Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien
International Association for Soaps, Detergents and Maintenance Products

Environmental Safety Check (ESC):

Overview of procedures for conducting an ESC Check and handling of notifications

(Version 3.0 – 1 January 2014)

Introduction:

This document sets out the procedures which shall govern the performance of the ESC Check as part of the requirements to qualify a company's product as meeting the Advanced Sustainability Profile for its category. Part A sets out procedures to be followed by companies and Part B sets out procedures to be followed by A.I.S.E. where it is required to be involved.

The flowchart displaying the procedures in schematic form is appended as an aid to following how the procedures fit together (see Appendix A). Box numbers in this document refer to the boxes in this flowchart.

Relevant background information on the ESC check can be found in the following documents:
1. ESC_Summary (pdf file)
2. ESC flowchart/decision tree (pdf file)
3. Manual for the ESC Tool (pdf file)
4. Calculation Tool for ESC Wave 1 Products (Excel sheet)
5. Form and instructions for stage 2 notification
6. List of experts

The latest versions of these documents can be found on the Charter documentation website:
http://www.sustainable-cleaning.com/en.companyarea_documentation.orb

Part A – Procedures to be followed by the Company

1. Ingredients to be checked

1.1. The ESC Check must be performed for each ingredient in the product applying for ASP status, unless the substance meets the criteria for *de minimis* exemption as defined in the ESC User Manual. Ingredients are generally identified by CAS numbers and represented by an ingredient number in the ESC Tool.

1.2. Substances that consist of multiple chemical constituents should be split for checking in the ESC Tool calculation into their single constituents according to CAS Numbers and/or ingredient numbers assigned in the Tool. In line with the definition of a substance in EU legislation, impurities deriving from the manufacturing process and additives necessary to preserve the stability of the substance (but excluding solvent) that form part of the substance need not be checked separately in the ESC Tool (e.g. trace LAB in LAS), unless it is clear that they may contribute significantly to environmental risk.
In the event that an ingredient is purchased as a commercial mixture and the identity and/or environmental data for all constituents is not known it may be permitted to treat the mixture as a single ingredient if environmental data is available for the mixture (see ESC Tool User Manual section 4.9)

1.3. All ESC Checks must be performed using the latest version of the ESC Tool issued on the Charter website at the time of the check. Charter 2010 Members will be notified when an updated version of the Tool is issued. The ESC Tool will be updated on basis of results of stage 2 notifications and extensions to cover new product categories (see Part B – 3.5).

The version of the ESC Tool should be recorded alongside the ASP documentation and archived for the purpose of random verification.

1.4. For the purpose of this document an ingredient is CLEAR when the result of the ESC check is "PESR < 1"[1] . An ingredient is NOT CLEAR when the result of the ESC check is "PESR > 1"[2] .

2. Stage 1 ESC Check

2.1. If the ingredient is already listed in the ESC tool [Box 1], and when the product type and dosage and use level of the ingredient are entered the result is CLEAR [Box 2], the product passes the ESC Check in respect of this ingredient.

If the ingredient is not listed in the ESC tool, the Company has the possibility to perform a stage 2 check (see 3).

2.2. Each ingredient is entered in the ESC Check Form until all ingredients have been entered. If the ESC result is CLEAR for all ingredients, the product passes the ESC Check. The ESC form, bearing the version date of the ESC Tool must be archived (for random verification).

If the ESC result is NOT CLEAR for one or more ingredients, the Company has the possibility to perform a stage-2 check .

[1] In the ESC tool the result will appear "green" or "amber".

[2] In the ESC tool the result will appear "red".

3. Stage 2 ESC Check

A stage 2 check may be performed if the ingredient is not present in the ESC database and/or if the Stage 1 check does not give a CLEAR result for all ingredients.

3.1. Additional ingredient not already in the ESC Tool

3.1.1. If an ingredient used in the product is not already listed in the ESC Tool, the Company may derive key data for the ingredient following the procedures defined in the ESC Tool Manual and its Appendices to perform a Stage 2 assessment [Box 4]. If the Company has no data for a non-proprietary ingredient, it has the possibility to use an external consultant (a list of consultants familiar with the requirements of the ESC scheme is available on the Charter documentation website) or request A.I.S.E. to work on the ingredient itself (see 3.1.2.2.).

