Risk assessment

Introduction

This risk assessment has been developed to evaluate compliance with the substance-related requirements of **Regulation (EU) 2025/40 on packaging and packaging waste (PPWR)** for rigid plastic buckets and their associated packaging components. The assessment covers products manufactured from virgin and recycled polypropylene (PP) and high-density polyethylene (HDPE), including in-mould labels (IMLs) and masterbatches, and other relevant intermediate materials.

The assessment focuses in particular on the requirements of **Article 5**, including:

- ~~the general obligation under **Article 5(1)** to minimise the presence and concentration of substances of concern in packaging and packaging components throughout the packaging life cycle;~~
- the combined concentration limit under **Article 5(4)** for lead, cadmium, mercury and hexavalent chromium; and
- the specific PFAS concentration limits for food-contact packaging under **Article 5(5)**.
- BPA under EU 2024/3190

The PPWR requirements apply not only to the finished packaging but also directly to **packaging components**. In-mould labels and other components incorporated into the finished bucket must therefore comply with the applicable Article 5 requirements. The conformity assessment consequently considers both the bucket body and cover, and all constituent materials and packaging components that may influence the chemical composition of the finished packaging.

The methodology follows a **material- and application-specific, risk-based approach**. It distinguishes between substances that have a known historical or technical use in a particular material or manufacturing process and substances for which there is no identified functional need. It also differentiates between the inherent compliance relevance of a material and the residual risk remaining after supplier qualification, formulation control, specifications, documentation and analytical verification have been applied. This approach is consistent with the risk-matrix methodology developed for PFAS in packaging, which uses material composition, functional use and known occurrence pathways to prioritise compliance activities rather than applying uniform testing to all packaging materials.

For virgin rigid injection-moulded PP and HDPE, the initial compliance relevance is generally low because PFAS, BPA and the heavy metals regulated under Article 5(4) are not normally required for the manufacture or performance of these products. Potential additional risks may, however, arise from masterbatches, IMLs or other intermediate materials.

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For recycled PP and HDPE, the assessment recognises a higher level of inherent uncertainty due to the potential carry-over of legacy additives, pigments and residues from previous packaging components, including IMLs. This risk is reduced by limiting recycled input to controlled and traceable rigid-grade streams suitable for injection moulding, thereby excluding flexible film grades and unknown mixed streams that may be associated with different additive and processing-aid profiles.

Compliance is demonstrated primarily through:

- controlled formulation and material specifications;
- supplier declarations and technical documentation;
- supplier confirmation of compliance with the relevant PPWR Article 5 requirements;
- batch-specific Certificates of Analysis or Certificates of Conformity where required;
- specific purchasing requirements for raw materials and packaging components; and
- targeted, risk-based analytical verification.

Analytical testing is used as a verification and escalation tool rather than as the sole basis for compliance. For heavy metals, this is consistent with the principles of **EN 13428:2004** and **CEN/CR 13695-1:2000**, which recognise supplier information, calculations and upstream data as appropriate primary evidence. For PFAS, total fluorine and organic fluorine measurements are treated as screening parameters that require interpretation in the context of the material, its functional use and the available supplier information. They do not, by themselves, establish compliance with the substance-specific limits of Article 5(5).

The purpose of this assessment is therefore to provide a structured and proportionate basis for:

- identifying relevant substance risks;
- classifying the inherent and residual compliance risk;
- defining the required level of supplier evidence;
- determining when additional analytical investigation is justified; and
- documenting the conformity-assessment rationale for the finished packaging and its components.

The risk assessment is intended to operate as a living document and should be reviewed when suppliers, raw materials, recycled input streams, formulations, IML constructions, manufacturing processes or applicable regulatory requirements change.

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Article 5.4 Heavy metals

Risk assessment for food contact products

While Regulation (EU) No 10/2011 does not explicitly prohibit heavy metal-based pigments as a class, it contains several provisions that make the intentional use of pigments based on **lead, cadmium, mercury and hexavalent chromium** incompatible with the regulatory framework for plastic food contact materials.

Firstly, substances intentionally used in the manufacture of plastic food contact materials must comply with the authorisation requirements of Regulation (EU) No 10/2011. In addition, substances classified as **carcinogenic, mutagenic or toxic for reproduction (CMR)** are generally not intended to be used as intentionally added starting substances unless the specific conditions and derogations laid down in the Regulation are fulfilled. Classical pigments based on lead, cadmium, mercury and hexavalent chromium are generally based on substances with harmonised CMR classifications under the CLP Regulation. Consequently, these should be reported in the SDS of the masterbatch.

