ACEA European Automobile Manufacturers Association

ANNEX Q:

Safety Data Sheet Compliance Checks

January 2021

ACEA European Automobile Manufacturers Association

KEY MESSAGES

a. Annex Q to the Automotive Industry Guideline on REACH (AIG-REACH) is titled, "Safety Data Sheet Compliance Checks", and presents guidance for downstream users on conducting plausibility checks on incoming safety data sheets (SDSs).
b. This is seen as necessary to fulfil legal obligations in the light of industry and authority experiences of poor data quality of SDSs in the supply chain.
c. The plausibility check guidance is given in a series of steps which may be seen as increasing in complexity.

KEY RECOMMENDATIONS

This Annex Q recommends the following as a minimum appropriate response by downstream users who receive SDSs from their suppliers:

a. Perform a plausibility check of received SDSs at a level appropriate to the circumstances;
b. In the event of new information on hazardous properties or the appropriateness of the risk management measures in the SDS, communicate such information to the supplier (Art. 34 REACH);
c. Keep records of plausibility checks performed, their outcomes, and any resultant actions;
d. Ensure that each person with a role in managing received SDSs and/or conducting plausibility checks has the appropriate training and is competent to perform their duties.

If the SDS fails at any stage of the plausibility check, this may lead to further obligations under REACH, CLP, or other legislation.

This Annex Q also provides guidance, with several examples, on the compliance actions that are required by a recipient of an extended safety data sheet, i.e. an SDS with attached exposure scenario(s) for substances or "safe use mixtures information" for complex mixtures.

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0. INTRODUCTION

The Automotive Industry Guideline on REACH (AIG-REACH) includes the recommendation in Section 4.6.1 that downstream users make "...a short general plausibility check of the SDS / Ext-SDS content." In addition, Annex K of the AIG-REACH provides a one-page summary of SDS obligations for manufacturers, importers and downstream users, including recommendations for downstream users in receipt of an SDS/Ext-SDS to check SDS/Ext-SDS information "...for errors and shortcomings (plausibility check)".

The purpose of this Annex Q to the AIG-REACH is to provide practical guidance on how such a plausibility check may be made (Chapters 1 to 5). This Annex Q also covers guidance on the compliance actions that are required when exposure scenarios are provided in extended safety data sheets, in order to meet REACH obligations workplace and environment safety (Chapter 6).

This Annex Q focusses on the perspective of downstream users (DUs), and as such is not intended as guidance on the requirements for creating SDSs, although some knowledge of these requirements is included in order to help DUs to perform an effective plausibility check.

ACEA strongly recommends that all actors in the automotive supply chain for substances and mixtures perform the plausibility check steps that are appropriate to their own circumstances for their incoming SDSs in order to improve the data quality of SDSs throughout the supply chain.

This Annex Q is valid from 1 January 2021.

0.1 LEGAL BACKGROUND

Safety data sheets are intended under REACH and other European legislation (e.g. CLP, BPR, Pyrotechnics, etc.) to be the primary means of transmitting data about chemical hazards along the supply chain. Manufacturers or importers (or only representatives) are initially responsible for the content of the SDS. Each further actor in the supply chain who places the substance or mixture on the market is responsible for the content of the SDS, whether that is created by the actor himself or the actor simply passes on the supplier's SDS.

This implies that each actor should perform a plausibility check on the content of the SDS that is received from the supplier at each stage in the supply chain.

An SDS is intended for the use of recipient employers, who must take it into account in order to meet their requirements to provide workers with "*… information on the hazardous chemical agents occurring in the workplace, such as the identity of those agents, the risks to safety and health, relevant occupational exposure limit values and other legislative provisions*" (Art. 8.1 Protection of Workers, 98/24/EC). Although employers may choose to provide their employees with access to the SDS itself, ECHA guidance also makes clear that this "*… does not release the employer from his obligations under Directive 98/24/EC*".

Therefore, this also implies that the employer has a responsibility to perform a plausibility check on the content of the supplier's SDS.

Legal frameworks support the many-eye principle, by which it is expected that others in the supply chain should identify and correct any errors in SDS data before it is passed on to the last industrial or professional user. In practice, automotive industry experience is that many incoming SDS have errors in classification of substances and of mixtures, and the ECHA Project "REACH – EN – FORCE 2" found that 52% of 4496 SDSs checked for basic plausibility were non-compliant, potentially leading to incorrect regulatory conclusions and inappropriate or inadequate risk management measures.

It should be remembered that compliance with the direct requirements of REACH and other relevant legislation should be seen as a minimum for overall legal compliance. Under civil law, each employer also has a so-called "duty of care" to its employees, and in order to meet that duty of care, the employer should do all that is reasonable and required to protect employees health and safety and the environment. If harm occurs as a result of missing or incorrect SDS information, employers may be required to demonstrate they have indeed done all that is reasonable and required.

This Annex Q presents guidance for DUs on conducting plausibility checks on incoming SDS (Chapters 1 to 5). The guidance is given in a series of steps which may be seen as increasing in

complexity (see Chapter 0.3 SDS Compliance Check Navigator). It is up to DUs to determine what level of detail to go to for their SDS plausibility check, according to their own circumstances.

This Annex Q recommends the following as a minimum appropriate response by DUs who receive SDSs from their suppliers:

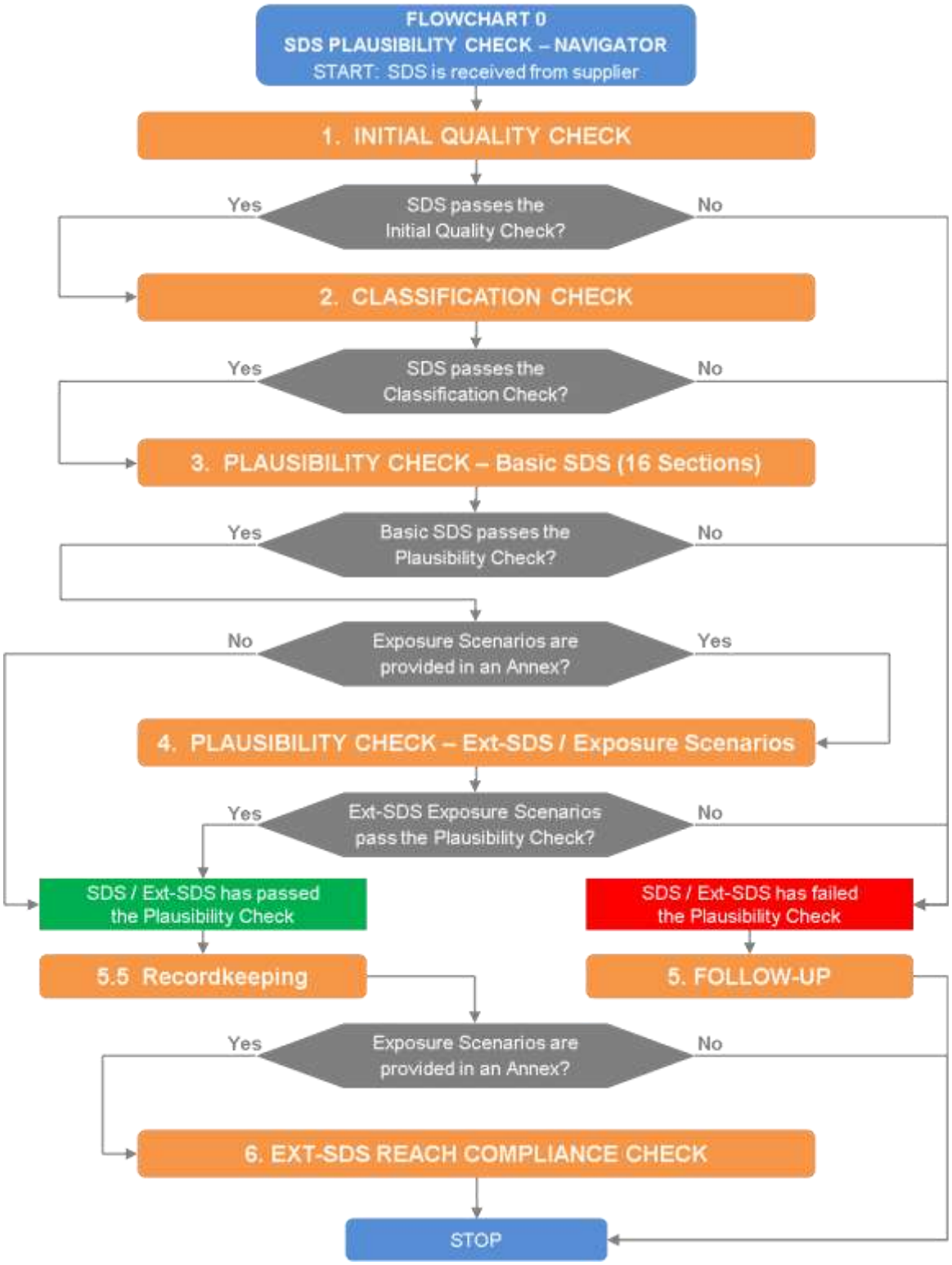
- Perform a plausibility check of received SDSs at a level appropriate to the circumstances;
- If there are good reasons for doubting the accuracy or completeness of the SDS, resolve the issue through contact with the supplier;
- In the event of new information on hazardous properties or the appropriateness of the risk management measures in the SDS, communicate such information to the supplier (Art. 34 REACH);
- Keep records of plausibility checks performed, their outcomes, and any resultant actions;
- Ensure that each person with a role in managing received SDSs and/or conducting plausibility checks has the appropriate training and is competent to perform their duties.

If the SDS fails at any stage of the plausibility check, this may lead to further obligations under REACH, CLP, or other legislation (see Chapter 5).

Although there are no legal time limits for performing an SDS plausibility check, it is recommended to complete this in a reasonably short time, in order to increase the likelihood of a satisfactory agreement between the supplier and the recipient.

In some cases, there is no legal requirement to provide an SDS, but it is nevertheless useful to receive similar information in the same format (see ECHA Guidance on Compilation of SDSs, 3.21) but under a different title, and indicating somehow that an actual SDS is not required. In such cases, it may also be useful to perform a plausibility check at a suitable level.

0. 2 SDS COMPLIANCE CHECK NAVIGATOR



1. INITIAL QUALITY CHECK

The requirements for European SDSs are set out in Annex II of the REACH Regulation, first published in December 2006. In order to harmonise with the CLP Regulation, REACH Annex II was amended by Regulation No 453/2010, which set out the SDS formats to be followed during the transition for classification and labelling from the Dangerous Substances Directive (DSD) and Dangerous Preparations Directive (DPD) to the CLP Regulation. Since the amended format requirements of Regulation No 453/2010 were published on 31 May 2010, it follows that any SDS last revised before that date must be assumed to be in an incorrect format.

