

A close-up photograph of a microscope's objective lenses and eyepiece, rendered in a blue-tinted color scheme. The lenses are in sharp focus, with some text like 'Plan' and '0.25' visible on them.

STEPTOE & JOHNSON LLP

When Experience Matters®

Downstream Users under REACH

Laura C. Atlee

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TOPICS COVERED

- 1. Who is a Downstream User (DU)?**
 - ✓ Definition of DU
 - ✓ Definitions relating to DU
- 2. What must a DU Do?**
 - ✓ Safety Data Sheet (SDS)
 - ✓ Exposure Scenarios (ES)
 - ✓ Chemical Safety Reports (CSR)
- 3. Comparing a DU's "use" to an Exposure Scenario:**
 - ✓ Checking compliance with the ES
 - ✓ When a 'use' is outside the ES
- 4. Authorization**
- 5. Restriction**
- 6. Information for Downstream Customers**
- 7. New/Additional Information**

DEFINITION OF DOWNSTREAM USER

A Downstream User is:

1. Natural/legal person established within the Community,
2. who uses a substance, on its own or in a preparation,
3. in the course of his industrial or professional activities.

REMEMBER: The DU is someone other than the “manufacturer” or the “importer”:

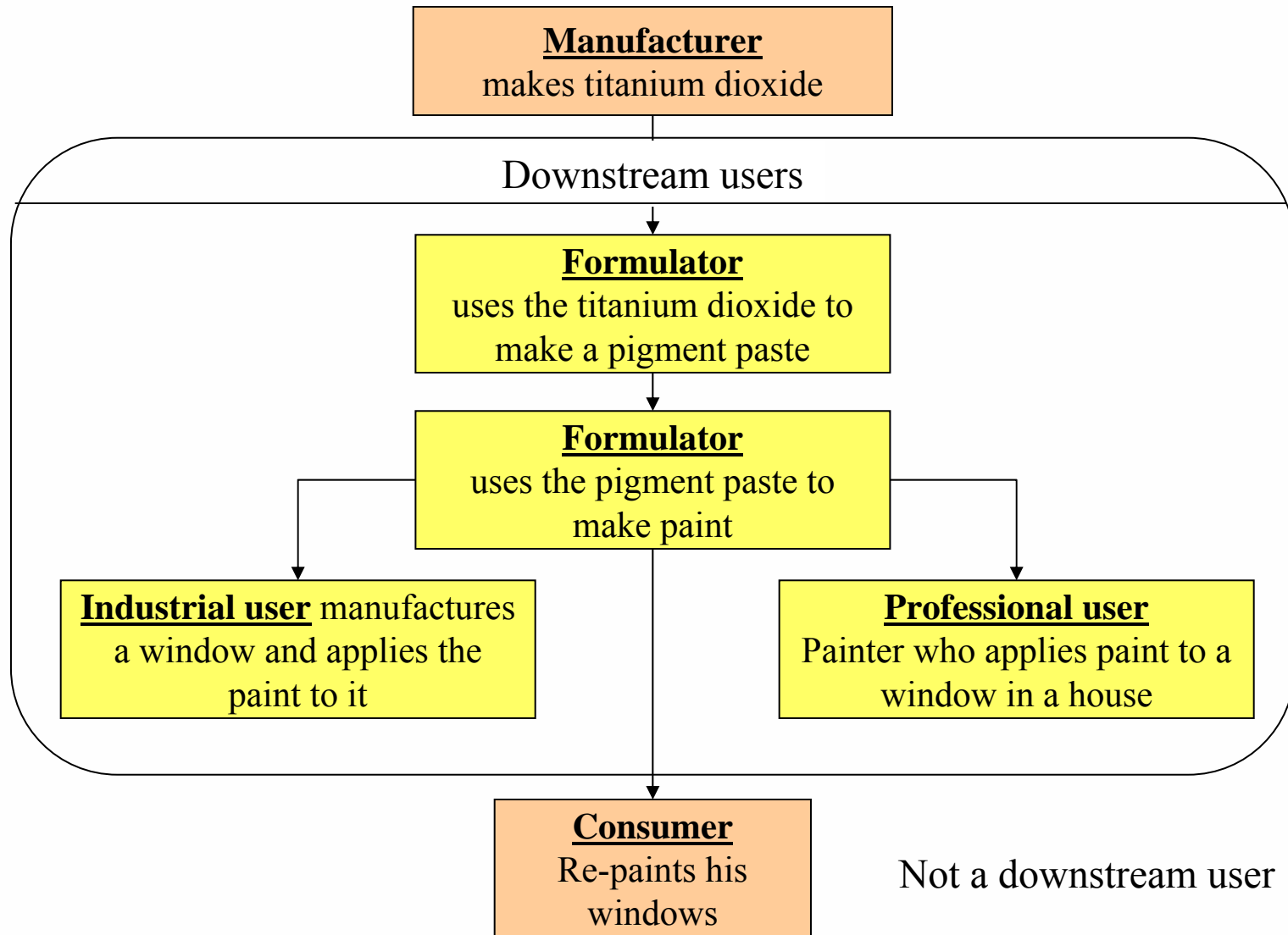
- **Manufacturer:** means any natural or legal person established within the Community who manufactures a substance within the Community;
- **Importer:** means any natural or legal person established within the Community who is responsible for import;

DEFINITION OF DOWNSTREAM USER

If a representative is appointed by a non-Community manufacturer the importer(s) within the same supply chain will be regarded as downstream users.

