

**FECC GOOD PRACTICE GUIDANCE
STORAGE TANK MANAGEMENT FOR
BIOCIDAL ACTIVE SUBSTANCES**



Fecc
EUROPEAN ASSOCIATION OF
CHEMICAL DISTRIBUTORS

AIM AND SCOPE

This document has been written to provide guidance for those companies involved in the supply chain of biocidal Active Substances (ASs). Recommendations based on practical experience are provided and therefore the document is considered a good practice guidance for industry.

DEFINITIONS & ABBREVIATIONS

AS: Active Substance – in this context the Active Substance is the chemical substance as defined in the BPR EU 528/2012

Industry: Biocidal Active Substances are stored in tank not only at sites of distributors but also at manufacturer's and downstream user's sites for this reason we use the term "industry" to include any eventualities.

Supplier/AS/PT combination: The combination of the attributes "supplier", "Active Substance" and "Product Type" define the "product"

Product: is the product in a larger sense, i.e. the goods delivered, not to be confounded with the "Biocidal Product"

PM: Product Manager

DISCLAIMER

This document aims to assist users in complying with their obligations under the Biocidal Products Regulation. However, users are reminded that the text of the Biocidal Products Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. Fecc does not accept any liability regarding the use that may be made of the information contained in this document.

INTRODUCTION

To ensure business and delivery, industry regularly need to have more than one supplier for a Biocidal Active Substance (AS). This guidance describes how to comply with the need of traceability during storage of an AS, in the same storage tank, when all the sources are Article 95 compliant. The legal requirements for ASs are taken into account, whereby, for example, an expiry date is not relevant for ASs.

FIGURE 1
Chemical distributors in the supply chain of biocides business



- Distributors link Biocidal Active Substance manufacturers to the formulators of Biocidal Product
- The distributor's role however can be more active by being itself listed on Art 95 and have access to alternative suppliers
- Their role can also include that of an authorization holder
- A typical role of a distributor is being a consolidator that sources from different suppliers, pools the same chemical products in tank(s) and customizes material on demand of customer
- Present Guidance Paper focuses on the role of distributors of Biocidal Active Substances (AS)
- This document shall serve as Guidance for compliant pooling of AS from different suppliers, while guarantee full traceability

1. MANAGEMENT OF DIFFERENT ARTICLE 95 SOURCES IN THE SAME STORAGE TANK

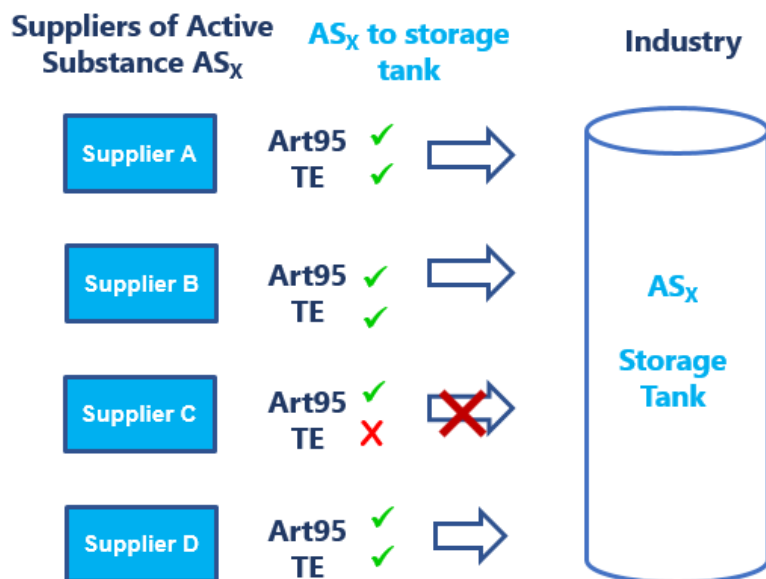
There are 2 possible situations (Figure 2):

1. Some suppliers are listed under Article 95 and the AS's are Technically Equivalent (TE)
→ Suppliers A and D.
2. Tank operator is listed under Article 95 and has TE per supplier, so he can take also AS from Supplier B, in addition to Suppliers A and D.