3.1.2. If the ESC result for the newly added ingredient is CLEAR, to pass the ESC Check in respect of this ingredient [Box 7] the Company must notify A.I.S.E. (via "charter-notification@aise.eu") the identity of the ingredient as well as basic data [Box 6]. This should be done using the form and instructions to be downloaded on the Charter documentation website. A.I.S.E. may need to request further information about the data used, and source or justification, and the Company must be willing to supply that if requested for any ingredients that are not proprietary (e.g. not covered by patents or exclusive supply contracts to one single company). If the Company does not notify A.I.S.E., or if the Company is not willing to supply the requested data or justification for a non-proprietary ingredient, the ingredient does not pass the ESC Check and the product does not qualify on that aspect of the ASP [Box 11].

3.1.2.1. If A.I.S.E. ratifies the data used [Box 7], the Company will be notified and the successful ESC pass in respect of the ingredient is confirmed. In this case, A.I.S.E. will consider whether, bearing in mind how widely the ingredient is likely to be used, the ESC Tool should be revised to add the new ingredient. Revisions to the ESC Tool will be periodically issued (see Part B – 3.5).

3.1.2.2. If A.I.S.E. concludes it cannot ratify the data used, it may decide to work on the ingredient itself [Box 9] and suggest alternative data. If the Company finds this leads to a "CLEAR result" for the ingredient, the product passes the ESC Check in respect of that ingredient [Box 10].

3.1.2.3. If A.I.S.E. concludes it cannot ratify the data and if A.I.S.E. does not suggest alternative data that lead to a CLEAR result, the ingredient does not pass the ESC Check and the product does not qualify on that aspect of the ASP [Box 11]. A company may investigate possible refinements according to Section 3.2 below and the instructions in the ESC Tool Manual and its Appendices

3.1.3. Notification to A.I.S.E. is also required for ingredients that are proprietary to the Company. Minimal information on this ingredient should be provided to the A.I.S.E. Secretariat, who will treat the information as confidential (see Part B – 2.2.3.).

3.2. Existing ingredient in the ESC Tool

3.2.1. If the ESC result for an ingredient [Box 2] is Red (PESR>1) and that the Company still wants to apply the ASP to its formulation, a Stage 2 ESC Check is needed. To carry out this Stage 2 ESC Check the Company needs to perform a higher-tier assessment to refine the data used for the check [Box 3]. If the Company does not wish to perform the Stage 2 check, the ingredient does not pass the ESC Check and the product does not qualify on that aspect of the ASP [Box 11].

3.2.2. To perform a higher tier environmental risk assessment as a Stage 2 Check [Box 4] the Company should follow the instructions in the ESC Tool Manual and its Appendices, in particular Annex D. Higher tier risk assessment will require some specific expertise for example in the use of eco-toxicological data in risk assessment. If not available within the Company it may be necessary to use an external consultant. A list of consultants familiar with the requirements of the ESC scheme is available on the Charter documentation website.

3.2.3. If the higher tier environmental risk assessment leads to a CLEAR result for the ingredient, A.I.S.E. must be notified (via charter-notification@aise.eu) of the data in the Tool that have been refined in the Stage 2 Check [Box 6]. This should be done using the supplied form and instructions available on the Charter documentation website. A.I.S.E. may need to request further information about the data used, and source or justification, and the Company must be willing to supply that if requested. If the Company does not notify A.I.S.E., or is not willing to supply the requested data or justification, the ingredient cannot get a CLEAR result for the ESC Check and the product does not qualify on that aspect of the ASP [Box 11].

3.2.3.1. If A.I.S.E. ratifies the refinement [Box 7], the Company will be notified and the successful pass in respect of the ingredient is confirmed. In this case, A.I.S.E. will consider whether, bearing in mind for example other notified refinements, the ESC Tool should be revised. Revisions to the ESC Tool will be periodically issued as new versions of the ESC Tool (see Part B – 3.5).

