A P P E N D I X 3

Review of Annex IV of the Regulation No. 1907/2006 (REACH) Review of proposals for insertion or deletion of substances from Annex IV of REACH

REVIEW OF ANNEX IV OF REGULATION (EC) NO. 1907/2006 (REACH)

REVIEW OF PROPOSALS FOR INSERTION OR DELETION OF SUBSTANCES FROM ANNEX IV OF REACH

Prepared by DHI, Milieu Ltd. and Protection Through Knowledge (PKT) Ltd.

INTRODUCTION

Annex IV of REACH identifies substances that are exempted from the registration, evaluation and downstream user provisions of REACH *on the basis that sufficient information is known about these substances so that they are considered to cause minimum risk because of their intrinsic properties* (Article 2(7)(a)).

The stakeholders were invited to submit dossiers for additions to, or deletions of substances from, the Annex IV of REACH. The submissions were first sent to either the national competent authority of the home country of the applicant or to one of the following industry organisations: CEFIC, CONCAWE and REACH Alliance with a copy to the Commission. The competent authorities or the industry organisations performed an initial screening of the submissions against the agreed criteria set out in the document 'Criteria for Inclusion of Substances in Annex IV of Regulation (EC) No. 1907/2006 Concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)', hereafter called the Criteria Document.

Following the initial screening a total of 292 proposals for insertion and 2 proposals for deletion were forwarded and evaluated by the contractor. Some of the submissions were not evaluated as they had the form as 'position papers' and some of the submissions were lacking a dossier.

The review by the contractor comprised (i) a completeness check of the submissions according to the requirements for information and documentation and (ii) an evaluation of the documentation for compliance with the criteria laid down in the Criteria Document. In order to fulfill the requirements on documentation a complete dossier was required. A complete dossier includes according to section 4 (1) of the Criteria Document:

- An overall conclusion
- A conclusion (descriptive and numerical) per endpoint
- The information specified in section 3 on 'Information requirements' and a completed format in accordance with the instructions in Appendix 2 (including completed Tables 1-4, robust study summaries, and descriptions and justifications for adaptations according to column 2 or Annex IX of REACH).

According to the criteria, minimum risk because of intrinsic properties could only be concluded if all the criteria for physicochemical properties, toxicological properties and ecotoxicological properties mentioned in sections 2.1-2.3 in the Criteria Document were met.

The results of the reviews are presented below in the Table entitled 'Results of Review of Submissions for Annex IV of REACH', which includes summaries of the individual substance reviews and conclusions on whether the submissions passed or failed the requirements described in the Criteria Document.

METHODOLOGY

The methodology applied for the review was a stepwise process consisting of the following steps:

- Examination of whether a complete dossier was submitted or not. Submissions without a complete dossier, e.g. proposals which could better be characterised as 'position papers', were not evaluated
- Submissions with a complete dossier were reviewed to identify if there were data gaps in the dossier. Such data gaps could be, e.g., missing robust study summaries, or missing justification for applying the adaptations according to column 2 of Annexes VII-X of REACH or according to Annex XI of REACH
- For the complete submissions containing all the required data, the next step was to examine if the ecotoxicological criteria were met. If one criterion was not met, the submission was regarded as failing the criteria, and the data related to other criteria were not considered further (Criteria Document, section 5.1)
- The submissions fulfilling the ecotoxicological criteria were further evaluated to examine if the toxicological and physicochemical criteria were met.

The review of the submissions followed strictly the Criteria Document both in terms of the information and documentation requirements and in relation to compliance with the defined criteria.

Section 3 of the Criteria Document, defining the information requirements, prescribes that:

- Robust study summaries shall be provided for a minimum of one key study per endpoint for physicochemical, toxicological and ecotoxicological properties (section 3 (4))
- The standard information corresponding to the endpoints set out in Annexes VII-X is required with the clarifications specified in section 3 (2), including the possibility to apply the specific rules for adaptation provided in column 2 of the Annexes (this would require that a description and justification is provided in the submission as stated in Appendix 2 of the Criteria Document)
- The general rules for adaptation of the standard testing regime as described in Annex XI, sections 1 and 2, may be applied provided that their use is fully justified (this would require that a description and justification is provided in the submission as stated in Appendix 2 of the Criteria Document).

The approach used to evaluate the information contained in the submissions was to apply the principles described in the REACH Annexes VII-X and XI; these principles and the way they have been used in the review of the submissions are summarised below.

Robust study summaries
According to the definition in REACH (Article 3), a 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.

In the review of the submissions, only the submissions including for key endpoints robust study summaries or study summaries containing the same level of information as a robust study summary have been accepted. For example, for some substances the data available in the form of a report from IUCLID IV does not comply with the required level of information, whereas, for other substances, a IUCLID IV report does contain a sufficient and, thus, acceptable level of information.

If no information in form of a robust study summary is presented, then a clear justification for adaptation is required.

Adaptation according to column 2 of Annexes VII-X
Column 2 of Annexes VII-X permits adaptation in relation to exceptions from the standard information requirements. The Criteria Document permits using the specific rules in column 2 with the exception of adaptations based on exposure or risk considerations.

In the review of the submissions, it was evaluated whether an adaptation from the standard testing regime of Annexes VII-X proposed by the applicant was valid and sufficiently justified.

Applying the adaptation from the standard testing regime requires, first of all, that the reason for doing so shall be valid. This means the specific rules given in column 2 of Annexes VII-X shall apply and they shall be documented and justified. For example, if the applicant seeks waiving of a specific endpoint by stating the substance is ‘readily biodegradable’, then this adaptation is only regarded as justified, if ready biodegradability has been demonstrated in a valid study.

For the future registration of substances under REACH, the proposed long term toxicity test depends on the chemical safety assessment. For the current review of Annex IV, a minimum one long-term toxicity study for the most sensitive organism (crustacean or fish) is required. There is no waiving possibility for this endpoint.

In absence of terrestrial data, equilibrium partitioning can be applied together with data on the aquatic toxicity to calculate the potential for effects in the terrestrial environment. Exposure based waiving of the standard information required for demonstrating effects on terrestrial organisms is not considered as valid. Furthermore, reference to data confirming the ready biodegradability of a substance cannot be used as an argument for omitting information on effects on terrestrial organisms, as rapid biodegradation does not ensure minimum risk of possible future uses, where the substance is released directly into the soil environment.

Adaptation according to Annex XI
Annex XI includes general rules for adaptation of the standard testing regime set out in Annexes VII-X, which are detailed in three sections: (i) Testing does not appear scientifically necessary, (ii) Testing is technically not possible, and (iii) Substance-tailored exposure-driven testing. The Criteria Document states that the general rules in Annex XI, sections 1 and 2, may be applied in submissions for Annex IV, whereas the rules in section 3 do not apply as they are based on an

exposure assessment and, thus, a known use of the substance which cannot take exposure resulting from unknown future uses into account (Criteria Document, section 3 (7)).

In the review of the submissions, the following principles were applied to evaluate the justification of proposed adaptations referring to Annex XI.

Use of existing data. Data from experiments not carried out according to GLP or the test methods referred to in REACH, Article 13 (3), and historical human data, were only accepted in the evaluation of the submissions, when the conditions described in Annex XI, section 1.1 were met. First of all, this requires that the data are considered as adequate and reliable for the particular endpoint and that adequate and reliable documentation is provided.

Weight of evidence. Weight of evidence combining several independent sources may lead to the assumption/conclusion that a substance has or has not a particular dangerous property. This type of argumentation requires that adequate and reliable documentation is provided for each individual endpoint for which the weight of evidence is applied.

Qualitative or quantitative structure-activity relationship ((Q)SAR). In absence of experimental data, results obtained by use of QSAR models can be applied. The approach applied in the review was that the QSAR models applied in the submissions should be commonly recognised and used within the application area of the models (e.g., the application area could be that the model is valid for water soluble substances). A justification that the validity criteria of the applied QSAR model were fulfilled was considered as a mandatory documentation requirement. Examples of QSAR results that were not accepted in the review include: (i) QSAR calculations for substances that were not within the application area of the model and (ii) predictions of ready biodegradability when no other evidence for ready biodegradability was presented.

Grouping of substances and read-across approach. The grouping and read-across approach permits the prediction of physicochemical, ecotoxicological and toxicological properties within a group of substances. It requires that the properties of the substances are alike or follow a regular pattern as a result of structural similarities. The similarities may be based on a common functional group, common precursor or breakdown products with similar structure or a constant pattern in the changing of the potency of the properties across the group.

A justification based on a physical and/or chemical description of the structural similarities was considered as a mandatory requirement for the grouping approach. As the results of the endpoints in Annexes VII-X may depend on different functional groups or structural similarities within the group of substances (especially if the group is broad) it is required to document the relationship between structural similarities and effect for each effect type.

Adequate and reliable documentation shall be provided in relation to the use of the read-across approach. When data for one substance are used for the assessment of another substance, the structures of both substances and their structural similarities need to be described. It should also be clear that the actual data for the substance used in the read-across to another substance must be adequately described and documented. Furthermore, the mere reference to substances in the current Annex IV has not been considered sufficient, if the above mentioned details of the read-across were not provided.

Criteria for commonly known substances

Section 3 (8) of the Criteria Document describes the possibility that commonly known substances can be evaluated case-by-case. This applies only to substances for which there are clear scientific evidence that prolonged daily and continuous human and environmental exposure does not lead to more than minimum risk. Waiving of the standard information requirements for such substances may refer to Annex XI, particularly sections 1.1 (Use of existing data) and 1.2 (Weight of evidence).

It shall be justified that the information required in Annexes VII-X would not add useful data to the already available information. The approach taken in the review was that clear scientific evidence (in the form of quantitative data or observations) should be provided for all individual endpoints for substances where reference to section 3 (8) of the Criteria Document is made.

Submissions for deletion

Section 4(5) of the Criteria Document, defining the documentation requirements prescribes that:

- Dossier containing a conclusion that the substance does not meet the criteria shall be provided
- Documentation and justification shall be provided by completion of the relevant sections of the format (Appendix 2).

The approach taken in the review was that the documentation should be reliable and that the data should give rise to concerns by the indication that the criteria were not met for at least one endpoint.

The results of the reviews are presented below in the Table entitled ‘Results of Review of Submissions for Annex IV of REACH’.

Regarding the proposals for deletion from Annex IV of Carbon and Graphite discussion on the nanoforms of the two substances is included as part of the evaluation of the existing entries in Appendix 2.

RESULTS OF REVIEW OF SUBMISSIONS FOR ANNEX IV OF REACH

Summary and conclusions on proposals for insertion of a substance in Annex IV of REACH

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
219	Crystal Glass	No	No	Austria	A dossier covering “Full lead crystal”, “Lead crystal” and “Crystal glass” is representing “Crystal glass” and “Full lead crystal”. No clear identification is described for the Crystal glass and the Full lead crystal” as no IUPAC name, EINECS or CAS number are given. According to the dossier no structural formula can be specified as the glass is a macromolecular network of an irregular structure and vitreous state. The dossier indicates that glass may have different compositions and variable content of colouring agents and heavy metals. No experimental studies are available for the leached metals from crystal glass. A risk based approach is taken to evaluate possible effects from leached metals from the glass material. The concentrations of the leached metal from full lead crystal found by use of a leaching method are compared to limit concentrations set up for toys, drinking water, surface water, foodstuff and FAO/WHO limits on tolerable intake. In general, Cd, Cr, and Sb, and Pb is considered as critical in the risk assessment of the leached metals from crystal glass. For the evaluation of the toxicity to invertebrates a maximum concentration of 100 mg/L is used instead of the criteria of 1000 mg/L. By use of rough extrapolation assuming extraction of 1000 mg crystal glass per liter the leached concentrations of Cd, Cr, and Pb are above the Negligible Addition, NA set by the Dutch authority. Based on the concerns raised for the metals leached from the crystal glass together with the unclear identification of crystal glass the documentation is considered as incomplete for inclusion in Annex IV.	Fail
225	Fructose		200-333-3	Austria	The proposal was submitted in the form of an expert statement.	

