting point < 160 °C, or if preliminary results exclude self-heating of the substance up to 400 °C.			
5.13. Oxidising properties	Study shall be conducted, however, the study does not need to be conducted if: - the substance is explosive; or - the substance is highly flammable; or - the substance is an organic peroxide; or - the substance is incapable of reacting exothermically with combustible materials, for example on the basis of the chemical structure (e.g. organic substances not containing oxygen or halogen atoms and these elements are not chemically bonded to nitrogen or oxygen, or inorganic substances not containing oxygen or halogen atoms). The full test does not need to be conducted for solids if the preliminary test clearly indicates that the test substance has oxidising properties. Note that as there is no test method to determine the oxidising properties of gaseous mixtures, the evaluation of these properties must be realised by an estimation method based on the comparison of the oxidising potential of gases in a mixture with that of the oxidising potential of oxygen in air.			
5.14. Granulometry	Study shall be conducted, however, the study does not need to be conducted if the substance is marketed or used in a non solid or granular form.			
5.18. Stability in organic solvents and identity of relevant degradation products			Study shall be proposed. The study is only required if stability of the substance is considered to be critical. The study does not need to be conducted if the substance is inorganic.	
5.19. Dissociation constant			Study shall be proposed. , however, the study does not need to be conducted if: - the substance is hydrolytically unstable (half-life less than 12 hours) or is readily oxidisable in water; or - the substance is not soluble in water or does not contain any ionic structure.	
5.20. Viscosity			Study shall be proposed.	

6. toxicological information

In vivo testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided.

	1 tonne or more	**10 tonnes or more**	**100 tonnes or more**	**1000 tonnes or more**
6.1. Skin irritation or skin corrosion The assessment of this endpoint shall comprise the following consecutive steps: (1) an assessment of the available human and animal data, (2) an assessment of the acid or alkaline reaction, (3) *in vitro* study for skin corrosion, (4) *in vitro* study for skin irritation.	Study shall be conducted, however, steps 3 and 4 do not need to be conducted if: - the substance is corrosive; or - the substance is a strong acid (pH < 2.0) or base (pH > 11.5); or - the substance is flammable in air at room temperature; or - the substance is very toxic in contact with skin; or - the acute toxicity study by the dermal route does not indicate skin irritation up to the limit dose level (2000 mg/kg body weight).			
6.1.1. *In vivo* skin irritation		Study shall be conducted, however, the study does not need to be conducted if: - the substance is corrosive; or - the substance is a strong acid (pH < 2.0) or base (pH > 11.5); or - the substance is flammable in air at room temperature; or - the substance is very toxic in contact with skin; or - the acute toxicity study by the dermal route does not indicate skin irritation up to the limit dose level (2000 mg/kg buffalo weight); or - the data available from the testing strategy foreseen in 6.1 is adequate to classify the substance as skin corrosive or skin irritant.		
6.2. Eye irritation The assessment of this endpoint shall comprise the following consecutive steps: (1) an assessment of the available human and animal data, (2) an assessment of the acid or alkaline reaction, (3) *in vitro* study for eye irritation	Study shall be conducted, however, step 3 does not need to be conducted if: - the substance is corrosive; or - the substance is a strong acid (pH < 2.0) or base (pH > 11.5); or - the substance is flammable in air at room temperature; or - the substance is classified as irritant in contact with skin and provided that the registrant classifies the substance as eye irritant.			
6.2.1. *In vivo* eye irritation		Study shall be conducted, however, the study does not need to be conducted if: - the substance is corrosive; or - the substance is a strong acid (pH < 2.0) or base (pH > 11.5); or - the substance is flammable in air at room temperature; or - the substance is classified as irritant in contact with skin and provided that the registrant classifies the substance as eye irritant; or - the data available from the testing strategy foreseen in 6.2 is adequate to classify the substance as eye irritant.		
6.3. Skin sensitisation The assessment of this endpoint shall	Study shall be conducted, however, step 2 does not need to be conducted if: - the substance is corrosive, very toxic or irritant in contact with skin; or - the substance is a strong acid (pH < 2.0) or base (pH > 11.5); or - the substance is flammable in air at room temperature.			