- An exempted re-importer exempted is regarded as a downstream user.
- **Distributor:** any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties;
 - A distributor or a consumer is **not** a downstream user.

WHO IS A DOWNSTREAM USER?



Definitions Related to Downstream Users

- Actors in the supply chain: means all manufacturers and/or importers and/or downstream users in a supply chain.
- Identified use: means a use of a substance on its own or in a preparation, or a use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user.
- Supplier of a substance or a preparation: means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a preparation, or a preparation.
- Recipient of a substance or a preparation: means a downstream user or a distributor being supplied with a substance or a preparation.

WHAT MUST A DOWNSTREAM USER DO?

Check information from your supplier (safety data sheet, exposure scenario or other) to make sure your use is safe.



Check that you comply with any restrictions or authorisation conditions.



Pass relevant information on hazards, risk management measures to your supplier.



Pass information to industrial and professional customers on safe use.

Safety Data Sheets (SDS)

- DU **will receive** an safety data sheet (SDS) from a supplier when:
 - A substance/preparation is classified as dangerous; or
 - A substance is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) (criteria in REACH Annex XIII); or
 - A substance is included in the list of substances subject to authorisation (for a reason other than either of the above two).
- A SDS **may be requested** from a supplier when a preparation is not dangerous, but contains:
 - in an individual concentration of ≥ 1 % by weight for non-gaseous preparations and $\geq 0,2$ % by volume for gaseous preparations at least one substance posing human health or environmental hazards; or
 - in an individual concentration of $\geq 0,1$ % by weight for non-gaseous preparations at least one substance that is PBT or vPvB (criteria set out in Annex XIII or has been included for reasons other than those referred to in point (a) in the list of substances subject to authorisation; or
 - a substance for which there are Community workplace exposure limits.

Safety Data Sheets (SDS)

Any supplier of a substance/preparation who does not have to supply a SDS must provide the recipient with the following:

- (a) the registration number(s), if available, for any substances for which information is communicated under points (b), (c) or (d);
- (b) if the substance is subject to authorisation and details of any authorisation granted or denied in this supply chain;
- (c) details of any restriction imposed;
- (d) any other available and relevant information about the substance that is necessary to enable appropriate risk management measures (RMM) to be identified and applied including specific conditions resulting from the application of section 3 of Annex XI (Substance-tailored exposure-driven testing)

Chemical Safety Reports (CSR) and Exposure Scenarios (ES)

- A chemical safety assessment (CSA) must be performed and a chemical safety report (CSR) completed for all substances subject to registration in quantities of **10 tonnes** or more per year per registrant.
- A CSA does not need to be performed for a substance which is present in a preparation if the concentration of the substance in the preparation is less than the lowest of any of the concentrations provided in Art. 14(2)
- If the CSA shows that the substance meets the criteria for classification as dangerous in accordance with the Dangerous Substances Directive or is assessed to be a PBT or vPvB, the CSA must include an exposure assessment with resulting exposure scenario (ES).