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
218	Full Lead Crystal	No	No	Austria	A dossier covering “Full lead crystal”, “Lead crystal” and “Crystal glass” is representing “Crystal glass” and “Full lead crystal”. No clear identification is described for the Crystal glass and the Full lead crystal” as no IUPAC name, EINECS or CAS number are given. According to the dossier no structural formula can be specified as the glass is a macromolecular network of an irregular structure and vitreous state. The dossier indicates that glass may have different compositions and variable content of colouring agents and heavy metals. No experimental studies are available for the leached metals from crystal glass. A risk based approach is taken to evaluate possible effects from leached metals from the glass material. The concentrations of the leached metal from full lead crystal found by use of a leaching method are compared to limit concentrations set up for toys, drinking water, surface water, foodstuff and FAO/WHO limits on tolerable intake. In general, Cd, Cr, and Sb, and Pb is considered as critical in the risk assessment of the leached metals from crystal glass. For the evaluation of the toxicity to invertebrates a maximum concentration of 100 mg/L is used instead of the criteria of 1000 mg/L. By use of rough extrapolation assuming extraction of 1000 mg crystal glass per liter the leached concentrations of Cd, Cr, and Pb are above the Negligible Addition, NA set by the Dutch authority. Based on the concerns raised for the metals leached from the crystal glass together with the unclear identification of crystal glass the documentation is considered as incomplete for inclusion in Annex IV.	Fail
226	Invert Sugar		232-393-1	Austria	The proposal was submitted in the form of an expert statement.	
227	Sugar Factory Lime as a specific form of Calcium Carbonate		207-439-9	Austria	The proposal was submitted in the form of an expert statement.	
72	4-O-alpha-D-glucopyranosyl-D-glucitol (maltitol)	585-88-6 (maltitol)	209-567-0 (maltitol)	Belgium	A dossier covering Maltitol, Maltitol syrup, Sorbitol syrup and Polyglycitol syrup is submitted. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Information on the following endpoints for physicochemical properties is not included in the dossier: 7.9, 7.12 and 7.13. Toxicological and ecotoxicological information on the following endpoints is not included in the dossier: 8.1, 8.2, 8.3 and 9.1. WHO Food additives series are included as robust study summaries. The EPI suite model system was used for the documentation of the ready biodegradability of Maltitol and Sorbitol. Documentation on the biodegradability on the syrups is lacking. The dossier is missing clear documentation for the adaptations done according to column 2 in Annexes VII-X and according to Annex XI section 1 and 2.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
44	Calcium gluconate	299-28-5	206-075-8	Belgium	A dossier with limited number of robust study summaries is submitted. The dossier is covering Gluconic acid and the sodium, calcium and potassium salts hereof. Documentation is not complete. Data on the following endpoints are not included and justifications for adaptation are not acceptable: 8.3, 8.4.2, 8.4.3, 8.6.2, 8.7. For the ecotoxicological endpoints only data on biodegradability and acute toxicity to fish is submitted. Data for all other ecotoxicological endpoints are not included and the justifications for adaptation are not acceptable.	Fail
13	Calcium lactobionate	5001-51-4	225-668-2	Belgium	A dossier with no data other than physicochemical data and without robust study summaries is submitted. The dossier is covering lactobionic acid and the sodium, calcium and potassium salts hereof. Documentation is not complete and justifications are not acceptable for all toxicological and ecotoxicological endpoints. In general there is not sufficient information to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Read across is made to gluconate indicating a low oral toxicity of gluconate (NOAEL>1 g/kg bw in a 4wk study). The dossier is stating that the effects were likely due to the accompanying cation (sodium) rather than caused by the gluconate anion. By this it is questioned how the cation influence the toxicity, but this was not discussed or questioned in the dossier covering the three salts of lactobionic acid.	Fail
97	Caramel	8028-89-5	232-435-9	Belgium	A dossier with only very few data and robust study summaries is submitted. Documentation is not complete. Data is submitted for mutagenicity and repeated dose toxicity. Data are lacking for all other toxicological and ecotoxicological endpoints and justifications for adaptation are not acceptable. Read across is made to fructose, glucose, sucrose, but no documentations are included.	Fail
95	D-Fructose	57-48-7	200-333-3	Belgium	A dossier with no data other than physicochemical data and without robust study summaries is submitted. Documentation is not complete. Data are lacking for all toxicological and ecotoxicological endpoints and justifications for adaptation are not acceptable. Read across is made to fructose, glucose, sucrose, trehalulose, isomaltulose and isomaltose, but no documentations are included.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
41	D-gluconic acid	526-95-4	208-401-4	Belgium	A dossier with limited number of robust study summaries is submitted. The dossier is covering Gluconic acid and the sodium, calcium and potassium salts hereof. Documentation is not complete. Data on the following endpoints are not included and justifications for adaptation are not acceptable: 8.3, 8.4.2, 8.4.3, 8.6.2, 8.7. For the ecotoxicological endpoints only data on biodegradability and acute toxicity to fish is submitted. Data for all other ecotoxicological endpoints are not included and the justifications for adaptation are not acceptable.	Fail
11	D-lactobionic acid (4-O-beta-D galactopyranosyl-D-gluconic acid)	96-82-2	202-538-3	Belgium	A dossier with no data other than physicochemical data and without robust study summaries is submitted. The dossier is covering lactobionic acid and the sodium, calcium and potassium salts hereof. Documentation is not complete and justifications are not acceptable for all toxicological and ecotoxicological endpoints. In general there is not sufficient information to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met.	Fail
45	D-maltobionic acid 4-O-alpha-D-glucopyranosyl-gluconic acid	534-42-9	-	Belgium	A dossier with no data other than physicochemical data and without robust study summaries is submitted. Documentation is not complete. Data are lacking for all toxicological and ecotoxicological endpoints and justifications for adaptation are not acceptable. Read across is mentioned to gluconates and lactobionates, but no data are included.	Fail
52	Erythritol	149-32-6	205-737-3	Belgium	A dossier with robust study summaries is submitted. Documentation is incomplete as sufficient information is lacking to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Data on the following endpoints are not included and justifications for adaptation are not acceptable: 7.8; 7.10; 7.12; 7.17, 8.1-8.3 and 9.1; 9.3; 9.4.	Fail
99	Invert Sugar	8013-17-0	232-393-1	Belgium	A dossier with no data other than physicochemical data and without robust study summaries is submitted. Documentation is not complete. Data are lacking for all toxicological and ecotoxicological endpoints and justifications for adaptation are not acceptable. Read across is made to fructose, glucose, sucrose, trehalulose, isomaltulose and isomaltose, but no documentations are included.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
22	Isomalt (Mixture of 6-O-α-D-glucopyranosyl-D-sorbitol (1,6-GPS) and1-O-α-D-glucopyranosyl-D-mannitol (1,1-GPM) which are simultaneously obtained by the hydrogenation of 6-O-α-D-glucopyranosyl-D-fructose)	Isomalt: 64519-82-0 1,6-GPS: 534-73-6 1,1-GPM: 20942-99-8	1,6-GPS: 208-605-3 1,1-GPM: 244-122-4 no distinct EINECS was allocated to Isomalt	Belgium	A dossier with robust study summaries is submitted. Documentation is not complete. Data for the endpoints 8.1, 8.2, 8.3, 8.5, and all ecotoxicological endpoints are not included and the justifications for adaptation are not acceptable. Robust study summary for biodegradability (9.2) is incomplete as test method is not fully described. It is stated that there are no indications for toxicity to the aquatic or terrestrial system or for accumulation in the environment. However a statement of "no indications for toxicity or accumulation" is insufficient to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Descriptions and justifications for applying read across from substances already on the Annex IV are not acceptable without documentations.	Fail
100	Isomaltose	499-40-1	207-879-1	Belgium	A dossier with no data other than physicochemical data and without robust study summaries is submitted. Documentation is not complete. Data are lacking for all toxicological and ecotoxicological endpoints and justifications for adaptation are not acceptable. Read across is made to fructose, glucose, sucrose, trehalulose, isomaltulose and maltodextrin, but no documentations are included.	Fail
47	Isomaltulose (6-O-α-D-glucopyranosyl-D-fructose)	13718-94-0	237-282-1	Belgium	A dossier with only very few data and robust study summaries for four toxicological endpoints is submitted. Documentation is incomplete and justifications are missing. Data on the following endpoints are not included and justification for adaptation is not acceptable: 8.1-8.3 and 8.5. Data are not provided as it is stated that no particular concerns for skin and eye irritation or skin sensitisation have arisen from common use of sugars in households and no acute toxicity study has been performed with reference to a repeated dose study. Isomaltulose is approved as a novel food / food ingredient under Regulation 258/97/EC. Data on all ecotoxicological endpoints are missing and justification is not acceptable. Data on a biodegradability study is submitted but they are not acceptable for showing ready biodegradability. Adaptations are done according to Column 2 of Annexes VII-X and Annex XI, saying that toxic effects to the aquatic or terrestrial system are unlikely due to degradability and low potential for bioaccumulation.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
69	Lactitol, 4-O-Beta-D-Galactopyranosyl-D-Glucitol	81025-04-9	209-566-5	Belgium	The documentation is incomplete and insufficient to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Information on endpoint 9.4 is not included in the dossier. The dossier is missing clear documentation for adaptations. The dossier is missing clear documentation in the robust study summaries. Robust study summaries on the endpoints 9.1 and 9.2 are incomplete. Description and justification for applying the adaptation from the standard testing regime according to column 2 in Annexes VII-X are missing for the endpoints 9.2 and 9.3. It is stated that there are no indications for accumulation in the environment. However, a statement of "no indications for accumulation" is insufficient to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Description and justification for applying read across from substances already on the Annex IV according to Annex XI section 1.5 are incomplete.	Fail
73	Maltitol syrup	-	-	Belgium	A dossier covering Maltitol, Maltitol syrup, Sorbitol syrup and Polyglycitol syrup is submitted. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Information on the following endpoints for physicochemical properties is not included in the dossier: 7.9, 7.12 and 7.13. Toxicological and ecotoxicological information on the following endpoints is not included in the dossier: 8.1, 8.2, 8.3 and 9.1. WHO Food additives series are included as robust study summaries. The EPI suite model system was used for the documentation of the ready biodegradability of Maltitol and Sorbitol. Documentation on the biodegradability on the syrups is lacking. The dossier is missing clear documentation for the adaptations done according to column 2 in Annexes VII-X and according to Annex XI section 1 and 2.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
15	Palatinose syrup	glucose 50-99-7, fructose 57-48-7, sucrose 57-50-1, isomaltose 499-40-1, isomaltulose 13718-94-0, trehalulose 51411-23-5	glucose 200-075-1, fructose 200-333-3, sucrose 200-334-9, isomaltose 207-879-1, isomaltulose 237-282-1, trehalulose 257-183-7	Belgium	A dossier without robust study summaries is submitted. Palatinose syrup is not identified by a CAS or EINECS No. but by its constituent sugars glucose, fructose, sucrose, isomaltose, isomaltulose and trehalulose. Adaptations according to Annex XI are done for all toxicological endpoints e.g. saying that from sugars common use in households no particular concerns for skin and eye irritation or skin sensitisation have arisen, no mutagenicity is seen for sugars (weight of evidence). However no documentation has been provided. With reference to a FDA report it is stated that a long-standing history of safe exposure to humans and environment exist for glucose, fructose, sucrose and isomaltose. Read across are made for isomaltulose and trehalulose. Adaptations according to Annex XI are done for the ecotoxicological endpoints but justification for adaptation is not acceptable without any documentation.	Fail
68	Pentane 1,2,3,4,5-pentol/1,2,3,4,5-Pentahydroxypentane (Xylitol)	87-99-0	201-788-0	Belgium	The documentation is incomplete and insufficient to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Information on the following endpoints is not included in the dossier: 7.8, 7.12, 7.13, 9.2. The dossier does not include clear documentation for the applied adaptations. Description and justification for applying the adaptation from the standard testing regime according to column 2 in Annexes VII-X and Annex XI section 1 and 2 are missing for the following endpoints: 9.2, 9.3 and 9.4. It is stated that there are no indications for toxicity or accumulation in the aquatic or terrestrial environment. However, a statement of "no indications for toxicity or accumulation" is insufficient to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Description and justification for applying read across from substances already on the Annex IV according to Annex XI section 1.5 are incomplete.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
63	Polyglycitol syrup	-	-	Belgium	A dossier covering Maltitol, Maltitol syrup, Sorbitol syrup and Polyglycitol syrup is submitted. The documentation is incomplete and insufficient to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Information on the following endpoints for physicochemical properties is not included in the dossier: 7.9, 7.12 and 7.13. Toxicological and ecotoxicological information on the following endpoints is not included in the dossier: 8.1, 8.2, 8.3 and 9.1. WHO Food additives series are included as robust study summaries. The EPI suite model system was used for the documentation of the ready biodegradability of Maltitol and Sorbitol. Documentation on the biodegradability on the syrups is lacking. The dossier is missing clear documentation for the adaptations done according to column 2 in Annexes VII-X and according to Annex XI section 1 and 2.	Fail
43	Potassium gluconate	299-27-4	206-074-2	Belgium	A dossier with limited number of robust study summaries is submitted. The dossier is covering Gluconic acid and the sodium, calcium and potassium salts hereof. Documentation is not complete. Data on the following endpoints are not included and justifications for adaptation are not acceptable: 8.3, 8.4.2, 8.4.3, 8.6.2, 8.7. For the ecotoxicological endpoints only data on biodegradability and acute toxicity to fish is submitted. Data for all other ecotoxicological endpoints are not included and the justifications for adaptation are not acceptable.	Fail
14	Potassium lactobionate	-	-	Belgium	A dossier with no data other than physicochemical data and without robust study summaries is submitted. The dossier is covering lactobionic acid and the sodium, calcium and potassium salts hereof. Documentation is not complete and justifications are not acceptable for all toxicological and ecotoxicological endpoints. In general there is not sufficient information to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Read across is made to gluconate indicating a low oral toxicity of gluconate (NOAEL>1 g/kg bw in a 4wk study). The dossier is stating that the effects were likely due to the accompanying cation (sodium) rather than caused by the gluconate anion. By this it is questioned how the cation influence the toxicity, but this was not discussed or questioned in the dossier covering the three salts of lactobionic acid.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
42	Sodium gluconate	14906-97-9 and 527-07-1	238-976-7 and 208-407-7	Belgium	A dossier with limited number of robust study summaries is submitted. The dossier is covering Gluconic acid and the sodium, calcium and potassium salts hereof. Documentation is not complete. Data on the following endpoints are not included and justifications for adaptation are not acceptable: 8.3, 8.4.2, 8.4.3, 8.6.2, 8.7. For the ecotoxicological endpoints only data on biodegradability and acute toxicity to fish is submitted. Data for all other ecotoxicological endpoints are not included and the justifications for adaptation are not acceptable.	Fail
12	Sodium lactobionate	27297-39-8	-	Belgium	A dossier with no data other than physicochemical data and without robust study summaries is submitted. The dossier is covering lactobionic acid and the sodium, calcium and potassium salts hereof. Documentation is not complete and justifications are not acceptable for all toxicological and ecotoxicological endpoints. In general there is not sufficient information to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Read across is made to gluconate indicating a low oral toxicity of gluconate (NOAEL>1 g/kg bw in a 4wk study). The dossier is stating that the effects were likely due to the accompanying cation (sodium) rather than caused by the gluconate anion. By this it is questioned how the cation influence the toxicity, but this was not discussed or questioned in the dossier covering the three salts of lactobionic acid.	Fail
74	Sorbitol syrup	68425-17-2 (hydrogenated glucose syrup);	270-337-8 (hydrogenated glucose syrup)	Belgium	A dossier covering Maltitol, Maltitol syrup, Sorbitol syrup and Polyglycitol syrup is submitted. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Information on the following endpoints for physicochemical properties is not included in the dossier: 7.9, 7.12 and 7.13. Toxicological and ecotoxicological information on the following endpoints is not included in the dossier: 8.1, 8.2, 8.3 and 9.1. WHO Food additives series are included as robust study summaries. The EPI suite model system was used for the documentation of the ready biodegradability of Maltitol and Sorbitol. Documentation on the biodegradability on the syrups is lacking. The dossier is missing clear documentation for the adaptations done according to column 2 in Annexes VII-X and according to Annex XI section 1 and 2.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
46	Trehalulose (1-O-α-D-glucopyranosyl-D-fructose)	51411-23-5	257-183-7	Belgium	A dossier with no data other than physicochemical data and without robust study summaries is submitted. Documentation is not complete. Data are lacking for all toxicological and ecotoxicological endpoints and justifications for adaptation are not acceptable. Read across is mentioned to sucrose, glucose, fructose and isomaltulose, but no data are included.	Fail
120	(2R,3R)-2,3-dihydroxybutanedioic acid (Tartaric Acid)	87-69-4	201-766-0	CEFIC	The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Data for very few physicochemical and toxicological endpoints are included, whereas no ecotoxicological data are included. Adaptations from the standard testing regime have not been applied.	Fail
214	(Z)-tetradec-9-enoic acid	544-64-9	208-876-8	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
205	12-hydroxy-octadecanoic acid	106-14-9	203-366-1	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
60	2-hydroxypropane-1,2,3-tricarboxylic acid (Citric acid)	77-92-9 (anhydrous) 5949-29-1 (citric acid monohydrate)	201-069-1	CEFIC	A full dossier with robust study summaries is submitted. The robust study summaries are not marked with reference numbers of the relevant sections in Annexes VII-X and some studies are not sufficiently described to conclude on the tests. Data are lacking for the endpoints 8.1-8.3. No data for terrestrial toxicity is included in the dossier (9.4). For toxicity to invertebrates, data for only one test is submitted. It is not clear whether the test is an acute or a chronic test. Acute toxicity to fish is reported as LC50 = 440-760 mg/L, which fails the criterion (EC/LC50 > 1000 mg/L). The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
211	9,12,15-Octadecatrienoic acid, (9Z,12Z,15Z)-	463-40-1	207-334-8	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
204	9,12-Octadecadienoic acid	60-33-3	200-470-9	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
129	9-Hexadecenoic acid	2091-29-4	-	CEFIC	A dataset covering a group of C_{10}-C_{22} Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
154	9-Octadecenoic acid (Z)-, potassium salt	143-18-0	205-590-5	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
172	9-Octadecenoic acid (Z)-, sodium salt	143-19-1	205-591-0	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
156	9-Octadecenoic acid, 12-hydroxy-, monopotassium salt, [R-(Z)]-	7492-30-0	231-314-8	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
30	Ammonium dihydrogenorthophosphate (Monoammonium phosphate)	7722-76-1	231-764-5	CEFIC	A dossier with no data is submitted. Data for all endpoints are lacking and no adaptations according to the rules in Annexes VII-X, column 2, or Annex XI have been applied. The dossier is stating "not a skin irritant, not an eye irritant, not a skin sensitiser, no concern, non-hazardous" but no documentation is provided. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. The substance is inorganic, however it is stated that the substance is readily biodegradable. The attached IUCLID report provides data which are not included in Table 4 in the dossier. Based on data from the IUCLID report the substance fails the criteria for inclusion into Annex IV. The IUCLID report states "May cause local irritation", "Prolonged or repeated contact may lead to chronic dermatitis", "Slightly eye irritant". The toxicity to fish also fails the criteria of >1000 mg/L (155 mg/L).	Fail
58	Animal Fat	92113-40-1	295-644-4	CEFIC	A dossier with no data is submitted. Data for all endpoints are lacking and no adaptations according to the rules in Annexes VII-X, column 2, or Annex XI have been applied. The dossier is stating "not a skin irritant, not an eye irritant, not a skin sensitiser, no concern, non-hazardous, etc." but no documentation is provided. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Gelatine is proposed for grouping and read across, but no justifications are given.	Fail
57	Bone meal	68409-75-6	270-061-8	CEFIC	A dossier with no data is submitted. Data for all endpoints are lacking and no adaptations according to the rules in Annexes VII-X, column 2, or Annex XI have been applied. The dossier is stating "not a skin irritant, not an eye irritant, not a skin sensitiser, no concern, non-hazardous, etc." but no documentation is provided. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Gelatine is proposed for grouping and read across, but no justifications are given.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
56	Bone, defatted	97926-21-1	308-236-9	CEFIC	A dossier with no data is submitted. Data for all endpoints are lacking and no adaptations according to the rules in Annexes VII-X, column 2, or Annex XI have been applied. The dossier is stating "not a skin irritant, not an eye irritant, not a skin sensitiser, no concern, non-hazardous, etc." but no documentation is provided. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Gelatine is proposed for grouping and read across, but no justifications are given.	Fail
127	Calcium bis(dihydrogenorthophosphate)	7758-23-8	231-837-1	CEFIC	A dossier with no data is submitted. Data for all endpoints are lacking and no adaptations according to the rules in Annexes VII-X, column 2, or Annex XI have been applied. The dossier is stating "not a skin irritant, not an eye irritant, not a skin sensitiser, no concern, non-hazardous" but no documentation is provided. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. The substance is inorganic, however it is stated that it is readily biodegradable. IUCLID report is attached.	Fail
7	Calcium Carbonate (Sugar Factory Lime)	-	207-439-9	CEFIC	Expert Statement was provided as part of the proposal. Incomplete documentation to demonstrate that criteria for minimum risk because of intrinsic properties of the substance are met.	Fail
173	Calcium distearate	1592-23-0	216-472-8	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
125	Calcium hydrogenorthophosphate	7757-93-9 (anhydrous) and 7789-77-7 (dihydrate)	231-826-1	CEFIC	A dossier with no data is submitted. Data for all endpoints are lacking and no adaptations according to the rules in Annexes VII-X, column 2, or Annex XI have been applied. The dossier is stating "not a skin irritant, not an eye irritant, not a skin sensitiser, no concern, non-hazardous" but no documentation is provided. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. The substance is inorganic, however it is stated that it is readily biodegradable. IUCLID report is attached.	Fail
29	Calcium magnesium orthophosphate	25618-23-9	247-131-1	CEFIC	A dossier with no data is submitted. Data for all endpoints are lacking and no adaptations according to the rules in Annexes VII-X, column 2, or Annex XI have been applied. The dossier is stating "not a skin irritant, not an eye irritant, not a skin sensitiser, no concern, non-hazardous" but no documentation is provided. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. The substance is inorganic, however it is stated that it is readily biodegradable. Attached IUCLID report does not provide any data.	Fail
126	Calcium phosphate	10103-46-5	233-283-6	CEFIC	A dossier with no data is submitted. Data for all endpoints are lacking and no adaptations according to the rules in Annexes VII-X, column 2, or Annex XI have been applied. The dossier is stating "not a skin irritant, not an eye irritant, not a skin sensitiser, no concern, non-hazardous" but no documentation is provided. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. The substance is inorganic, however it is stated that it is readily biodegradable. IUCLID report is attached.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
175	Calcium(2+) 12-hydroxyoctadecanoate	3159-62-4	221-605-8	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
267	Canola oil, low erucic rapeseed oil	120962-03-3		CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The modelling is predicting that the substance is not readily biodegradable. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
210	Capric acid (Decanoic acid)	334-48-5	206-376-4	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
3	Carrageenan, PES (Processed Eucheuma Seaweed)	9000-07-1	232-524-2	CEFIC	A dossier is submitted with robust study summaries for toxicological information only. Data are missing on 7.9, 7.10, 7.12, 7.13, 7.14, 7.17 and 8.4.3. Documentation for ecotoxicological properties is incomplete and adaptations according to Annex VII-X and XI are not fully justified or invalid justifications are made. Data (EC-values etc.) for aquatic toxicity are given based on EPI Suite modelling of D-Galactose, but no documentation on the modelling is included. Modelled data indicates that the aquatic toxicity criteria may not be met.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
245	Castor oil, dehydrated	64147-40-6	264-705-7	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail
237	Castor oil, hydrogenated	8001-78-3	232-292-2	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
298	Castor oil, hydrogenated	8001-78-3	232-292-2	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. Read across is made from a substance not part of the submission. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail
113	Coconut Oil	8001-31-8	232-281-2	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. A modelling compound is used for the modelling but justification for using the modelling substance is not directly given. The modelling substance is not part of the submission. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. Read across is made from a substance not part of the submission. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
292	Coconut Oil	8001-31-8	232-281-2	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail
51	Collagen	09007-34-5	232-697-4	CEFIC	A dossier with no data is submitted. Data for all endpoints are lacking and no adaptations according to the rules in Annexes VII-X, column 2, or Annex XI have been applied. The dossier is stating "not a skin irritant, not an eye irritant, not a skin sensitiser, no concern, non-hazardous" but no documentation is provided. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Gelatine is proposed for grouping and read across but no justifications are given.	Fail
55	Collagen (ox)	09050-08-2	232-937-8	CEFIC	A dossier with no data is submitted. Data for all endpoints are lacking and no adaptations according to the rules in Annexes VII-X, column 2, or Annex XI have been applied. The dossier is stating "not a skin irritant, not an eye irritant, not a skin sensitiser, no concern, non-hazardous, etc." but no documentation is provided. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Gelatine is proposed for grouping and read across, but no justifications are given.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
53	Collagen hydrolysate	92113-31-0	295-635-5	CEFIC	A dossier with no data is submitted. Data for all endpoints are lacking and no adaptations according to the rules in Annexes VII-X, column 2, or Annex XI have been applied. The dossier is stating "not a skin irritant, not an eye irritant, not a skin sensitiser, no concern, non-hazardous, etc." but no documentation is provided. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Gelatine is proposed for grouping and read across, but no justifications are given.	Fail
54	Collagen ossein	121543-31-5	310-156-4	CEFIC	A dossier with no data is submitted. Data for all endpoints are lacking and no adaptations according to the rules in Annexes VII-X, column 2, or Annex XI have been applied. The dossier is stating "not a skin irritant, not an eye irritant, not a skin sensitiser, no concern, non-hazardous, etc." but no documentation is provided. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Gelatine is proposed for grouping and read across, but no justifications are given.	Fail
108	Corn Steep Liquor (CSL)	66071-94-1	266-113-4	CEFIC	Documentation is incomplete. Robust study summaries are only included for 7.3; 7.5; 7.7; 8.5.1; 8.6.2; 8.4.1; 8.4.2 and for lactid acid (read across to 9.1). Remaining documentation is lacking and justification according to Annex VII-X and XI is not complete/fully justified. Therefore documentation is incomplete and it cannot be concluded if the criteria for minimum risk are met. CSL is a mixture of water soluble fractions of maize steeped. It is questioned if CSL is to be considered as a preparation under REACH.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
266	Cottonseed oil	8001-29-4	232-280-7	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. The modelling is not presented in the submission, only the data obtained. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. Studies performed on the WAF of the substance find toxicity to invertebrates in the range 100-1000 mg/l indicating that the criteria for inclusion in Annex IV are not fulfilled. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail
246	Decanoic acid, ester with 1,2,3-propanetriol octanoate	65381-09-1	265-724-3	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
124	Dipotassium (+)-(2R,3R)-2,3-dihydroxybutanedionate (dipotassium tartrate)	921-53-9	213-067-8	CEFIC	The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Data for very few physicochemical endpoints are included, whereas no toxicological and ecotoxicological data are included. Adaptations from the standard testing regime have not been applied.	Fail
123	Disodium (+)-(2R,3R)-2,3-dihydroxybutanedionate (Sodium tartrate dihydrate)	6106-24-7	212-773-3	CEFIC	The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Data for very few physicochemical endpoints are included, whereas no toxicological and ecotoxicological data are included. Adaptations from the standard testing regime have not been applied.	Fail
206	Docosanoic acid	112-85-6	204-010-8	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
162	Dodecanoic acid, calcium salt	4696-56-4	225-166-3	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
160	Dodecanoic acid, magnesium salt	4040-48-6	223-727-7	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
157	Dodecanoic Acid, Potassium salt	10124-65-9	233-344-7	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
212	Eicosanoic acid (Arachidic acid) C20H40O2	506-30-9	208-031-3	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
207	Erucic acid {(Z)-docos-13-enoic acid}	112-86-7	204-011-3	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
37	Fatty acids C16-18, Methyl esters	85586-21-6	287-824-6	CEFIC	A dossier with very few data and without robust study summaries is submitted. No adaptations according to the rules in Annexes VII-X, column 2, or Annex XI have been applied. Data are missing for most endpoints: 7.5; 7.8; 7.10; 7.12; 8.3-8.9; (except 8.5.1) 9.1-9.4 (except 9.1.1 and 9.2.1.1). Link is provided to an IUCLID data set for the substance, in which the few data are documented. Based on the data in the IUCLID data set the substance fails the ecotoxcicological criteria. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met.	Fail
196	Fatty acids peanut oil	68424-13-5	270-275-1	CEFIC	No dossier available	