	1 tonne or more	10 tonnes or more	100 tonnes or more	1000 tonnes or more
comprise the following consecutive steps: (1) an assessment of the available human and animal data, (2) Murine Local Lymph Node Assay (LLNA).	If classification for skin sensitisation is possible from the results of the first step, the following step may be omitted and the registrant shall classify the substance as skin sensitising. If the LLNA is not adequate for the substance in question, the Guinea Pig Maximisation Test (GPMT) may be used.			
6.4. Mutagenicity				
6.4.1. *In vitro* gene mutation study in bacteria	Study shall be conducted			
6.4.2. *In vitro* cytogenicity study in mammalian cells	This mutagenicity study shall be considered in case of a positive result in 6.4.1.	Study shall be conducted, however, the study does not need to be conducted - if adequate data from an *in vivo* cytogenicity test are available or - the substance is known to be carcinogenic category 1 or 2.		
6.4.3.*In vitro* gene mutation study in mammalian cells	This mutagenicity study shall be considered in case of a positive result in 6.4.1.	Study shall be conducted, if a negative result in 6.4.1. and 6.4.2. However, the study does not need to be conducted if adequate data from a reliable in vivo mammalian gene mutation test are available.		
6.4.4 *In vivo* mutagenicity studies	Appropriate *in vivo* mutagenicity studies shall be considered in case of a positive result in any of the mutagenicity studies in 6.4		Study shall be proposed if there is a positive result in any of the mutagenicity studies in 6.4 and there are no results available from an *in vivo* study, an appropriate *in vivo* mutagenicity study shall be proposed by the registrant. If there is a positive result from any in vivo study available, further appropriate in vivo studies shall be proposed.	Study shall be proposed if appropriate, in case of a positive result in any previous mutagenicity study further mutagenicity studies shall be proposed by the registrant.
6.5. Acute toxicity		Study shall be conducted The study/ies do(es) not need to be conducted if: - precise doses of the substance cannot be administered due to the chemical or physical properties of the substance; or - the substance is corrosive; or - the substance is flammable in air at room temperature. For gases and volatile liquids (vapour pressure above 10^{-2} Pa at 20°°C) the information shall be provided for the inhalation route (6.5.2). For substances other than gases, the information mentioned under 6.5.1. to 6.5.3. shall be provided for at least two routes, one of which the oral route.		

	1 tonne or more	10 tonnes or more	100 tonnes or more	1000 tonnes or more
		The choice for the second route will depend on the nature of the substance and the likely route of human exposure. If there is only one route of exposure, information for only that route need be provided. The appropriate second route shall be chosen on the following basis:		
6.5.1. By oral route **6.5.2. By inhalation** **6.5.3. By dermal route**		*Testing by the <u>inhalation route</u> is <u>appropriate</u> if:* (1) exposure of humans via inhalation is likely; and (2) one of the following conditions is met: – the substance has a vapour pressure above 10^{-2} Pa at 20 °C; or – the substance is a powder containing more than 1% particles on a w/w basis, with particle size mass median aerodynamic diameter (MMAD) less than 100 µm; or the substance will be used in a manner which generates aerosols, particles or droplets in an inhalable size range (> 1% on a w/w basis of particles with MMAD < 100 µm). *Testing by the <u>dermal route</u> is <u>appropriate</u> if:* (1) skin contact in production and/or use is likely; and (2) the physicochemical properties suggest a significant rate of absorption through the skin; and (3) one of the following conditions is met: - toxicity is observed in an acute oral toxicity test at low doses; or - systemic effects or other evidence of absorption is observed in skin and/or eye irritation studies; or - *in vitro* tests indicate significant dermal absorption; or - significant acute dermal toxicity or dermal penetration is recognised for structurally-related substances. Testing by the dermal route is inappropriate if the absorption by the skin is unlikely as indicated by molecular weight (MW > 800 or molecular diameter > 15 Å) and low liposolubility (log Kow below -1 or above 4).		
6.6. Repeated dose toxicity				Further studies shall be proposed by the registrant or may be required by the competent authority of the evaluating Member State in accordance with Articles 39, 40 or 44 in case of: - toxicity of particular concern (e.g. serious/severe effects); or - indications of an effect for which the available evidence is inadequate for toxicological and/or risk characterisation; In such cases it may also be