3.2.3.2. If A.I.S.E. decides it cannot ratify the refinement, it may decide to work on the ingredient itself [Box 9] and suggest an alternative refinement. If the Company finds this leads to a CLEAR result for the ingredient, the product passes the ESC Check in respect of that ingredient [Box 10].

3.2.3.3. If A.I.S.E. cannot suggest an alternative refinement, the ingredient does not get a CLEAR result in the ESC Check and the product does not qualify on that aspect of the ASP [Box 11]. The Company may investigate other possible refinements according to the instructions in the ESC Tool Manual and its Appendices, and repeat the process. If no further refinement is attempted and notified to A.I.S.E., the product does not pass the ESC on the ingredient and the Company must not use the Charter 2010 ASP logo in connection with the product .

3.2.4. If, after attempting to refine the data for an existing or new ingredient [Box 4] the ESC result for the ingredient is NOT CLEAR [Box 5], the Company may enquire whether A.I.S.E. would work on the ingredient itself [Box 8].

3.2.4.1. If A.I.S.E. works on the ingredient [Box 9] it may suggest a refinement. If the Company finds this leads to a CLEAR result for the ingredient, the product passes the ESC Check in respect of that ingredient [Box 10].

3.2.4.2. If A.I.S.E. does not suggest an alternative refinement, the ingredient does not get a CLEAR result in the ESC Check and the product does not qualify on that aspect of the ASP [Box 11]. The Company may investigate other possible refinements according to the instructions in the ESC Tool Manual and its Appendices, and repeat the process. If no further refinement is attempted and notified to A.I.S.E. , the product does not pass the ESC on the ingredient and the Company must not use the Charter 2010 ASP logo in connection with the product .

Part B Handling of notifications of ESC stage 2 assessment by A.I.S.E. and subsequent revision/refinement of the Tool

1. General ESC Stage 2 notification

1.1. ESC Stage 2 notification scenarios

Stage 2 ESC notifications to the A.I.S.E. Secretariat can be undertaken in the following cases: (see Part A)

- new ingredient (non-proprietary)
- new ingredient (proprietary)
- existing ingredient - higher tier assessment for ingredient already listed in ESC Tool on any of the following aspects:
  - category tonnage
  - background tonnage
  - substance fate data
  - substance eco-toxicity data
  - environmental exposure data (environmental monitoring data)

1.2. Team dealing with notifications

The A.I.S.E. Secretariat will be supported by a team of company experts, and external experts, as needed (consultants and/or academia). For confidentiality reasons the name of the notifier will be not be disclosed to the supporting team. Information on a proprietary ingredient will not be disclosed to company experts.

1.3. ESC stage 2 notification procedure and timings

1.3.1. Upon receipt of the notification, the A.I.S.E. Secretariat will check if the reporting is complete. If the required data is complete, an acknowledgment of receipt will be sent to the Company. If this is not the case, the Company will be requested to provide the missing information. The A.I.S.E. Secretariat will keep records of all e-mail exchanges and of all notifications for 5 years

1.3.2. In all cases, feedback on validity of the submitted data will be provided to the Company within 60 calendar days after receiving of the duly completed notification[3]. For every correction required i.e. any re-submission or correction, the deadline applies from the re-submission date. In case action is needed from notifying companies based on feedback from the A.I.S.E. secretariat (e.g. update of the information notified, provide justification for data, etc.), the Company should reply within 60 calendar days as well.

1.3.3. Should external experts need to be involved, these deadlines may be extended in agreement by both the A.I.S.E. Secretariat and the Company. Notifications will be handled on a first come first served basis, starting from the point where data input provided is considered complete.

1.3.4. If the data supplied for the ingredient has not been ratified by the A.I.S.E. Secretariat as valid for the ESC check, the file for the ingredient is closed. The file will only be re-opened upon new notification based on substantive new data. The product will thus only pass the ESC check when the new data for the relevant ingredient have been ratified by A.I.S.E. as valid. The A.I.S.E. Secretariat can decide to postpone closing of the file for an ingredient if it deems this to be appropriate.