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
147	Fatty acids sunflower oil	84625-38-7	283-413-0	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
134	Fatty acids tall oil	61790-12-3	263-107-3	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
297	Fatty acids tall oil	61790-12-3	263-107-3	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail
151	Fatty acids, C10-14	90990-09-3	292-770-1	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
193	Fatty acids, C10-16	68002-90-4	268-105-6	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
187	Fatty acids, C12-18, potassium salts	91032-02-9	293-008-0	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
195	Fatty acids, C12-20 and C12-20-unsatd.	68334-03-2	269-808-0	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
137	Fatty acids, C14-18	67701-02-4	266-926-4	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
176	Fatty acids, C14-18 and C16-18-unsatd., potassium salts	68002-80-2	268-094-8	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
168	Fatty acids, C14-18 and C16-18-unsatd., sodium salts	67701-11-5	266-935-3	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
138	Fatty acids, C14-18 and C16-22-unsatd.	68002-87-9	268-101-4	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
144	Fatty Acids, C16-18 and C18 unsaturated	68953-27-5	273-195-5	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
179	Fatty acids, C16-18 and C18-unsatd., sodium salts	68424-26-0	270-286-1	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
36	Fatty acids, C16-18, C18 unsaturated methyl esters	67762-38-3	267-015-4	CEFIC	A dossier with very few data (non-documented) and without robust study summaries is submitted. No adaptations according to the rules in Annexes VII-X, column 2, or Annex XI have been applied. Data are missing for most endpoints: 7.5; 7.8; 7.10; 7.12; 8.3-8.9; (except 8.5.1 - but no documentation is provided) 9.1-9.4 (except 9.1.1 and 9.2.1.1 - but no documentation is provided). The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
184	Fatty acids, C16-18, calcium salts	85251-71-4	286-484-6	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
186	Fatty acids, C16-18, magnesium salts	91031-63-9	292-967-2	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
180	Fatty acids, C16-18, sodium salts	68424-38-4	270-299-2	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
202	Fatty acids, C16-20	68937-76-8	273-087-8	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
192	Fatty acids, C16-22	68002-88-0	268-103-5	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
141	Fatty acids, C16-22 and C18-22-unsatd	95912-82-6	306-078-5	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
181	Fatty acids, C16-22, calcium salts	68604-59-1	271-700-3	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
152	Fatty acids, C18-22	90990-11-7	292-772-2	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
200	Fatty acids, C6-10	68937-74-6	273-085-7	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
201	Fatty acids, C8-10	68937-75-7	273-086-2	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
148	Fatty acids, C8-16	85631-26-1	287-973-7	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
150	Fatty acids, C8-18	90990-08-2	292-769-6	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
183	Fatty acids, C8-18 and C18-unsatd., calcium salts	84776-34-1	283-960-5	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
169	Fatty acids, C8-18 and C18-unsatd., magnesium salts	67762-33-8	267-011-2	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
136	Fatty acids, castor-oil, hydrogenated	61790-39-4	263-131-4	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
185	Fatty acids, castor-oil, hydrogenated, calcium salts	85251-72-5	286-485-1	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
131	Fatty acids, coco	61788-47-4	262-978-7	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
203	Fatty Acids, coco heavy fractions	68937-85-9	273-096-7	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
232	Fatty acids, coco, calcium salts	64754-97-8	265-225-0	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
142	Fatty acids, coco, hydrogenated	68938-15-8	273-118-5	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
231	Fatty acids, coco, potassium salts	61789-30-8	263-049-9	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
158	Fatty acids, coco, sodium salts	61789-31-9	263-050-4	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
194	Fatty acids, Cotton-seed oil	68308-51-0	269-656-5	CEFIC	No dossier available	