	1 tonne or more	10 tonnes or more	100 tonnes or more	1000 tonnes or more
				more appropriate to perform specific toxicological studies that are designed to investigate these effects (e.g. immunotoxicity, neurotoxicity); or - particular concern regarding exposure (e.g. use in consumer products leading to exposure levels which are close to the dose levels at which toxicity is observed).
6.6.1. Short-term repeated dose toxicity study (28 days), one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure.		Study shall be conducted The **short-term toxicity study** (28 days) does not need to be conducted if: - a reliable sub-chronic (90 days) or chronic toxicity study is available, provided that an appropriate species and route of administration were used; or - where a substance undergoes immediate disintegration and there are sufficient data on the cleavage products; or - relevant human exposure can be excluded. The appropriate route shall be chosen on the following basis: *Testing by the dermal route is appropriate if:* (1) skin contact in production and/or use is likely; and (2) the physicochemical properties suggest a significant rate of absorption through the skin; and (3) one of the following conditions is met: - toxicity is observed in the acute dermal toxicity test at lower doses than in the oral toxicity test; or - systemic effects or other evidence of absorption is observed in skin and/or eye irritation studies; or - *in vitro* tests indicate significant dermal absorption; or - significant dermal toxicity or dermal penetration is recognised for structurally-related substances. *Testing by the dermal route is inappropriate if* the absorption by the skin is unlikely as indicated by molecular weight (MW > 800 or molecular diameter > 15 Å) and low liposolubility (log Kow < -1 or > 4). *Testing by the inhalation route is appropriate if:* (1) exposure of humans via inhalation is likely; and (2) one of the following conditions is met: - the substance has a vapour pressure above 10^{-2} Pa at 20 °C; or - the substance is a powder containing more than 1% particles on a w/w basis, with a particle size MMAD less than 100 μm; or the substance will be used in a manner which generates aerosols, particles or droplets in an inhalable size range (> 1% on a w/w basis of particles with MMAD < 100 μm). In the absence of contra-indications, the oral route shall be the preferred one.		

	1 tonne or more	10 tonnes or more	100 tonnes or more	1000 tonnes or more
			Study shall be proposed, unless already provided or if tests according to 6.6.2 are proposed. In this case, Section 3 of Annex IX shall not apply.	
6.6.2. Sub-chronic toxicity study (90-day), one species, rodent, male and female, most appropriate route of administration, having regard to the likely route of human exposure.		The **sub-chronic toxicity study** shall be proposed by the registrant if: - the frequency and duration of human exposure indicates that a longer term study is appropriate; and one of the following conditions is met: - other available data indicate that the substance may have a dangerous property that cannot be detected in a short-term toxicity study; or - appropriately designed toxicokinetic studies reveal accumulation of the substance or its metabolites in certain tissues or organs which would possibly remain undetected in a short-term toxicity study but which are liable to result in adverse effects after prolonged exposure. Further studies shall be proposed by the registrant or may be required by the competent authority of the evaluating Member State in accordance with Article 39, 40 or 44 in case of: - failure to identify a NOAEL in the 28 days study, unless the reason for the failure to identify a NOAEL is absence of adverse toxic effects; or - toxicity of particular concern (e.g., serious/severe effects); or - indications of an effect for which the available evidence is inadequate for toxicological and/or risk characterisation; In such cases it may also be more appropriate to perform specific toxicological	Study shall be proposed, however the sub-chronic toxicity study (90 days) does not need to be conducted if: - a reliable short-term toxicity study (28 days) is available showing severe toxicity effects according to the criteria for classifying the substance as R48, for which the observed NOAEL-28 days, with the application of an appropriate uncertainty factor, allows the extrapolation towards the NOAEL-90 days for the same route of exposure; or - a reliable chronic toxicity study is available, provided that an appropriate species and route of administration were used; or - the substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day "limit test", particularly if such a pattern is coupled with limited human exposure. The appropriate route shall be chosen on the following basis: *Testing by the dermal route is appropriate if:* (1) skin contact in production and/or use is likely; and (2) the physicochemical properties suggest a significant rate of absorption through the skin; and (3) one of the following conditions is met: - toxicity is observed in the acute dermal toxicity test at lower doses than in the oral toxicity test; or - systemic effects or other evidence of absorption is observed in skin and/or eye irritation studies; or - *in vitro* tests indicate significant dermal absorption; or - significant dermal toxicity or dermal penetration is recognised for structurally-related substances. *Testing by the dermal route is inappropriate if* the absorption by the skin is unlikely as indicated by molecular weight (MW > 800 or molecular diameter > 15 Å) and low liposolubility (log Kow < -1 or > 4). *Testing by the inhalation route is appropriate if:* (1) exposure of humans via inhalation is likely; and (2) one of the following conditions is met: - the substance has a vapour pressure above 10^{-2} Pa at 20 °C; or - the substance is a powder containing more than 1% particles on a w/w basis, with a particle size MMAD less than 100 µm; or	