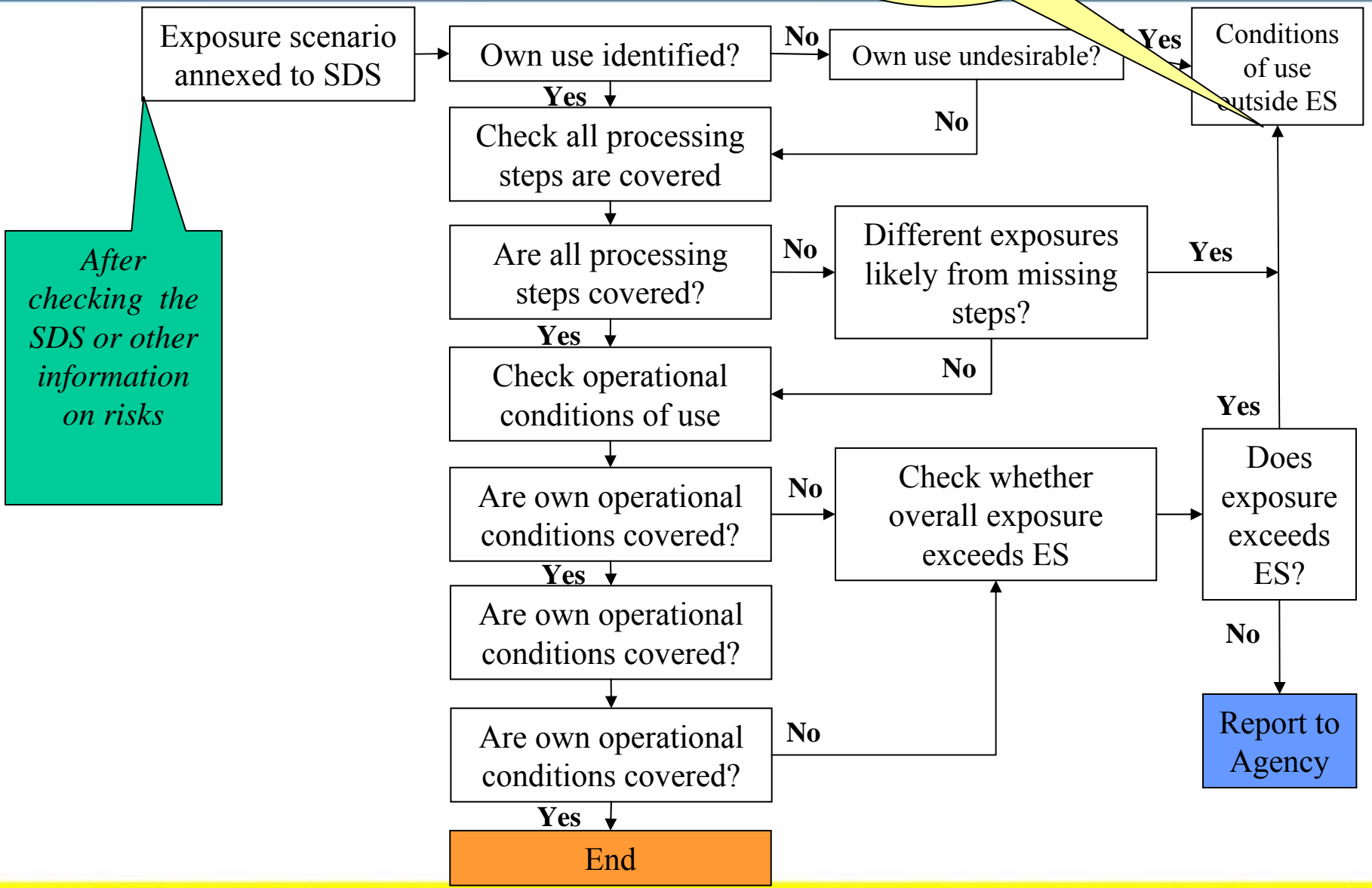
Safety Data Sheets, Chemical Safety Reports and Exposure Scenarios

DU should:

1. Identify the substances and preparations used in their industrial processes.
2. Ask their supplier whether they have already established use and exposure categories/exposure scenarios for the substance/substances in preparations that they supply.
 - DU may also check SDS provided to them to see whether their uses are already covered in the SDS.
3. If their uses are not yet covered, DU may provide to their supplier information to develop an exposure scenario/use and exposure category.

