



The technical association
of the European lubricants
industry



The technical committee
of petroleum additive
manufacturers in Europe

ATIEL/ATC
Generic Exposure
Scenarios

Document 0: Guidance for applying the ATIEL/ATC GES Process

A step-by-step guide to identifying whether a GES is required for a lubricant or lubricant additive product and selecting the appropriate GES.

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Applying the ATIEL / ATC GES Process

The ATIEL/ATC GES process has been designed to support the communication of safe use information for the hazardous components¹ used in Lubricant formulations via attaching a 'mixture' Exposure Scenario Annex to the SDS. The controls identified within each GES are expected to be sufficient to address the risks associated with all typical components regardless of whether these components have already been registered and an ES received from your supplier.

ATIEL's expectation is that most Lubricants products should fit within the boundary conditions of the relevant GES specified in this process. However, for products that do not fit the boundary conditions, it will be necessary to develop an exposure scenario specific to that product, and the GES provides a starting point. The GESs have been prepared based on typical hazard classifications and typical component substance concentrations in finished products used in typical applications.

An overview of the process is given below together with reference to the relevant supporting documents and further explanation.

How to use this guidance

This guidance provides a step-by-step guide to identifying whether a GES is required and, if yes, selecting the appropriate GES for your lubricant or lubricant additive product. It advises you which documents you need to download from the ATIEL website, provides a description of what they contain, and details on how to apply them.

The methodology used to develop the GES documents is considered by the ATIEL / ATC GES Working Group to be robust. The control measures identified are considered to represent good practice for the product hazards covered by the GES process.

A description of the full process is included in the document titled 'GES Process Flow Charts'. The flow charts contained in this document guide you through the various steps and decisions you need to make when assessing your product. An overview of the process is given below:

Note: Sections of the GES Process Flow Charts are included in this guidance document to help orientate you through the process. It is essential that you use the separate flow chart document when applying this process, as the flow chart sections inserted in this document are not intended to be read.

¹ As required by REACH Articles 31, 37 and 39

ATIEL/ATC GES Process Overview (see: [Document 1 – ATIEL-ATC GES Process Flow Chart](#))

1. Allocate Products to Use Groups and attach ES Annex to Product SDS ([Flow Chart Step 1a and 1b](#))

- Allocate own products to applications (see: [Document 2 – ATIEL-ATC Applications](#) and [Document 3 – ATIEL-ATC Lubricant DUCC Table](#)).

If you have not yet mapped your products to the ATIEL use groups, you need to download the 'ATIEL-ATC Applications' ([Doc2](#)) and 'ATIEL/ATC Lubricant DUCC Table' ([Doc3](#)) documents. These will help you to determine the GES use groups that apply to your products.

The GES are divided into 'Industrial' and 'Professional' Sectors of Use, as relevant to the use group.

For products sold into the consumer/domestic market no Safety Data Sheets are required, thus no consumer GESs have been prepared. Formulators selling into the consumer market are advised to ensure they can demonstrate compliance with their obligation to meet the consumer safe use requirements received from their suppliers.

Please see ATIEL-REACH website FAQ number 9 for an explanation of industrial, professional and consumer use.

- Check whether any products are classified for human health and/or environment.

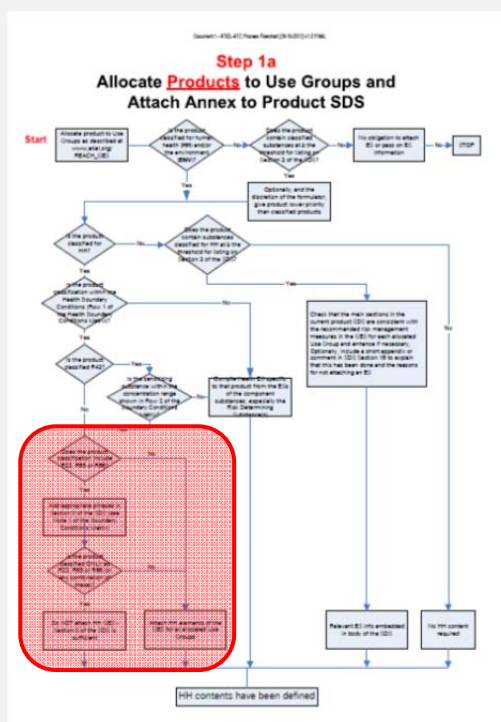
If your products are neither classified as hazardous nor contain hazardous components required to be listed in Section 3 of the SDS^{2,3}, there is no further action.