2. Specific processing of notifications for the different scenarios

The A.I.S.E. Secretariat will perform the following checks depending upon which of the following scenarios applies.

2.1. New non-proprietary ingredient

[3] This 60-day deadline may be revised in the future, as experience is gained, depending on the number of notifications received.

2.1.1. The A.I.S.E. Secretariat will first check whether the notified ingredient is a new ingredient, in the sense that it is not already listed in the ESC Tool or covered via another entry in the ESC Tool (e.g. different name but similar chemical identity). If needed, the Secretariat will contact experts from the ESC team or an external expert.

2.1.2. Once the ingredient is confirmed as a new ingredient, further assessment of information notified will take place with a view to incorporate the new ingredient and corresponding data in the next version of the ESC Tool.

2.1.3. New non-proprietary ingredients and corresponding data will be incorporated in the next version of the ESC Tool providing:

- Two or more companies are using it: this can be determined if several companies notify the same ingredient or via enquiry to companies or via the companies' websites.
- It is not exempt from ESC calculation (e.g. inorganics, REACH Annexes IV/V, HERA)

2.1.4. If the new ingredient meets the exemption conditions, this will be recorded and feedback sent to the Company. The ingredient will be considered as passing the ESC check for the specific product involved.

2.1.5. If it is confirmed that it is not exempt, all the data notified will be assessed for relevance and quality. For doing so, the A.I.S.E. Secretariat will be assisted by environmental risk assessment experts (ESC team or an external expert if needed). The experts may contact the Company to ask more information if needed. This will be done using the functional e-mail address. The experts will use the following as guidance for verification:

- Relevance: the data used should be in line with the ESC calculation method requirements (e.g. endpoint selected for PNEC value).
-Quality: The source of information will be checked, the values and the justification for the values used (e.g. tonnage information source, factor applied to take account of other A.I.S.E. product categories and other industries, chemical name associated with CAS number, basis for removal rate calculation, unit reported for each data, whether the assessment factor value is appropriate, etc.)

2.1.6. Once the data are confirmed as relevant and of good quality, the data submitted in respect of the ingredient are ratified as valid for use in the ESC. They are then candidates for inclusion into the next version of the ESC Tool.

2.1.7. If the data contained in the notification are not deemed to be relevant or quality is unsatisfactory, the A.I.S.E. Secretariat will write back to the Company requesting an update of the notification. If, after having updated the data, the ingredient still fails to get acceptance by A.I.S.E. experts, the ingredient will be considered as <u>not</u> passing the ESC Check.

2.1.8. If upon ratification of the data submitted to the A.I.S.E. Secretariat it appears that two or more companies are using the ingredient and the assessment is of adequate quality, the

ingredient and corresponding data will be included in the next version of the Tool. If it cannot be determined whether other companies may be using the same ingredient, the ingredient will not be included in the ESC Tool.

2.2. New proprietary ingredient

2.2.1. In this scenario, the data and information to be submitted to the A.I.S.E. Secretariat is limited. No proprietary ingredient will be incorporated into the ESC Tool as long as the justification for the proprietary character continues to apply (e.g. expiry of exclusive supply contract). (see 2.2.3). [Note that the owner of a proprietary ingredient should make available relevant ESC parameters to any company they license to use the proprietary ingredient so that the licensee company can use those parameters in the Tool to perform ESC checks on their own products.]

2.2.2. Information contained in the notification form will be accessible to staff at the A.I.S.E. Secretariat only and, if needed, an external consultant(s) operating under confidentiality. In the latter case, the Company will be informed.

2.2.3. Justification of the proprietary character: The ratification by the A.I.S.E. Secretariat will mostly consist in checking the justification provided by the Company as to why the ingredient is considered as proprietary (patent protection, exclusive supply agreement, supplier is sole manufacturer, etc.). While supporting documents do not need to be provided, the Company should stand ready to provide such documents to A.I.S.E. or to auditors (external verifiers), on request.

2.2.4. In addition, the A.I.S.E. Secretariat will check the information submitted for relevance and quality (chemical identity of the ingredient and category tonnage assumed, if a niche category projection is used in the calculation) and expiry of exclusive supply contract.