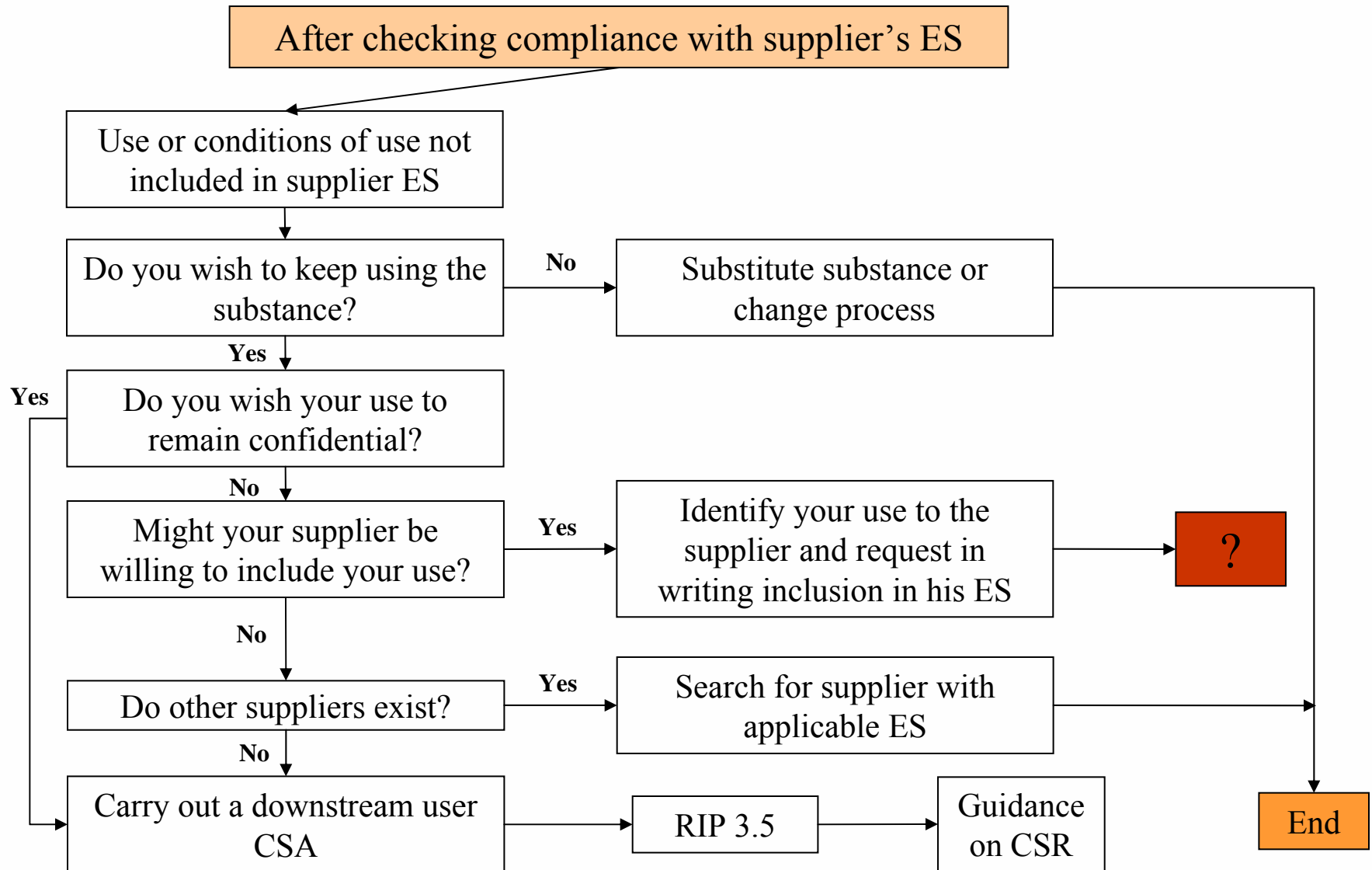
CHECKING COMPLIANCE WITH SUBSTITUTION OF EXPOSURE SCENARIO

In the next slide...



After checking the SDS or other information on risks

CONDITIONS OF USE OUTSIDE SUPPLIER ES



Accepted or Rejected Use?