	1 tonne or more	10 tonnes or more	100 tonnes or more	1000 tonnes or more
		studies that are designed to investigate these effects (e.g., immunotoxicity, neurotoxicity); or - the route of exposure used in the initial repeated dose study was inappropriate in relation to the expected route of human exposure and route-to-route extrapolation cannot be made; or - particular concern regarding exposure (e.g. use in consumer products leading to exposure levels which are close to the dose levels at which toxicity to humans may be expected); or - effects shown in substances with a clear relationship in molecular structure with the substance being studied, were not detected in the 28 days study.	- the substance will be used in a manner which generates aerosols, particles or droplets in an inhalable size range (> 1% on a w/w basis of particles with MMAD < 100 μm). In the absence of contra-indications, the oral route shall be the preferred one. Further studies shall be proposed by the registrant or may be required by the competent authority of the evaluating Member State in accordance with Articles 39, 40 or 44 in case of: - failure to identify a NOAEL in the 90 days study unless the reason for the failure to identify a NOAEL is absence of adverse toxic effects; or - toxicity of particular concern (e.g. serious/severe effects); or - indications of an effect for which the available evidence is inadequate for toxicological and/or risk characterisation; In such cases it may also be more appropriate to perform specific toxicological studies that are designed to investigate these effects (e.g. immunotoxicity, neurotoxicity); or - particular concern regarding exposure (e.g. use in consumer products leading to exposure levels which are high relative to the dose levels at which toxicity to humans may be expected).	
6.6.3 A long-term repeated toxicity study				A long-term repeated toxicity study (≥ 12 months) may be proposed by the registrant or required by the competent authority of the evaluating Member State in accordance with Articles 39, 40 or 44 if the frequency and duration of human exposure indicates that a longer term study is appropriate and one of the following conditions is met: - serious or severe toxicity effects of particular concern were observed in the 28 days or 90 days study for which the available evidence is inadequate for toxicological or risk characterisation; or - effects shown in substances with a clear

	1 tonne or more	10 tonnes or more	100 tonnes or more	1000 tonnes or more
				relationship in molecular structure with the substance being studied were not detected in the 28 days or 90 days study; or - the substance may have a dangerous property that cannot be detected in a 90 days study.
6.7 Reproductive toxicity		Study shall be conducted The studies do not need to be conducted if: - the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented; or - the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented; or - relevant human exposure can be excluded.	Study shall be proposed, however, the studies do not need to be conducted if: - the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented; or - the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented.	
6.7.1. Screening for reproductive/developmental toxicity		Study shall be conducted in, one species (OECD 421), if there is no evidence from available information on structurally related substances, from (Q)SAR estimates or from in vitro methods that the substance may be a developmental toxicant.		
6.7.2. Developmental toxicity study, one species, most appropriate route of administration, having regard to the likely route of human exposure (Annex X B.31 or OECD 414) The study shall be initially performed on one species. A decision on the need to perform a study on a second species should be based on the outcome of the first test.		Study shall be conducted, a positive result in the screening (6.7.1) shall be confirmed at this level by a developmental toxicity study	Study shall be proposed, however, the study need not be conducted if: - the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented; or - the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented	