Industry can store this AS in the same storage tank, as long as all the sources are Article 95 compliant and the TE of the AS's with the reference source is ensured.

FIGURE 2

Active Substances from four different suppliers in one tank



2. MANAGEMENT OF DIFFERENT SUPPLIERS HAVING DIFFERENT PTs

In the same way that different sources of the same AS can be used for the same Biocidal Product, it is possible to store the AS in the same storage tank. The AS should then also be approved for the same Product Type (PT) (if there would be differences to the PTs, just the common denominator for the PTs will be supported).

FIGURE 3
Use of one storage tank – no need for separation

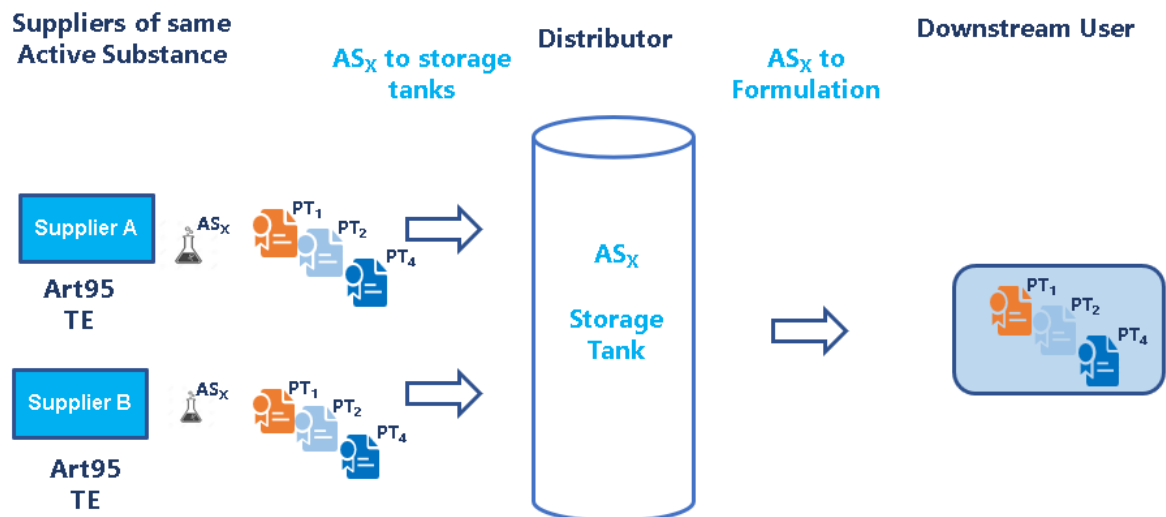
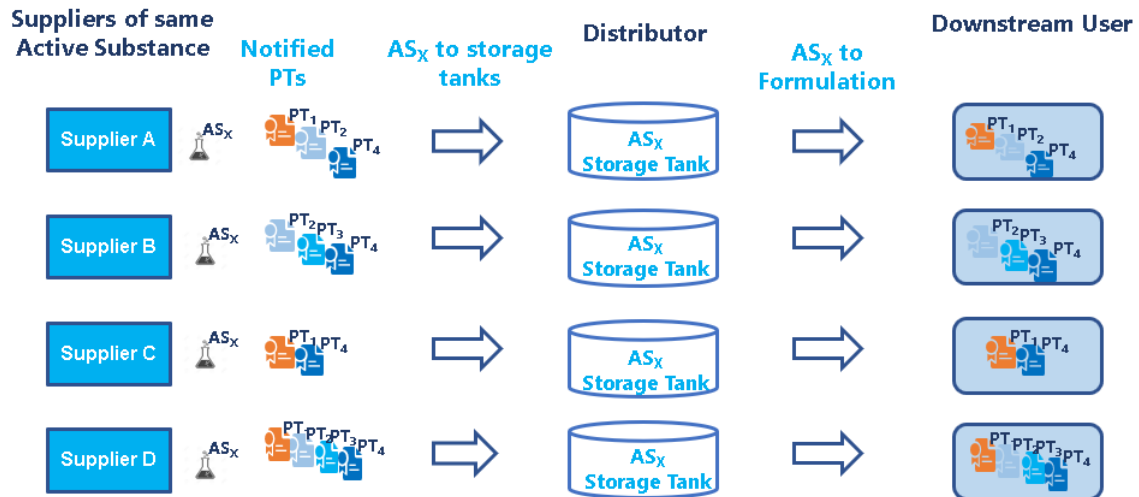