² Physical properties (for example flammability, explosivity) are not considered as hazardous in this context, since safe use controls are not dealt with via the Exposure Scenario but included within the body of the SDS.

³ according to Regulation (EC) No. 1272/2008 [CLP] or According to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD].

- For products whose classification includes (R22, R65, R66), appropriate controls are recommended to be communicated as standard phrases within Section 8 of the SDS, and are not included in the GES. These phrases should be added to the SDS regardless of whether a GES has been attached to the SDS or not.

For products classified as R22, R65 and R66 standard risk management measures apply which are general for the product as a whole, rather than for a specific Use Group/ Exposure Scenario. In addition, R65 and R66 are hazards based on phys-chem properties for which a reference value e.g. a DNEL cannot be derived.



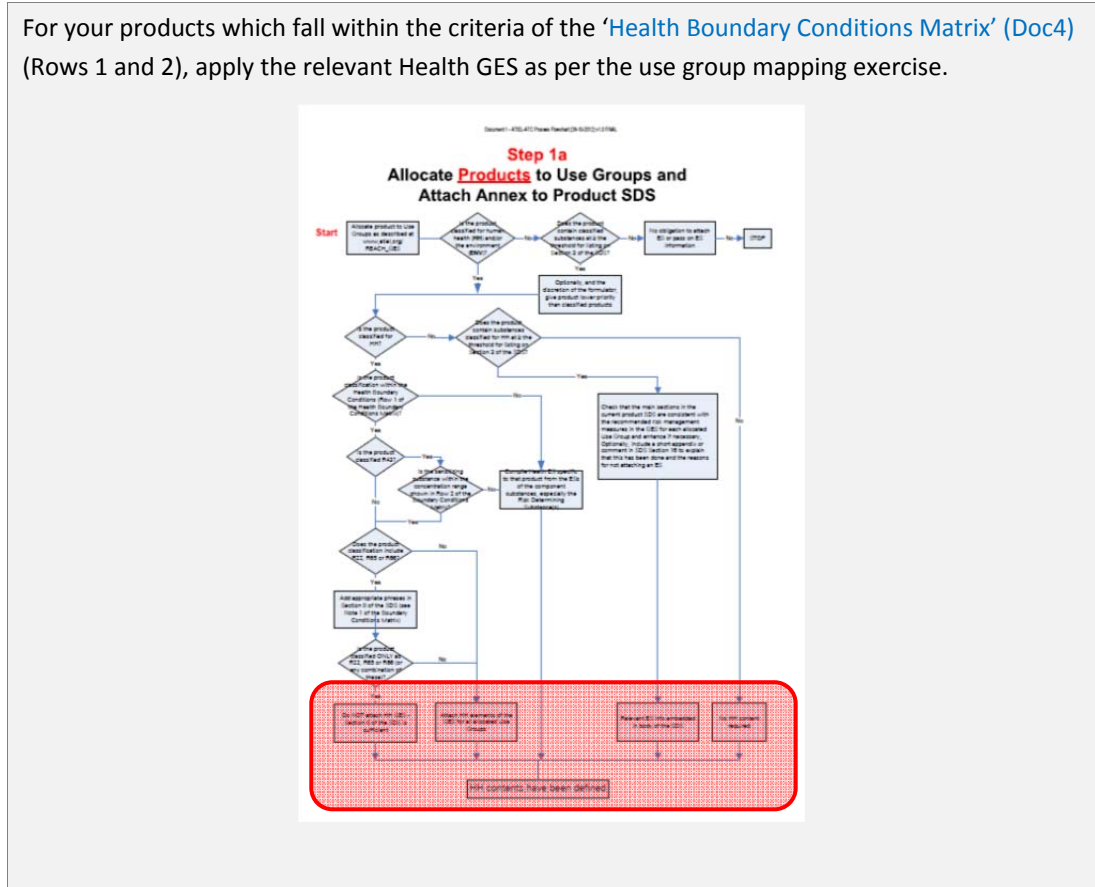
For these hazards the following phrases based on a qualitative risk assessment are recommended for inclusion within Section 8 of the Safety Data Sheet:

- R65 and R22: Do not ingest. If swallowed then seek immediate medical assistance. (Standard phrase [E14]).
- R66: If repeated and/or prolonged skin exposure to the substance is likely, then wear suitable gloves tested to EN374 and provide employee skin care programmes. (Standard phrase [PPE20]).

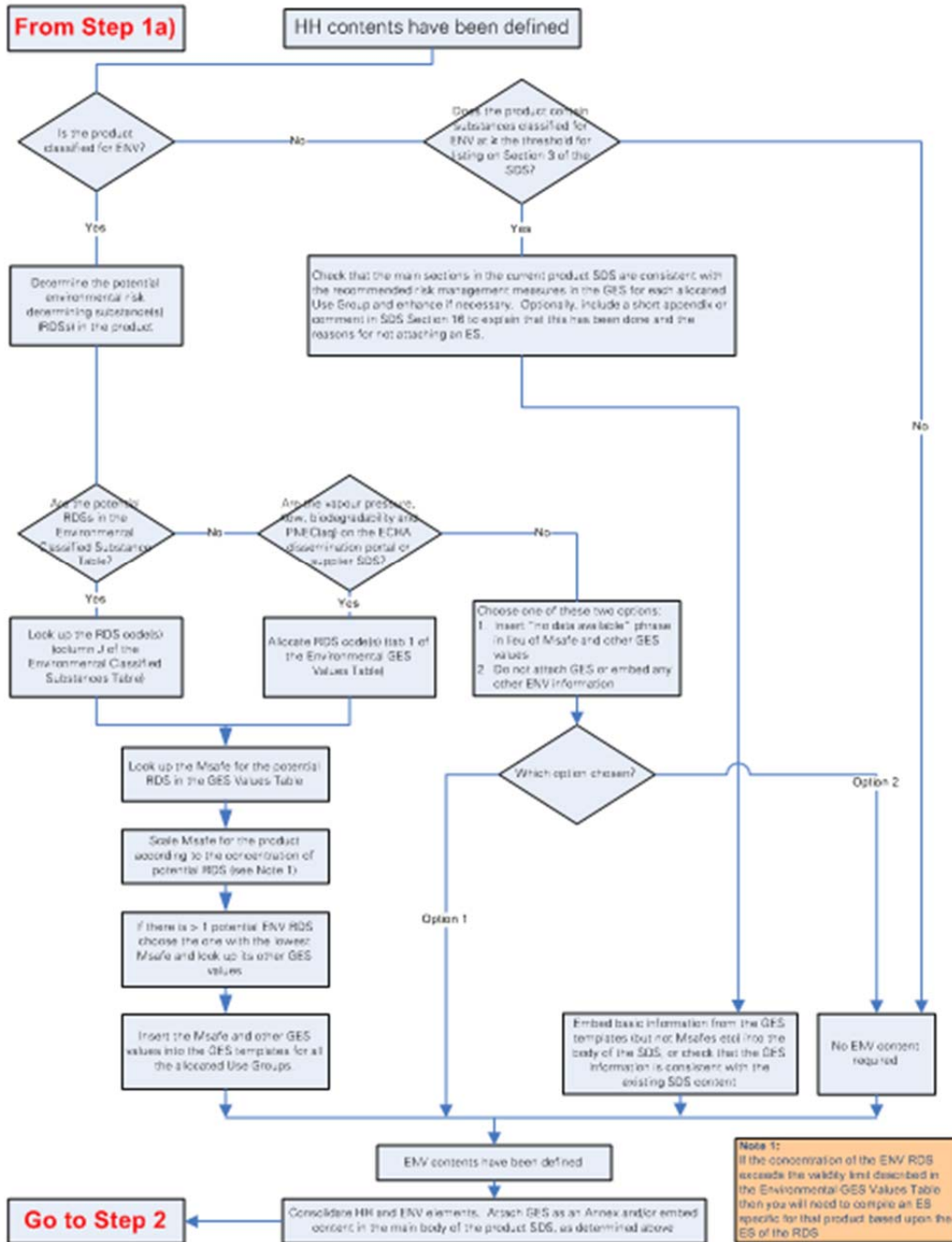
It is possible that the raw material SDS with these classifications may include Exposure Scenarios in which case a check of the relevant ES contents for consistency with the main sections of the product SDS is necessary. Alternatively, a copy of the relevant GES may be attached