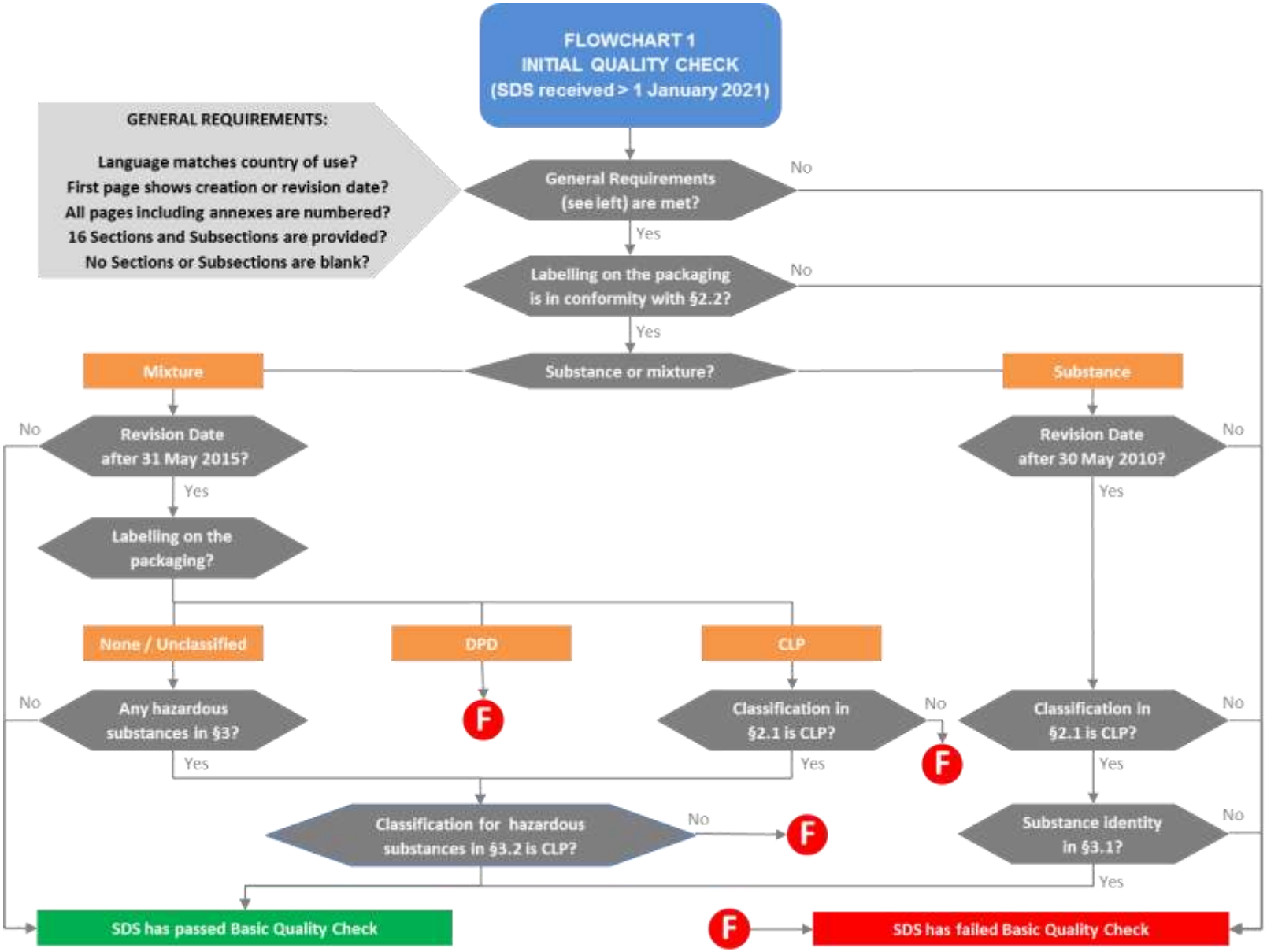
Under the amended REACH Annex II requirements, all substances have been subject to CLP rules since 1 June 2010. For mixtures, the CLP rules for classification, labelling and packaging came into effect on 1 June 2015. Before that date, mixtures were classified, labelled and packaged according to the DPD rules, if the supplier did not voluntarily change to CLP in advance. It follows that the rules governing the structure and content of SDSs also changed on 1 June 2015 to correspond with the implementation of CLP rules.

Regulation No 453/2010 also added a derogation for mixtures already in the supply chain under DPD rules before 1 June 2015, which were allowed to be sold on through the supply chain under the DPD rules until 1 June 2017. However, this transitional derogation to the CLP rules did not apply if the mixture in the supply chain was decanted into another packaging or if the packaging or labelling was otherwise changed (Art. 2 Regulation No 453/2010).

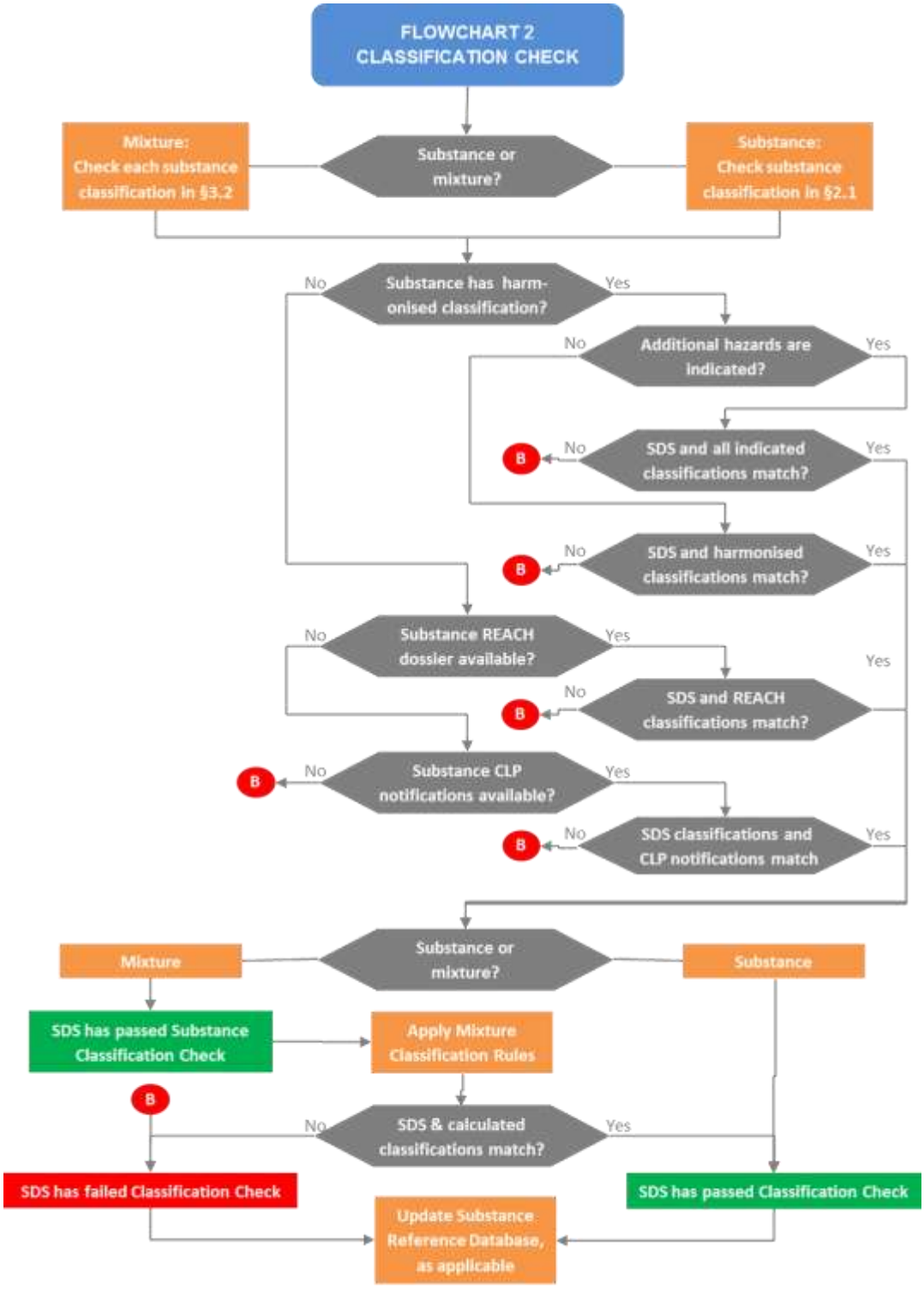
Regulation (EU) 2015/830 was published on 29 May 2015 and further amended Annex II REACH in line with CLP requirements and GHS Revision 5. This added in Art. 2 REACH the further derogation that: "… *safety data sheets provided to any recipient before 1 June 2015 may continue to be used and need not comply with the Annex to this Regulation* [i.e. Annex II REACH] *until 31 May 2017*".

With the expiry of the transitional derogations, all SDSs received after 31 May 2017 must be in CLP-only format for the classification and labelling sections of the SDS.

Finally, Regulation (EU) 2020/878 was published on 26 June 2020 to amend Annex II REACH in line with CLP requirements and GHS Revision 7. The current status of Annex II REACH requirements are summarised in Flowchart 1, below.


FLOWCHART 1
INITIAL QUALITY CHECK
(SDS received > 1 January 2021)
GENERAL REQUIREMENTS:
Language matches country of use?
First page shows creation or revision date?
All pages including annexes are numbered?
16 Sections and Subsections are provided?
No Sections or Subsections are blank?
General Requirements (see left) are met?
No
Yes
Labelling on the packaging is in conformity with §2.2?
No
Yes
Substance or mixture?
Mixture
Substance
Revision Date after 31 May 2015?
No
Yes
Revision Date after 30 May 2010?
No
Yes
Labelling on the packaging?
None / Unclassified
DPD
CLP
Any hazardous substances in §3?
No
Yes
F
Classification in §2.1 is CLP?
No
Yes
F
Classification in §2.1 is CLP?
No
Yes
Classification for hazardous substances in §3.2 is CLP?
No
F
Substance identity in §3.1?
No
Yes
SDS has passed Basic Quality Check
F
SDS has failed Basic Quality Check

2. CLASSIFICATION CHECK



2.1 SUBSTANCES CLASSIFICATION CHECK

In order to check that a substance classification in an SDS is correct, it is necessary to have a source of validated substance classification data. ECHA's main source of substance classification data followed by the Classification & Labelling (C&L) Inventory, which includes:

- Harmonised classifications established under CLP (also referred to as "legal classifications");
- Substances registered under REACH;
- Substances notified under CLP.

Of the above, the harmonised classifications are legally binding, and so must be used whenever they are available. However, other sources of substance classification information (such as the SDS Sections 9, 11 and 12, the C&L Inventory, or reference databases) should still be reviewed and any additional hazard classes that are not mentioned in the harmonised classifications should be added as appropriate (see Art. 4.3 CLP).