FIGURE 4

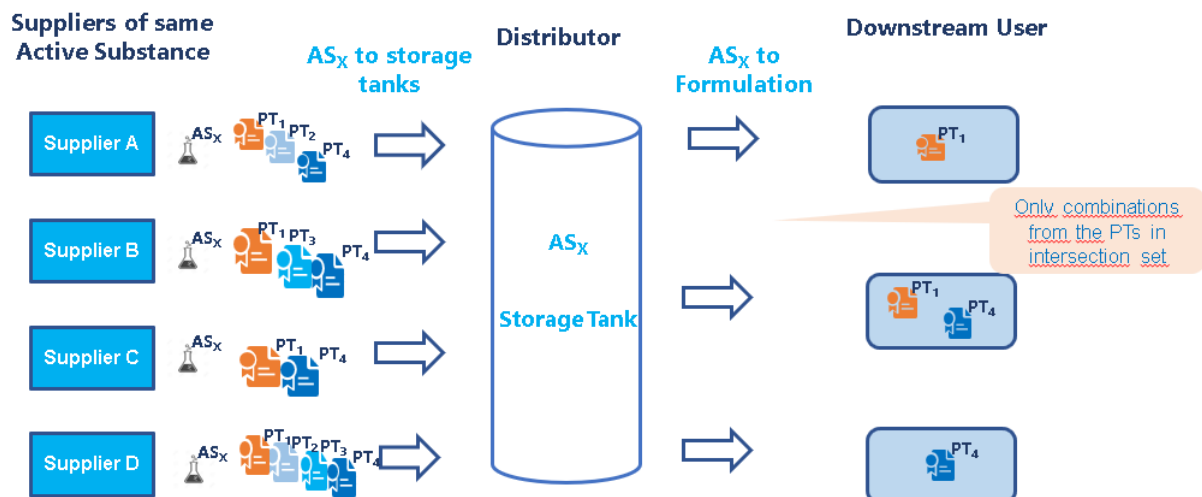
Separating product streams allows full traceability but requires separate storage equipment



However, the more realistic scenario is that not each supplier has the same product type combination in its portfolio which implies that the tank operator has to deal with finding the common denominators. In example of Figure 5, tank operator can sell AS with PT1, PT4 or combination of those two.

FIGURE 5

When storage facility does not allow separation of product streams the number of PT is limited