	1 tonne or more	10 tonnes or more	100 tonnes or more	1000 tonnes or more
6.7.3. Two-generation reproductive toxicity study, one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure, if the 28-day or 90-day study indicates adverse effects on reproductive organs or tissues.		The two-generation reproductive toxicity study shall be proposed by the registrant if there are indications of potential reproductive toxicity from a repeated dose toxicity study (90 days) (e.g. histopathological effects on the gonads) or the substance has a close structural relationship with a known reproductive toxicant.	Study shall be proposed, however, the study need not be conducted if: - the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented; or - the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented	
6.7.4. Two-generation reproductive toxicity study, one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure, unless already provided under 6.7.3				Study shall be proposed, however, the study need not be conducted if: - the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented; or - the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented; or - the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and there is no or no significant

	1 tonne or more	10 tonnes or more	100 tonnes or more	1000 tonnes or more
				human exposure.
6.8 Toxicokinetics **6.8.1. Assessment of the toxicokinetic behaviour of the substance to the extent that can be derived from the relevant available information**		Study shall be conducted		
6.9. A carcinogenicity study				Study may be proposed or may be required by the competent authority of the evaluating Member State in accordance with Articles 39, 40 or 44 if: - the substance has a widespread dispersive use or there is evidence of frequent or long-term human exposure; and - the substance is classified as mutagenic category 3 or there is evidence from the repeated dose study(ies) that the substance is able to induce hyperplasia and/or pre-neoplastic lesions.

7. ecotoxicological information

	1 tonne or more	10 tonnes or more	100 tonnes or more	1000 tonnes or more
7.1. Aquatic toxicity				
7.1.1. Short-term toxicity testing on *Daphnia*	Study shall be conducted , however, the study does not need to be conducted if: - the substance is highly insoluble (water solubility < 10 µg/l); or - the substance is unlikely to cross biological membranes (MW > 800 or molecular diameter > 15 Å; or - a long-term toxicity study is available. The registrant may consider long-term toxicity testing (7.1.5) instead of short-term.			
7.1.2. Growth inhibition study on algae		Study shall be conducted , however, the study does not need to be conducted if: - the substance is highly insoluble (water solubility < 10 µg/l); or - the substance is unlikely to cross biological membranes (MW > 800 or molecular diameter > 15 Å).		
7.1.3. Short-term toxicity testing on fish: The registrant may consider long-term toxicity testing instead of short-term.		Study shall be conducted , however, the study does not need to be conducted if: - the substance is highly insoluble (water solubility < 10 µg/l); or - the substance is unlikely to cross biological membranes (MW > 800 or molecular diameter > 15 Å); or - a long-term toxicity study is available.		
7.1.4. Activated sludge respiration inhibition testing, unless there is a low probability of emission into the sewage treatment system		Study shall be conducted , however, the study does not need to be conducted if: - the substance is highly insoluble (water solubility < 10 µg/l); or - the substance is found to be readily biodegradable and the applied test concentrations are in the range of concentrations that can be expected in the influent of a sewage treatment plant. The study may be replaced by a nitrification inhibition test if available data show that the substance is likely to be an inhibitor of microbial growth or function.		
7.1.5 Long-term toxicity testing on *Daphnia*	The long-term aquatic toxicity study on ***Daphnia*** shall be conducted if the comparison of the (predicted) environmental exposure with the results from the short-term aquatic toxicity data indicates the need to investigate further the effects on aquatic organisms; The long-term aquatic toxicity study on ***Daphnia*** shall be considered if the substance is poorly water soluble (water solubility < 1 mg/l).		Study shall be proposed, however, the study does not need to be conducted if: - the substance is unlikely to cross biological membranes (MW > 800 or molecular diameter > 15 Å); or - direct or indirect exposure of the aquatic compartment is unlikely.	Long-term toxicity testing shall be proposed by the registrant if the chemicals safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. The choice of the appropriate test(s) depends on the results of the safety assessment.
7.1.6. Long-term toxicity testing on fish		The long-term aquatic toxicity study on fish shall be proposed by the registrant or may be required by the competent authority of the evaluating Member State in accordance with Article 39, 40 or 44 if the comparison of the (predicted) environmental exposure with the results from the short-term aquatic toxicity data indicates the need to investigate further	Study shall be proposed, however the study does not need to be conducted if: - the substance is unlikely to cross biological membranes (MW > 800 or molecular diameter > 15 Å); or - direct or indirect exposure of the aquatic compartment is unlikely.	Long-term toxicity testing shall be proposed by the registrant if the chemicals safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. The choice of the appropriate test(s) depends on the results of the safety