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
133	Fatty acids, dehydrated castor-oil	61789-45-5	263-061-4	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
143	Fatty acids, fish-oil, hydrogenated	68938-25-0	273-119-0	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
153	Fatty Acids, Olive oil	92044-96-7	295-376-8	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
139	Fatty acids, palm kernel-oil	101403-98-9	309-936-7	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
145	Fatty acids, palm kernel-oil, potassium salts	70969-43-6	275-067-4	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
182	Fatty acids, palm kernel-oil, potassium salts	70969-43-6	275-067-4	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
159	Fatty acids, palm kernel-oil, sodium salts	61789-89-7	263-097-0	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
197	Fatty acids, palm-oil	68440-15-3	270-438-7	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
146	Fatty acids, palm-oil, hydrogenated	84238-17-5	282-486-6	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
191	Fatty acids, palm-oil, hydrogenated, sodium salts	93763-22-5	297-840-5	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
167	Fatty acids, palm-oil, potassium salts	66072-07-9	266-119-7	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
149	Fatty acids, rape-oil	85711-54-2	288-314-6	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
188	Fatty acids, rape-oil, hydrogenated, calcium salts	91697-59-5	294-321-5	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
189	Fatty acids, rape-oil, hydrogenated, magnesium salts	91697-61-9	294-323-6	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
233	Fatty acids, tall-oil, calcium salts	68154-86-9	268-922-8	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
165	Fatty acids, tallow, calcium salts	64755-01-7	265-228-7	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
135	Fatty acids, tallow, hydrogenated	61790-38-3	263-130-9	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
166	Fatty acids, tallow, hydrogenated, calcium salts	66071-81-6	266-106-6	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
190	Fatty acids, tallow, hydrogenated, magnesium salts	91697-83-5	294-345-6	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
177	Fatty acids, tallow, hydrogenated, potassium salts	68153-66-2	268-892-6	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
178	Fatty acids, tallow, hydrogenated, sodium salts	68309-30-8	269-672-2	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
170	Fatty acids, tallow, sodium salts	8052-48-0	232-491-4	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
132	Fatty acids, vegetable-oil	61788-66-7	262-994-4	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
198	Fatty acids, vegetable-oil, satd.	68648-23-7	271-983-3	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
199	Fatty acids, vegetable-oil, unsatd.	68648-24-8	271-984-9	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
5	Fructose	-	200-333-3	CEFIC	Expert Statement was provided as part of the proposal. Incomplete documentation to demonstrate that criteria for minimum risk because of intrinsic properties of the substance are met.	Fail
105	Fructose	57-48-7	200-333-3	CEFIC	A dossier without robust study summaries is submitted. The submitted data includes summary from EPISuite (excluding ecotox data) and a FDA Food Additive Summary Report. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Documentation for ecotoxicological data is missing and the justifications for adaptations are not acceptable.	Fail
49	Gelatine	09000-70-8	232-554-6	CEFIC	A dossier with no data is submitted. Data for all endpoints are lacking and no adaptations according to the rules in Annexes VII-X, column 2, or Annex XI have been applied. The dossier is stating "not a skin irritant, not an eye irritant, not a skin sensitiser, no concern, non-hazardous" but no documentation is provided. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Substances similar to gelatine and/or by-products of the gelatine industry are proposed for grouping and read across but no justifications are given. IUCLID datasheets are attached for gelatine, gelatine hydrolysate and calcium hydrogenorthophosphate, but without providing sufficiently described data.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
50	Gelatine hydrolysate	68410-45-7	270-082-2	CEFIC	A dossier with no data is submitted. Data for all endpoints are lacking and no adaptations according to the rules in Annexes VII-X, column 2, or Annex XI have been applied. The dossier is stating "not a skin irritant, not an eye irritant, not a skin sensitiser, no concern, non-hazardous" but no documentation is provided. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Gelatine is proposed for grouping and read across but no justifications are given. IUCLID datasheets are attached, but without providing sufficiently described data.	Fail
257	Glycerides, C10-18	85665-33-4	288-123-8	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
247	Glycerid-es, C12-18	67701-26-2	266-944-2	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail
248	Glycerides, C14-18	67701-27-3	266-945-8	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
250	Glycerides, C14-18 and C16-18-unsatd	67701-29-5	266-947-9	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail
87	Glycerides, C14-C18 mono- and di-	67701-33-1	266-952-6	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
252	Glycerides, C16-18	68002-71-1	268-084-3	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail
251	Glycerides, C16-18 and C18-unsatd	67701-30-8	266-948-4	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
263	Glycerides, C16-18 and C18-unsatd. Mono-, di- and tri-	68424-61-3	270-312-1	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail
259	Glycerides, C16-18 and C18-unsatd. Mono-, di- and tri-	91744-20-6	294-582-5	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
89	Glycerides, C16-18 mono-	91052-47-0	293-208-8	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail
88	Glycerides, C16-18, mono- and di-,	85251-77-0	286-490-9	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
256	Glycerides, C8-10	85409-09-2	287-075-5	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail
249	Glycerides, C8-18 and C18-unsatd	67701-28-4	266-946-3	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
258	Glycerides, C8-18 and C18-unsatd. Mono-, di- and tri-	91052-27-6	293-185-4	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail
241	Glycerides, coco mono-	61789-05-7	263-027-9	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
253	Glycerides, mixed coco, decanoyl and octanoyl	68606-18-8	271-729-1	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail
255	Glycerides, mixed decanoyl and octanoyl	73398-61-5	277-452-2	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
234	Glycerides, tall-oil mono-, di-, and tri-	97722-02-6	307-751-6	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail
262	Glycerides, vegetable-oil mono- and di-	97488-91-0	307-030-6	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
261	Glycerides, vegetable-oil mono- and di-, hydrogenated	97488-92-1	307-031-1	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail
254	Glycerides, wheat germ-oil mono-, di- and tri-	68990-07-8	?	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
1	Glycerol	56-81-5	200-289-5	CEFIC	A full dossier is submitted with robust study summaries from IUCLID. Adaptations have been provided in accordance with Column 2 of Annexes VII-X and Annex XI. Documentation for ecotoxicological properties are for many endpoints unclear or incomplete. Toxicity to invertebrates is based on a 24 hours study (9.1.1), test on short term toxicity to fish is lacking important information on test conditions (9.1.3), no long term toxicity tests have been provided (9.1.5, 9.1.6) and the justification for the proposed adaptation is not valid as it is based on risk considerations (The applicant claims that the information/data are not needed, since a risk assessment (OECD/ICCA) allegedly results in unproblematic risk characterization ratios). No data are provided on effects on terrestrial organisms (9.4) and the adaptation is not acceptable.	Fail
236	Glycerol trilaurate	538-24-9	208-687-0	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
85	Glycerol tristearate	555-43-1	209-079-6	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail
265	Grapeseed oil	8024-22-4	284-511-6	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. A modelling compound is used for the modelling but justification for using the modelling substance is not directly given. The modelling substance is not part of the submission. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The modelling is predicting that the substance is not readily biodegradable. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
174	Hexadecanoic acid, potassium salt	2624-31-9	220-088-6	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
268	High oleic sunflower oil	210823-73-7		CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. A modelling compound is used for the modelling but justification for using the modelling substance is not directly given. The modelling substance is not part of the submission. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The modelling is predicting that the substance is not readily biodegradable. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
274	Hydrogenated palm olein	93334-36-2	297-11-1	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. Read across is made from a substance not part of the submission. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The modelling is predicting that the substance is not readily biodegradable. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail
278	Hydrogenated coconut oil	84836-98-6	284-283-8	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
281	Hydrogenated cottonseed oil	68334-00-9	269-804-9	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. The CAS no. are given for the substances which read across is made from. The modelling is predicting that the substance is not readily biodegradable. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail
275	Hydrogenated palm kernel oil	84540-04-5	283-093-2	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
277	Hydrogenated palm kernel olein	93334-38-4	297-113-2	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail
276	Hydrogenated palm kernel stearin	68990-82-9	273-627-2	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
272	Hydrogenated palm oil	68514-74-9	271-056-3	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. Read across is made from a substance not part of the submission. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The modelling is predicting that the substance is not readily biodegradable. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail
273	Hydrogenated palm stearin	93334-37-3	297-112-7	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. Read across is made from a substance not part of the submission. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The modelling is predicting that the substance is not readily biodegradable. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
269	Hydrogenated rapeseed oil	84681-71-0	283-532-8	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The modelling is predicting that the substance is not readily biodegradable. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail
299	Hydrogenated shea butter	92797-40-5	296-576-8	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. A modelling compound is used for the modelling but justification for using the modelling substance is not directly given. The modelling substance is not part of the submission. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The modelling is predicting that the substance is not readily biodegradable. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
279	Hydrogenated shea olein	93333-83-6	297-053-7	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. A modelling compound is used for the modelling but justification for using the modelling substance is not directly given. The modelling substance is not part of the submission. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The modelling is predicting that the substance is not readily biodegradable. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail
280	Hydrogenated shea stearin	93348-60-8	297-203-1	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. A modelling compound is used for the modelling but justification for using the modelling substance is not directly given. The modelling substance is not part of the submission. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The modelling is predicting that the substance is not readily biodegradable. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
270	Hydrogenated soybean oil	8016-70-4	232-410-2	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The modelling is predicting that the substance is not readily biodegradable. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail
271	Hydrogenated sunflower oil	91723-20-5	294-524-9	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The modelling is predicting that the substance is not readily biodegradable. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
116	Illipe Fat	91770-65-9	294-851-7	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. A modelling compound is used for the modelling but justification for using the modelling substance is not directly given. The modelling substance is not part of the submission. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The modelling is predicting that the substance is not readily biodegradable. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail
295	Illipe Fat	91770-65-9	294-851-7	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
282	Interesterified shea butter	97593-46-9	307-351-1	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. A modelling compound is used for the modelling but justification for using the modelling substance is not directly given. The modelling substance is not part of the submission. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The modelling is predicting that the substance is not readily biodegradable. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail
6	Invert Sugar	-	200-333-3, 200-075-1, 200-334-9	CEFIC	Expert Statement was provided as part of the proposal. Incomplete documentation to demonstrate that criteria for minimum risk because of intrinsic properties of the substance are met.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
130	Isooctadecanoic acid	30399-84-9	250-178-0	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
78	Lactitol, 4-O-Beta-D-Galactopyranosyl-D-Glucitol	81025-04-9	209-566-5	CEFIC	The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Information on the endpoint 9.4 is not included in the dossier. The dossier is missing clear documentation for adaptations. The dossier is missing clear documentation on robust study summaries. Robust study summaries on the endpoints 9.1 and 9.2 are incomplete. Description and justification for applying the adaptation from the standard testing regime according to column 2 in Annexes VII-X are missing for the following endpoints: 9.2 and 9.3. It is stated that there are no indications for accumulation in the environment. However, a statement of "no indications for accumulation" is insufficient to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Description and justification for applying read across from substances already on the Annex IV according to Annex XI section 1.5 are incomplete.	Fail
33	Lanolin	8006-54-0	232-348-6	CEFIC	A dossier without robust study summaries is submitted. Data and justifications for adaptations are missing for the following endpoints: 8.4, 8.6, 8.7, 8.8, 9.1, 9.2, 9.3, 9.4. It is stated that the substance is inherently biodegradable, but no documentation is provided. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met.	Fail
34	Lanolin Alcohol	8027-33-6	232-430-1	CEFIC	A dossier without robust study summaries is submitted. Data and justifications for adaptations are missing for the following endpoints: 8.4, 8.6, 8.7, 8.8, 9.1, 9.2, 9.3, 9.4. It is stated that the substance is inherently biodegradable, but no documentation is provided. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
128	Magnesium hydrogenorthophosphate	7757-86-0	231-823-5	CEFIC	A dossier with no data is submitted. Data for all endpoints are lacking and no adaptations according to the rules in Annexes VII-X, column 2, or Annex XI have been applied. The dossier is stating "not a skin irritant, not an eye irritant, not a skin sensitiser, no concern, non-hazardous" but no documentation is provided. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. The substance is inorganic, however it is stated that it is readily biodegradable. IUCLID report is attached.	Fail
38	Methyl Ester, Palm based	91051-34-2	293-086-6	CEFIC	A dossier with very few data (non-documented) and without robust study summaries is submitted. No adaptations according to the rules in Annexes VII-X, column 2, or Annex XI have been applied. Data are missing for most endpoints: 7.5; 7.8; 7.10; 7.12; 8.2-8.9; (except 8.5.1 - but no documentation is provided) 9.1-9.4 (except 9.1.1 and 9.2.1.1 - but no documentation is provided). The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met.	Fail
39	Methyl Ester, Palm Kernel based	91051-32-0	293-084-5	CEFIC	A dossier with very few data (non-documented) and without robust study summaries is submitted. No adaptations according to the rules in Annexes VII-X, column 2, or Annex XI have been applied. Data are missing for most endpoints: 7.5; 7.8; 7.10; 7.12; 8.3-8.9; (except 8.5.1 - but no documentation is provided) 9.1-9.4 (except 9.1.1 and 9.2.1.1 - but no documentation is provided). The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met.	Fail
40	Methyl Myristate	124-10-7	204-680-1	CEFIC	A dossier with very few data and without robust study summaries is submitted. No adaptations according to the rules in Annexes VII-X, column 2, or Annex XI have been applied. Data are missing for most endpoints: 7.8; 7.10; 7.12; 8.3-8.9; (except 8.5.1) 9.1-9.4 (except 9.1.1 and 9.2.1.1). Link is provided to an IUCLID data set for the substance, in which the few data are documented. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