Secondly, **Article 6(3)(a)** of Regulation (EU) No 10/2011 does not provide the general derogation for salts of these metals. Annex II explicitly states that salts of **lead, cadmium, chromium and mercury** are **not permitted** under the Article 6(3)(a) derogation, whereas salts of a number of other metals (e.g. sodium, potassium, calcium, magnesium, etc.) are permitted. This demonstrates that the legislator intentionally excluded these metals from the simplified authorisation mechanism.

Furthermore, the finished plastic article must comply with the migration restrictions established in Annex II, including the specific migration limits applicable to lead, cadmium, mercury and chromium, present as NIAS.

A comparable regulatory approach is found for **printing inks**, which form part of the **in mould labels** and are frequently used in food packaging.

The **Swiss Ordinance on Materials and Articles in Contact with Food (SR 817.023.21)** establishes a positive list for printing ink substances (Annex 10). For non-listed substances, their use is only permitted where migration is not detectable (10 µg/kg) **and** the substance is **not classified as a CMR substance**. Consequently, printing ink raw materials intentionally based on lead, cadmium, mercury or hexavalent chromium would generally not satisfy these requirements.

Similarly, the **German Printing Ink Ordinance (Bedarfsgegenständeverordnung)** establishes a positive-list system for intentionally added substances. For printing inks applied to the non-food-contact side of food packaging, non-listed substances may only be used where they **do not possess CMR properties** and exhibit **no detectable migration (10 µg/kg detection limit)**. This reflects the same regulatory principle applied under the Swiss Ordinance and reinforces the exclusion of intentionally added CMR substances from food packaging printing inks.

In addition to these legal requirements, the **EuPIA Charter on Raw Material Selection and Exclusion for Printing Inks and Related Products** (formerly the EuPIA Exclusion

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Policy) establishes an industry-wide stewardship programme that goes beyond the minimum legal requirements. EuPIA members commit to excluding or substituting substances presenting severe health hazards, including CMR substances, when selecting raw materials for printing inks intended for food contact applications. This voluntary industry standard has become the benchmark for the European food packaging printing ink sector and further discourages the intentional use of pigments based on lead, cadmium, mercury or hexavalent chromium.

Finally, this regulatory approach is fully consistent with the long-standing EU policy on packaging. Since the adoption of **Directive 94/62/EC on Packaging and Packaging Waste (PPWD)**, the four heavy metals **lead, cadmium, mercury and hexavalent chromium** have been specifically regulated through maximum concentration limits in packaging and packaging components. Article 11 of the PPWD introduced progressive concentration limits that culminated in the current **100 mg/kg** limit for the combined concentration of these four metals. Although neither the PPWD nor the PPWR explicitly states that their intentional use is prohibited, this concentration limit has, in practice, prevented the use of classical pigments based on these heavy metals in packaging for more than three decades. **Regulation (EU) 2025/40 (PPWR)** maintains this policy in Article 5(4), confirming the legislator's consistent objective of eliminating the intentional incorporation of lead, cadmium, mercury and hexavalent chromium into packaging.

Overall conclusion

Taken together, the regulatory framework for plastic food contact materials, the specific provisions applicable to food packaging printing inks, the EuPIA industry stewardship principles and the long-standing packaging legislation all point in the same direction. While there is no single provision explicitly stating that pigments based on lead, cadmium, mercury or hexavalent chromium are prohibited, the combined effect of:

- the restrictions on intentionally added CMR substances;
- the exclusion of salts of these metals from the Article 6(3)(a) derogation in Regulation (EU) No 10/2011;
- the migration requirements of Annex II;
- the Swiss and German printing ink legislation requiring positive-listed or non-CMR substances with non-detectable migration; and
- the concentration limits established since 1994 under the PPWD and continued in PPWR Article 5(4),

provides a strong scientific and regulatory basis to conclude that the intentional use of classical pigments based on **lead, cadmium, mercury or hexavalent chromium** is not compatible with the current European regulatory framework for food contact packaging.

Conclusion statement — heavy metals risk classification for plastic buckets

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Using the same **risk-based logic** as the PFAS risk matrix[1], but applying it to **lead, cadmium, mercury and hexavalent chromium**, the risk for a producer of plastic buckets can generally be classified as **low**, provided that the buckets are made from conventional virgin polyolefins, such as **PP or HDPE**, and no heavy-metal-based pigments, stabilisers, recycled content or unknown colour masterbatches are used.