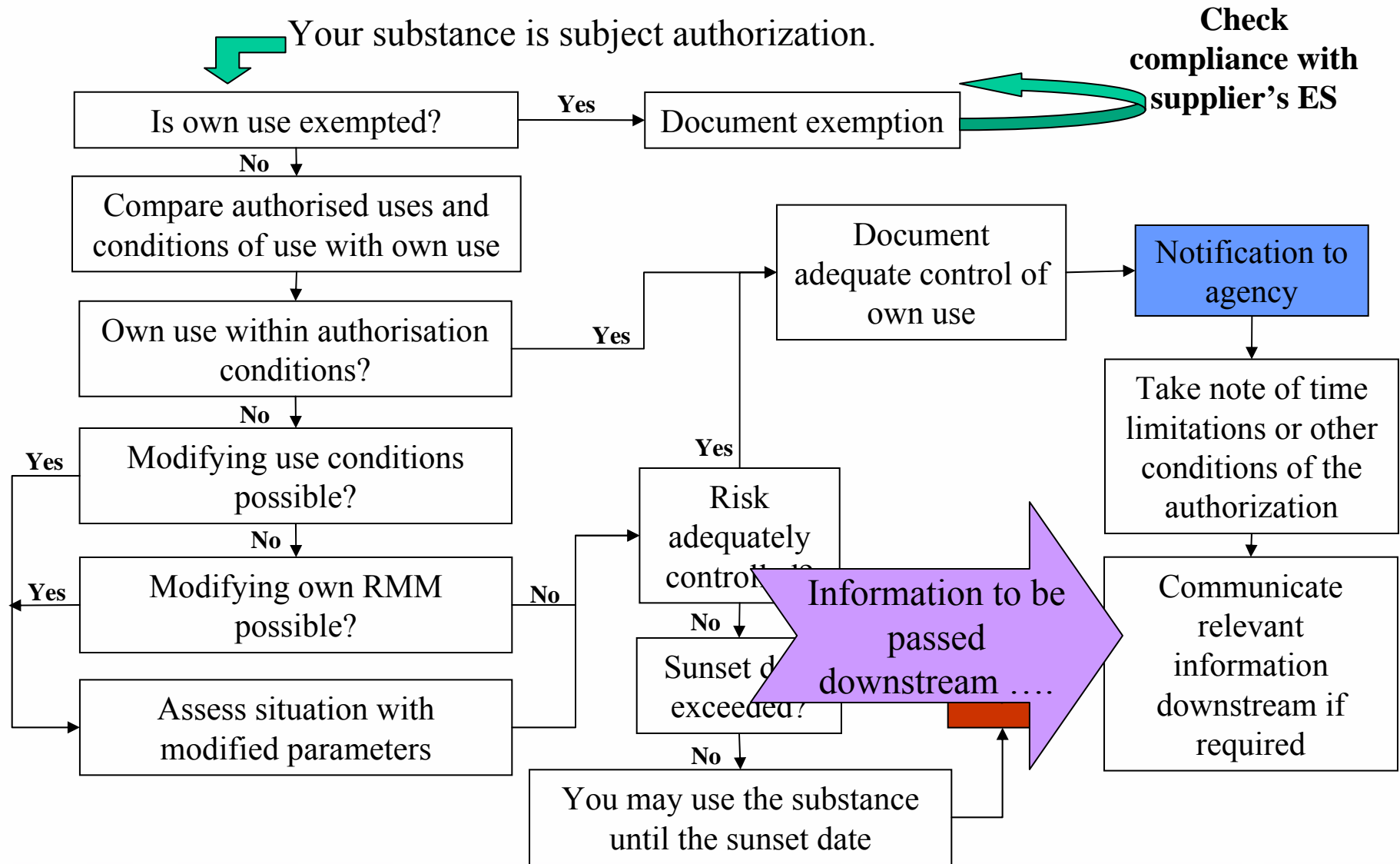
- When can a supplier refuse to include my use?
- They are not obliged to include the use in the ES if:
 1. They choose not to sell to the DU; or
 2. They conclude that it is not possible to develop an ES for a given use for reasons of environmental or health protection.
- If it is because of 2, the supplier must report it to the Agency.

Accepted or Rejected Use?

A DU does not need to prepare a CSR in any of the following cases:

- (a) a SDS is not required to be communicated with the substance or preparation
- (b) a CSR is not required to be completed by his supplier in accordance with Article 14;
- (c) DU uses the substance/preparation in a total quantity of less than 1 tonne/year;
- (d) DU implements or recommends an ES which includes as a minimum the conditions described in the ES communicated to him in the SDS;
- (e) the substance is present in a preparation in a concentration lower than any of the concentrations set out in Article 14(2);
- (f) DU is using the substance for the purposes of PPORD, provided that the risks to human health and the environment are adequately controlled in accordance with the requirements of legislation for the protection of workers and the environment.