2.2.5. Feedback will be provided to the Company within 60 calendar days. For every correction required i.e. any re-submission, the deadline applies from the re-submission date.

2.3. Existing ingredient - higher tier assessment for ingredient already listed in ESC Tool

2.3.1. Any decision on refinement will have to be based on data provided by the formulator company to AISE staff. A.I.S.E. will check the data and assumption used by the Company to refine the risk assessment. The process will be similar to the one described for new non-proprietary ingredients.

The A.I.S.E. Secretariat will be assisted by the ESC team of experts and/or external experts if needed (e.g. for tonnage information). In all cases, the A.I.S.E. Secretariat will check data and information for relevance and quality (see above under 1.).

Background tonnage, substance fate data and substance eco-toxicity data, once checked and ratified by A.I.S.E. experts, will be incorporated into the next version of the ESC Tool, so that all companies use the same basis for their ESC check.

2.3.1.1. Category tonnage: the A.I.S.E. Secretariat will check the tonnage assumption based on expert judgement and, where available, market data. In case of doubt, the A.I.S.E. Secretariat may seek more information from external sources such as Nielsen (statistical data).

2.3.1.2. Background tonnage: the A.I.S.E. Secretariat will check the tonnage assumption based on expert judgement and, where available, market data. In case of doubt, A.I.S.E. may ask more information to external sources such as product data providers or other industry association for sectors that contribute to the background release.

2.3.1.3. Substance fate data (removal rate) The A.I.S.E. Secretariat will work with an external expert in environmental risk assessment where needed. Experts from the ESC team may also be consulted. The source of the data needs to be checked and information shared within the team.

2.3.1.4. Substance eco-toxicity data: The A.I.S.E. Secretariat will work with an external expert in environmental risk assessment where needed. Experts from the ESC team may also be consulted. Source needs to be checked and information shared within the team.

2.3.1.5. Environmental exposure data (environmental monitoring data): Environmental monitoring data are usually proprietary information (unless it is obtained from literature or from supplier safety data sheets). If this is the case, this shall be clearly indicated in the notification. The Company should stand ready to provide such documents to the A.I.S.E. Secretariat, under confidential agreement, or to auditors (external verifiers), on request.

2.3.2. In case of data obtained from Safety Data Sheets of suppliers, the A.I.S.E. Secretariat will ask permission to use the data for the ESC Tool upgrade from the SDS originator (the name and contact details will have to be provided by the Company, where not mentioned on the SDS).

In case of data from the literature (internet or scientific publications), copyright law applies. If the publication belongs to one the Charter members, the company then accepts to make available the data at no cost for the purpose of the ESC check.

2.3.3. Once the data are confirmed as relevant and of good quality, the data are ratified as valid for use in the ESC Tool to check whether individual products pass the ESC Check, and data will be included into the next version of the ESC Tool.

2.3.4. If the data contained in the notification are not deemed to be relevant or quality is unsatisfactory, the A.I.S.E. Secretariat will write back to the Company requesting an update of the notification.

2.3.5. The A.I.S.E. Secretariat may consider that the ingredient concerned does not pass the ESC check in the above situations if for example the ingredient has already been highly refined and best data were established or if data provided are not relevant or not of satisfactory quality. In such cases the substance will be communicated to the A.I.S.E. Sustainability Steering Group for evaluation of further refinement (e.g. generating new data, liaison with supplier organisations similarly to HERA).

2.3.6. If the data supplied for the ingredient has not been confirmed by the A.I.S.E. Secretariat as valid for the ESC check, the file for the ingredient is closed. The file will only be re-opened upon new notification based on substantive new data. The product will thus only pass the ESC check when the new data for the relevant ingredient have been ratified by A.I.S.E. as valid. The A.I.S.E. Secretariat can decide to postpone closing of the file for an ingredient if it deems this to be appropriate.

