



Roundtable on
Sustainable Biomaterials

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RSB Reactive Guidance on the Risk Assessment Tool (RG-2020-06)

RSB Procedure for Risk Management

RSB-PRO-60-001

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Approved

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1. Background and Objective

The objective of this document is to provide guidance to the Certification Bodies, Accreditation Body and Participating Operators on the use of RSB Risk Assessment Tool in case of multi-site certification scope.

The RSB Procedure for Risk Management [RSB-PRO-60-001] aims to make sure that Participating Operators (PO) identify, evaluate, mitigate and monitor the risk(s) related to their operations while putting in place RSB requirements.

The POs shall update their risk management approach periodically, in particular before every new audit (main and surveillance) and whenever the certification scope is changed or their operations are modified. For this, a self-risk assessment shall be performed using the RSB Risk Assessment Tool.

Request for clarification:

- When a PO includes additional site(s) to an existing RSB certification scope, how should the Risk Assessment Tool be updated?
- Is the risk grading cumulative for all sites within the certification scope?

2. Relevant standard references

- a. RSB Procedure for Risk Management [RSB-PRO-60-001]: Section F.3.1 requires POs to identify their risks using the “RSB Risk Assessment Tool” and determines their risk class¹ (Low, Medium or High).
- b. RSB Risk Assessment Tool (Annex 1 of the RSB-PRO-60-001): is a tool to identify relevant risks in the context of the RSB certification system.
- c. RSB Procedure for Participating Operators [RSB-PRO-30-001]: Section F.1.6 requires POs to carry out a self-risk assessment of the operations as defined in the certification scope, in conformity with the RSB Procedure for Risk Management.
- d. RSB Procedure for Certification Bodies and Auditors [RSB-PRO-70-001]: determines the frequency of surveillance audits and the period of validity of RSB certificates based on the risk class results calculated from the RSB Risk Assessment Tool. In addition, requires that the risk class calculated by the PO shall be verified and confirmed by the auditor.

3. Guidance

When an RSB certification scope includes multiple sites, the following approach is allowed for a PO, as per the steps below:

- a. The RSB Risk Assessment Tool shall be used to identify all risks related to the operations and sites covered by the certification scope;
- b. The risk score is calculated individually for each site included within the certification scope;
- c. The highest risk score from (b) shall be considered as representative of the multi-site scope and used to identify the risk class attributed to the PO. It means that, in any case, **the risk class attributed to the PO shall not be lower than any individual risk class of the sites included in the certification scope.**

¹ A risk class is attributed to every operator involved in the RSB certification process in order to reflect upon the contextual elements which might make the process towards RSB certification more demanding or difficult. The risk class of an operator should not be considered as an indicator of its level of compliance with the RSB Standard.



- d. The approach described in this guidance does not change the interpretation of any other requirements of the RSB Procedure for Risk Management. A risk management plan (as required in RSB-PRO-60-001, Section F.4.1) shall be implemented by the PO covering all operations and sites of the certification scope, as well as all issues in the high risk and medium risk categories identified for each site individually.