35	Methyl Palmitate	112-39-0	203-966-3	CEFIC	A dossier with very few data (non-documented) and without robust study summaries is submitted. No adaptations according to the rules in Annexes VII-X, column 2, or Annex XI have been applied. Data are missing for most endpoints: 7.3; 7.5; 7.8; 7.10; 7.12; 8.3-8.9; (except 8.5.1 - but no documentation is provided) 9.1-9.4 (except 9.1.1 and 9.2.1.1 - but no documentation is provided). The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met.	Fail
48	Microcrystalline cellulose, Cellulose gel	9004-34-6	-	CEFIC	A dossier is submitted with robust study summaries. Documentation is incomplete. Data on following endpoints are missing: 7.3, 7.5, 8.7.1, 8.7.3 and data for all ecotoxicological endpoints. Justification for adaptation from the standard testing regime is that the substance is unlikely to cross cell membranes, it breaks down to glucose units and thus considered as non-toxic in the environment. Read across/grouping to cellulose pulp is mentioned, but no data are included.	Fail
67	Microcrystalline Cellulose, cellulose gel	9004-34-6	-	CEFIC	A dossier is submitted with robust study summaries. Documentation is incomplete. Data on following endpoints are missing: 7.9, 7.12, 7.13, 7.17, 8.7.1, 8.7.3. For the ecotoxicological endpoints: 9.1, 9.2.1.1, 9.3.4, 9.4.1 QSAR estimations (EPI Suite) are provided for the primary monomer D-glucose. It is stated that "Modeling for D-glucose indicates very low ecotoxicity for the monomer and it would be expected that the ecotoxicity of the polymeric microcrystalline cellulose would be even less of a concern" however same conclusion can not be done in relation to biodegradability (Molecule size 180 versus 30,000-300,000 for cellulose). Justifications based on ready biodegradability are not acceptable. Read across/grouping to cellulose pulp is mentioned, but no data are included.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
243	Monoglycerides, hydrogenated tallow	61789-09-1	263-031-0	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail
244	Monoglycerides, tallow	61789-13-7	263-035-2	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
121	Monopotassium (+)-(2R,3R)-2,3-dihydroxybutanedionate (monopotassium tartrate)	868-14-4	212-769-1	CEFIC	The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Data for very few physicochemical endpoints are included, whereas no toxicological and ecotoxicological data are included. Adaptations from the standard testing regime have not been applied.	Fail
122	Monopotassium monosodium (+)-(2R,3R)-2,3-dihydroxybutanedionate (potassium sodium tartrate tetrahydrate)	6381-59-5	212-769-1	CEFIC	The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Data for very few physicochemical endpoints are included, whereas no toxicological and ecotoxicological data are included. Adaptations from the standard testing regime have not been applied.	Fail
242	Monosodium citrate	18996-35-5	242-734-6	CEFIC	A dossier with no data is submitted. Data for all endpoints are lacking and no adaptations according to the rules in Annexes VII-X, column 2, or Annex XI have been applied. The dossier is stating "not a skin irritant, not an eye irritant, not a skin sensitiser, no concern, non-hazardous" but no documentation is provided. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met.	Fail
213	Myristic acid (Tetradecanoic acid)	544-63-8	208-875-2	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
140	Octadecadienoic acid	121250-47-3	-	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
208	Octadecanoic acid, 9,10-dihydroxy	120-87-6	204-432-2	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
239	Octadecanoic acid, ester with 1,2,3-propanetriol	11099-07-3	234-325-6	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail
163	Octadecanoic acid, magnesium salt	557-04-0	209-150-3	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
164	Octadecanoic acid, potassium salt	593-29-3	209-786-1	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
155	Octadecanoic acid, sodium salt	822-16-2	212-490-5	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
235	Octanoin, tri- (Octanoic acid 1,2,3-propanetriyl)	538-23-8	208-686-5	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail
109	Olive Oil	8001-25-0	232-277-0	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. A modelling compound is used for the modelling but justification for using the modelling substance is not directly given. The modelling substance is not part of the submission. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The modelling is predicting that the substance is not readily biodegradable. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
289	Olive Oil	8001-25-0	232-277-0	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail
114	Palm kernel Oil	8023-79-8	232-425-4	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. A modelling compound is used for the modelling but justification for using the modelling substance is not directly given. The modelling substance is not part of the submission. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
293	Palm kernel Oil	8023-79-8	232-425-4	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail
286	Palm kernel olein	91079-13-9	293-399-8	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. A modelling compound is used for the modelling but justification for using the modelling substance is not directly given. The modelling substance is not part of the submission. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
285	Palm kernel stearin	92129-07-2	295-808-5	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. A modelling compound is used for the modelling but justification for using the modelling substance is not directly given. The modelling substance is not part of the submission. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail
112	Palm Oil	8002-75-3	232-316-1	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. A modelling compound is used for the modelling but justification for using the modelling substance is not directly given. The modelling substance is not part of the submission. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. Read across is made from a substance not part of the submission. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. Studies performed on the WAF of the substance find toxicity to invertebrates in the range 100-1000 mg/l indicating that the criteria for inclusion in Annex IV are not fulfilled. The modelling is predicting that the substance is not readily biodegradable. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
291	Palm Oil	8002-75-3	232-316-1	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail
284	Palm olein	93334-39-5	297-114-8	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. A modelling compound is used for the modelling but justification for using the modelling substance is not directly given. The modelling substance is not part of the submission. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. Read across is made from a substance not part of the submission. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. Studies performed on the WAF of the substance find toxicity to invertebrates in the range 100-1000 mg/l indicating that the criteria for inclusion in Annex IV are not fulfilled. The modelling is predicting that the substance is not readily biodegradable. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
283	Palm stearin	91079-14-0	293-400-1	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. A modelling compound is used for the modelling but justification for using the modelling substance is not directly given. The modelling substance is not part of the submission. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. Read across is made from a substance not part of the submission. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. Studies performed on the WAF of the substance find toxicity to invertebrates in the range 100-1000 mg/l indicating that the criteria for inclusion in Annex IV are not fulfilled. The modelling is predicting that the substance is not readily biodegradable. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail
110	Peanut Oil	8002-037	232-296-4	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. A modelling compound is used for the modelling but justification for using the modelling substance is not directly given. The modelling substance is not part of the submission. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The modelling is predicting that the substance is not readily biodegradable. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
238	Peanut oil; arachidic oil	8002-03-7	232-296-4	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail
65	Pectin	9000-69-5	232-553	CEFIC	The documentation is incomplete and insufficient to demonstrate that the criteria for minimum risk are met. Data for ecotoxicology do not confirm that minimum risk can be predicted from the intrinsic properties as data confirming ready biodegradability have not been submitted, although the dossier includes information on microbial degradation of pectin in plants and the aquatic environment. Aquatic toxicity (endpoints 9.1.1, 9.1.3) is based on QSARs although as a high molecular weight polymer, pectin is out of the domain of the QSAR model. Other ecotoxicological properties (remaining endpoints in 9.1, 9.2, 9.3, 9.4) are predicted on the basis of application of Annex IX sections 1 and 2 or adaptation according to Column 2 of Annexes VII - IX. On the basis of these considerations, the substance is likely to meet the criteria for minimum risk to the environment. A comprehensive toxicological data package was submitted, containing robust study summaries, however the requisite tests on skin and eye irritation (8.1.1 and 8.2.1), in vitro cytogenicity study in mammalian cells (8.4.2) and In vitro gene mutation study in mammalian cells (8.4.3) have not been submitted and criteria for adaptation according to Column 2 of Annexes VII - IX have not been met. The substance meets the criteria for minimum risk in relation to other toxicological endpoints.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
79	Pentane 1,2,3,4,5-pentol/1,2,3,4,5-Pentahydroxypentane (Xylitol)	87-99-0	201-788-0	CEFIC	The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Information on the following endpoints is not included in the dossier: 7.8, 7.12, 7.13. The documentation is also incomplete as the dossier is missing clear documentation for adaptations. Description and justification for applying the adaptation from the standard testing regime according to column 2 in Annexes VII-X and Annex XI section 1 and 2 are missing for the following endpoints: 9.2, 9.3 and 9.4. It is stated that there are no indications for toxicity or accumulation in the aquatic or terrestrial environment. However, a statement of "no indications for toxicity or accumulation" is insufficient to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Description and justification for applying read across from substances already on the Annex IV according to Annex XI section 1.5 are incomplete.	Fail
59	Pork Fat	94349-77-6	305-195-9	CEFIC	A dossier with no data is submitted. Data for all endpoints are lacking and no adaptations according to the rules in Annexes VII-X, column 2, or Annex XI have been applied. The dossier is stating "not a skin irritant, not an eye irritant, not a skin sensitiser, no concern, non-hazardous, etc." but no documentation is provided. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Gelatine is proposed for grouping and read across, but no justifications are given.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
209	Ricinoleic acid	141-22-0	205-470-2	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
117	Sal Oil	91770-61-5	294-848-0	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. A modelling compound is used for the modelling but justification for using the modelling substance is not directly given. The modelling substance is not part of the submission. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The modelling is predicting that the substance is not readily biodegradable. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
296	Sal Oil	91770-61-5	294-848-0	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail
111	Sesame Oil	8008-74-0	232-370-6	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. A modelling compound is used for the modelling but justification for using the modelling substance is not directly given. The modelling substance is not part of the submission. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The modelling is predicting that the substance is not readily biodegradable. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
290	Sesame Oil	8008-74-0	232-370-6	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail
115	Shea Butter	91080-23-8 / 68424-60-2	266-984-4	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. A modelling compound is used for the modelling but justification for using the modelling substance is not directly given. The modelling substance is not part of the submission. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The modelling is predicting that the substance is not readily biodegradable. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
294	Shea Butter	91080-23-8 / 68424-60-2	266-984-4	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail
288	Shea olein	93348-61-9	297-204-7	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. A modelling compound is used for the modelling but justification for using the modelling substance is not directly given. The modelling substance is not part of the submission. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The modelling is predicting that the substance is not readily biodegradable. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
287	Shea stearin	93348-62-0	297-205-2	CEFIC	The submission covers 36 vegetable oils and fats. The oils and fats are described by the typical fatty acid composition. Data on toxicological endpoints are not documented in the dossier, but a reference list is provided. No robust study summaries are included. Data on physicochemical and ecotoxicological endpoints are mainly obtained by EPI Suite modelling. A modelling compound is used for the modelling but justification for using the modelling substance is not directly given. The modelling substance is not part of the submission. Read across is applied to other oils and fats but no justification on substance level is directly given. A general justification is given saying that all vegetable derived oils and fats are comprised of linear carbon chains that differ only in length and level of saturation. The CAS no. are given for the substances which read across is made from. Ecotoxicological endpoints for which modelling and read across is applied beyond the validity range of the applied model (acute ecotoxicity): 9.1.1, 9.1.2, and 9.1.3. The application area of the model is Log Kow up to 5.0 for acute toxicity to fish and daphnids and up to 6.4 for acute toxicity to green algae. The modelling is predicting that the substance is not readily biodegradable. The documentation in the dossier is incomplete and the criteria for inclusion in Annex IV are not fulfilled.	Fail
2	Sodium Alginate	9005-38-3	232-680-1	CEFIC	A full dossier is submitted with robust summaries. Adaptations have been applied in accordance with Column 2 of Annexes VII-X and Annex XI. QSAR estimations on physicochemical parameters are included and criteria for ready biodegradation are confirmed. Data on 7.9-7.11, 7.13 and 7.14 are lacking. Data on 9.1.6.2, 9.1.6.3, 9.3.2 are lacking. Data (EC-values etc.) for aquatic toxicity are given based on EPI Suite modelling of guluronic acid, but no documentation on the modelling is included. The applicant states that modelling for guluronic acid indicates very low ecotoxicity for the monomer and that it would be expected that the ecotoxicity for the polymeric sodium alginate would be of even less concern. Data provided on fate and behavior are also based on modelling with guluronic acid but no justification for using guluronic acid instead of sodium alginate is given. No data are provided for effects to the terrestrial environment (9.4). The justification for this is that sodium alginate is derived from, and is a major component of, seaweed and is not toxic to terrestrial plants or animals.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
31	Sodium dihydrogenorthophosphate (monosodium phosphate)	7758-80-7	231-449-2	CEFIC	A dossier with no data is submitted. Data for all endpoints are lacking and no adaptations according to the rules in Annexes VII-X, column 2, or Annex XI have been applied. The dossier is stating "not a skin irritant, not an eye irritant, not a skin sensitiser, no concern, non-hazardous" but no documentation is provided. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. The substance is inorganic, however it is stated that the substance is readily biodegradable. The attached IUCLID report provides data which are not included in Table 4 in the dossier. Data in IUCLID are acute test on fish and acute oral and dermal toxicity to rat/rabbit.	Fail
86	Stearic acid, monoester with glycerol	31566-31-1	250-705-4	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. There is a large toxicological data set for this class of substances that shows only minor toxicological effects, namely minor irritation in some cases, and some indication of possible carcinogenic effects at very high doses (far in excess of the average daily fat uptake in humans) that are not considered to be toxicologically relevant. The data-set for ecotoxicity is, however, sparse. The major problem with the dossier is that the grouping strategy used by the applicant, particularly that the group used to support the substance is very large (ca. 100 members), and the discussion of structure-activity (chain length, branching of chains, unsaturation) is not sufficiently well argued. It is stated that the group is homogenous without adequate justification. There is a lack of justification for the grouping approach to be applied to each endpoint based on structural considerations. There are not sufficient data to support fulfilment of the criteria on the ecotoxicity for such a large and in-homogenous group of substances in terms of e.g. biodegradability representing different structures (branching of chains, unsaturation, esterification). Conclusions on chronic toxicity are based on only two studies with Daphnia representing mono- and diglycerides and conclusions on bioaccumulation are based on only one study for a triglyceride. Toxicity to bacteria is based on only two studies with limited reliability. In addition, not all the included test study summaries on biodegradability indicate that the criteria for ready biodegradability are met.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