- Attach appropriate Human Health GES(s) if relevant boundary conditions are met (see: [Document 5a – ATIEL-ATC GES Use Group A](#) and [Document 5b – ATIEL-ATC GES Use Groups B-F](#)).

For your products which fall within the criteria of the 'Health Boundary Conditions Matrix' (Doc4) (Rows 1 and 2), apply the relevant Health GES as per the use group mapping exercise.



Step 1b Allocate Products to Use Groups and Attach Annex to Product SDS (continued)

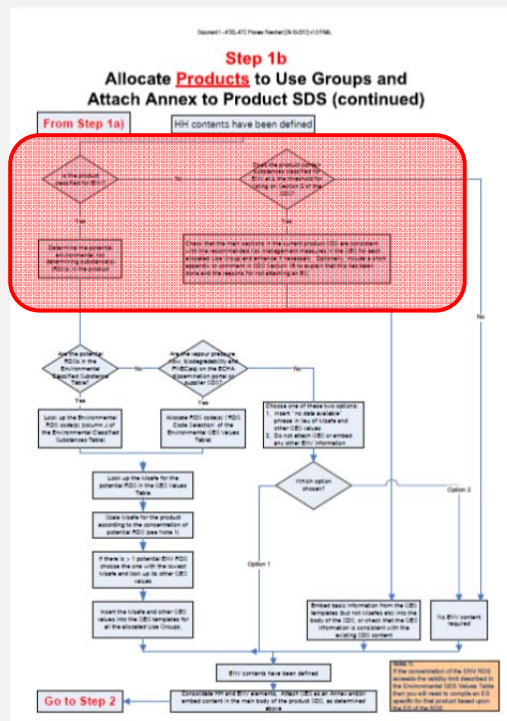


For products classified for the Environment (Follow Step 1b)

- Check environmental hazard classifications (see: [Document 6 – ATIEL-ATC Environmental Classified Substance Table](#) and [Document 7 – ATIEL-ATC Environmental GES Values Table](#))

As for human health hazard, for the environment early in this process you have the opportunity to eliminate from the process all products that do not contain environmentally hazardous substances, i.e. which are not listed in section 3 of the Safety Data Sheet (SDS) of the product, since these products do not require an environmental section of the exposure scenario.

For products that do contain substances listed in section 3 of the SDS, you will need to determine the classification and concentration of the risk determining substance (RDS). The RDS is the Environmental Classified Substance (ECS) that drives the risk posed by the product in which it is present and when following the process below derives the lowest Msafe value.



You need to assess each ECS listed in section 3 of the SDS in order to determine which is likely to be the RDS based on the substance hazard classification hierarchy and concentration. Then look up this substance in the ‘[Environmental Classified Substance Table](#)’ (Doc6) and following the process below determine the Msafe value. Repeat this if there is more than one candidate for RDS . The ECS Table provides a route to the assignment of codes and thence the appropriate GESs.