This conclusion is justified because, unlike PFAS, these four heavy metals are not normally functionally required in modern plastic bucket production. They have also been subject to packaging restrictions since the **PPWD**, now continued under **PPWR Article 5(4)**, through the combined **100 mg/kg limit** for Pb, Cd, Hg and Cr(VI). In addition, EU plastic food contact rules do not provide a general salts derogation for lead, cadmium, chromium or mercury under Article 6(3)(a) / Annex II of Regulation (EU) No 10/2011, and many classical pigments based on these metals would raise CMR-related concerns.

Unlike PFAS, these four heavy metals have not been identified as substances that are functionally required in modern plastic bucket manufacture. Furthermore, they have been specifically regulated in packaging since the adoption of the Packaging and Packaging Waste Directive (94/62/EC), with the current maximum combined concentration of **100 mg/kg** maintained under Article 5(4) of the PPWR. This long-standing regulatory approach has effectively eliminated the intentional use of classical lead-, cadmium-, mercury- and hexavalent chromium-based pigments from compliant packaging applications.

Consistent with the methodology established in **EN 13428:2004** and the supporting technical report **CR 13695-1:2000**, compliance should primarily be demonstrated using **formulation knowledge, supplier declarations, calculations and other upstream information**, with analytical measurements used where necessary to verify compliance or resolve uncertainty. EN 13428 explicitly states that the supplier shall determine the presence of the four regulated heavy metals by **measurement and/or calculation and/or upstream information and data**, demonstrating that supplier information and controlled formulation are considered appropriate primary evidence rather than routine end-product testing.

Accordingly, for Dijkstra, as producer of food-contact plastic buckets, the preferred and proportionate compliance strategy is:

- maintain documented control over raw materials, pigments, masterbatches, labels, printing inks and additives;
- obtain supplier declarations confirming that **lead, cadmium, mercury and hexavalent chromium compounds are not intentionally added** and that the materials comply with the applicable food contact and packaging legislation;
- verify compliance through formulation review and supply-chain documentation; and
- reserve analytical testing (e.g. ICP-OES, ICP-MS or XRF) for situations where supplier information is unavailable or inconsistent or where other risk indicators justify additional verification.

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This approach is fully aligned with the risk-based philosophy of the attached PFAS article[1], where documentation and material knowledge are used as the primary compliance tools and analytical testing is targeted towards higher-risk scenarios rather than being applied routinely to all products.

Non-food contact products based on recycled polymers

The use of recycled polypropylene (rPP) and recycled high-density polyethylene (rHDPE) in non-food contact buckets presents a higher inherent compliance relevance for the heavy metal requirements of **Article 5(4) of the PPWR** than virgin polymers. This increased relevance is primarily associated with the potential presence of legacy pigments, stabilisers and other additives originating from previous applications within the recycling stream. Unlike virgin polymers, recycled materials may contain historical substances that were compliant under previous legislation but are no longer acceptable under the current regulatory framework.

However, the residual compliance risk is considered **low**, provided that recycled materials are sourced from **controlled and traceable recycling streams** operating under robust quality management systems and supported by appropriate supplier documentation.

Our assessment is based on the following risk mitigation measures already implemented or currently being introduced:

- Recycled PP and HDPE are sourced exclusively from qualified suppliers using controlled recycling processes with documented traceability of the input material streams.
- Suppliers declare that the recycled materials have been assessed for compliance with the applicable requirements of **PPWR Article 5**, including the heavy metal restrictions of **Article 5(4)**.
- Raw material specifications are being updated to explicitly require compliance with the concentration limits established in **PPWR Article 5(4)** for the combined concentration of lead, cadmium, mercury and hexavalent chromium.
- Suppliers will be required to provide **Certificates of Conformity (CoC)** and/or **Certificates of Analysis (CoA)** confirming compliance with these requirements as part of the supplier qualification and raw material approval process.
- A **risk-based verification programme** will be implemented, including periodic spot testing of selected recycled raw materials and finished products. Testing will focus on higher-risk situations, including new suppliers, changes in recycling sources, imported recycled materials, coloured recycled compounds and other materials where the level of confidence provided by the available documentation is reduced.

