

## Food safety of Protact®

### Compliance with current and future food contact legislation

#### Protact is a fully compliant packaging material

Current food contact legislation is designed to:

- safeguard human health
- protect packaged foodstuffs from unacceptable changes in composition and quality.

Protact laminated steel is fully compliant with all relevant European and USA food contact legislation. Furthermore, well-controlled purity levels of all chemical substances used in Protact enable compliance to upcoming legislation on non-intentionally added substances (NIAS).

Using a packaging steel substrate laminated with a three-layer polymer coating system on each side, the chemical substances used in Protact are specifically formulated without bisphenol A diglycidyl ether (BADGE), novolac glycidyl ether (NOGE), Bisphenol A (BPA) or bisphenol F diglycidyl ether (BFDGE). Protact complies with food contact legislation as set out in:

- the Plastic Implementation Measure (PIM) under European Commission (EC) legislation
- the Code of Federal Regulation (CFR) under the USA’s Food and Drug Administration legislation.

#### European Union (EU) and USA food contact regulations

In the manufacture of Protact, Tata Steel maintains strict compliance to the EU and USA food contact regulatory systems and their requirements. Adherence to all relevant legislated procedures ensures that Protact is certified compliant with food safety legislation.

In the EU, substances and practices are scientifically evaluated by the independent European Food Safety Authority (EFSA) and formulated into practical legislation by the European Commission. The EC regulates food contact materials through:

- Frame Work Regulation (EC 1935/2004) – defining general principles
- GMP Regulation (EC 2023/2006) – defining general principles
- Plastic Implementation Measure (PIM, EU 10/2011) and amendments – defining requirements specific to polymers and polymer coatings.

Protact undergoes the required EC compliance testing which is based on composition, processing and storage conditions. Composition of the packed food product is used to select the appropriate stimulant. Heat processing, storage time and temperatures during the test are based on actual conditions during can processing.

In the USA, the Food and Drug Administration (FDA) has a central role in scientific evaluation of new substances, formulation of legislation and enforcement of regulations. Food safety is regulated through:

- the Code of Federal Regulation (CFR)
- a specific Food Contact Notification (FCN)



Food contact legislation is designed to protect consumer health and ensure product quality.

- Generally Regarded as Safe (GRAS)
- CFR175.300 – regulating polymer packaging materials.

Protact undergoes compliance testing as required by the FDA. In FDA regulations, food composition defines the extraction liquid. Heat processing of the extraction liquid is based on heat processing of the canned food product. This approach to testing focuses on the dominant part in the pickup of substances from packaging materials.

#### Independent compliance testing

Protact compliance testing is undertaken by TNO Triskelion, an independent and respected European research institute. The institute evaluates and certifies compliance to the relevant European and American food contact legislation (see figure 1).

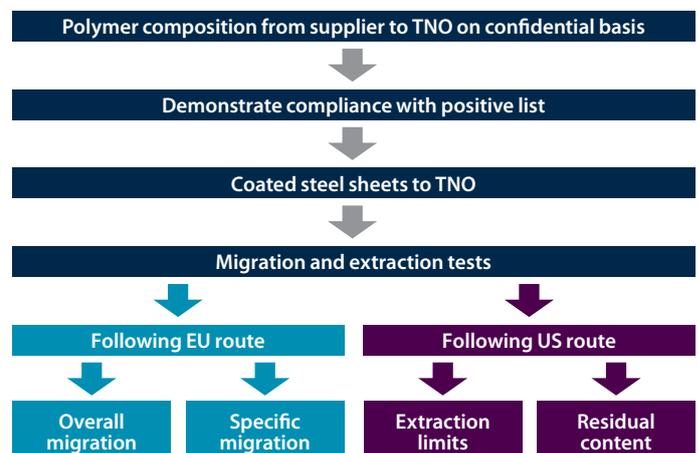


Figure 1: Steps in the Protact food safety certification process executed by independent institute, TNO Triskelion.

TNO Triskelion uses migration cells to establish substance migration and extraction from packaging materials (see figure 2). By testing product stimulants and the packaging material in secure migration cells, inert test conditions are ensured. A fixed volume and surface area of packaging material is tested. This rigorous testing is in line with food contact legislation.