Self-classification = (**harmonised classification** + **additional hazards not covered by harmonised classification**)

Table 2: Substances Classification Examples – Harmonised Classification and Additional Hazards

Product identifier	Substance name	Harmonised classification	Additional Hazards in EU not covered by harmonised classification**	Remark	Result (self-classification)
CAS 64-18-6 EC 200-579-1 INDEX 607-001-00-0 REACH 01-2119491174-37	Formic acid	Skin Corr. 1A, H314	Flam. Liq. 3, H226 Eye Dam. 1, H318 Acute Tox. 4, H302 Acute Tox. 3, H331 Met. Corr. 1, H290	Flash point: 49.5 °C LD_{50} (oral, rat): 730 mg/kg LD_{50} (vapour, rat, 4 h): 7,85 mg/l UN 1779	Flam. Liq. 3, H226 Skin Corr. 1A, H314 Eye Dam. 1, H318 Acute Tox. 4, H302 Acute Tox. 3, H331 Met. Corr. 1, H290
CAS 64-17-5 EC 200-578-6 INDEX 603-002-00-5 REACH 01-2119457610-43	Ethanol	Flam. Liq. 2, H225	Eye Irit. 2, H319	SCL (Eye Irrit. 2): >= 50 %	Flam. Liq. 2, H225 Eye Irrit. 2, H319
CAS 2634-33-5 EC 220-120-9 INDEX 613-088-00-6 REACH 01-2120761540-60	1,2-benzisothiazol-3(2H)-one	Acute Tox. 4*, H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Skin Sens. 1, H317 Aquatic Acute 1, H400	Aquatic Chronic 2, H411	LD_{50} (oral, rat): 490 mg/kg	Acute Tox. 4 , H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 2, H411

** Minimum classification (see CLP Annex VI, 1.2.1)*

*** It is possible to have more than one self-classification within a REACH dossier, depending on the manufacturing process and/or impurities.*

A typical large automotive supplier company, vehicle manufacturer or aftermarket products distributor may have to keep track of hundreds of substances for SDS classification as well as to ensure compliance with many other regulations. It is therefore recommended that each company establishes and maintains its own internal substance reference database for this purpose. As an alternative, commercial substance reference databases are available by subscription. The key feature of such reference databases, whether in-house or commercial, is that they must be continuously updated based on the latest data from the C&L Inventory as well as other sources such as recent SDSs. It is therefore recommended to confirm with database providers whether they accept responsibility for their substance database contents.

In order to make the most complete SDS plausibility check possible, it is recommended to collect full (100%) substance composition information from suppliers of substances and mixtures (for which a non-disclosure agreement may be necessary). Only with the full composition can an SDS recipient confirm that the correct substances are listed on the SDS. In addition, full compositions are useful for tracking compliance with other chemical regulations, and essential for example in the case of aftermarket product sales outside Europe.

The steps involved in the substances classification check are shown in Flowchart 2 (above). The substance classification details should appear in Section 3.2 of the SDS for mixtures, or in Section 2.1 of the SDS for substances on their own.

The basis of the substance classification check is to compare the SDS substance classifications with the best available validated substance classification data. As stated above, if a harmonised substance classification exists, this must be used, but it may also be worthwhile to check the REACH dossier for any additional hazards not reflected in the harmonised classification.

Failing an existing harmonised classification, a company's (in-house or commercial) reference database should be the next best source, especially if it is well maintained with the latest available data.

If neither of those is available, either REACH registrations or CLP notifications may be referred to. However, it should be noted that several different substance classifications may be submitted in REACH registration dossiers and/or CLP notifications, and so these should only be used in the absence of better validated sources. If used the company's (in-house or commercial) reference database should always be updated with the latest available data.

In case a substance on the SDS is not listed in the recipient's own reference database, the substance should be added. For this it is necessary to conduct further research in order to determine the hazardous properties of the substance and to confirm the classification, for which the same order of reliability as above may be applied, as well as to determine the status of other regulations, for example the worldwide registration status in the existing regional/national chemical inventories.

Especially for supplied products that the recipient is likely to use directly in the production of vehicles/parts (e.g. vehicle fill fluids), or in aftermarket products (e.g. paint or adhesive) that may be sold anywhere in the world, it is recommended that the recipient obtains details of the applicability of worldwide regulations, such as chemical inventories in place in China, USA, Korea, Philippines, Australia, Canada, New Zealand, Malaysia, Russia, etc. It is also important to note that sometimes confidential inventory registrations may be in place that are only valid for the manufacturer/supplier, and not for the OEM itself, meaning that it would not be allowed to import the chemical product by the OEM.

2.2 MIXTURES CLASSIFICATION CHECK

The European legal framework foresees that it should be possible to confirm the classification of a mixture using the information on substances listed on the SDS, along with other supporting information on the SDS. However, due to industry experience of SDS data quality problems, it is once again recommended to collect and use full compositions from suppliers in order to confirm that the overall mixture classification is correct. Even if not done as a matter of routine, collecting full composition details may be the only way to confirm plausibility in case of inconsistencies in the SDS data.

In special cases it may be required to obtain from the supplier an original SDS for critical raw materials, for example for polymers, oligomers, or other so far confidential substances.

Classification rules for mixtures are defined in the CLP Regulation. Since the CLP rules are different from the previous DPD rules, it is important to recognise that the previous classification of a substance under the DPD may not read across directly to the CLP classification for the same substance.

In addition to the regulations themselves, several guidance documents are available to help in determining the correct overall classification based on substance composition and overall properties of the mixture (see Chapter 8, References). Nevertheless, classification remains an expert task, too complex to be explained in this Annex Q, and so, as with all aspects of SDS compliance, appropriate training and competency is required for the individuals leading this work.

3. PLAUSIBILITY CHECK – BASIC SDS (16 SECTIONS)

Table 3 below shows each heading and sub-heading required in the 16 sections of the basic SDS. The headings and sub-headings must be written out in full, e.g. the first heading should be written as "SECTION 1: Identification of the substance/ mixture and of the company/ undertaking". No sub-headings may be left blank, so if no information is available or none is applicable for a given sub-heading, a short statement such as "Not applicable" should be used instead of missing out that sub-heading or leaving it blank.

The table identifies the key content to be found under each sub-heading, and provides a summary of suggested checks that should be carried out during an SDS plausibility check. Finally, Table 3 also indicates which content has relevance with, and should be cross-checked against, the exposure scenarios (ESs), if applicable.

Table 3: Plausibility Check – Basic SDS (16 Sections)

Heading	Sub-Heading	Key Content	Suggested Checks	ES Relevance
SECTION 1: Identification of the substance/ mixture and of the company/ undertaking	1.1 Product identifier	Substances: • Substance name and Identification number(s), including CAS, EC and REACH Registration number where applicable • "Nanoform" where applicable*	• Product Identifiers must match the information on the label • If a REACH registration number is provided without the registrant suffix, request the full number from your supplier in case this is needed for enforcement purposes. • The REACH registration status of each ingredient substance should be checked (see http://apps.echa.europa.eu/registered/registered-sub.aspx), especially in the case of non-European suppliers. • In case of doubt the supplier should be requested to confirm in writing that all ingredient substances in the product have a valid REACH registration number and to provide these, or explain why they do not (e.g. below registration threshold). • Substances which do not yet have a registration should be checked thoroughly to confirm that they are permitted for use in Europe. • Nanoform, if indicated, must be consistent with other sections (e.g. Section 2, 3, 9, 11 & 12)	
		Mixtures: • Trade name • Unique Formula Identifier (UFI), if available*	• Product identifiers (including UFI) must match the information on the label.	
		• Substances and mixtures: Synonyms, company product codes, etc.	• None	
	1.2 Relevant identified uses of the substance or mixture and uses advised against	• Identified uses identified uses relevant for the recipient(s) • Main uses advised against	• The identified uses must match the actual intended uses. • The actual intended uses must not include any of the uses advised against. • If use is as an "intermediate" under Strictly Controlled Conditions (SCC), this should be confirmed to the supplier and documented.	See ES/SDS Relevance Table.

Heading	Sub-Heading	Key Content	Suggested Checks	ES Relevance
	1.3 Details of the supplier of the safety data sheet	• Name of the "supplier" of the SDS (manufacturer, importer, only representative, DU or distributor) • Full address • Telephone number • Email address of competent person	• Supplier details must match the label.	
	1.4 Emergency telephone number	• Emergency number	• If not available 24 hours per day, the available hours must be stated. • The number for an official advisory body may be given.	
SECTION 2: Hazards identification	2.1 Classification of the substance or mixture	• Substances: CLP classification • Mixture: Overall CLP classification of the mixture	• See Flowchart 1 for a summary of SDS classification requirements. • For details of the substance classification check see Chapter 2.1. • For details of the mixture classification check see Chapter 2.2. • If not classified as hazardous according to CLP, this must be clearly stated, including reference to the regulation (i.e. (EC) No 1272/2008). • The most important adverse effects must be consistent with SDS Sections 9 to 12 of the SDS. • For substances, check on the C&L Inventory and/or the registration dossier (go to http://echa.europa.eu, then "Search for Chemicals").	
	2.2 Label elements	• CLP: hazard pictograms, signal words, hazard statements, precautionary statements	• See Flowchart 1 for a summary of SDS labelling requirements. • Any applicable REACH authorisation numbers must be mentioned here, and match those on the packaging label. • Label elements must match the labels on the packaging. • Symbols and/or pictograms may be shown in colour or black and white.	

Heading	Sub-Heading	Key Content	Suggested Checks	ES Relevance
	2.3 Other hazards	• PBT or vPvB status • Other hazards, e.g. formation of air contaminants, or dust, dust explosion hazards, cross-sensitisation, suffocation, freezing, odour or taste, hazards to soil-dwelling organisms, ozone creation • Endocrine disruption, if applicable*	• PBT or vPvB status must match the Results of PBT or vPvB Assessment in Subsection 12.5. • Endocrine disruption, if mentioned, must be consistent with the data in Sections 11 & 12. • Only those hazards that are not covered by a classification should be mentioned here.	