This conformity assessment strategy is consistent with the principles of **EN 13428:2004** and **CEN/CR 13695-1:2000**, which recognise that compliance with the heavy metal requirements should primarily be demonstrated through **supplier information, formulation knowledge, calculations and other documented**

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upstream evidence, while analytical testing is used as a targeted verification measure where justified by the assessed risk.

Although recycled plastics inherently present a higher probability of containing legacy heavy metals than virgin materials, the combination of controlled sourcing, supplier declarations confirming compliance with Article 5(4), strengthened purchasing specifications, mandatory CoA/CoC documentation and risk-based analytical verification provides an appropriate and proportionate level of assurance. Consequently, the residual risk of non-compliance with **PPWR Article 5(4)** is considered **low**, and the implemented control measures are considered consistent with recognised European conformity assessment practices and the risk-based compliance philosophy promoted by the PPWR.

Article 5.5 PFAS

Risk assessment for food contact products

PFAS are not intrinsically associated with polypropylene (PP) or high-density polyethylene (HDPE) used in rigid injection-moulded food contact packaging. Instead, the scientific literature demonstrates that PFAS have historically been used in very specific packaging applications where their unique surface-active properties provide a technical function, such as grease and water resistance in fibre-based packaging, fluorinated surface treatments, high-performance coatings, fluoropolymer processing aids for flexible film extrusion, and certain printing ink and coating formulations.

The material-based PFAS risk matrix developed by Wack et al. specifically distinguishes between packaging materials where PFAS are technically relevant and those where they are not. Virgin **PP** and **HDPE** used in rigid packaging are classified as **Risk Class 1 (very low probability)** because PFAS are neither technically necessary nor historically associated with these materials. Where PFAS have been identified in plastic packaging, they are primarily associated with polymer processing aids used during **film extrusion**, multilayer constructions, coatings, fluorinated surface treatments or contamination introduced through recycling streams rather than the base polymer itself.

Rigid injection-moulded buckets manufactured from virgin PP or HDPE do not require any of the functions for which PFAS have historically been used. The manufacturing process does not involve blown or cast film extrusion, grease-resistant barrier treatments, anti-fog coatings, release coatings or fluorinated surface modifications. Consequently, there is **no known technical or historical basis** for the intentional incorporation of PFAS into the polymer formulation.

Furthermore, the referred PFAS risk matrix clearly distinguishes between **compliance relevance** and **toxicological risk**. The matrix is intended as a structured compliance-screening tool supporting Article 5 of the PPWR by classifying packaging materials according to the likelihood that PFAS are present or technically relevant. It does not assume that all packaging materials present an equal probability of PFAS occurrence, but instead promotes a proportionate, material-based approach to compliance. Virgin

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PP and HDPE therefore represent one of the lowest-risk material groups identified within the framework.

The same article also concludes that supplier information and material knowledge should form the primary basis of compliance for low-risk materials, while analytical testing should be reserved for higher-risk packaging categories or where uncertainty exists. It explicitly states that analytical parameters such as **Total Fluorine (TF)** and **Extractable Organic Fluorine (EOF)** should be regarded as supportive screening tools rather than standalone compliance indicators, particularly for plastics where fluorine-based screening is significantly less informative than for fibre-based packaging.

In-mould labels (IMLs)

The only intermediate materials used on the buckets that exhibit a higher theoretical PFAS relevance than the rigid PP/HDPE substrate are the **in-mould labels (IMLs)**. These consist of a polypropylene label film together with printing inks, varnishes and other printing-related intermediate materials. The PFAS based processing aids were used in the past as processing aid during production of the polypropylene label substrate. Since the publication of PPWR, the label industry are rapidly replacing these processing aids by PFAS-free processing aids.

Certain printing inks, coatings and varnishes are also recognised as potential historical PFAS application areas due to the former use of fluorinated wetting agents and surface-active additives. However, these applications have become increasingly uncommon following regulatory developments and industry substitution initiatives.

The supplied in-mould label is an intermediate material intended for incorporation into packaging. Although it is not itself packaging at the point of supply, its constituent materials become part of the finished packaging after moulding and therefore contribute directly to compliance with Article 5 of the PPWR. Consequently, the IML supplier is required to provide sufficient technical information and supporting documentation demonstrating that the supplied material is suitable for manufacturing packaging that complies with the applicable Article 5 requirements, including the substance restrictions of Articles 5(4) and 5(5), where relevant.

Overall conclusion

The virgin PP/HDPE substrate used for the bucket body is classified as **Risk Class 1 (Very Low)** in accordance with the material-specific PFAS risk matrix developed by Wack et al., reflecting the absence of any known historical or technical use of PFAS in rigid injection-moulded polyolefins.