161	Tetradecanoic acid, magnesium salt	4086-70-8	223-817-6	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail
171	Tetradecanoic Acid, Potassium salt	13429-27-1	236-550-5	CEFIC	A dataset covering a group of C10-C22 Fatty acids and their Na-, K-, Ca- and Mg-salts is submitted. The grouping approach is applied and the justification is based on the description of the common functional group, the likelihood of common precursors and/or breakdown products and incremental or constants change across the category. The group has ca. 100 members of which 87 are proposed for inclusion in Annex IV. The group contains fatty acids of variable structure (saturated or unsaturated, even- or odd-carbon, hydroxyl groups, methyl-branching, second carboxylic group). A common conclusion is provided for the group of substances. Robust study summaries may be attached for individual substances supplied with EPI Suite modelling for physicochemical and ecotoxicological endpoints. In case of data gaps waiving according to Column 2 of Annexes VII-X or according to Annex XI is applied. The information in the dossier does not fulfill the criteria for inclusion in Annex IV. For the ecotoxicological properties documentation is incomplete. Robust study summaries are missing and for estimated values, the applied QSARs are used outside the validity range (Kow too high). In general data on long term toxicity and effects on terrestrial organisms are lacking and the justification for waiving is not acceptable.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
61	Tripotassium 2-hydroxypropane-1,2,3 tricarboxylate monohydrate (Tripotassium citrate)	6100-05-6	212-755-5	CEFIC	A dossier with no data is submitted. Data for all endpoints are lacking and no adaptations according to the rules in Annexes VII-X, column 2, or Annex XI have been applied. The dossier is stating "not a skin irritant, not an eye irritant, not a skin sensitiser, no concern, non-hazardous, etc." but no documentation is provided. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Citric acid is proposed for grouping and read across, but no justifications are given.	Fail
62	Trisodium 2-hydroxypropane-1,2,3, tricarboxylate dihydrate (trisodium citrate dihydrate)	6132-04-3	200-675-3	CEFIC	A dossier with no data is submitted. Data for all endpoints are lacking and no adaptations according to the rules in Annexes VII-X, column 2, or Annex XI have been applied. The dossier is stating "not a skin irritant, not an eye irritant, not a skin sensitiser, no concern, non-hazardous, etc." but no documentation is provided. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Citric acid is proposed for grouping and read across, but no justifications are given.	Fail
94	Xanthan gum	11138-66-2	234-394-2	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. The documentation is incomplete, so it has not been clearly demonstrated that the criteria for minimum risk are met. The toxicological data is extensive and robust, and it can be concluded that the substance does not pose a hazard to humans, although some data of unknown reliability indicates skin irritation is possible in some circumstances. However, the read-across from another sugar (diutan gum) has not been thoroughly substantiated. The largest weakness in the dossier is that there is very little data for the ecotoxicological endpoints, particularly 9.1.1, 9.1.2, 9.1.4, and long-term toxicity (9.1.5. and 9.1.6), and on ready biodegradability (9.2.1.1). These, and the partition coefficient (7.8), have been estimated using a simple programme (Biowin?) with an unrealistically low MW (180-715 vs 1 000 000), with no substantiation of this procedure.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
98	Xanthan gum	11138-66-2	-	CEFIC	The information in the dossier does not fulfil the criteria for inclusion in Annex IV. The documentation is incomplete, so it has not been clearly demonstrated that the criteria for minimum risk are met. The toxicological data is extensive and robust, and it can be concluded that the substance does not pose a hazard to humans, although some data of unknown reliability indicates skin irritation is possible in some circumstances. However, the read-across from another sugar (diutan gum) has not been thoroughly substantiated. The largest weakness in the dossier is that there is very little data for the ecotoxicological endpoints, particularly 9.1.1, 9.1.2, 9.1.4, and long-term toxicity (9.1.5. and 9.1.6), and on ready biodegradability (9.2.1.1). These, and the partition coefficient (7.8), have been estimated using a simple programme (Biowin?) with an unrealistically low MW (180-715 vs 1 000 000), with no substantiation of this procedure.	Fail
83	Calcium gluconate	299-28-5	206-075-8	CEFIC/France	A dossier covering Gluconic acid, Glucono-delta-lactone, Sodium gluconate, Calcium gluconate and Potassium gluconate is submitted. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Data for the following endpoints are missing: 7.9, 7.10, 7.12, 7.13, 7.14, 7.17, 8.3, 8.4.2, 8.4,3, 8.5.2/3, 8.7.3, 8.8, 9.1.4, 9.1.5, 9.1.6, 9.2.1.2, 9.2.1.4 and 9.4. Toxicity to fish for glucono-delta-lactone (LC50 = 360 mg/l) fails the criteria for inclusion into Annex IV. The applicant has attached QSAR estimations (EPI suite V4.10) on physicochemical data and degradation. Weight of evidence and historical use are being used for argumentation for lack of data. Compliance with criteria for ecotoxicological properties is confirmed for existing data but documentation, e.g. in the form of a study report or other primary source of data is not included.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
80	Gluconic acid	526-95-4	208-401-4	CEFIC/France	A dossier covering Gluconic acid, Glucono-delta-lactone, Sodium gluconate, Calcium gluconate and Potassium gluconate is submitted. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Data for the following endpoints are missing: 7.9, 7.10, 7.12, 7.13, 7.14, 7.17, 8.3, 8.4.2, 8.4,3, 8.5.2/3, 8.7.3, 8.8, 9.1.4, 9.1.5, 9.1.6, 9.2.1.2, 9.2.1.4 and 9.4. Toxicity to fish for glucono-delta-lactone (LC50 = 360 mg/l) fails the criteria for inclusion into Annex IV. The applicant has attached QSAR estimations (EPI suite V4.10) on physicochemical data and degradation. Weight of evidence and historical use are being used for argumentation for lack of data. Compliance with criteria for ecotoxicological properties is confirmed for existing data but documentation, e.g. in the form of a study report or other primary source of data is not included.	Fail
81	Glucono-delta-lactone	90-80-2	202-016-5	CEFIC/France	A dossier covering Gluconic acid, Glucono-delta-lactone, Sodium gluconate, Calcium gluconate and Potassium gluconate is submitted. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Data for the following endpoints are missing: 7.9, 7.10, 7.12, 7.13, 7.14, 7.17, 8.3, 8.4.2, 8.4,3, 8.5.2/3, 8.7.3, 8.8, 9.1.4, 9.1.5, 9.1.6, 9.2.1.2, 9.2.1.4 and 9.4. Toxicity to fish for glucono-delta-lactone (LC50 = 360 mg/l) fails the criteria for inclusion into Annex IV. The applicant has attached QSAR estimations (EPI suite V4.10) on physicochemical data and degradation. Weight of evidence and historical use are being used for argumentation for lack of data. Compliance with criteria for ecotoxicological properties is confirmed for existing data but documentation, e.g. in the form of a study report or other primary source of data is not included.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
84	Potassium gluconate	299-27-4	206-074-2	CEFIC/France	A dossier covering Gluconic acid, Glucono-delta-lactone, Sodium gluconate, Calcium gluconate and Potassium gluconate is submitted. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Data for the following endpoints are missing: 7.9, 7.10, 7.12, 7.13, 7.14, 7.17, 8.3, 8.4.2, 8.4,3, 8.5.2/3, 8.7.3, 8.8, 9.1.4, 9.1.5, 9.1.6, 9.2.1.2, 9.2.1.4 and 9.4. Toxicity to fish for glucono-delta-lactone (LC50 = 360 mg/l) fails the criteria for inclusion into Annex IV. The applicant has attached QSAR estimations (EPI suite V4.10) on physicochemical data and degradation. Weight of evidence and historical use are being used for argumentation for lack of data. Compliance with criteria for ecotoxicological properties is confirmed for existing data but documentation, e.g. in the form of a study report or other primary source of data is not included.	Fail
82	Sodium gluconate	527-07-1	208-407-7	CEFIC/France	A dossier covering Gluconic acid, Glucono-delta-lactone, Sodium gluconate, Calcium gluconate and Potassium gluconate is submitted. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Data for the following endpoints are missing: 7.9, 7.10, 7.12, 7.13, 7.14, 7.17, 8.3, 8.4.2, 8.4,3, 8.5.2/3, 8.7.3, 8.8, 9.1.4, 9.1.5, 9.1.6, 9.2.1.2, 9.2.1.4 and 9.4. Toxicity to fish for glucono-delta-lactone (LC50 = 360 mg/l) fails the criteria for inclusion into Annex IV. The applicant has attached QSAR estimations (EPI suite V4.10) on physicochemical data and degradation. Weight of evidence and historical use are being used for argumentation for lack of data. Compliance with criteria for ecotoxicological properties is confirmed for existing data but documentation, e.g. in the form of a study report or other primary source of data is not included.	Fail
32	Methyl-cis-9-octadecenoate (Fatty acids, rape-oil, Me esters)	85586-25-0	287-828-8	CONCAWE	A dossier with robust study summaries is submitted. The robust study summaries are incomplete and it is unclear where to find data mentioned in Table 4. Data for the toxicological endpoints 8.6, 8.7, 8.8 and for the ecotoxicological endpoints 9.1.4, 9.1.5 or 9.1.6 (long term toxicity), 9.2.1.3, 9.2.1.4, 9.2.2.1, 9.2.3, 9.3.1, 9.3.3 and 9.4 are not included. Biodegradability is given based on an ultimate biodegradability test. No adaptations according to the rules in Annexes VII-X, column 2, or Annex XI have been applied. The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
215	Fructose		200-333-3	DK, NL, AT	The proposal was submitted in the form of an expert statement.	
216	Invert sugar		200-333-3	DK, NL, AT	The proposal was submitted in the form of an expert statement.	
217	Sugar Factory Lime as a specific form of Calcium Carbonate		207-439-9	DK, NL, AT	The proposal was submitted in the form of an expert statement.	
102	Beta-cyclodextrin, cycloheptaamylose	7585-39-9	231-493-2	France	A dossier with robust study summaries is submitted. Data for the following endpoints are missing: 7.9, 7.13, 7.14, 7.17, 8.6.1, 8.7.1, 9.1, 9.2.1.2 and 9.2.1.4. Documentation is not complete. Compliance with criteria for ecotoxicological properties is not confirmed - no short term toxicity data are available on invertebrates, algae and fish. No long term toxicity data are available on invertebrates and fish and there are no data from tests on juvenile fish, FELS, and embryo/sac fry stages. Data for biodegradability is estimated by EPI suite modelling.	Fail
103	D-erythro-hex-2-enoic acid gamma-lactone (Erythorbic acid)	89-65-6	201-928-0	France	A dossier with robust study summaries is submitted. Data for the following endpoints are missing: 7.9, 7.10, 7.13, 7.14, 7.17, 8.1-8.3, 8.6.1, 8.7.1, 8.7.3, 9.1, 9.2.1.2 and 9.2.1.4. Documentation is not complete. Compliance with criteria for ecotoxicological properties is not confirmed - no short term toxicity data are available on invertebrates, algae and fish. No long term toxicity data are available on invertebrates and fish and there are no data from tests on juvenile fish, FELS, and embryo/sac fry stages (9.1) and no data on terrestrial toxicity (9.4). Data for biodegradability is estimated by EPI suite modelling.	Fail
4	Glass	-	-	France	According to the dossier no clear identification can be described for the glass as no IUPAC name, EINECS or CAS number can be given. Moreover the existing EINECS number for glass does not correspond to the glass produced by European glass producers as it was registered by the chemical industry. Information on the molecular and structural formula is not specified, but a description on “oxide glass” is given in the executive summary. The dossier states that only few special types of glasses are put on the market as chemicals on their own and that glass is mainly marketed as articles. The dossier is stating that 175 entries in CAS are related to glass. The dossier also indicates that glass may have different compositions and variable content of fluxes, stabilizers, colouring agents including heavy metals. Based on the unclear identification of “glass” the documentation is considered to be incomplete for inclusion in Annex IV.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
104	Sodium salt of 2,3 didehydro-D-erythro-hexono-lactone (erythorbic acid sodium salt, sodium erythorbate)	6381-77-7	228-973-9	France	A dossier with robust study summaries is submitted. Data for the following endpoints are missing: 7.9, 7.10, 7.13, 7.14, 7.17, 8.1-8.3, 8.6.1, 8.7.1, 8.7.3, 9.1, 9.2.1.2 and 9.2.1.4. Documentation is not complete. Compliance with criteria for ecotoxicological properties is not confirmed - no short term toxicity data are available on invertebrates, algae and fish. No long term toxicity data are available on invertebrates and fish and there are no data from tests on juvenile fish, FELS, and embryo/sac fry stages (9.1) and no data on terrestrial toxicity (9.4). Data for biodegradability is estimated by EPI suite modelling.	Fail
223	Vinasse			France	Documentation is incomplete as no information regarding physicochemical, toxicological and ecotoxicological data is submitted.	Fail
19	Calcium gluconate (glycogenic acid)	299-28-5	206-075-8	Germany	A dossier with limited number of robust study summaries is submitted. The dossier is covering Gluconic acid and the sodium, calcium and potassium salts hereof. Documentation is not complete. Data on the following endpoints are not included and justifications for adaptation are not acceptable: 8.3, 8.4.2, 8.4.3, 8.6.2, 8.7. For the ecotoxicological endpoints only data on biodegradability and acute toxicity to fish is submitted. Data for all other ecotoxicological endpoints are not included and the justifications for adaptation are not acceptable.	Fail
25	Calcium lactobionate	5001-51-4	225-668-2	Germany	A dossier with no data other than physicochemical data and without robust study summaries is submitted. The dossier is covering lactobionic acid and the sodium, calcium and potassium salts hereof. Documentation is not complete and justifications are not acceptable for all toxicological and ecotoxicological endpoints. In general there is not sufficient information to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Read across is made to gluconate indicating a low oral toxicity of gluconate (NOAEL>1 g/kg bw in a 4wk study). The dossier is stating that the effects were likely due to the accompanying cation (sodium) rather than caused by the gluconate anion. By this it is questioned how the cation influence the toxicity, but this was not discussed or questioned in the dossier covering the three salts of lactobionic acid.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
91	Caramel	8028-89-5	232-435-9	Germany	A dossier with only very few data and robust study summaries is submitted. Documentation is not complete. Data is submitted for mutaginicity and repeated dose toxicity. Data are lacking for all other toxicological and ecotoxicological endpoints and justifications for adaptation are not acceptable. Read across is made to fructose, glucose, sucrose, but no documentations are included.	Fail
90	D-Fructose (Fruit Sugar, Levulose)	57-48-7	200-333-3	Germany	A dossier with no data other than physicochemical data and without robust study summaries is submitted. Documentation is not complete. Data on the following endpoints are not included and justification for adaptation is not acceptable: 8.1-8.3 and 8.5 Read across is made to fructose, glucose, sucrose, trehalulose, isomaltulose and isomaltose, but no documentations are included. The applicant has attached results from QSAR estimations (EPI Suite) on aquatic toxicity and biodegradability except 9.4.2/ 9.4.3 (terrestrial toxicity), but no documentation on the modelling is attached.	Fail
16	D-gluconic acid	526-95-4	208-401-4	Germany	A dossier with limited number of robust study summaries is submitted. The dossier is covering Gluconic acid and the sodium, calcium and potassium salts hereof. Documentation is not complete. Data on the following endpoints are not included and justifications for adaptation are not acceptable: 8.3, 8.4.2, 8.4.3, 8.6.2, 8.7. For the ecotoxicological endpoints only data on biodegradability and acute toxicity to fish is submitted. The applicant has attached results from QSAR estimations (EPI Suite) on aquatic toxicity and biodegradability except 9.4.2/ 9.4.3 (terrestrial toxicity) for gluconic acid, but no documentation on the modelling is attached.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
23	D-lactobionic acid	96-82-2	202-538-3	Germany	A dossier with no data other than physicochemical data and without robust study summaries is submitted. The dossier is covering lactobionic acid and the sodium, calcium and potassium salts hereof. Documentation is not complete and justifications are not acceptable for all toxicological endpoints. The applicant has attached results from QSAR estimations (EPI Suite) on aquatic toxicity and biodegradability except 9.4.2/ 9.4.3 (terrestrial toxicity) for lactobionic acid, but no documentation on the modelling is attached.	Fail
27	D-maltobionic acid 4-O-alpha-D-glucopyranosyl-gluconic acid	534-42-9	-	Germany	A dossier with no data other than physicochemical data and without robust study summaries is submitted. Documentation is not complete. Data are lacking for all toxicological endpoints and justifications for adaptation are not acceptable. Read across is mentioned to gluconates and lactobionates, but no data are included. The applicant has attached results from QSAR estimations (EPI Suite) on aquatic toxicity and biodegradability except 9.4.2/ 9.4.3 (terrestrial toxicity), but no documentation on the modelling is attached.	Fail