Heading	Sub-Heading	Key Content	Suggested Checks	ES Relevance
SECTION 3: Composition/ information on ingredients	3.1 Substances	• Substance name and Identification number(s), including CAS, EC and REACH Registration number where applicable • ATE, M-factor and SCL, if available***** • For nanoforms, particle characteristics*****	• See Flowchart 1 for a summary of SDS classification requirements. • For details of the substance classification check see Chapter 2.1 (above). • Nanoform, if indicated, must be consistent with other sections (e.g. Section 1, 2, 9, 11 & 12) • For substances, check if ATE, M-factor and/or SCL should be mentioned here, using internal or commercial substance database, or check on the C&L Inventory and/or the registration dossier (go to http://echa.europa.eu, then "Search for Chemicals").	
	3.2 Mixtures	• Hazardous substance name and Identification number(s), including CAS, EC and REACH Registration number where applicable • Concentration (fixed percentage or range) • CLP hazard class(es) and category code(s) and hazard statements • ATE, M-factor and SCL, if available*****	• See Flowchart 1 for a summary of SDS classification requirements. • For details of the substance classification check see Chapter 2.1 (above). • If percentage ranges are used, the classification derived should be based on the highest value in the range quoted. • Confirm that the ingredients listed are those that are present in the delivery state, which may not necessarily be the same as the ingredients that were used as raw materials to form the mixture (e.g. acids and bases mixed together would react to form salts). • If only the codes are used for the hazard statements, there must be a reference to the full text of each code in Section 16. • If the substance does not meet the classification criteria, the reason for indicating the substance in Subsection 3.2 must be given (e.g. "non-classified vPvB substance", "substance with a Community workplace exposure limit". • For substances in mixtures, see 3.1 above. If ATE, M-factor and/or SCL are mentioned, these must be considered in the mixture classification check (see Part 2.2).	
SECTION 4: First aid measures	4.1 Description of first aid measures	• First aid instructions and advice	• First aid-measures should be consistent with the precautionary statements in Section 2.1.	
	4.2 Most important symptoms and effects, both acute and delayed	• Summary of the most important symptoms and effects, both acute and delayed		

Heading	Sub-Heading	Key Content	Suggested Checks	ES Relevance
	4.3 Indication of any immediate medical attention and special treatment needed	• Testing and monitoring for delayed effects, antidotes and contraindications. • Specific treatment to be available at the workplace.		
SECTION 5: Firefighting measures	5.1 Extinguishing media	• Suitable and Unsuitable extinguishing media	• No priority actions for the plausibility check.	See ES/SDS Relevance Table.
	5.2 Special hazards arising from the substance or mixture	• E.g. hazardous combustion products		
	5.3 Advice for firefighters	• Protective actions or protective equipment for firefighters		
SECTION 6: Accidental release measures	6.1 Personal precautions, protective equipment and emergency procedures	• PPE advice and emergency procedures for non-emergency personnel and for emergency responders	• If references are made to other sections, those sections should be adequately completed.	See ES/SDS Relevance Table.
	6.2 Environmental precautions	• E.g. keep away from drains, surface and ground water		
	6.3 Methods and material for containment and cleaning up	• Advice on containing a spill • Advice on clean-up • Other information on spills and releases		
	6.4 Reference to other sections	• References to Sections 7, 8 and 13, if appropriate		

Heading	Sub-Heading	Key Content	Suggested Checks	ES Relevance
SECTION 7: Handling and storage	7.1 Precautions for safe handling	• Recommendations for safe handling • Advice to prevent handling incompatible substances/mixtures • Occupational hygiene advice	• No priority actions for the plausibility check.	
	7.2 Conditions for safe storage, including any incompatibilities	• Storage advice, consistent with SDS Section 9 and 10	• Ensure that any advice on avoidance of metal containers matches the hazards given in other sections.	
	7.3 Specific end use(s)	• Advice on intended specific end uses • Reference to industry specific guidance	• Ensure that the information matches Section 1.2.	See ES/SDS Relevance Table.
SECTION 8: Exposure controls/ personal protection	8.1 Control parameters	• Community and/or national occupational exposure limit values for each substance • Community and/or national biological limit values	• Where substances are identified in both Subsection 8.1 and Section 3, the substance identifiers must match. • For substances with a chemical safety report (which require an Ext-SDS), including those substances in mixtures, DNEL / PNEC values must be given here.	See ES/SDS Relevance Table.

Heading	Sub-Heading	Key Content	Suggested Checks	ES Relevance
	8.2 Exposure controls	• Engineering controls • Detailed specifications of Individual protection measures (e.g. for gloves: type of material and thickness, minimum breakthrough time) • Environmental exposure controls • For a substance registered as an isolated intermediate, confirmation that the SDS is consistent with the specific conditions	• Exposure control information may be provided in the attached ES instead of in Section 8.2. • Summaries in Section 8.2 must be consistent with the information in the ES.	
SECTION 9: Physical and chemical properties	9.1 Information on basic physical and chemical properties	• Properties, references to test methods, units, reference conditions • Information with regard to physical hazard classes	• Data must be consistent with the classification in Subsection 2.1 (e.g. extreme pH, flammable liquids, aspiration toxicity). • This section should provide supporting information for the safety characteristics and related test methods for physical hazards, identified in Subsection 2.1 (see Art. 8.2 CLP). • If it is known that the SDS covers a nanomaterial form, then that should be described here, and this should match any other comments about nano forms that may also be mentioned in other sections (e.g. Section 1, 2, 3, 11 & 12).	See ES/SDS Relevance Table.
	9.2 Other information			
SECTION 10: Stability and reactivity	10.1 Reactivity	• Reactivity hazards and specific test data, considering exposure to substances, containers and contaminants during transportation, storage and use	• Information must match Section 7.	

Heading	Sub-Heading	Key Content	Suggested Checks	ES Relevance
	10.2 Chemical stability	• Stability under normal ambient storage and handling conditions	• Information must match Section 7.	
	10.3 Possibility of hazardous reactions	• Whether, and conditions under which, hazardous reactions may occur	• Information must match Subsection 10.5.	
	10.4 Conditions to avoid	• Conditions that might result in a hazardous situation	• Information must be in compliance with the other Subsections in Section 10.	
	10.5 Incompatible materials	• Substances or mixtures with which a reaction could produce a hazardous situation	• Information must match Subsection 10.3.	
	10.6 Hazardous decomposition products	• Known and reasonably anticipated hazardous decomposition products	• Information must match Section 5.	
SECTION 11: Toxicological information	11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**	• Toxicological health effects and available data used, including appropriate information on toxicokinetics, metabolism and distribution	• Information must match the REACH registration data (if applicable). • Information must match / support the substance and mixture classifications in Section 2.1 and 3 or, if not, an explanation must be given here (e.g. classification based on human experience). • For mixtures the ATE_{mix} value, or the ATE for each substances should be stated, and it should be able to estimate it by using the toxicity data. • Any CMR statement must be consistent with the ingredients information in Subsection 2.1 and/or 3.2. • Endocrine disruption, if mentioned, must be consistent with the data in Subsection 2.3.	
	11.2 Information on other hazards**	• Endocrine disrupting properties* • Other adverse health effects not covered in the main section*		

Heading	Sub-Heading	Key Content	Suggested Checks	ES Relevance
SECTION 12: Ecological information	12.1 Toxicity 12.2 Persistence and degradability 12.3 Bioaccumulative potential 12.4 Mobility in soil 12.5 Results of PBT and vPvB assessment 12.6 Endocrine disrupting properties** 12.7 Other adverse effects**	• Information to evaluate environmental impact where released to the environment • Relevant test data, indicating species, media, units, test duration and test conditions • Bioaccumulation, persistence and degradability for each relevant substance in the mixture and/or for hazardous transformation products • Endocrine disrupting properties*	• Information must match the REACH registration data (if applicable). • Information must match / support the substance and mixture classifications in Section 2.1 and 3 or, if not, an explanation must be given here. • The results of PBT or vPvB Assessment in Subsection 12.5 (only for those substances / substances in mixtures for which a CSR was carried out) must match the PBT or vPvB status in Subsection 2.3. • Endocrine disruption, if mentioned, must be consistent with the data in Subsection 2.3.	
SECTION 13: Disposal considerations	13.1 Waste treatment methods	• Waste treatment containers and methods • Avoidance of sewage disposal • Special precautions • Relevant EU, national or regional provisions	• European Waste Code must be provided, and must match the uses in Subsection 1.2. • Information provided should be specific, practical advice (e.g. it should not simply refer to following local regulations). • Consider that different waste codes may be applied to the product and the packaging.	See ES/SDS Relevance Table.

Heading	Sub-Heading	Key Content	Suggested Checks	ES Relevance
SECTION 14: Transport information	14.1 UN number or ID number**	• Basic classification • information for road, rail, sea, inland waterways or air transportation	• Information must be consistent with the substance and mixture classifications in Section 2.1 and 3 or deviations should be explained. • All information should be sufficient to enable transport of the product without any questions coming back.	
	14.2 UN proper shipping name			
	14.3 Transport hazard class(es)			
	14.4 Packing group			
	14.5 Environmental hazards			
	14.6 Special precautions for user			
	14.7 Maritime transport in bulk according to IMO instruments**			
SECTION 15: Regulatory information	15.1 Safety, health and environmental regulations/ legislation specific for the substance or mixture	• Information relevant to EU or national legislation, such as: • REACH authorisations • REACH restrictions • Ozone depleting substances • Persistent organic pollutants • Export and import of dangerous chemicals • Seveso category	• Confirm applicability of indicated legislation with substance identity information in Section 3.	
	15.2 Chemical safety assessment	• Indication if a chemical safety assessment has been carried out by the supplier.	• If a chemical safety assessment is indicated, confirm that an ES (for a hazardous substance) or safe use information (for hazardous complex mixtures) is attached, or that the resulting risk management measures (for the mixture) are included in the other SDS sections as appropriate.	

Heading	Sub-Heading	Key Content	Suggested Checks	ES Relevance
SECTION 16: Other information		• Information relevant to the SDS compilation of the safety data sheet, such as: • Changes to previous version • Abbreviations and acronyms • Literature references and sources for data • Full text of Hazard or Precautionary statements • Health and environment training appropriate to workers	• No priority actions for the plausibility check.	
ANNEX: Exposure Scenarios (as applicable)			• See Chapter 4. Plausibility Check – Ext-SDS (Exposure Scenarios).	

** This requirement is optional from 1 January 2021; obligatory from 1 January 2023.*
*** This sub-heading is optional from 1 January 2021; obligatory from 1 January 2023.*

4. PLAUSIBILITY CHECK – EXT-SDS (EXPOSURE SCENARIOS)

An Exposure Scenario (ES) is required for each substance that is:

- Placed on the market above 10 tpa;
- Classified as hazardous under CLP or assessed to be PBT or vPvB.

See the AIG-REACH Part 5.6, which also covers other options for including exposure scenarios for substances into SDSs for mixtures. Industry experience shows that some attached ESs are not yet complete or compliant, and therefore do not enable the DU to make a REACH compliance check (Art. 37 REACH) without having further questions back to suppliers (upstream communication).

Therefore, Table 4 below explains how to perform a Plausibility Check on an Exposure Scenario, and refers to Chapter 6 which provides a recommended Ext-SDS REACH Compliance Check.

If an SDS for a mixture includes more than one ES for the various substances, it is recommended to perform the Ext-SDS Plausibility Check for each substance for which the ES is provided.

Although the strict legal requirement is to provide the ES in the local language of the market, ACEA members recognise that in practice it is often better to have in addition the original ES in English, since this version is often a more accurate original than the local translation.

Table 4 below uses ECHA's example format, which is not a legal requirement, but should be used as a standard structure for exposure scenarios. It is always recommended to use ECHA's latest available version.