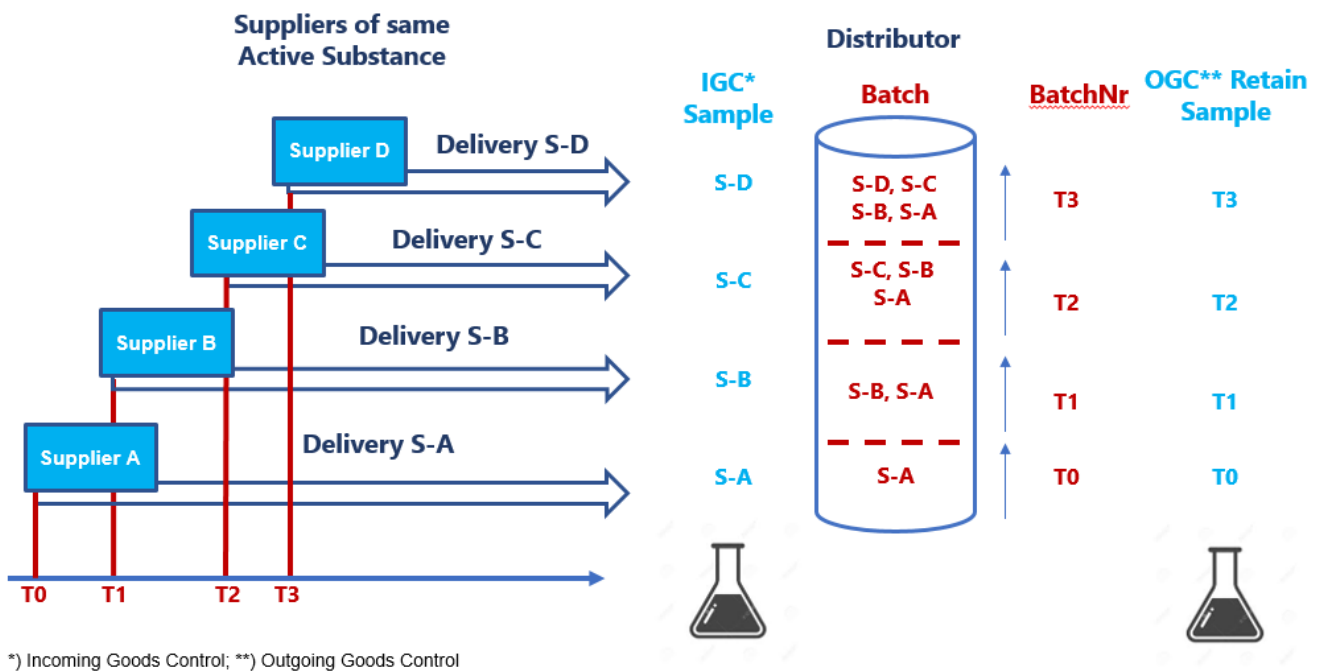


3. APPROACH FOR BATCH NUMBER MANAGEMENT

To allow full traceability, a flawless Batch Number Management is of primary importance. To achieve this, an accurate sample taking must be put in place.

Figure 6 shows 4 suppliers (their products fulfilling the requirements to be put in one tank) with one delivery (batch) each at time T0, T1, T3 and T4. Before unloading a sample must be taken and retained from each delivery. To connect the outbound batches to inbound batch the outbound batch needs to bear the date of the loading in the tank as attribute in its batch identifier sequence.