3. Additional procedural elements

3.1. Enquiries to refine ESC Tool on specific ingredients

In addition to the scenarios above-mentioned, A.I.S.E might be approached by companies that have not enough data or expertise for a Stage 2 ESC on their specific ingredient, to enquire whether A.I.S.E. may choose to work on the data for that ingredient (e.g. if more companies are interested in having a the ingredient added to or refined in the Tool). In case A.I.S.E. chooses not to work on the ingredient, A.I.S.E. will direct these companies to the services of an external consultant.

3.2. List of external consultants

A list of knowledgeable external experts that can assist either the A.I.S.E. Secretariat or companies that do not have the required expertise is available in the Charter documentation website. The list is open to any knowledgeable experts provided they meet the profile requirements set out in this list. A.I.S.E. reserves the right to verify the credentials of the applicants.

This list is not compulsory in the sense that companies may choose to consult knowledgeable experts other than those mentioned in the list. When a company hires a consultant, all contractual aspects, including confidentiality of data/information exchanged between the company and the consultant, will be dealt with by the company and the consultant and will not involve A.I.S.E.

3.3. Prioritisation of notifications

In case the number of notifications is not manageable within existing A.I.S.E. resources, or too many requests are received (Box 9), prioritisation may be applied considering, *Inter Alia*:

-Data on similar ingredients suggest refinement is unlikely to improve position (existing ingredients);

-A.I.S.E. has no direct access to the data to perform the check;

-The ingredient was notified by several companies;

-The stage 2 assessment concerns a new ingredient in a niche product category.

3.4. Dispute settlement procedure

In case the Company disagrees with the decision fed back by A.I.S.E. that the data notified for an ingredient are not valid for the ESC check, they may consult an independent expert. The A.I.S.E. team will duly consider the external expert's opinion. The final decision resides within A.I.S.E. (Board).

3.5. Periodical upgrading of the ESC Tool

The ESC tool will be subject to various updates as and when new data are provided, made available (c.f. REACH registrations), and according to stage 2 notifications as ratified by A.I.S.E.

Upgrades, when necessary, will take place at the beginning of the month and companies will be informed. The nature and impact of the upgrade will be duly communicated to companies.

Companies should duly note the potential impact on ASP compliance of such updates as follows:

3.5.1. **Updates not leading to a re-checking of ESC compliance for a given formulation ("regular update"):** The ESC Tool will be updated on basis of results of stage 2 notifications, their ratification by A.I.S.E. and availability of other data.

Companies will be invited to take note of the update but will not be asked to re-submit their reformulation through this update ESC Tool. In case of a random verification the version of the ESC Tool used by the external verifier will be the one used by the Company at the date of the initial ESC check.

Also see Part B – 2.1.3. on new non-proprietary ingredients.

3.5.2. **Updates leading to a higher PESR and requiring a re-checking of ESC compliance for a given formulation ("Ingredient Alert updates"):** The ESC Tool will be updated on basis of results of stage 2 notifications, their ratification by A.I.S.E. and availability of other data.

If newly available data would lead to a higher PESR for a particular ingredient, the data will be examined by the A.I.S.E. support team and possibly by external experts and the need to

update the ESC Tool will be assessed. In addition a call to Charter members may be made to obtain additional data that could help with the assessment. In case the A.I.S.E. support team concludes that the ESC Tool needs to be updated accordingly, companies will be alerted. The companies using this ingredient will have 12 months from the publication of the "Ingredient Alert"/updated ESC Tool to re-check the ingredient and comply with the new requirements if need be. Different cases may apply (see appendix c):

- All ingredients stay green: keep record of new ESC calculation, no need to redeclare to A.I.S.E.
- At least one ingredient gives a PESR >1
    - Either the company stop using the ASP logo
    - Either company reformulates to continue using ASP logo

It can be noted, that one who owns data may proceed to a stage 2 refinement.