Table 4: Plausibility Check – Ext-SDS (Exposure Scenarios)

Heading / Sub-Heading	Key Content	Suggested Checks	Basic SDS Section Relevance	Ch. 6 REACH Compliance Check
General		• ESs should consist of relevant data that can be followed by DUs for the purposes of REACH compliance (see Part 6); an ES that consists only of prose text is unlikely to be sufficient for DUs. • Compare RMM measures given in ES with those in the basic SDS. • Check that the overall content of the ES is consistent with the content of the basic SDS.		
1. ES Title / Use Name (contributing scenario)		• The ES title and contributing scenarios must match the relevant identified uses specified in (or referenced from) Subsection 1.2.	1.2	6.1
2. Conditions of use affecting exposure		• Header only, no priority actions for the plausibility check.		
2.1 Environment contributing scenario	• Product (article) characteristics	• The information must match Sections 9 & 12.	7, 8, 9	
	• Amount used, frequency and duration of use (or from service life)	• No priority actions for the plausibility check.	7, 8	6.3, 6.4
	• Technical and organisational conditions and measures	• The information must match Sections 7 & 8.2 (environmental exposure control).	6, 7, 8.2	6.3
	• Conditions and measures related to sewage treatment plant	• The information must match Section 8.2 (environmental exposure control).	8.2, 13	
	• Conditions and measures related to treatment of waste (including article waste)	• The information must match Section 13.	13	
	• Other conditions affecting environmental exposure	• No priority actions for the plausibility check.	7	
	• Additional good practice advice; Obligations according to Art. 37.4 REACH do not apply	• No priority actions for the plausibility check.		

Heading / Sub-Heading	Key Content	Suggested Checks	Basic SDS Section Relevance	Ch. 6 REACH Compliance Check
2.2 Worker contributing scenario	• Product (article) characteristics	• The information must match Sections 9.	7, 8, 9	
	• Amount used (or contained in articles), frequency and duration of use/exposure	• No priority actions for the plausibility check.	7, 8	6.2, 6.4
	• Technical and organisational conditions and measures	• The information must match Sections 7 & 8.2 (engineering controls).	5, 6, 7, 8.2	6.2
	• Conditions and measures related to personal protection, hygiene and health evaluation	• The information must match Sections 8.2 (specifications of individual protection measures).	5, 6, 7, 8.2	
	• Other conditions affecting workers exposure	• No priority actions for the plausibility check.	7, 8	6.2, 6.4
	• Additional good practice advice. Obligations according to Art. 37.4 REACH do not apply	• No priority actions for the plausibility check.		
3. Exposure estimation and reference to its source		• Header only, no priority actions for the plausibility check.		
3.1 Environment contributing scenario	• Release Rate • Release Estimation Method • Exposure estimation tool used • Protection Target • Predicted Environmental Concentration (PEC) (Exposure Estimate) • RCR	• Check that all required data is provided. • Check calculation of RCR.		6.3. 6.4
3.2 Worker contributing scenario	• Route of exposure and type of effects • Exposure estimate • RCR	• Check that all required data is provided. • Check calculation of RCR.		6.2, 6.4
4. Guidance to DU to evaluate whether the DU works inside the boundaries set by the ES	• Scaling method • Scalable parameters • Boundaries of scaling	• Check that all required data is provided.		6.4

5. PLAUSIBILITY CHECK FOLLOW-UP

5.1 CONTACTING SUPPLIER

If the SDS has failed the Plausibility Check, contact the supplier. REACH imposes a duty to communicate up the supply chain in case of the recipient having any new information on hazardous properties, including classification, or any other information that might call into question the appropriateness of the risk management measures identified in the supplier's SDS (see Art. 34 REACH).

In all cases, it is recommended to:

- Be precise about reasons for rejection;
- Where possible, give regulatory reference (e.g. Annex II REACH, ECHA SDS Guidance, etc.);
- Ask for an SDS revision and agree time limit;
- Confirm any agreements or additional data in writing;
- Follow up on agreed actions, and escalate internally as required.

> ***"Suppliers in a supply chain shall cooperate to meet the requirements for classification, labelling and packaging in this Regulation."***
> **(Art. 4.9 CLP)**

5.2 RESUBMITTING SDSS

In case the supplier agrees to revise and resubmit an SDS, the Plausibility Check process begins again on receipt of the revised SDS.

5.3 CLASSIFICATION CHECK FAILURE

Classification discussions may include the following:

- If a registration dossier exists, why the classification is different?
- If no registration dossier exists, why the classification has not been notified?
- Are there any tests available to confirm the classification?

In the case of a disagreement between recipient and supplier on classification that is not solved by discussion between them, there are several options open to the recipient, who can:

a. Accept and/or use the supplier's classification. This may be a temporary solution, while further investigations or tests are performed. However, the recipient should not take this as an easy option, especially if the recipient has information that calls the supplier's classification into question. In that case, either changing the product (Option b) or a self-classification (Option c) may be the better options, due to the potential liability associated with accepting the supplier's classification.

   Note that this option is not possible in the case of more than one supplier having more than one classification. Note also that taking this option does nothing to improve the data quality of SDSs in the supply chain.

b. Change the product, or the supplier, or both. This option is clearly more difficult in the case of thoroughly qualified production materials (such as vehicle adhesives) than for non-essential ancillary materials (such as toilet cleaners).

c. Perform a self-classification, based on expert judgement and confidence with reliable evidence. It follows that, in cases where the SDS includes the REACH Registration Number for the substance, the recipient would have the C&L notification duty according to Art. 38.4 REACH within 6 months (see http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/submitting-a-downstream-user-report-classification-differences).

   DUs do not need to report to ECHA as long as their self-classification is the same as one or more of their suppliers, or if they use the substance, on its own or in mixtures, in quantities of less than 1 tpa (see Art. 38.5 REACH).

   It also follows that for substances that are not REACH Registered, the recipient has the chance to perform a self-classification without the obligation to notify ECHA.

   A further option to discuss and publish the classification with other affected notifiers is to make a voluntary notification to the C & L inventory (Art. 39 CLP, see http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/notification-to-the-cl-inventory). This can be done as an intermediate solution, since the DU has 6 months before the DU CRS duty applies (see Art. 39.2 REACH).

d. Ask the national Competent Authority's CLP Helpdesk and/or the applicable local enforcement agency for advice. Further support may be obtained from the relevant Trade Associations.

5.4 OTHER PLAUSIBILITY CHECK FAILURE

In the case of any other reason other than the classification for the SDS failing the Plausibility Check, there are again several options open to the recipient, who can:

a. Accept and/or use the supplier's SDS information. Again, this may be a temporary solution, while further updates may subsequently be required. However, the recipient should not follow this option if the recipient has information that calls the supplier's SDS content into question. In that case, changing the product (Option b) may be the better option. Note that Option A is not possible in the case of more than one supplier having conflicting SDS content.

b. Ignore minor discrepancies which are not reasonably expected to lead to harm (e.g. spelling errors, missing page numbering, a mistake in a sub-heading). However, several minor discrepancies might call the competence of the Supplier into question.

c. Change the product, or the supplier, or both.

d. Ask the relevant Competent Authority and/or the applicable local enforcement agency for advice.

5.5 RECORDKEEPING

REACH includes the general requirement to assemble and keep available all the information that has been used to maintain REACH compliance; this should be taken as the minimum requirement when applied to SDSs. However, due to the potential relevance of SDS information to long term human health and environmental protection, it is recommended to maintain SDS information indefinitely.

Whether kept in hardcopy or electronic formats, it is recommended to maintain a backup in a future-proof electronic format such as PDF files. It is recommended to keep relevant records concerning the receipt of each SDS as follows:

a. Document the Plausibility Check content and results, and document all decisions taken and resultant actions and their outcomes.

b. Where relevant, add the accepted SDS to the recipient company's own SDS document management system (see also obligations for provide access to SDS information in Art. 35 REACH).

c. Move any now obsolete SDSs to the recipient company's own SDS archive.

d. Update the recipient company's own substance reference database to take account of new information received.

6. EXT-SDS REACH COMPLIANCE CHECK

General remarks

Exposure scenario(s) for mixtures do not exist, because mixtures are not themselves subject to REACH registration and no chemical safety report is legally required for them. Instead, a DU may receive "Safe Use Mixtures Information" (SUMI) for complex mixtures, in which the ES information of several ingredients is consolidated. Although there is no standardised format specified under REACH, this SUMI looks similar to an ES and it is recommended to be taken as additional input for the workplace and environmental safety assessments on site.

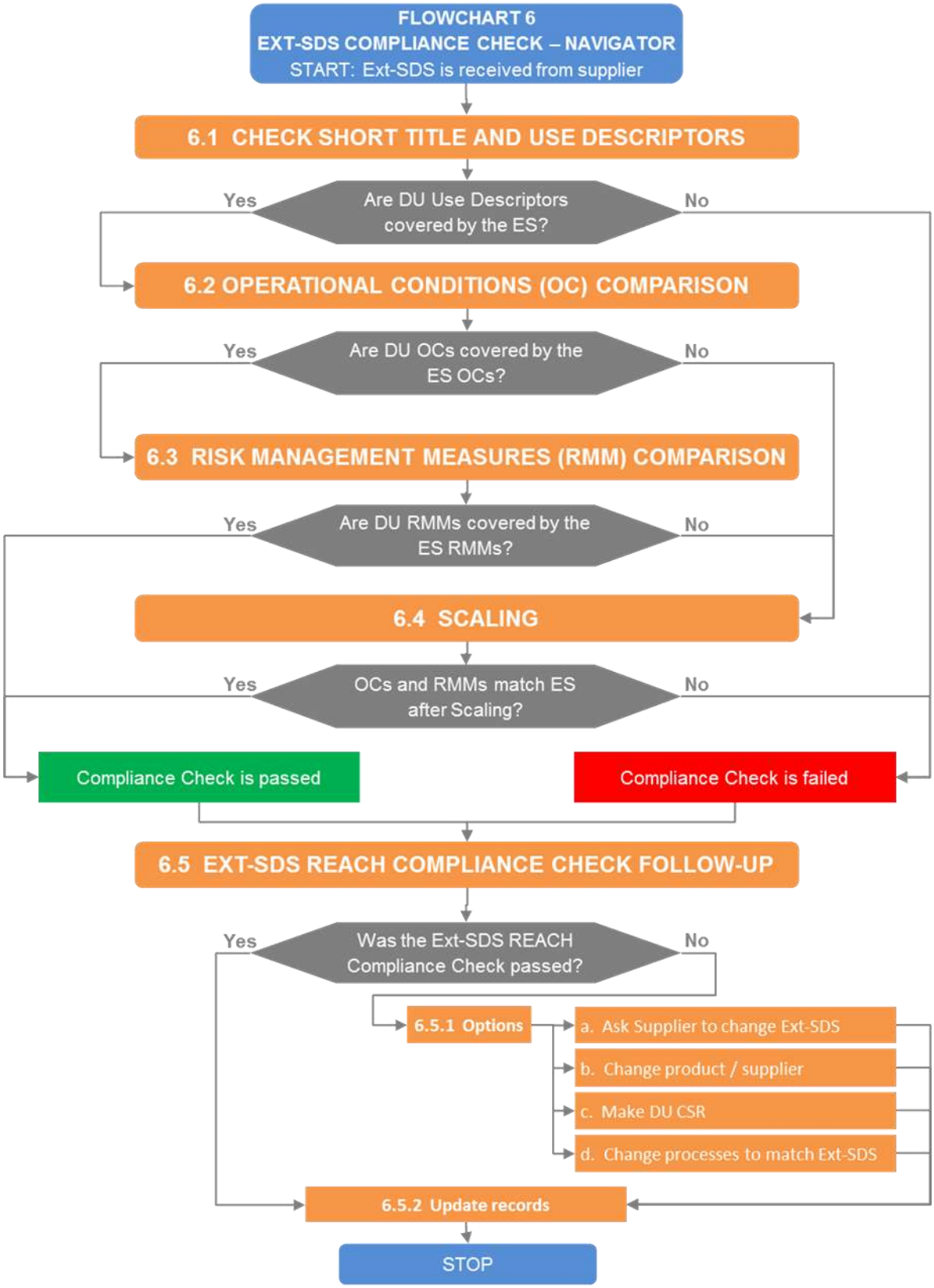
In the following chapters, wherever Ext-SDSs or ESs are mentioned, they can also be understood to include SUMIs where applicable.