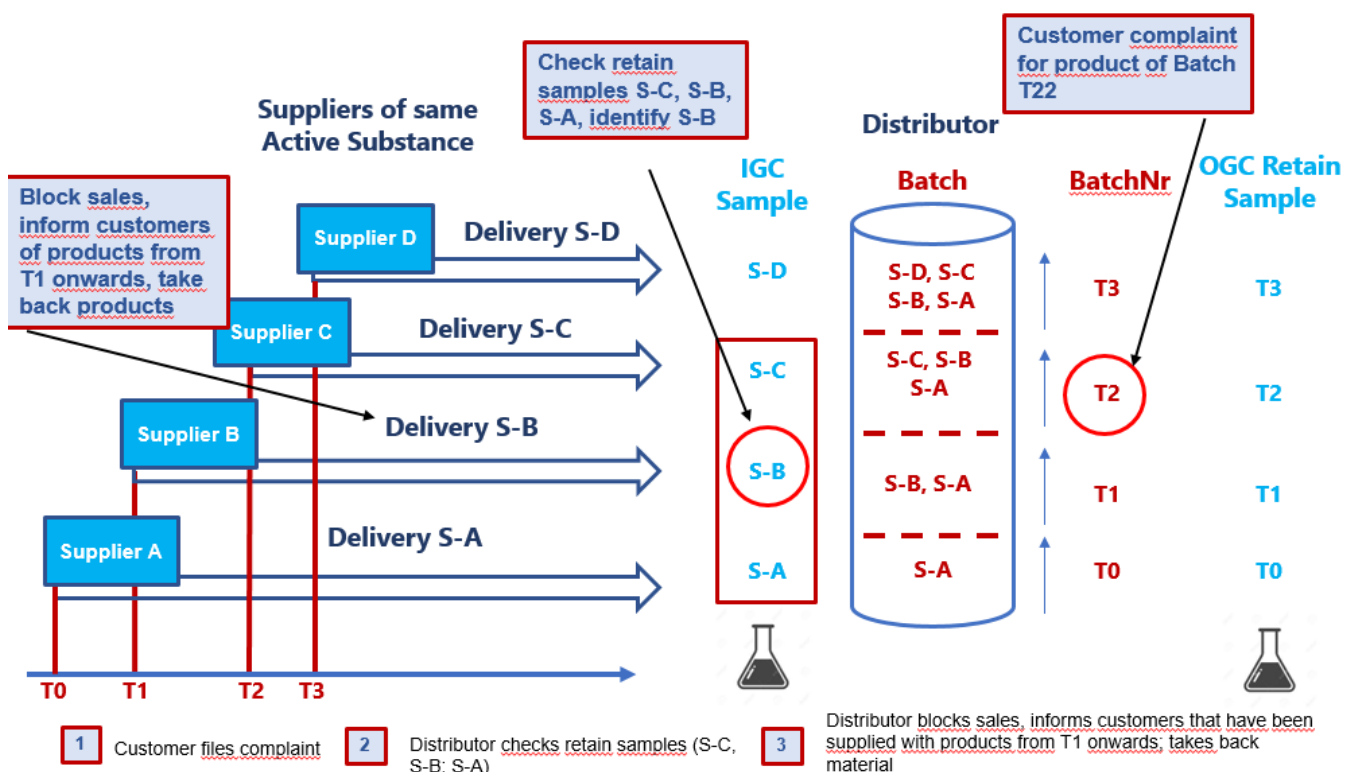
FIGURE 6
Sample taking



4. COMPLAINT HANDLING

Figure 7 shows the process in case of a complaint from a customer of outbound batch T2. Good practice would be to validate retain sample T2. In case the defect is validated, that implies that the inbound batches S-C, S-B or S-A could be the source. The quickest way would be the testing of S-A: if defective, a testing of S-B and S-C would not be necessary. In case of S-A being ok, then good practice should be to validate S-B, if ok, then S-C must be defective.

FIGURE 7
Customer complaint: Tracing defective product



Recall procedure in case S-B would imply the block of further delivery of active substance from this tank containing S-B, hence outbound batch T2 and T1, when intermediate stock, i.e. filled IBC on premise.