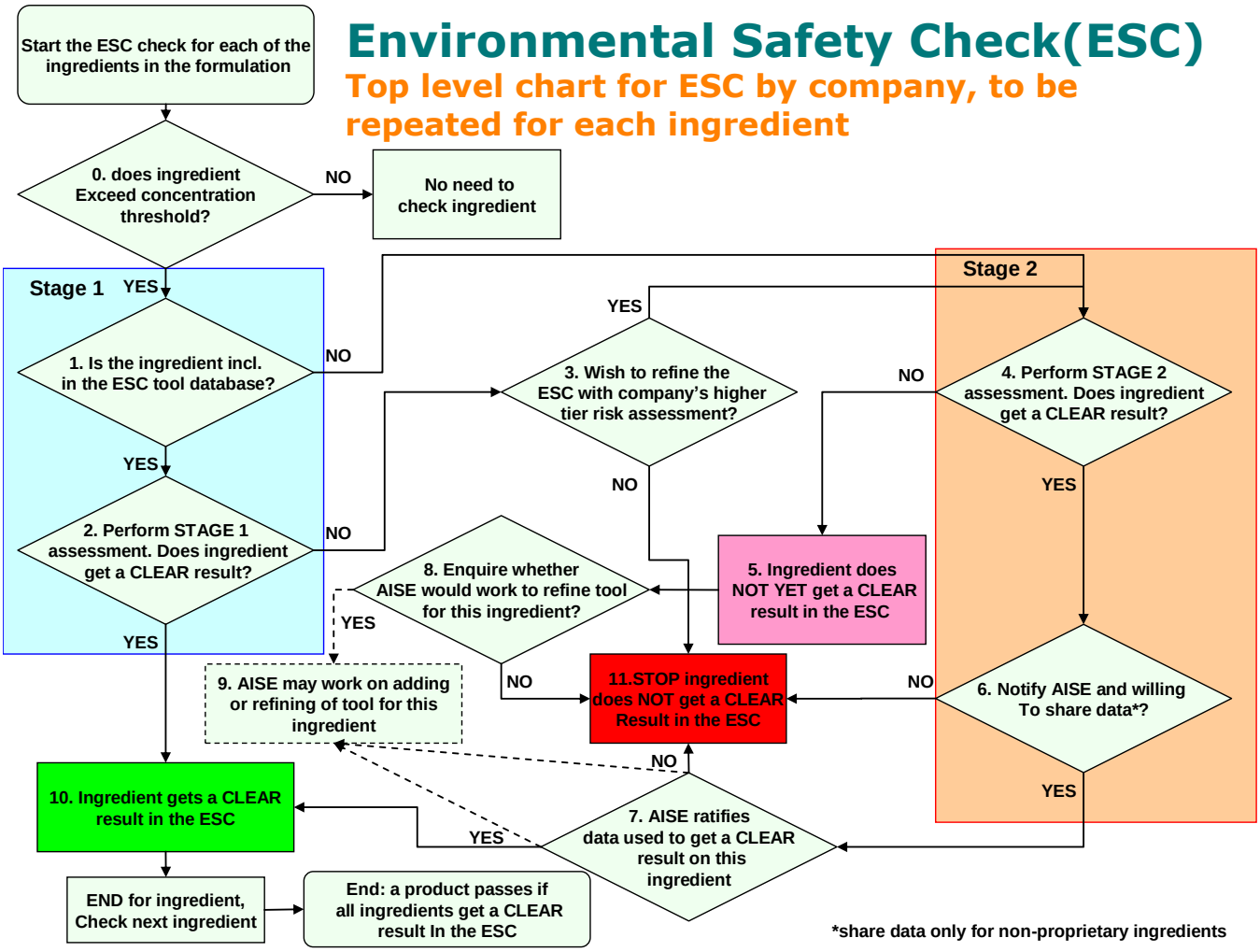
In case of random audit, the ESC version of the tool initially used/declared will be the reference but only during the 12 months period (after provision of the new ESC tool). After, it is the new version of the ESC tool that will be used for audits.

APPENDIX A.

Schematic representation of the ESC procedures via a flow chart

The flow charts presented below provide a rough outline of the ESC decision tree and are presented here for information only. In all cases the procedures in the text are prevalent.

In the flow-chart presented below the light blue box represents ESC Stage 1, whereas the orange box represents the ESC Stage 2 .