If the ECS is not listed in this table you need to collect the values of four parameters (see tab “RDS code selection” of ‘[Environmental GES Values Table](#)’ (Doc7)) and use them to assign an RDS code. The likely sources of these parameters include the ECS Safety Data Sheet or ECHA dissemination website of registered substances.

Using the RDS code you can then look up and check a number of parameters (e.g. Msafe) that need to be inserted into the environmental section of the GES. Note: the derivation of the Msafe value at the product level has assumed a certain concentration of the RDS in the generic product as shown in the tab “Msafe product” of ‘[Environmental GES Values Table’ \(Doc7\)](#) (above the table).

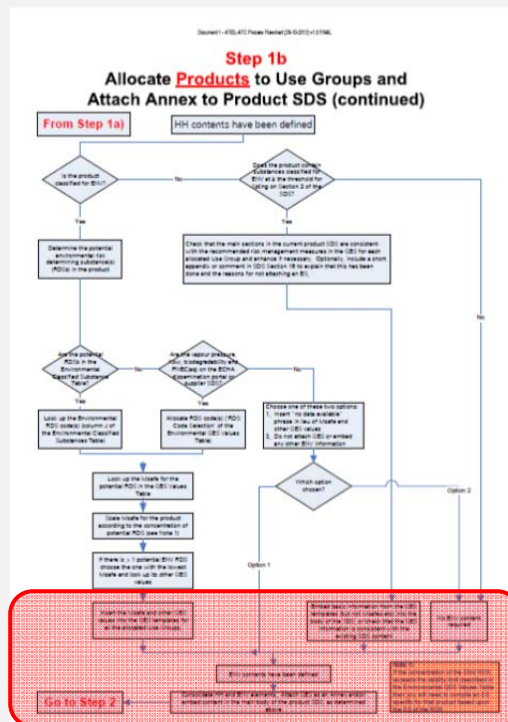
The Msafe value can be adjusted up or down to reflect the actual concentration of the RDS used in your product where it differs from that assumed (see tab “Treat rate” of ‘[Environmental GES Values Table’ \(Doc7\)](#)), but ensure that you stay within the validity limit.

If your products contains several ECSs you need to repeat these steps; then include the lowest value for the Msafe at the product level in the appropriate GES .

- Attach appropriate environmental GES(s) if relevant boundary conditions are met (see: [Document 5a – ATIEL-ATC GES Use Group A](#) and [Document 5b - ATIEL-ATC GES Use Groups B-F](#)).

For your products which contain ECS listed in section 3 of the SDS, select the GES as per the use group mapping exercise in Step 1b of the flow chart and fill in the variable parameters fields according to the RDS code.

The GES is then appended in an Annex to the SDS of your product. You will need to repeat this exercise for all relevant products as required.



- For some products only one of either Human Health or Environmental GES may be required. This may be communicated by the use of the following suggested phrases in the relevant sections of the GES, or other means determined by individual companies:
 - 'No exposure assessment is presented for Human Health'
(Standard phrase [G39]) or
 - 'No exposure assessment is presented for Environment'
(Standard phrase [G40]).

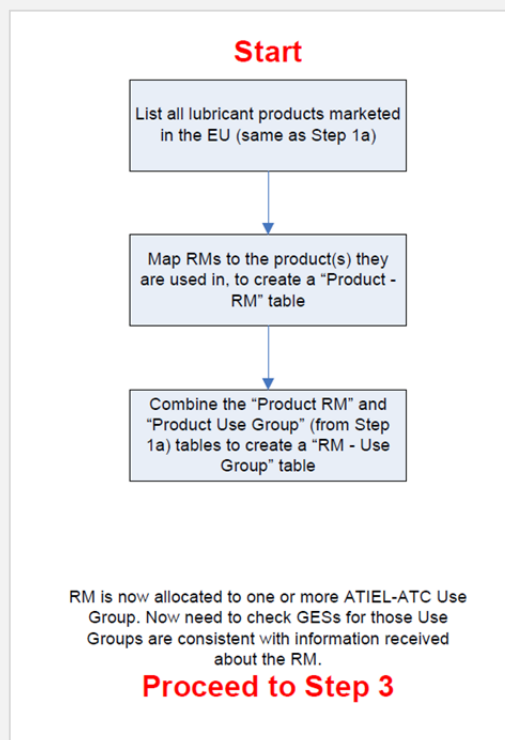
2. Verify the contents of the GES by checking the incoming raw material details