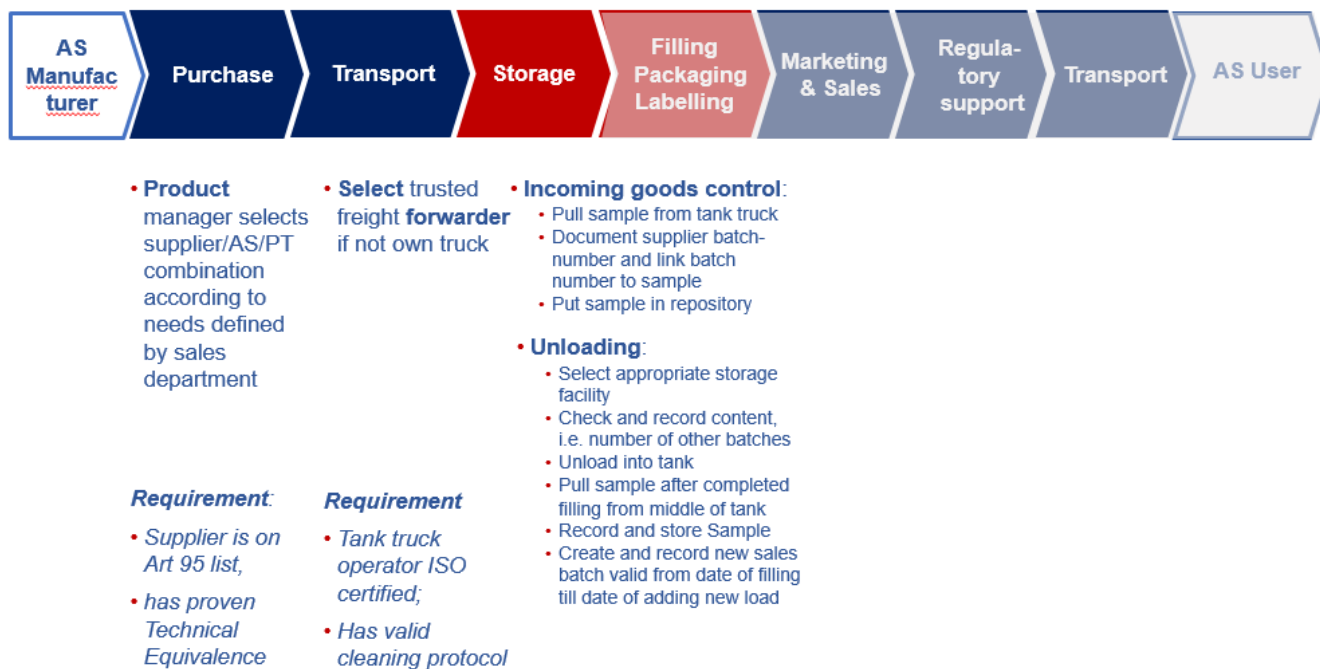
Goods Return procedure would include AS of outbound batches T2 and T1. But not T0.

It is recommended to have a procedure indicating that after X loads / dedicated time the tank should be emptied before starting a new loading cycle. There is no need for additional analytical data, as all suppliers deliver from the reference source or with the proved TE.

Figure 8 shows the inbound control and sampling procedure.

FIGURE 8

Flow Chart: process for handling inbound products



5. SCENARIO ON HOW TO HANDLE IMPURITIES – RISK MITIGATION

In case of impurities / soiling / contamination it is recommended to follow this procedure:

- Identify the concerned batches by analysis of the retain samples
- Block the identified batches within the ERP-System
- Call back the delivered batches from customer
- Empty the storage tank and clean it

FIGURE 9

Flow Chart: process for risk mitigation of outbound products



• **Tank storage goods:**

- Ensure batch management allows traceability
- No non-Biocidal chemicals in tank
- Put sample in repository

• **Marketing:**

- Identify customers with need for Biocidal actives
- Ensure customer ge
- Promote biocidal uses

• **Regulatory:**

- Offer support in case of questions
- Correct regulatory non-compliance
- Search for alternative

• **Use:**

- Customer is limited to uses described on the label of AS
- Correct regulatory non-compliance
- Search for alternative

• **Batch number linkage:**

- Recording of Batch numbers from supplier
- Sample taken from Truck Tank before unloading
- Sample and Batch number from supplier are linked in the database

• **Establishing own batch numbers:**

- After each unloading of new deliveries, which is at the same time loading in tank, a sample from the own tank has to be taken and retained
- The batch number contains the date of loading in its batch number sequence. To connect the outbound batches to inbound batch the outbound batch needs to bear the date of the loading in the tank as attribute in its batch identifier sequence.



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