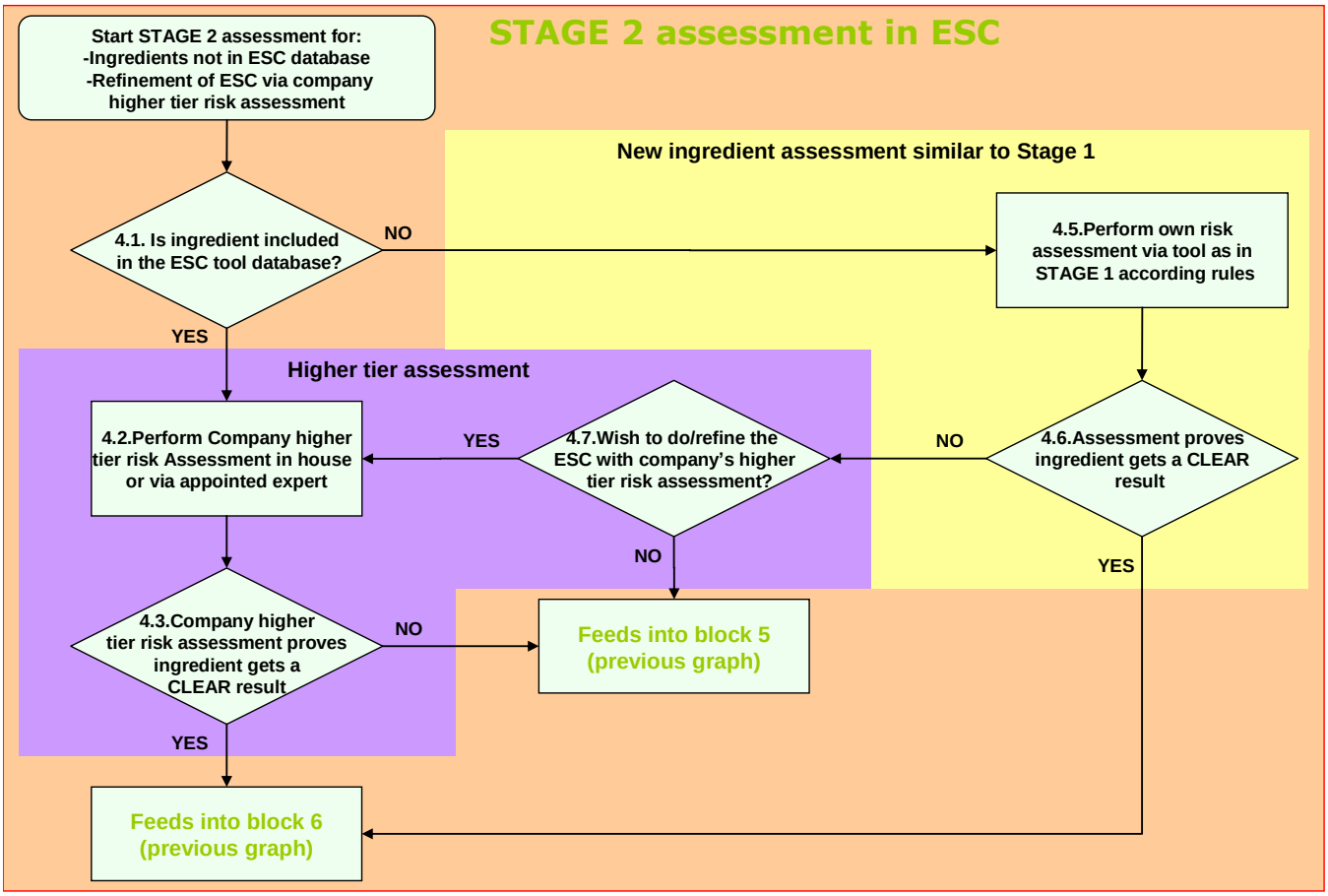


-------- : indicates work that may be done by A.I.S.E. on a different timeframe on refining data for a specific ingredient.

The decision tree of the ESC stage 2 is further detailed in the graph on the next page.

APPENDIX B

Detail of the decision tree of the ESC stage 2



APPENDIX C

Detail of Ingredient Alert