If the finished bucket, however, also incorporates **in-mould labels (IMLs)**, which are intermediate materials containing films, printing inks, varnishes and coatings. These materials have a higher inherent PFAS relevance than the rigid buckets because certain substrates, ink and coating formulations have historically used fluorinated substances for specific technical purposes. Consequently, the overall PFAS compliance relevance of the finished bucket is determined not only by the polymer substrate but also by the IML.

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Nevertheless, this additional PFAS relevance is effectively mitigated through a structured supply-chain compliance approach. Although in-mould labels (IMLs) are supplied as intermediate materials and are not themselves subject to the essential requirements applicable to finished packaging, they become an integral part of the packaging after the injection moulding process. For this reason, suppliers are required to provide sufficient technical information demonstrating that the supplied IMLs are suitable for incorporation into packaging that complies with Article 5(5) of the PPWR, including evidence supporting compliance with the three PFAS limits established by that Article. These information requirements are incorporated into supplier qualification, purchasing specifications and contractual documentation. Combined with the absence of any known technical need for PFAS in the specified IML construction and the implementation of targeted supplier verification and risk-based spot testing, these measures reduce the residual PFAS compliance risk for the finished bucket to Low.

BPA and other bisphenols (EU 2024/3190)

Virgin polypropylene (PP) and high-density polyethylene (HDPE) used for food contact products are assessed as presenting a **very low residual BPA contamination risk**, provided that the materials are sourced from qualified suppliers, manufactured under controlled food-contact specifications and no BPA-based additives, coatings, adhesives, inks or other BPA-containing intermediate materials are used.

This conclusion is based on the absence of any known technical function for BPA in conventional virgin PP and HDPE applications. BPA is not required as a monomer, additive, stabiliser, pigment component or processing aid for the manufacture of rigid PP/HDPE food contact articles. Therefore, unlike materials such as polycarbonate, epoxy coatings or certain varnish systems, virgin PP/HDPE food contact products do not have a historical or functional association with BPA.

The regulatory basis is strengthened by the implementation of **Commission Regulation (EU) 2024/3190**, which prohibits the use of BPA and its salts in the manufacture of several food contact material categories, including plastics, varnishes and coatings, printing inks, adhesives, silicones, rubber and ion-exchange resins, subject only to limited derogations.

Accordingly, the compliance assessment for virgin PP/HDPE food contact products is based primarily on formulation knowledge and supplier documentation confirming that BPA is not intentionally used in the manufacture of the polymer, masterbatches, or any relevant intermediate materials. Where in-mould labels (IMLs) are incorporated into the finished product, the IMLs constitute packaging components and suppliers are therefore required to demonstrate compliance with the applicable requirements of Regulation (EU) 2024/3190. In addition, suppliers are required to confirm compliance with the applicable requirements of the Swiss Food Contact Materials Ordinance (SR 817.023.21), which has aligned its provisions with Regulation (EU) 2024/3190 by prohibiting the use of bisphenol A (BPA), its salts and other hazardous bisphenols in food contact materials, including plastics, printing inks, varnishes and coatings, subject only to limited derogations.

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This confirmation shall cover the complete IML construction, including the polypropylene label film, printing inks, varnishes, coatings, primers and any other functional layers. Compliance with both the EU and Swiss requirements is incorporated into the supplier qualification process and purchasing specifications, requiring suppliers to provide appropriate Declarations of Conformity and supporting technical documentation demonstrating compliance with the applicable bisphenol restrictions. Under the Swiss Ordinance, business-to-business supply of printing inks and printed food contact materials is also supported by Declaration of Compliance requirements, providing an additional level of supply-chain assurance.

Internal Manufacturing Controls

In addition to supplier qualification and raw material controls, an internal assessment has been performed to evaluate the potential for cross-contamination during storage, handling and manufacturing. The production facilities do not intentionally process materials containing BPA, PFAS or heavy metal-based additives, pigments or other substances restricted under Article 5 of the PPWR. Raw materials are managed through established identification, storage and traceability procedures, while production planning, equipment cleaning and changeover procedures minimise the potential for cross-contamination between products. Based on the manufacturing processes, the materials handled and the implemented quality management measures, the likelihood of cross-contamination resulting in non-compliance with the applicable PPWR Article 5 requirements is considered negligible, resulting in a very low residual manufacturing risk.

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