	1 tonne or more	10 tonnes or more	100 tonnes or more	1000 tonnes or more
The information shall be provided for one of the following: 7.1.6.1 Fish early-life stage (FELS) toxicity test (OECD 210) 7.1.6.2 Fish short-term toxicity test on embryo and sac-fry stages (Annex X C.15 or OECD 212) 7.1.6.3 Fish, juvenile growth test (Annex X C.14 or OECD 215)		effects on aquatic organisms. The long-term aquatic toxicity study on fish shall be considered if the substance is poorly water soluble (water solubility < 1 mg/l).	7.1.6.1. The FELS toxicity test shall be proposed by the registrant or may be required by the competent authority of the evaluating Member State in accordance with Articles 39, 40 or 44 if the substance has a potential to bioaccumulate.	assessment.
7.2. Degradation				
7.2.1. Biotic 7.2.1.1 Ready biodegradability		Study shall be conducted, however, t.	he study does not need to be conducted if the substance is inorganic.	
7.2.1.2. Simulation testing on ultimate degradation in surface water		The study shall be proposed by the registrant or may be required by the competent authority of the evaluating Member State in accordance with Article 39, 40 or 44 if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance. The choice of the appropriate test(s) depends on the results of the safety assessment.	Study shall be proposed, however the study need not be conducted if: - the water solubility of the substance is below 10 µg/l; - the substance is readily biodegradable.	
7.2.1.3. Soil simulation testing		The study shall be proposed by the registrant or may be required by the competent authority of the evaluating Member State in accordance with Article 39, 40 or 44 if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance. The choice of the appropriate test(s) depends on the results of the safety assessment.	The study shall be proposed by the registrant or may be required by the competent authority of the evaluating Member State in accordance with Articles 39, 40 for substances with a high potential for adsorption to soil However, the study need not be conducted: - if the substance is readily biodegradable; or - if direct or indirect exposure of soil is unlikely. Furthermore the study may be required by the competent authority of the evaluating Member State in accordance with Article 44.	
7.2.1.4. Sediment simulation testing		The study shall be proposed by the registrant or may be required by the	The study shall be proposed by the registrant or may be required by the competent authority of the evaluating Member State in accordance with	