224	Epoxidized soybean oil	8013-07-8	232-391-0	Germany	Documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Data in the dossier are not documented, as no Robust Study Summaries are included. Reference is made to IUCLID, but the report is not available. Data for growth inhibition of aquatic plants fails the ecotoxicological criteria (L(E)C> 1000mg/L).	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
71	High-alumina, low-silica fibres	287922-11-6	not available	Germany	The information in the dossier does not fulfill the criteria for inclusion in Annex IV. The documentation is incomplete as insufficient information is provided for several end-points to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. It is also clear that the substance can be bioavailable, in that it is soluble in acidic solution. It is also possible for the substance to interact with DNA, as evidenced by the positive Ames test. However, any reasoning about what happens after the fibres encounter the acidic environment in the body is lacking. Information on acute toxicity (8.5) is missing and the case for route-to-route extrapolation from the inhalation study is not clearly made.	Fail
92	Invert Sugar	8013-17-0	232-393-1	Germany	A dossier with no data other than physicochemical data and without robust study summaries is submitted. Documentation is not complete. Data are lacking for all toxicological and ecotoxicological endpoints and justifications for adaptation are not acceptable. Read across is made to fructose, glucose, sucrose, trehalulose, isomaltulose and isomaltose, but no documentations are included.	Fail
21	Isomalt (Mixture of 6-O-α-D-glucopyranosyl-D-sorbitol (1,6-GPS) and1-O-α-D-glucopyranosyl-D-mannitol (1,1-GPM) which are simultaneously obtained by the hydrogenation of 6-O-α-D-glucopyranosyl-D-fructose)	Isomalt: 64519-82-0 1,6-GPS: 534-73-6 1,1-GPM: 20942-99-8	1,6-GPS: 208-605-3 1,1-GPM: 244-122-4 no distinct EINECS was allocated to Isomalt	Germany	A dossier with robust study summaries is submitted. Documentation is not complete. Data for the endpoints 8.1, 8.2, 8.3, 8.5 are not included and the justifications for adaptation are not acceptable. Robust study summary for biodegradability (9.2) is incomplete as test method is not fully described. Descriptions and justifications for applying read across from substances already on the Annex IV are not acceptable without documentations. The applicant has attached results from QSAR estimations (EPI Suite) on aquatic toxicity and biodegradability except 9.4.2/ 9.4.3 (terrestrial toxicity), but no documentation on the modelling is attached.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
93	Isomaltose	499-40-1	207-879-1	Germany	A dossier with no data other than physicochemical data and without robust study summaries is submitted. Documentation is not complete. Data are lacking for all toxicological endpoints and justifications for adaptation are not acceptable. Read across is made to fructose, glucose, sucrose, trehalulose, isomaltulose and maltodextrin, but no documentations are included. The applicant has attached results from QSAR estimations (EPI Suite) on aquatic toxicity and biodegradability except 9.4.2/ 9.4.3 (terrestrial toxicity), but no documentation on the modelling is attached.	Fail
9	Isomaltulose	13718-94-0	237-282-1	Germany	A dossier with only very few data and robust study summaries for four toxicological endpoints is submitted. Documentation is incomplete and justifications are missing. Data on the following endpoints are not included and justification for adaptation is not acceptable: 8.1-8.3 and 8.5. Data are not provided as it is stated that no particular concerns for skin and eye irritation or skin sensitisation have arisen from common use of sugars in households and no acute toxicity study has been performed with reference to a repeated dose study. Isomaltulose is approved as a novel food / food ingredient under Regulation 258/97/EC. The applicant has attached results from QSAR estimations (EPI Suite) on aquatic toxicity and biodegradability except 9.4.2/ 9.4.3 (terrestrial toxicity), but no documentation on the modelling is attached.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
10	Palatinose syrup	glucose 50-99-7, fructose 57-48-7, sucrose 57-50-1, isomaltose 499-40-1, isomaltulose 13718-94-0, trehalulose 51411-23-5	glucose 200-075-1, fructose 200-333-3, sucrose 200-334-9, isomaltose 207-879-1, isomaltulose 237-282-1, trehalulose 257-183-7	Germany	A dossier without robust study summaries is submitted. Palatinose syrup is not identified by a CAS or EINECS No. but by its constituent sugars glucose, fructose, sucrose, isomaltose, isomaltulose and trehalulose. Adaptations according to Annex XI are done for all toxicological endpoints e.g. saying that from sugars common use in households no particular concerns for skin and eye irritation or skin sensitisation have arisen, no mutagenicity is seen for sugars (weight of evidence). However no documentation has been provided. With reference to a FDA report it is stated that a long-standing history of safe exposure to humans and environment exist for glucose, fructose, sucrose and isomaltose. Read across are made for isomaltulose and trehalulose. The applicant has attached results from QSAR estimations (EPI Suite) on aquatic toxicity and biodegradability for the constituent sugars but without sufficient justification and documentation on the modelling.	Fail
18	Potassium gluconate	299-27-4	206-074-2	Germany	A dossier with limited number of robust study summaries is submitted. The dossier is covering Gluconic acid and the sodium, calcium and potassium salts hereof. Documentation is not complete. Data on the following endpoints are not included and justifications for adaptation are not acceptable: 8.3, 8.4.2, 8.4.3, 8.6.2, 8.7. For the ecotoxicological endpoints only data on biodegradability and acute toxicity to fish is submitted. Data for all other ecotoxicological endpoints are not included and the justifications for adaptation are not acceptable.	Fail
26	Potassium lactobionate	-	-	Germany	A dossier with no data other than physicochemical data and without robust study summaries is submitted. The dossier is covering lactobionic acid and the sodium, calcium and potassium salts hereof. Documentation is not complete and justifications are not acceptable for all toxicological and ecotoxicological endpoints. In general there is not sufficient information to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Read across is made to gluconate indicating a low oral toxicity of gluconate (NOAEL>1 g/kg bw in a 4wk study). The dossier is stating that the effects were likely due to the accompanying cation (sodium) rather than caused by the gluconate anion. By this it is questioned how the cation influence the toxicity, but this was not discussed or questioned in the dossier covering the three salts of lactobionic acid.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
17	Sodium gluconate	14906-97-9 and 527-07-1	238-976-7 and 208-407-7	Germany	A dossier with limited number of robust study summaries is submitted. The dossier is covering Gluconic acid and the sodium, calcium and potassium salts hereof. Documentation is not complete. Data on the following endpoints are not included and justifications for adaptation are not acceptable: 8.3, 8.4.2, 8.4.3, 8.6.2, 8.7. For the ecotoxicological endpoints only data on biodegradability and acute toxicity to fish is submitted. Data for all other ecotoxicological endpoints are not included and the justifications for adaptation are not acceptable.	Fail
24	Sodium lactobionate	27297-39-8	-	Germany	A dossier with no data other than physicochemical data and without robust study summaries is submitted. The dossier is covering lactobionic acid and the sodium, calcium and potassium salts hereof. Documentation is not complete and justifications are not acceptable for all toxicological and ecotoxicological endpoints. In general there is not sufficient information to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Read across is made to gluconate indicating a low oral toxicity of gluconate (NOAEL>1 g/kg bw in a 4wk study). The dossier is stating that the effects were likely due to the accompanying cation (sodium) rather than caused by the gluconate anion. By this it is questioned how the cation influence the toxicity, but this was not discussed or questioned in the dossier covering the three salts of lactobionic acid.	Fail
264	Toilet soap, shaving cream			Germany	No dossier available	
20	Trehalulose (1-O-α-D-glucopyranosyl-D-fructose)	51411-23-5	257-183-7	Germany	A dossier with no data other than physicochemical data and without robust study summaries is submitted. Documentation is not complete. Data are lacking for all toxicological endpoints and justifications for adaptation are not acceptable. Read across is mentioned to sucrose, glucose, fructose and isomaltulose, but no data are included. The applicant has attached results from QSAR estimations (EPI Suite) on aquatic toxicity and biodegradability except 9.4.2/ 9.4.3 (terrestrial toxicity), but no documentation on the modelling is attached.	Fail
8	Tannin	1401-55-4	215-753-2	Germany, CEFIC, NL, Reach Alliance	The documentation is incomplete. Data are lacking for endpoints 7.3, 7.5, 7.8, 7.13 and 7.17. Also toxicological data for the endpoints 8.3, 8.4, 8.6-8.9; and all ecotoxicological data are missing. The dossier is missing robust study summaries and no adaptations from the standard testing regime are done.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
70	Fatty acids, C16-18 and C18-unsaturated Methyl esters	67762-38-3	267-015-4	Italy	A dossier is submitted with robust study summaries in IUCLID format. The documentation is incomplete and insufficient to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Data on ecotoxicological properties are incomplete. Long term toxicity study for aquatic organisms is missing and waiving from the standard testing regime is not acceptable. Documentation on fate and behavior in the environment for endpoints under 9.3 is missing. It is stated that the substances has a low potential for sorption to soil and that the substance has no potential to bioaccumulate but documentation is lacking. The dossier is referring to but not including valid QSAR with proven scientific validity for the waiving from bioaccumulation testing. The substance fails the criteria based on the log Kow of 5.02. Data for effects on terrestrial organisms are lacking and justification for adaptation is not acceptable.	Fail
106	Methyl-cis-9-octadecenoate (Fatty acid-rape oil- Me ester (RME)	85586-25-0	287-828-8	Italy	The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Information on the following endpoints is not included in the dossier: 8.4.2, 8.8, 9.1.6.1, 9.1.6.2, 9.1.6.3, 9.2.1.4, 9.4.1 and 9.4.2. The dossier is missing clear documentation in robust study summaries as the documentation is based on IUCLID data files and MSDS. Read across has been applied for several endpoints and from several other fatty acid esters. However the justification for applying the read across approach is missing.	Fail
101	Calcium Carbonate	471-34-1	207-439-9	REACH Alliance	A dossier with robust study summaries is submitted. Documentation is not complete and the applicant has not included sufficient data for all relevant ecotoxicological endpoints. The documentation used for the justification for the adaptations for the following endpoints is considered to be either insufficient or unclear: 9.1.3, 9.1.4, 9.1.6.2, 9.1.6.3, 9.3.1, 9.3.2, 9.4.1-9.4.4 and 9.4.6. References made to external positive lists are not considered valid.	Fail
107	Calcium Sulfate	7778-18-9	231-900-3	REACH Alliance	A dossier with only two robust study summaries is submitted. Adaptations according to Column 2 of Annexes VII-X and Annex XI are applied. Documentation is not complete and justifications for adaptations are not complete. Justifications are not acceptable for 9.1.4, 9.1.5-9.1.6, 9.3.1-3, 9.4.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
77	Tannin	1401-55-4	215-753-2	REACH Alliance	The documentation is incomplete. Data are lacking for endpoints 7.3, 7.5, 7.8, 7.13 and 7.17. Also toxicological data for the endpoints 8.3, 8.4, 8.6-8.9; and all ecotoxicological data are missing. The dossier is missing robust study summaries and no adaptations from the standard testing regime are done.	Fail
229	Lactose	not submitted	not submitted	REACH Alliance/NL/ DK	The proposal was submitted in the form of an expert statement.	
230	Milk fat and milk fat components	not submitted	not submitted	REACH Alliance/NL/ DK	The proposal was submitted in the form of an expert statement.	
228	Milk proteins and milk protein hydrolyses	not submitted	not submitted	REACH Alliance/NL/ DK	The proposal was submitted in the form of an expert statement.	
222	Ceramic frits	65997-18-4	266-047-6	Spain	Documentation: All end points available or adaptation applied according to column 2 of Annexes VII-X or to Annex X. Robust study summaries included. All adaptations described and justified except for 9.4.2 Effect on soil microorganisms. Review on ecotoxicology. Meeting of the criteria for aquatic toxicity has not been clearly demonstrated. The acute toxicity of the eluates of the test material to Daphnia magna was in one test below 1000 mg/l (437 mg/l). For the long-term toxicity testing to early life-stages of fish, results obtained for Pb in an acute and subchronic (90 days) test was compared with the solubility of the Pb in the ceramic frits, showing a lower solubility than the LC50 for Pb. This was also done with Cd but without robust study summary for the toxicity of Cd. A very low potential to bioaccumulate in aquatic species is stated but has not been clearly demonstrated Metals as Pb are known to accumulate in aquatic organisms. It has been demonstrated that the solubility of the metals in the frits is low but the potential for bioaccumulation has not been studied or demonstrated. It can be questioned whether the Ceramic frits are considered as a substance or a preparation under REACH.	Fail
118	Lard	61789-99-9	263-100-5	Spain	The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. The dossier is missing robust study summaries and descriptions and justifications for applying the adaptation from the standard testing regime and for applying the read across approach are not given.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
119	Lard oil	8016-28-2	232-405-5	Spain	The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. The dossier is missing robust study summaries and descriptions and justifications for applying the adaptation from the standard testing regime and for applying the read across approach are not given.	Fail
96	Hydrogenated glucose syrup	68425-17-2	270-337-8	The Netherlands	A dossier without robust study summaries is submitted. Information on the following endpoints is not included: 7.1, 7.3, 7.5, 7.17, 8.4, 8.5.2/3, 8.7, 8.8, 9.1, 9.3, 9.4. Extensive lack of information on ecotoxicological properties. The applicant points to section 3.8 in the criteria document to be considered, but no justification for waiving of data in line with the rules in Annex XI is presented. The applicant has attached reports from IUCLID, US FDA, US EPA etc. but did not include the information in the dossier.	Fail
66	Glass	-	-	UK	According to the dossier no clear identification can be described for the glass as no IUPAC name, EINECS or CAS number can be given. Moreover the existing EINECS number for glass does not correspond to the glass produced by European glass producers as it was registered by the chemical industry. Information on the molecular and structural formula is not specified, but a description on “oxide glass” is given in the executive summary. The dossier states that only few special types of glasses are put on the market as chemicals on their own and that glass is mainly marketed as articles. The dossier is stating that 175 entries in CAS are related to glass. The dossier also indicates that glass may have different compositions and variable content of fluxes, stabilizers, colouring agents including heavy metals. Based on the unclear identification of “glass” the documentation is considered to be incomplete for inclusion in Annex IV.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
76	Lactitol, 4-O-Beta-D-Galactopyranosyl-D-Glucitol	81025-04-9	209-566-5	UK	The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Information on the endpoint 9.4 is not included in the dossier. The dossier is missing clear documentation for adaptations. The dossier is missing clear documentation on robust study summaries. Robust study summaries on the endpoints 9.1 and 9.2 are incomplete. Description and justification for applying the adaptation from the standard testing regime according to column 2 in Annexes VII-X are missing for the endpoints 9.2 and 9.3. It is stated that there are no indications for accumulation in the environment. However, a statement of "no indications for accumulation" is insufficient to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Description and justification for applying read across from substances already on the Annex IV according to Annex XI section 1.5 are incomplete.	Fail
75	Pentane 1,2,3,4,5-pentol/1,2,3,4,5-Pentahydroxypentane (Xylitol)	87-99-0	201-788-0	UK	The documentation is incomplete as sufficient information is missing to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Information on the following endpoints is not included in the dossier: 7.8, 7.12, 7.13. The documentation is also incomplete as the dossier is missing clear documentation for adaptations. Description and justification for applying the adaptation from the standard testing regime according to column 2 in Annexes VII-X and Annex XI section 1 and 2 are missing for the following endpoints: 9.2, 9.3 and 9.4. It is stated that there are no indications for toxicity or accumulation in the aquatic or terrestrial environment. However, a statement of "no indications for toxicity or accumulation" is insufficient to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Description and justification for applying read across from substances already on the Annex IV according to Annex XI section 1.5 are incomplete.	Fail