- Allocate raw materials to use groups (**Flow chart Step 2**)

Having completed steps 1a and 1b of the flow chart for all of your products, you are now in a maintenance phase.

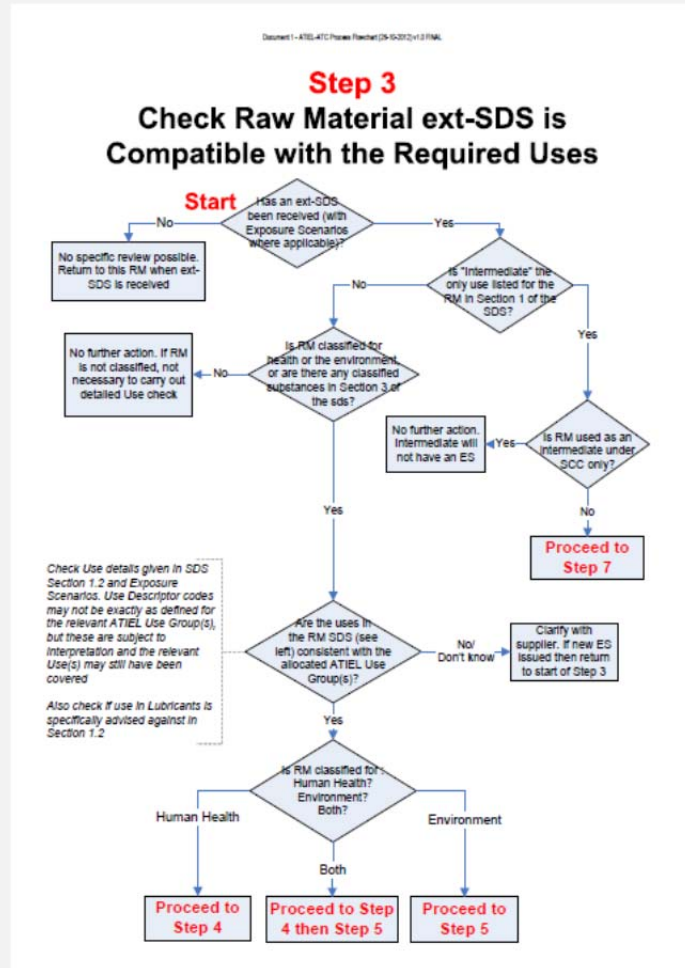
When you receive extended SDSs containing exposure scenarios for component raw materials of the finished product, you will need to follow the steps 2-5 in the flow chart to ensure the assigned GES(s) is/are consistent with the received information. This exercise will need to be repeated whenever you receive a new or updated extended SDS for the product raw materials. It is advised that this validation check is formally documented.

Step 2 of the flow chart requires you to map incoming raw material substances / components to the GES Use Groups.



- On receipt of the incoming raw material SDS, check relevant uses are covered for your finished products (**Flow chart Step 3**).

Step 3 is a confirmation step that the GES use group has been covered by the registration of the raw material. Check against the flow chart and pay attention to the note on use group descriptors as interpretations may differ.



