Risk Assessment Methodology and Strategy for Compliance with PPWR Article 5.1 (Substances of Concern)

1. Purpose

This methodology describes the risk-based approach used by Dijkstra to demonstrate compliance with Article 5.1 of Regulation (EU) 2025/40 (PPWR) regarding Substances of Concern (SoCs) in packaging.

Because harmonised supply chain communication on PPWR Article 5.1 is still developing, Dijkstra has implemented an alternative evidence-based assessment strategy that combines supplier documentation, substance inventory management, regulatory screening and continuous supplier engagement. The objective is to identify substances of concern, evaluate their regulatory relevance and support continuous minimisation in accordance with Article 5.1.

2. Background

Article 5.1 requires that packaging is manufactured so that the presence and concentration of substances of concern are minimised throughout the life cycle, including their presence in secondary raw materials generated from recycling.

At present, most suppliers do not yet provide PPWR-specific declarations describing:

- the presence of Substances of Concern under Article 5.1;
- justification for their continued use;
- evidence that concentrations have been minimised;
- supplier reduction or substitution programmes.

Instead, suppliers generally provide documentation developed under existing legislation, such as:

- POP Regulation declarations;
- REACH SVHC declarations (typically stating <0.1% w/w);
- Safety Data Sheets (SDS);
- Food Contact Declarations of Compliance (DoCs);
- other regulatory declarations.

Recognising this current limitation within the supply chain, Dijkstra applies a structured risk assessment methodology that extracts and consolidates substance information from all available regulatory documentation.

3. Risk Assessment Strategy

The Dijkstra strategy consists of five complementary assessment steps.

Step 1 – Collection of Available Supplier Information

For every raw material and packaging component, Dijkstra requests all available regulatory documentation, including where applicable:

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- Declaration of Compliance (DoC)
- Safety Data Sheet (SDS)
- REACH SVHC declarations
- POP declarations
- other available regulatory declarations

Although these documents are not specifically designed for PPWR Article 5.1 compliance, they provide valuable evidence regarding the substances intentionally present in supplied materials.

Step 2 – Substance Inventory
Dijkstra maintains a central substance inventory using the Packaging Compliance software platform.

For every supplied material:

- substances identified in supplier Declarations of Compliance are extracted;
- where concentration information is available, it is recorded;
- substances reported in Safety Data Sheets are added to the same inventory;
- duplicate entries are merged into one consolidated substance profile.

This creates a comprehensive inventory of intentionally reported substances throughout the supply chain.

Step 3 – Regulatory Screening
All identified substances are automatically screened against relevant regulatory resources, including where applicable:

- Persistent Organic Pollutants (POP)
- REACH Candidate List (SVHC)
- CLP harmonised classifications
- other internally maintained regulatory substance databases

The Packaging Compliance platform allows continuous comparison between supplier substance information and updated regulatory databases, ensuring that newly identified Substances of Concern can be recognised even when supplier declarations have not yet been updated.

Step 4 – Identification of Additional Substances of Concern
Article 5.1 also refers to substances that negatively affect reuse or recycling.

At present, no harmonised European list exists specifically identifying substances that impair recycling performance.

Therefore, Dijkstra applies an expert-based approach.

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Whenever reliable scientific evidence or recognised recycling guidance identifies a substance as having a negative impact on:

- recycling,
- recyclate quality,
- sorting efficiency,
- reuse systems,

that substance may be added to the internal Substance of Concern database used by the Packaging Compliance software.

This allows these substances to be included in future risk assessments even before specific regulatory lists become available.

Step 5 – Risk Evaluation and Continuous Improvement
Whenever a Substance of Concern is identified in a supplied raw material:

1. the substance is evaluated against the applicable regulatory framework;
2. suppliers are contacted to obtain additional information;
3. suppliers are requested to explain:
    - whether minimisation has been implemented;
    - whether substitution is technically feasible;
    - whether reduction plans exist.

Where appropriate, Dijkstra also evaluates internally whether alternative:

- raw materials,
- formulations,
- suppliers,
- technologies

can reduce or eliminate the identified Substance of Concern.

This continuous improvement process supports progressive minimisation in accordance with Article 5.1.

4. Evidence-Based Compliance Assessment
Compliance with Article 5.1 is demonstrated using a weight-of-evidence approach.

The assessment combines information obtained from:

- supplier Declarations of Compliance;
- Safety Data Sheets;
- REACH SVHC declarations;

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- POP declarations;
- Packaging Compliance substance inventory;
- automated regulatory screening;
- supplier follow-up responses;
- internal expert evaluations;
- substitution and reduction activities.

Although current supply chain communication does not yet provide complete PPWR-specific minimisation declarations, the combined evidence provides a robust basis for identifying potential Substances of Concern and initiating appropriate risk management actions.

5. Continuous Monitoring
The assessment is not considered a one-time exercise.

The substance inventory is continuously maintained by:

- updating supplier documentation;
- monitoring changes in regulatory substance lists;
- incorporating newly identified substances relevant to recycling or reuse;
- periodically reviewing alternative materials and suppliers.

Whenever new information becomes available, the risk assessment is updated and any required corrective actions are initiated.

6. Conclusion
Dijkstra recognises that PPWR Article 5.1 introduces obligations that currently exceed the information routinely communicated within existing supply chains.

Pending wider implementation of PPWR-specific supplier declarations, Dijkstra applies a structured, evidence-based risk assessment methodology that:

- consolidates all available supplier substance information;
- performs systematic regulatory screening;
- identifies potential Substances of Concern;
- requests additional supplier information where necessary;
- evaluates opportunities for substitution and minimisation; and
- continuously updates the assessment as regulatory and technical knowledge evolves.

This methodology provides a documented and proportionate approach to demonstrating due diligence and supporting continuous compliance with the objectives of Article 5.1 of the PPWR.

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