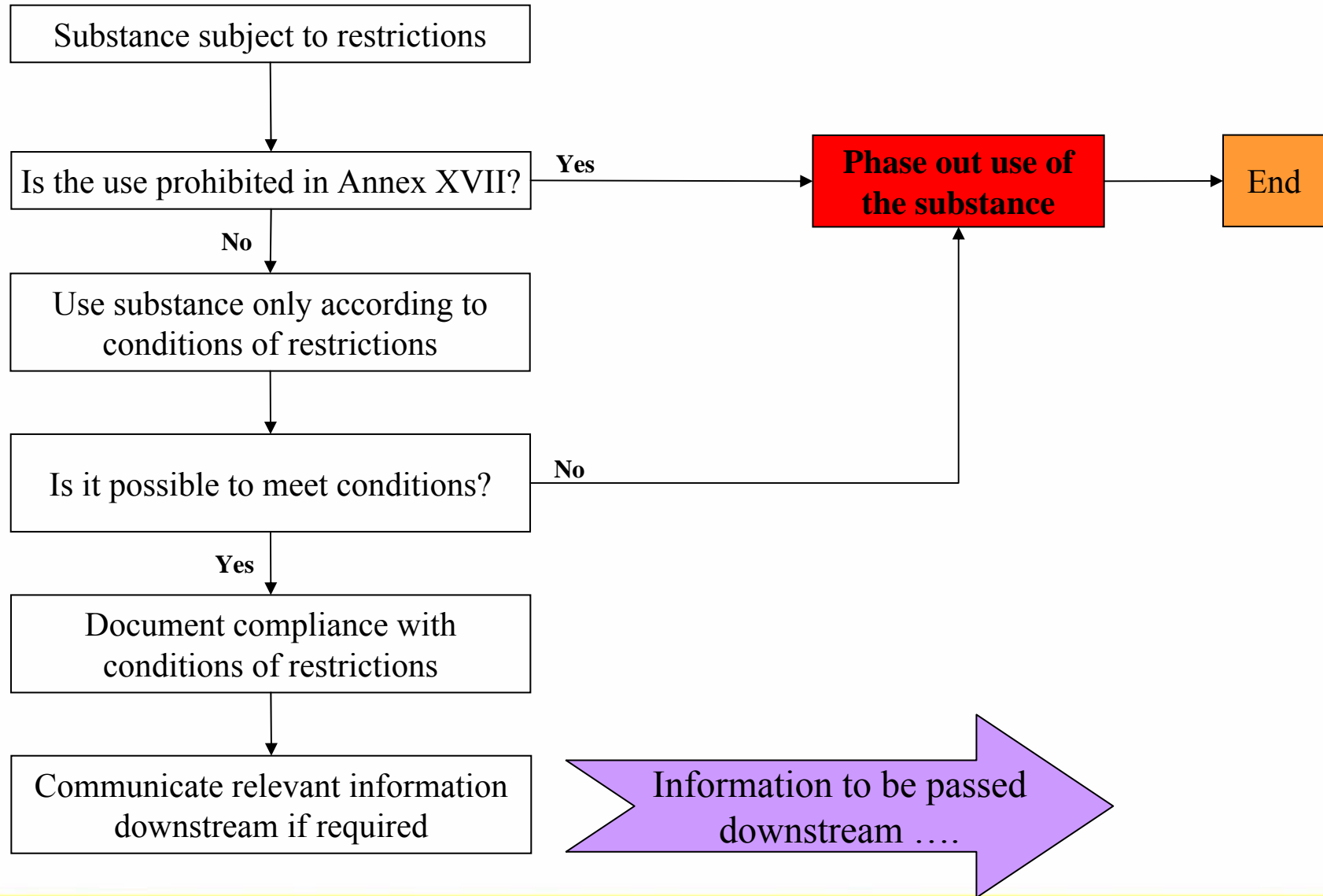
CHECKING COMPLIANCE WITH AUTHORIZATION



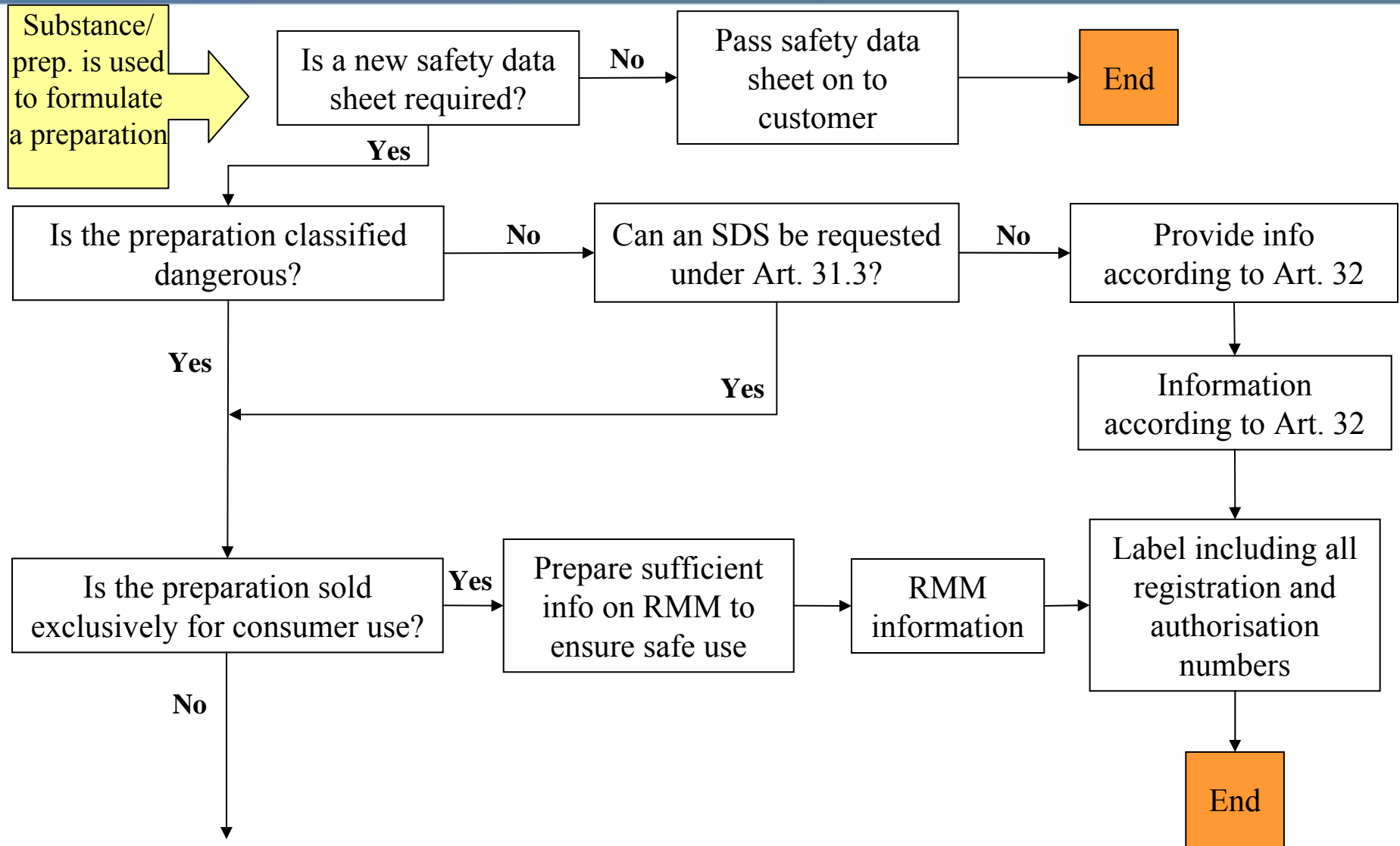
CHECKING COMPLIANCE WITH AUTHORIZATION

- What do I do if no suppliers have applied for and receive an authorization for my use?
 - Inform your supplier and ask him to apply for the authorization;
 - Combine forces with other DU who need authorization for the same use; or
 - Coordinate with your customers who depend on the product you make.