DUs may receive Ext-SDSs either for substances, if placed on the market (manufactured or imported) at more than 10 tpa, or for mixtures. To check whether an ES is needed refer to Section 15.2 of the SDS, where there should be a statement as to whether a CSR was carried out for the hazardous substances or substances in the mixture.

In case of ES information being integrated into the main body of the basic SDS the DU may find in Section 1.2, relevant identified uses, statements like: "*This safety data sheet contains an ES in an integrated form. Contents of the exposure scenario have been included into sections 1.2, 8, 9, 12, 15 and 16 of this safety data sheet.*"

According to Title V of REACH, DUs are obliged to check whether they are working within the described boundaries of the ES and document this result. In addition, where a substance is authorized or restricted (which shall be stated in Section 15 of the SDS), DUs have to check whether the conditions of use match their own.

The main tasks for a DU on receipt such an Ext-SDS is shown in the AIG-REACH, Chapter 5.6, "Safety Data Sheet and DU Obligations". The following Flowchart and Chapters describe how a DU can carry out a REACH compliance check in more detail, and give some practical examples.


FLOWCHART 6
EXT-SDS COMPLIANCE CHECK – NAVIGATOR
START: Ext-SDS is received from supplier
6.1 CHECK SHORT TITLE AND USE DESCRIPTORS
Are DU Use Descriptors covered by the ES?
Yes
No
6.2 OPERATIONAL CONDITIONS (OC) COMPARISON
Are DU OCs covered by the ES OCs?
Yes
No
6.3 RISK MANAGEMENT MEASURES (RMM) COMPARISON
Are DU RMMs covered by the ES RMMs?
Yes
No
6.4 SCALING
OCs and RMMs match ES after Scaling?
Yes
No
Compliance Check is passed
Compliance Check is failed
6.5 EXT-SDS REACH COMPLIANCE CHECK FOLLOW-UP
Was the Ext-SDS REACH Compliance Check passed?
Yes
No
6.5.1 Options
a. Ask Supplier to change Ext-SDS
b. Change product / supplier
c. Make DU CSR
d. Change processes to match Ext-SDS
6.5.2 Update records
STOP

6.1 CHECK SHORT TITLE AND USE DESCRIPTORS

REACH requires a registrant to deliver the identified uses by using the use descriptor system (see http://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf). Therefore the use descriptors are consequently part of the Ext-SDS and the ES. REACH obliges DUs who receive Ext-SDSs to check whether their current uses are covered. To simplify this comparison, it is recommended that DUs also adopt the use descriptor system to describe their own uses.

6.1.1 Example 1 – Short Title and Use Descriptors

A DU is using a hydraulic fluid in a production plant and receives an Ext-SDS for this product. In section 1.2, 16, or in an annex to the SDS, a table of contents with all available ESs including a short description in the header is attached. (For a mixture SDS, an overview of the Safe Use Mixture Information (SUMI) may be attached instead).

This example focusses on the ES No. 14, "Industrial use of hydraulic fluids at automotive industry".

Table 6.1.1: Example 1 – Overview on the Exposure Scenarios

ES No.	Short title of the exposure scenario	Use Descriptors					
		SU	PROC	ERC	spERC	PC	AC
1	Manufacture of substance, use as a process chemical, Use as an intermediate	SU 3 SU 8	PROC 1 PROC 2 PROC 3 PROC 4 PROC 8a PROC 8b PROC 9	ERC 6c	-	-	-
...							
14	Industrial use of hydraulic fluids at automotive industry	SU 3 SU 10	PROC 1 PROC 2 PROC 3 PROC 4 PROC 8a PROC 8b	ERC 2	-	PC 17	AC 1

STEP 1: The DU selects (or requests, if not attached) the ES that matches the actual on site use; in this case ES No. 14, "Industrial use of hydraulic fluids at automotive industry".

STEP 2: The DU starts the REACH compliance check process by comparing the use descriptors with the DU's own ones.

For this comparison the DU describes actual local workplace and environmental processes using the use descriptor system too. The result of the comparison for Example 1 is shown below:

Table 6.1.2: Example 1: Use Descriptors Comparison

Use Descriptors* in ES No. 14	Use Descriptors* at DU Local Site	Result
SU 3	SU 3	✓
SU 10	-	-
AC 1	AC 1	✓
PC 17	PC 17	✓
PROC 1,2,3, 4,8a,8b	PROC 9	?
ERC 2	ERC 7, ERC 9b	✘

In this example, PROC 1, 2, 3, 4, 8a, 8b* only describe the manufacturing process of the hydraulic fluids, and not their use at DU site. PROC 9*, which corresponds to the contributing workplace scenario "Transfer of substance or preparation into small containers (dedicated filling line, including weighing)", is missing in the ES, but is necessary for the DUs use. In addition, with regard to the environment, ERC 2 in the ES does not cover the DU's ERC 7 or 9b (necessary for repair shops). Therefore the DUs use conditions are not yet covered by the ES.

Sometimes missing PROCs are covered by other higher ranked PROCs (PROC hierarchy):
e.g. PROC2, "*Use in closed, continuous process with occasional controlled exposure*",
is covered by
PROC4 "*Use in batch and other process (synthesis) where opportunity for exposure arises*".

The DU has several options to get the DU uses covered (see AIG-REACH Chapter 5.6, or Chapter 6.5.1 in this Annex Q).

6.2 OPERATIONAL CONDITIONS (OC) COMPARISON

If the short title and use descriptors check (see Chapter 6.1, above) is passed, the next step of the REACH compliance check is to check if the DU is working within the boundaries of the ES. Firstly this means that DU has to compare actual local operational conditions (OCs) with those stated in the appropriate identified ES (see Chapter 6.3 for checking risk management measures (RMMs)).

6.2.1 Example 2 – Workplace OCs

For a cleaning agent the following OCs are stated in the appropriate ES:

Table 6.2.1: Example 2 – Workplace OCs (Control of Worker Exposure)

ES Information	ES Value	DU Local (Site) Value	Result
Duration and frequency of use	Covers frequency up to 1 hrs/day, 5 days/week	0.5 hrs/day, 5 days/week	✓
Human factors not influenced by risk management	Exposed skin areas: both hands (490 cm^2)	Used with both hands. Skin protection.	✓
Other operational conditions affecting worker exposure	Indoor use	Indoor use	✓
Conditions and measures related to personal protection, hygiene and health evaluation (worker)	Use with local exhaust ventilation (efficiency: 80 %)	Use with local exhaust ventilation (efficiency: 90 %)	✓

In Example 2, all OCs of the ES are matched by the DU.

If not, e.g. if the DU used the cleaning agent 2 hrs/day, a deeper check of the ES conditions would be required. For example, perhaps the DU use would be covered after scaling (see Chapter 6.4), or the DU could decides to implement the conditions described in the ES, or creates a downstream user chemical safety report (DU CSR) according to Art. 37 REACH.

6.2.2 Example 3 – Environmental OCs

For the environment, the OCs are in general different from the workplace OCs, and can sometimes be difficult to check. For the following exposure parameters, it is important to distinguish between those that can be influenced by the DU and those that cannot.

Parameters that the DU can mainly not influence…	Parameters that the DU can influence…
• Receiving water stream; • Sewage Treatment Plant (capacity, effluent rate); • Biodegradation in external Sewage Treatment Plant.	• Concentration of the substance / substance in a mixture); • Amount of substance / substance in a mixture; • Production efficiency (elimination/formation of the substance during production) Degradation through onsite STP; • Efficiency of the Risk Management measures (RMMs).

For the REACH Compliance check, DU shall compare the DU production data with the OCs stated in the appropriate ES:

Table 6.2.2.: Example 3 – Environmental OCs (Control of Environmental Exposure)

ES Information	ES Value – OCs	DU Local Site Value – OCs	Result
Annual amount per site	5 kt/a	7 kt/a	✘
Maximum allowable site tonnage (M_{safe})	100 kg/d	120 kg/d	✘
Removal efficiency fraction (onsite)	93.67 % efficiency water 0 % efficiency air	60 % after STP 0 % efficiency air	✘
Emission days per year	300	300	✓
Environmental factors not influenced by risk management			
Local freshwater dilution factor	10	24	✘
Type of Sewage treatment plant (STP)	onsite STP	onsite STP	✓
Sewage treatment flow rate	2000 m^3/d	9733 m^3/a	✘
River flow rate	18.000 m^3/d	225.083 m^3/a	✘
Other given operational conditions of use affecting environmental exposure			
Release fraction to air from process (initial release prior to RMM)	0.00001	No emission	✓
Release fraction to wastewater from process (initial release prior to RMM)	1	1	✓
Release fraction to soil from process (initial release prior to RMM)	0	0	✓

In Example 3, the DU will come to the conclusion that the DU OCs (values) may not be in compliance with those delivered in the supplier ES because for example the onsite maximum site tonnage is exceeding the allowable. DU has the option to scale (see Chapter 6.4) or to create an own DU-CSR according to Art. 37 REACH.

6.3 RISK MANAGEMENT MEASURES (RMM) COMPARISON

The DU must compare the RMM in a risk assessment with the recommended risk management measures, as indicated in the Ext-SDS. ECHA's DU Guidance states that the *"DU shall compare the information given on risk management measures, including their effectiveness, with those he apply."*

Related to RMM comparison, the effectiveness is important as key information. Effectiveness is the degree of exposure or emission reduction achieved by application of the risk management measure.

DU can be sure that their risk management measures are covered if their effectiveness is equal to, or higher than, what is specified in the exposure scenario.