	1 tonne or more	10 tonnes or more	100 tonnes or more	1000 tonnes or more
		competent authority of the evaluating Member State in accordance with Article 39, 40 or 44 if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance. The choice of the appropriate test(s) depends on the results of the safety assessment.	Articles 39, 40 for substances with a high potential for adsorption to soil However, the study need not be conducted: - if the substance is readily biodegradable; or - if direct or indirect exposure of soil is unlikely. - Furthermore the study may be required by the competent authority of the evaluating Member State in accordance with Article 44.	
7.2.1.5 Further confirmatory testing on rates of biodegradation (aerobic and/or anaerobic)				Further confirmatory testing on rates of biodegradation (aerobic and/or anaerobic) in environmental compartments (water, sediment, soil) with specific emphasis on the identification of the most relevant degradation products.
7.2.2 Abiotic 7.2.2.1 Hydrolysis as a function of pH		Study shall be conducted , however, the study does not need to be conducted if: - the substance is readily biodegradable; or - the water solubility of the substance is below 10 µg/l.		
7.2.3. Identification of degradation products			Study shall be proposed, unless the substance is readily biodegradable Further testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the fate and behaviour of the substance. The choice of the appropriate test(s) depends on the results of the safety assessment.	
7.2.4 Further degradation testing			Further degradation testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance. The choice of the appropriate test(s) depends on the results of the safety assessment.	
7.3. Fate and behaviour in the environment				
7.3.1.Adsorption/desorption screening study		Study shall be conducted , however, the study does not need to be conducted if: - based on the physicochemical properties the substance can be expected to have a low potential for adsorption (e.g. the substance has a low octanol water partition coefficient); or - the substance decomposes rapidly.		
7.3.2. Bioconcentration in (one) aquatic species, preferably fish			Study shall be proposed, however, the study need not be conducted if: - the substance has a low potential for bioaccumulation (ie log Kow < 3); or - the substance is unlikely to cross biological membranes (MW > 800 or molecular diameter > 15 Å); or	

	1 tonne or more	10 tonnes or more	100 tonnes or more	1000 tonnes or more
			- direct or indirect exposure of the aquatic compartment is unlikely.	
7.3.3. Further studies on adsorption/desorption			Study shall be proposed, depending on the results of the screening study required in 7.3.1 However, the study need not be conducted if: - based on the physicochemical properties the substance can be expected to have a low potential for adsorption (e.g. the substance has a low octanol water partition coefficient); or - the substance decomposes rapidly.	
7.3.4. Further environmental fate and behaviour studies				Further testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the fate and behaviour of the substance. The choice of the appropriate test(s) depends on the results of the safety assessment.
7.4. Effects on terrestrial organisms **7.4.1. Short-term toxicity to earthworms** **7.4.2. Effects on soil micro-organisms** **7.4.3. Short-term toxicity to plants**			Study shall be proposed, however, these studies do not need to be conducted if direct or indirect exposure of the soil compartment is unlikely. In the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the exposure to soil organisms. In the case of a significant exposure a selection out of the following tests shall be proposed by the registrant.	
7.4.4. Long-term toxicity testing on earthworms **7.4.5. Long-term toxicity testing on soil invertebrates** other than earthworms **7.4.6. Long-term toxicity testing on plants**			In particular for substances that have a high potential to adsorb to soil, the registrant shall consider long-term toxicity testing instead of short-term.	Long-term toxicity testing shall be proposed by the registrant when the comparison of the (predicted) environmental exposure with the results from the short-term toxicity test(s) indicates the need to investigate further the effects on terrestrial organisms. The choice of the appropriate test(s) depends on the outcome of this comparison. These studies do not need to be conducted if direct or indirect

	1 tonne or more	10 tonnes or more	100 tonnes or more	1000 tonnes or more
				exposure of the soil compartment is unlikely.
7.5. Long-term toxicity to sediment organisms				Long-term toxicity testing shall be proposed by the registrant when the comparison of the (predicted) environmental exposure with the results from the short-term toxicity test(s) indicates the need to investigate further the effects on sediment organisms. The choice of the appropriate test(s) depends on the results of the safety assessment.
7.6. Long-term or reproductive toxicity to birds				Study shall be proposed, however, the study need not be conducted if direct or indirect exposure of birds is unlikely.

8. other available physicochemical, toxicological and ecotoxicological information

Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided.

9. methods of detection and analysis

Description of the analytical methods shall be provided on request for substances manufactured or imported in quantities of 100 tonnes or more per year, for the relevant compartments for which studies were performed using the analytical method concerned. If the analytical methods are not available this shall be justified.