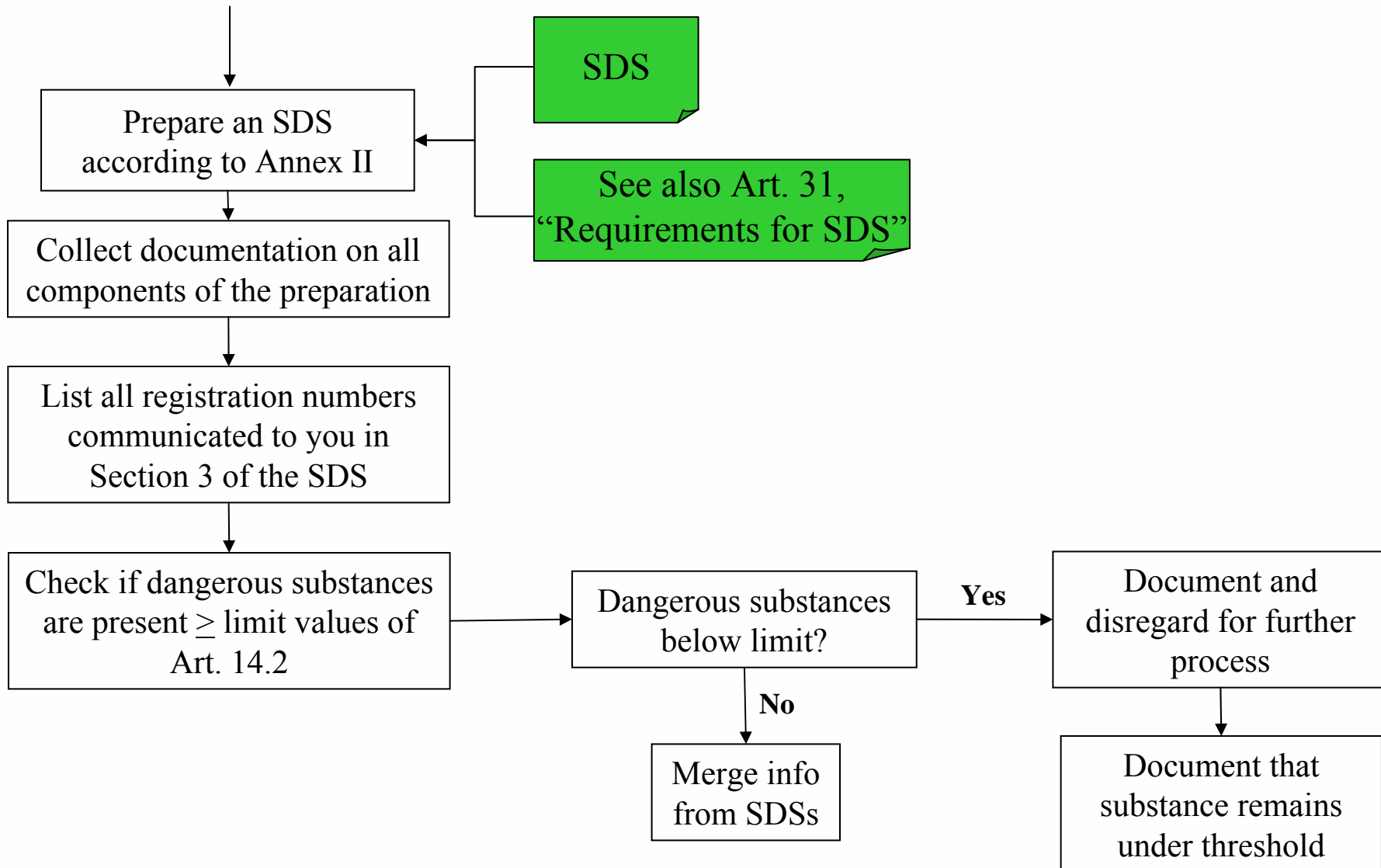
CHECKING COMPLIANCE WITH RESTRICTIONS



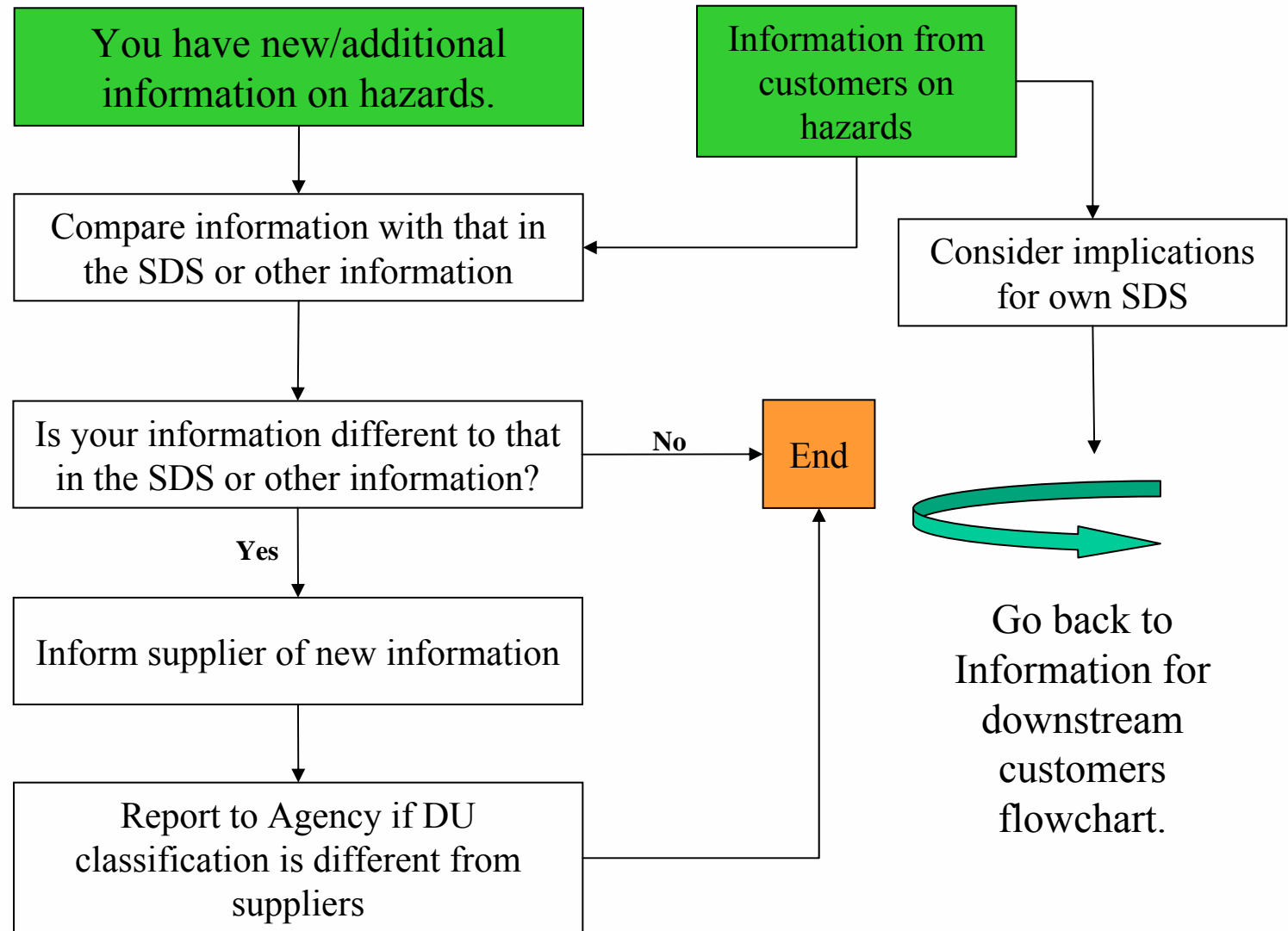
INFORMATION FOR DOWNSTREAM CUSTOMERS



INFORMATION FOR DOWNSTREAM CUSTOMERS (2)



INFORMING SUPPLIERS OF ADDITIONAL/NEW INFORMATION ON HAZARDS



Thank you