6.3.1 Example 4: Workplace RMMs

A DU receives the following RMMs for the workplace as part of an ES. The DU has to compare the RMMs given for each contributing scenario (CS) with the DU's own ones:

Table 6.3.1.1: Example 4 – Workplace RMMs (Control of Worker Exposure)

ES Information – Contributing Scenarios	ES Value – RMMs	DU Local Site Value – RMMs	Result
General exposures (closed systems) [CS15]. Use in contained batch processes [CS37].	Handle substance within a closed system [E47]. Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour) [E11].	Chemical product mainly used in closed system. Good standard ventilation used (15 air changes per hour).	✓
Process sampling [CS2].		Appropriate ventilation used during sampling.	
Laboratory activities [CS36].	No specific measures identified [EI18].	Appropriate gloves, eye and body protection used. For special uses hoods are provided.	✓
Bulk transfers [CS14].	Ensure material transfers are under containment or extract ventilation [E66].	Extract (local) ventilation used during bulk transfer operations.	✓
Mixing operations (open systems) [CS30]. With potential for aerosol generation [CS138].	Provide a good standard of general or controlled ventilation (10 to 15 air changes per hour) [E40].	Good standard ventilation used (15 air changes per hour).	✓
Manual [CS34]. Transfer from/pouring from containers [CS22].	Wear suitable eye protection and gloves tested to EN 375 [PPE 14]. See Section 8 of the Safety Data Sheet.	Appropriate half-mask used (protection factor: 10). Appropriate gloves (nitrile rubber) used.	✓
Drum/batch transfers [CS8].			
Equipment cleaning and maintenance [CS39].	Drain down and flush system prior to equipment break-in or maintenance [E55].	Ensured.	✓
Storage [CS67]. With occasional controlled exposure [CS140].	Handle substance within a closed system [E47].	Closed storage room used. Good standard ventilation (15 air changes per hour) installed.	✓

In Example 4, the applied RMMs at the DU site are equal or more stringent than those stated in the ES, ensuring the safe use of the substance. Therefore the estimated exposure at workplace should be similar to the exposure at DU site, and the resulting RCR should be less than 1.0, which has to be confirmed by measurement.

In the ES the following estimated exposure was used for the exposure assessment:

Table 6.3.1.2: Example 4 – Workplace Exposure Estimation and Reference to Sources

PROC	Exposure route	ES Estimated Exposure Value	ES RCR	DU Local Site Estimated Exposure Value	DU Local Site RCR	Result
PROC 1	Inhalation	0.01 ppm	0.00			
	Dermal	0.34 mg/kg bw/d	0.00			
PROC 2	Inhalation	10.00 ppm	0.56			
	Dermal	1.37 mg/kg bw/d	0.01			
PROC 3	Inhalation	17.50 ppm	0.56			
	Dermal	0.34 mg/kg bw/d	0.01			
PROC 4	**Inhalation**	**14.00 ppm**	**0.99**	**12.00 ppm**	**0.85**	✓
	Dermal	6.86 mg/kg bw/d	0.00			
PROC 8a	Inhalation	5.00 ppm	0.56			
	Dermal	13.71 mg/kg bw/d	0.00			
PROC 8b	Inhalation	7.00 ppm	0.79			
	Dermal	6.86 mg/kg bw/d	0.04			
PROC 9	Inhalation	10.00 ppm	0.56			
	Dermal	6.96 mg/kg bw/d	0.04			
PROC 14	Inhalation	15.00 ppm	0.85			
	Dermal	3.43 mg/kg bw/d	0.02			
PROC 15	Inhalation	10.00 ppm	0.39			
	Dermal	0.34 mg/kg bw/d	0.04			

It is obvious that PROC 4, "Use in batch manufacture of a chemical where significant opportunity for exposure arises" (e.g. during charging, sampling or discharge of material, and when the nature of the design is likely to result in exposure), is the most critical one for the inhalation route in the exposure estimation. The dermal route has to be checked separately (not included in this example).

DUs must determine their actual local exposures (inhalation route), calculate their own RCRs (exposure / DNEL) and compare the results with the ones stated in the ESs to make sure that their own uses are safe. It should be noted that if the DU uses OCs and RMMS stated within the ES, the RCR should be less than 1.0, as shown in the table above.

In this example all RMMs were already implemented at the DU site and the RCR of the critical PROC

4 was confirmed by exposure measurement, showing an exposure of 12 ppm during charging, sampling and discharging. Therefore no further action was required. For workplace RMMs it is recommended to document the REACH compliance check within the workplace risk assessment process.

6.3.2 Example 5 – Environmental RMMs

A DU receives the following RMMs for the environment as part of an ES. The DU has to compare the RMMs given with the actual local ones at the DU site:

Table 6.3.2.1: Example 5 – Environmental RMMs (Control of Environmental Exposure)

ES Information – Contributing Scenarios	ES Value – RMMs	DU Local Site Value – RMMs	Result
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	Treat air emissions to provide a typical removal efficiency of 0%. [TCR 7]	Air filter installed	✓
	Prevent discharge of undissolved substance to or recover from wastewater [TCR14]	Discharge prevented	✓
	Release fraction to air from process (after typical onsite RMMs consistent with EU Solvent Emissions Directive requirements) [OOC11]	Yes	✓
Organisational measures to prevent/limit release from site	Do not apply industrial sludge to natural soils [OMS2].	Industrial sludge is sampled and disposed of according to national regulation	✓
	Sludge should be incinerated, contained or reclaimed [OMS3].		
Conditions and measures related to municipal sewage treatment plant	Estimated substance removal from wastewater via domestic sewage treatment 93.67 (%) [STP3]	STP efficiency: 95 %.	✓
Conditions and measures related to external treatment of waste for disposal	Use the following chemical treatment methods for waste water: oil-water separation	Oil-Water separation is used prior to sewage plant treatment	✓
	External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW 3]		
Conditions and measures related to external recovery of waste	External recovery and recycling of waste should comply with applicable local and/or national regulations [ERW 1].	Waste are disposed of as hazardous waste	✓

In Example 5, the applied RMMs at DU site are equal to, or more stringent than, those stated in the

ES, thus ensuring the safe use of the substance. Therefore the predicted environmental concentration should be similar to the one at DU site, and the resulting RCR should be less than 1.0. Anyway, it is not possible to measure the real substance concentration in the appropriate environmental protection target, because no standard measurement method exists for all substances, and because often more general parameters are used.

PNECs are normally related to the specific STP and to its discharge into surface water, and are therefore site-specific. Waste substance concentrations in waste water are normally specific to the equipment used by the DU, and therefore one can calculate the main waste water substance concentration through measurement at specific local areas.

In case local permit limits exist, these as well as the REACH PNEC values must be complied with.

The following predicted environmental concentrations (PECs) calculated at the DU site (see Chapter 6.4.2) should not exceed the ones in the ES, and the RCR must be less than 1.0.

Table 6.3.2.2: Example 5 – Environmental Exposure Estimations and Reference to Sources

Industrial Use	Protection Target	ES PEC	ES RCR	DU Local Site PEC_{local}	DU Local Site RCR_{local}	Result
ERC2	Fresh water	0.01380 mg/l	0.0422			
	Marine water	0.00533 mg/l	0.0163			
	Fresh water sediment	0.01480 mg/kg	0.0546			
	Marine water sediment	0.05710 mg/kg	0.0211			
	Soil	0.01350 mg/kg	0.00665			
	STP	0.52700 mg/l	0.0810	0.45 mg/l	0.069	✓
	Air	0.23200 mg/m3	Not applicable			

In Example 5, no problems should arise because the RCR is well below 1.0. The critical protection target is the STP but also there the RCR is far below 1.0. Therefore no further action required.

6.4 SCALING

Data in Exposure Scenarios:

- Are often based on worst-case assumptions;
- Are often non fitting with the real on-site conditions;
- Should be modifiable to fit those conditions.

Therefore DU's are permitted to conclude that they fit into the ES conditions after a so-called "scaling" process.

"Scaling" can be used to make a qualitative assumption when the numeric values are not fully comparable. With simple words, scaling means that some of the exposure determined parameters given in the ES are modified in a way that they can be compared with the own parameters and fitting to them.

Sometimes "Scaling" can be done without using the original exposure assessment tools, but in most cases it is necessary to use the same calculation tool as stated in the ES. Unfortunately, no unique exposure assessment tool exists. The most important ones are ECETOC-TRA for workplace exposure assessment and EUSES for the environmental assessment. It may happen that DU has to apply more than one scaling tool. In general for scaling (as for many other aspects of the REACH process), special knowledge is required.

For end users such as the automotive industry, some suppliers have developed scaling tools for specific uses, e.g. pre-treatment and/or coating etc. DUs are recommended to ask their suppliers if they need support in understanding their scaling tools.

In general, scaling is only possible if:

- A quantitative risk assessment exists as a basis;
- Exposure assessment tools are used instead of measured data (e.g. worst-case scenarios);
- Exposure levels are not modified significantly, that means that the described conditions within the ES are only changed in a very small range.

If scaling tools are not offered via ES, then only linear standard equations can be used.

Sometimes the DU cannot use scaling because the exposure determining parameters (e.g. river flow rate, STP capacity / effluent rate) are not under the DU's influence. In such cases DU-CSR is the only option.

The borderline between the ability to apply scaling and the need to perform a DU CSR is crossed if very significant changes in operational conditions would have to be implemented in order to comply with the ES.

6.4.1 Example 6 – Workplace Scaling

An ES states that the frequency of use should not exceed 120 min/half-shift, and that the product shall be used with local exhaust ventilation with an efficiency of 80 %:

Table 6.4.1: Example 6 – Scaling: Workplace OCs (Control of Worker Exposure)

ES Information – Production Information	ES Value – OCs	DU Local Site Value – OCs	Result After Scaling
Duration and frequency of use	120 min; per half shift (4 h)	60 min / per shift (2 h)	✓
Human factors not influenced by risk management	Exposed skin areas: both hands (490 cm^2)	Exposed skin areas: both hands	✓
Other operational conditions affecting worker exposure	Indoor use	Indoor use	✓
Conditions and measures related to personal protection, hygiene and health evaluation (worker)	Use with local exhaust ventilation (efficiency: 80 %)	Use with local exhaust ventilation (efficiency: 70 %)	?

In Example 6, the DU can show relatively easily by scaling using a simple linear calculation) that the DU's local duration and frequency of use (60 min per 2 h) is equivalent to the OC specified in the ES (120 min per 4 h).

A question mark remains for the local exhaust ventilation, because the DU's local efficiency is 10 % lower than the value stated within the ES. Therefore it remains unclear whether the DU is working within the boundaries of the ES.

In this example, the ES states: "For scaling see: http://www.ecetoc.org/tra". Therefore the DU must use the same scaling tool, ECETOC-TRA. In ECETOC-TRA the DU has to change the value for local exhaust ventilation efficiency from 80 to 70 % and start a new calculation by keeping all other parameters as specified in the ES. The DU must then check if the newly calculated data within the tool results in a safe use.