- Check relevant raw material exposure scenario(s) against conditions of use contained in the GES for the product (**Flow chart Steps 4 & 5**) see:

[Document 4 - ATIEL-ATC Health Boundary Conditions Matrix](#)

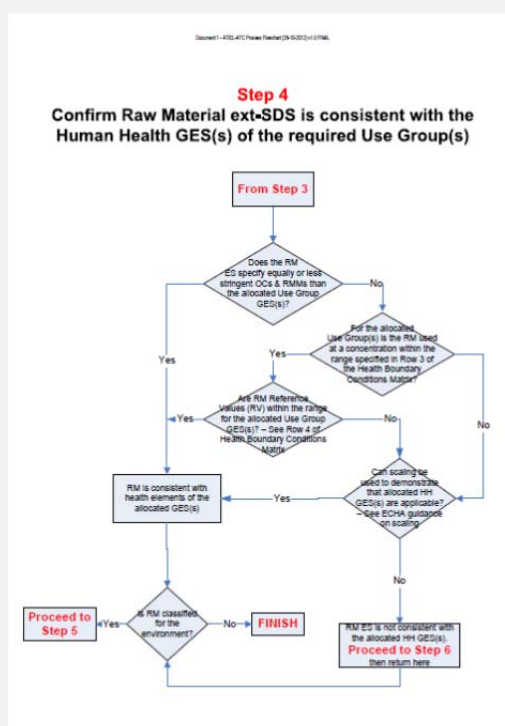
[Document 8 – ATIEL-ATC Health GES – Explanation of Fields](#)

[Document 9 - ATIEL-ATC Environmental GES - Explanation of Fields and Checks](#)

[Document 10 – ATIEL-ATC Checking Environmental Conditions of Use and Scaling as Part of Step 5 of the Flow Chart](#)

Step 4 (Human Health) is intended to determine if the human health aspects of the assigned GES are consistent with the information received in the ES from your supplier.

The first point to check is the operational conditions (OCs) and risk management measures (RMMs) communicated in the received ES. Operational conditions are the parameters that define the conditions under which an activity takes place, such as its duration, temperature etc. Risk Management Measures refer to actions taken to reduce exposure to a risk (these could include engineering control measures e.g. use of extract ventilation, administrative e.g. training and/or personal protective equipment).



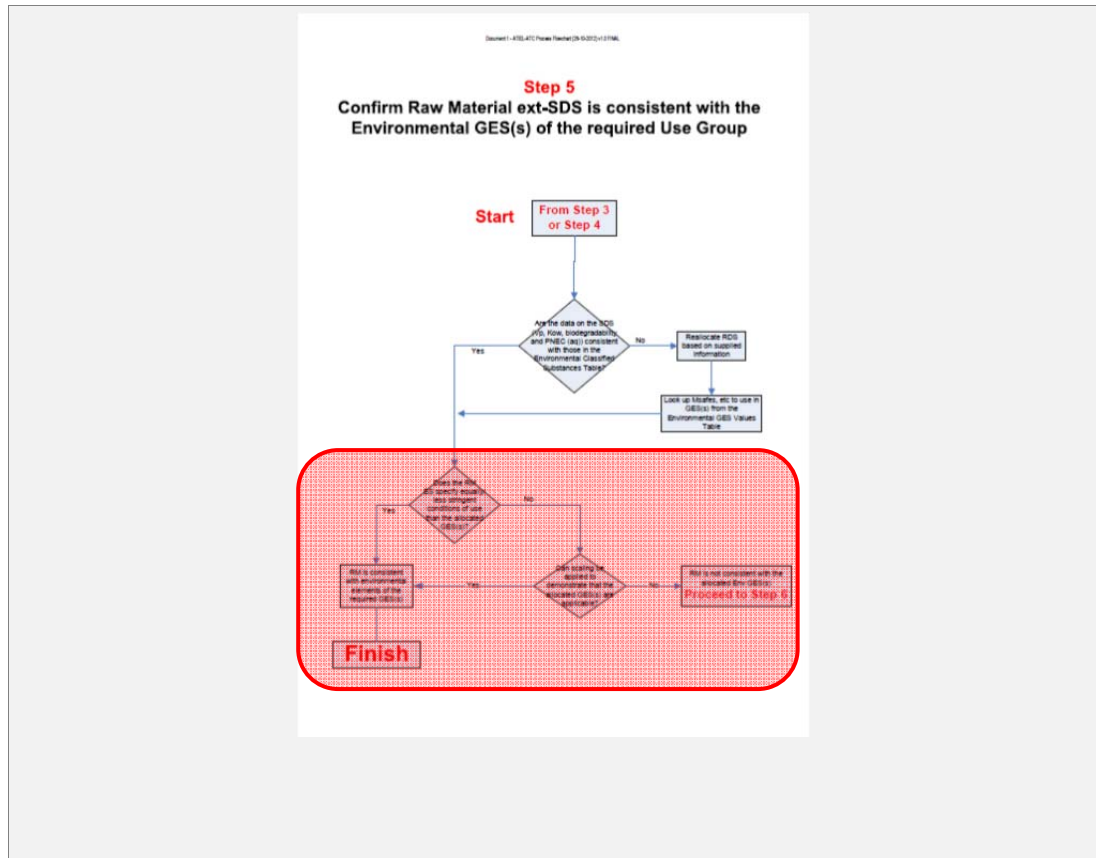
Check if the conditions and measures specified in the GES provide equivalent or better exposure reduction to those specified in the ES for the raw material; an explanation to help interpret the health GES is given in the document ‘[Health GES - Explanation of Fields](#)’ (Doc8). If yes, then you have verified that the GES is valid. If no, then you will also need to check the following and refer to the ‘[Health Boundary Conditions Matrix](#)’ (Doc4):