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association):		Pass/Fail
28	Titanium antimony chromium III oxide rutile (C.I. Pigment Brown 24)	68186-90-3	269-052-1	UK	A full dossier is submitted with robust study summaries. The documentation is incomplete as sufficient information is lacking to demonstrate that the criteria for minimum risk because of intrinsic properties of the substance are met. Information on endpoint 9.4 is not included in the dossier. The documentation is also incomplete as the dossier is lacking clear documentation for the applied adaptations. Description and justification for applying the read across approach according to Annex XI section 1.5 is lacking for the following endpoints: 9.1.5 and 9.1.6. The substance is poorly water soluble and long-term toxicity test should therefore be considered. Long-term toxicity study is submitted for C.I. Pigment Yellow 53, only. However, description and justification for applying read across from C.I. Pigment Yellow 53 according to Annex XI section 1.5 are incomplete. Description and justification for applying the adaptation from the standard testing regime according to column 2 in Annexes VII-X are missing for endpoint 9.3. The justification is based on the substance being almost completely insoluble in octanol, however the documentation is missing.	Fail

Summary and conclusions on proposals for deletion of a substance from Annex IV of REACH

	Identity of substance:				Summary of review	Conclusion
Ref. No.	Name	CAS-No.	EINECS	Submitted to (MS or industry association)		Proposal accepted / not accepted
220	Carbon	7440-44-0	231-153-3	The Commission	This proposal focuses solely on the problem with nanoparticles of carbon. This can be regarded as a 'worst-case'. Information is available for the following end-points: 8.5 (8.5.2, 8.5.3), 9.1 (9.1.5, 9.1.6.2), 9.4. The information in the dossier consists only of very short conclusions. There are no robust study summaries on any of the end-points. The proposal gives anecdotal evidence that nanoforms of carbon and graphite have the same identity (CAS number) as graphite and carbon. The proposal also presents evidence of adverse effects in cellular toxicity tests, and some in vivo studies. The composition of the test substance and the test methodology means that the results are not interpretable with regards to the criteria for exclusion from Annex IV. The toxicology of nanoforms is not well understood, and techniques for investigating nanoforms are not established. The results are not conclusive, but raise concerns for possible lung- and skin-effects greater than would be predicted from the toxicology of larger particles of carbon and graphite.	Accepted
221	Graphite	7782-42-5	231-955-3	The Commission	This proposal focuses solely on the problem with nanoparticles of carbon. This can be regarded as a 'worst-case'. Information is available for the following end-points: 8.5 (8.5.2, 8.5.3), 9.1 (9.1.5, 9.1.6.2), 9.4. The information in the dossier consists only of very short conclusions. There are no robust study summaries on any of the end-points. The proposal gives anecdotal evidence that nanoforms of carbon and graphite have the same identity (CAS number) as graphite and carbon. The proposal also presents evidence of adverse effects in cellular toxicity tests, and some in vivo studies. The composition of the test substance and the test methodology means that the results are not interpretable with regards to the criteria for exclusion from Annex IV. The toxicology of nanoforms is not well understood, and techniques for investigating nanoforms are not established. The results are not conclusive, but raise concerns for possible lung- and skin-effects greater than would be predicted from the toxicology of larger particles of carbon and graphite.	Accepted