Alternatively, the DU can show by exposure measurement that the use under the DU's local OCs and RMMs is safe, and document this thoroughly within the workplace risk assessment or use other exposure assessment methods.

In case that the RCR is already only just below 1.00,
it is possible that scaling will be unsuccessful.

6.4.2 Example 7 – Environmental Scaling

A DU has already determined the following parameters (see Example 3: onsite PEC; OCs / RMMs related to the environment) for the REACH compliance check:

Table 6.4.2: Example 7 – Scaling: Environmental OCs (Control of Environmental Exposure)

ES Information – Production Information	ES Value – OCs	DU Local Site Value – OCs	Result After Scaling
Maximum allowable site tonnage (M_{safe})	150 tpa *($PNEC_{aqua}$: 20,6 µg/l)*	20 tpa *(calculated via scaling;* *PEC_{local}: 1,2 µg/l)*	✓
Removal efficiency fraction (onsite) *(F_{STP})*	99 % efficiency water	*60 % STP efficiency* *90 % STP capacity*	✓
Emission days per year (T_{em})	300	300	✓
Environmental factors not influenced by risk management			
Local freshwater dilution factor (sewer)	10	24	✓
Type of Sewage treatment plant (STP)	onsite STP	onsite STP	✓
Sewage treatment flow rate	2000 m³/d	8000 m³/a	✓
River flow rate ($Q_{river\ flow\ rate}$)	18.000 m³/d	185.000 m³/a	✓
Other given operational conditions of use affecting environmental exposure			
Typical release to water after RMM (F_w):	10 %	*42 % (several production ways – average release)*	✓

Because DU recognizes that there are different efficiency factors for the OCs and RMMs, he uses scaling to show that the DU is working within the boundaries of the ES. The most important scaling tool for environmental (EUSES) is based on the calculation formula of the predicted environmental concentration (PEC) as shown below (linear approach):

$$PEC_{local} = \frac{M \times C \times (1 - F_w) \times (1 - F_{RMM}) \times (1 - F_{STP})}{Capacity \times Dilution \times T_{em}}$$

$$M_{safe} = \frac{PEC_{local} \times Capacity \times Dilution \times T_{em}}{C \times (1 - F_w) \times (1 - F_{RMM}) \times (1 - F_{STP})}$$

$$RCR_{local} = PEC_{local} / PNEC$$

PEC_{local}	predicted environmental concentration (local)
M	daily substance amount or M_{safe} (if PEC_{local} already determined)
C	concentration of the substance in the product
F_w	emission factor: substance amount
F_{RMM}	Efficiency of RMMs
F_{STP}	Estimated substance removal from STP
T_{em}	Duration of emission, workdays
Capacity	STP capacity
Dilution	Dilution Factor, Sewer

The use can be regarded as safe as long as the calculated maximum amount used at the DU site does not exceeding the M_{safe} value specified in the ES. The DU is concluded to be working within the boundaries of the ES as long as the RCR_{local} is less than 1.0.

Some authorities demand RCR of less than 0.5, which will of course influence the $M_{safe\ local}$, because normally the M_{safe} is calculated with an assumed RCR of 0.99.

In Example 7, following the scaling process the DU determined the PEC_{local}, calculated with the above formula the DU's local maximum safe amount (M_{safe}), and came to the conclusion that the DU operates well below the PEC and M_{safe} stated in the ES. The formula is applicable for freshwater / surface water. All other parameters relative to exposure can be changed too if required.

For coating processes, ACEA itself offers spERCs
(http://www.acea.be/industry-topics/tag/category/reach:
see REACH: Extended Safety Data sheets, 23/08/2013)

6.5 EXT-SDS REACH COMPLIANCE CHECK FOLLOW-UP

In case the above described REACH compliance check (steps 6.1 to 6.4) fails, the DU has several options:

6.5.1 Options in case the Ext-SDS Compliance Check Fails

a. Ask the supplier to change the Ext-SDS; communicate missing identified use upstream to the supplier and deliver sufficient information so that the supplier is able to register this missing use.

b. Change product / supplier

c. Make a DU CSR (see Art. 37 REACH) for the identified use that is not covered by the supplier's Ext-SDS; in parallel, the DU must report the missing identified uses to ECHA within 6 months (see Art. 38 REACH).

d. Change the DU process to match the Ext-SDS. The DU has 12 months' time to apply the OCs and RMMs of the ES.

6.5.2 Update Records

It is recommended to document the result of the REACH compliance check, either in hardcopy or electronic format. This can be done within the DU's own workplace safety or environmental risk assessment or by using special dedicated forms developed for internal use by each company.

7. ABBREVIATIONS & DEFINITIONS

AC	Article Category
ACEA	European Automobile Manufacturers Association
AIG-REACH	Automotive Industry Guideline on REACH
ATE	Acute Toxicity Estimate
ATEmix	Acute Toxicity Estimate for Mixture
Basic SDS	The 16 sections of the Safety Data Sheet *i.e. not including any attached Exposure Scenarios; see also SDS, Ext-SDS, ES*
C & L	Classification & Labelling
CLP	Classification, Labelling and Packaging Regulation No. 1272/2008
CMR	Carcinogenic, Mutagenic, Toxic for Reproduction
CSR	Chemical Safety Report
DNEL	Derived No Effect Level
DPD	Dangerous Preparations Directive 99/45/EC
DSD	Dangerous Substances Directive 67/548/EEC
DU	Downstream User
ECHA	European Chemical Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
End User	Downstream Users who use substances which do not remain in the product in the context of an industrial process or professional operation
ERC	Environmental Release Categories
ES	Exposure Scenario
Ext-SDS	Extended Safety Data Sheet *i.e. one that includes one or more Exposure Scenarios*
GHS	Globally Harmonized System of Classification and Labelling of Chemicals (United Nations)
IMO	International Maritime Organization
mg/kg bw/d	Milligrams per kilogram of body weight per day
OC	Operational Conditions
OEM	Original Equipment Manufacturer *In this document assumed to be the vehicle manufacturer*

PBT	Persistent, Bio-accumulative and Toxic
PC	Product Category
PEC	Predicted Exposure Concentration
PNEC	Predicted No Effect Concentration
PPE	Personal Protective Equipment
PROC	Process Category
RCR	Risk Characterisation Ratio
REACH	Registration, Evaluation, Authorisation (and Restriction) of Chemicals Regulation No. 1907/2006
RMM	Risk Management Measure
SCL	Specific Concentration Limit
SDS	Safety Data Sheet *Unless referred to as "Basic SDS, the term "SDS" is taken to also include Ext-SDS; see also Basic SDS, Ext-SDS*
spERC	Specific Environmental Release Category
STP	Sewage Treatment Plant
SU	Sector of Use
SUMI	Safe Use Mixtures Information
UFI	Unique Formula Identifier

8. REFERENCES

8.1 LEGISLATION

BPR: Biocidal Products Regulation (EU) No 528/2012

CLP: Classification, Labelling and Packaging of substances and mixtures Regulation (EC) No 1272/2008

DPD: Dangerous Preparations Directive 99/45/EC

DSD: Dangerous Substances Directive 67/548/EEC

Protection of Workers Directive 98/24/EC

Pyrotechnic Articles Directive 2013/29/EU

REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006; as amended by Regulation No 453/2010, by Regulation No 2015/830, and by Regulation No 2020/878

Solvent Emissions Directive 1999/13/EC

8.2 GUIDANCE, INFORMATION & TOOLS

ECHA Forum REACH-EN-FORCE 2 Project Report: Obligation of downstream users - formulators of mixtures
http://echa.europa.eu/documents/10162/13577/forum_report_ref2_en.pdf

ECHA Guidance for Downstream Users
https://echa.europa.eu/documents/10162/23036412/du_en.pdf/

ECHA Guidance on Information Requirements and Chemical Safety Assessment; Environmental Exposure Estimation
http://echa.europa.eu/documents/10162/13632/information_requirements_r16_en.pdf

ECHA Guidance on Information Requirements and Chemical Safety Assessment; Use Descriptor System
http://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf

ECHA Guidance on the Application of the CLP Criteria
https://echa.europa.eu/documents/10162/23036412/clp_en.pdf/58b5dc6d-ac2a-4910-9702-e9e1f5051cc5

ECHA Guidance on the Compilation of Safety Data Sheets
https://echa.europa.eu/documents/10162/23036412/sds_en.pdf/01c29e23-2cbe-49c0-aca7-72f22e101e20

ECHA Illustrative Example of the Exposure Scenarios to be Annexed to the Safety Data Sheet; Part 2: Example
http://echa.europa.eu/documents/10162/13632/illustrative_example_es_part2_example_en.pdf

ECHA Information on Chemicals; Search for Chemicals
http://echa.europa.eu/information-on-chemicals

ECHA Project "REACH – EN – FORCE 2"
http://www.echa.europa.eu/documents/10162/13577/forum_report_ref2_en.pdf

European Centre for Ecotoxicology and Toxicology of Chemicals – Targeted Risk Assessment (ECOTOC-TRA)
http://www.ecetoc.org/tra

European Union System for the Evaluation of Substances (EUSES)
https://ec.europa.eu/jrc/en/scientific-tool/european-union-system-evaluation-substances

Sample Templates for Safety Data Sheets
http://www.esdscom.eu/english/euphrac-phrases/sds-templates/

8.3 REVISION HISTORY

Document Footer	Chapter	Description
AIG V3.1 – Annex Q – 03/07/2015	All	First edition
AIG V3.1 – Annex Q – 21/03/2016	1	Text completely revised to match revised Flowcharts 1.1, 1.2 and 1.3
		Flowcharts 1a and 1b replaced by Flowcharts 1.1, 1.2 and 1.3
	2	Flowchart 2, Classification Check, updated: "as applicable" added to last box
	3	Authorisation number added to requirements for "2.2 Label Elements"
	8.1	Updated Reference for "REACH"
	8.3	New Chapter 8.3, "Revision History"
AIG V4.0 Annex Q – 01/12/2017	All	Reformatted to fit current ACEA document template
	0	"Valid from" data revised
	1	Text revised to account for the expiration of DSD/DPD transitional measures
		Flowcharts 1.1 and 1.2 revised, Flowchart 1.3 removed, to account for the expiration of DSD/DPD transitional measures
	3	Table 3 revised to take account of the expiration of DSD/DPD transitional measures (Sections 2, 3 & 16)
AIG V4.0 Annex Q – 26/02/2021	0	Remove Chapter 0.2 "Differences Between DSD/DPD and CLP", replace with Chapter 0.3 "SDS Compliance Check Navigator"
	1	Text revisions; Flowcharts 1.1 and 1.2 combined into one, "Flowchart 1"
	2.1	Table 2: replace "xylene" and "solvent naphtha" examples with "ethanol" and "1,2-benzisothiazol-3(2H)-one"
	3	Table 3 revised to take account of the changes introduced by Regulation No 2020/878
	7	GHS and SCL added
	8	8.1: REACH reference revised; 8.2: links updated