- if the Raw Material is used within the concentration range identified in the boundary conditions (Row 3). Note: if the incoming RM ES indicates a lower concentration to the upper limit of the boundary concentration, check whether the actual concentration used in the

formulated product is equal or less than the concentration specified in the incoming RM ES;
and

(b) that the Raw Material DNEL or Vapour Pressure are within the boundary Reference Values (Row 4).

If yes, then you have verified that the GES is valid. If no, you have the option to apply 'Scaling'. If still no, proceed to Step 6 and then return here to proceed to Step 5 if an Environmental review is required.



3. If the incoming Raw Material Exposure Scenario is not consistent with the GES (Step 6)

If the raw material exposure scenario information is not consistent with the GES follow further options (**Flow chart Step 6**).

Options include:

- For the environment, in certain situations the GES can be applied and attached, but this constitutes a DU CSA approach.
- Information is unclear in the Raw Material SDS - revert to supplier
- Carry out own Chemical Safety Assessment (CSA). If CSA shows GES is not adequate then create a ES specific to the product;
- Incorporate more stringent OCs/RMMs (as defined within the RM ES) into the GES to create a ES specific to the product(s) that contain the RM;
- Seek alternative supplier(s) and/or raw material(s) and review their ES for compliance with GES.

4. Raw material registered only as intermediate under strictly controlled conditions (SCC) (Step 7)

If the raw material has been registered only as an intermediate under strictly controlled conditions, follow **flow chart Step 7**.

5. Documenting the review of incoming raw materials

It is advised to document the outcome of the raw material review to support regulatory compliance checks.

6. Background to the development of the GES

- Human Health (**text under development**)
- Environment (**text under development**)

7. Glossary of Acronyms

CLP	Classification, Labelling and Packaging
CSA	Chemical Safety Assessment
DNEL	Derived No Effect Level
DSD	Dangerous Substances Directive
DPD	Dangerous Preparations Directive
DU	Downstream User
ECHA	European Chemicals Agency
ECS	Environmental Classified Substance
ENV	Environment
ES	Exposure Scenario
FAQ	Frequently Asked Questions
GES	Generic Exposure Scenario
HH	Human Health
OC	Operational Condition
PNEC	Predicted No Effect Concentration
PPE	Personal Protective Equipment
RDS	Risk Determining Substance
REACH	Registration Evaluation and Authorisation of Chemicals
RM	Raw Material
RMM	Risk Management Measure
RV	Reference Value
SDS	Safety Data Sheet
SCC	Strictly Controlled Conditions