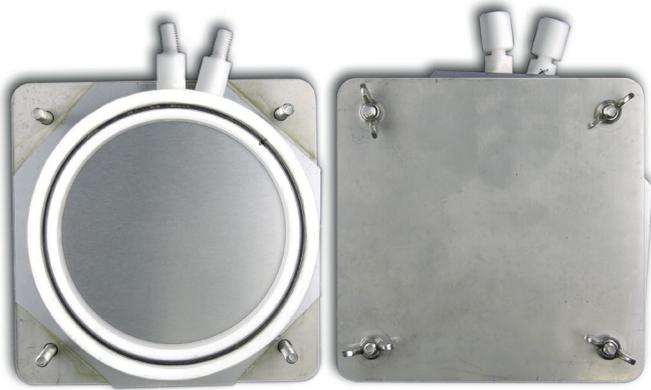


Figure 2: Use of migrations cells (open on left, closed on right) ensures the legislatively prescribed conditions for migration and extraction testing are securely met.

TNO Triskelion certification for Protact contains the following statements on Protact compliance:

- regarding compliance with FDA legislation – Protact “can be used for packaging, transporting, or holding food”
- regarding compliance with EC legislation – “overall migrations, relevant specific migrations and residual contents meet the limits of the ‘Regulations’”.

### Compliance with future NIAS legislation

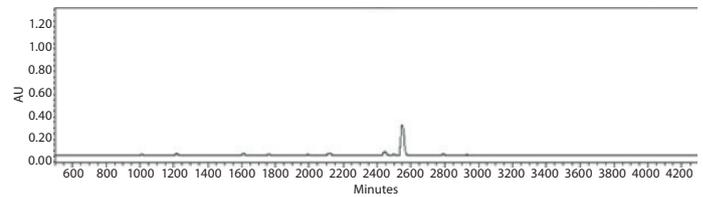
European and American legislation increasingly requires food safety evaluation of direct food contact materials with regard to non-intentionally added substances (NIAS). The objective is to prevent introduction into foodstuffs of:

- by-products
- impurities
- other non-intentionally added substances.

The scientific and regulatory debate on non-intentionally added substances is ongoing. Protact offers a safeguard against any tightening of NIAS regulation. Purity levels and processing conditions of the chemical substances used in Protact manufacture are well-controlled.

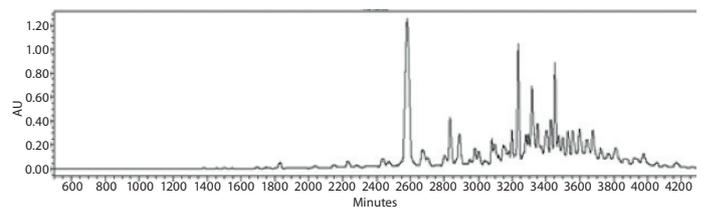
Independent screening confirms very few and less prominent ‘peaks’ when compared with the ‘forest of peaks’ in thermoset lacquer (see figure 3). Fewer and less prominent peaks indicate very few NIAS substances, proving that Protact has excellent levels of food safety.

Figure 3: Migration of can coating into food content. Graphs A and B comparing the level of non-intentionally added substances in thermoset lacquers and Protact polymer laminated steel.



Graph A: Protact (PET)

Shows the results of Protact coating screening undertaken by TNO Triskelion. Infrequent and less prominent ‘peaks’ are shown – confirming that Protact introduces very few non-intentionally added substances into packaged foodstuffs.



Graph B: Liquid coating (epoxy)

Shows the ‘forest of peaks’ found in a typical epoxyphenolic lacquer. These prominent and more frequent peaks represent a large number of non-intentionally added substances that could potentially transfer into foodstuffs.

One innovative regulatory methodology to assess the food safety of packaging materials is the screening of Non Intentionally Added Substances (NIAS). Following recommendation from the International Life Sciences Institute (ILSI) a NIAS screening was carried out for Protact. In typical food contact compliance tests the focus is on starting substances, however, NIAS screenings also measure impurities and reaction by-products in coatings. With this method endocrine (hormonal) and carcinogenic activity is evaluated by a standardised method. After a thorough and detailed chemical analysis of all substances, samples of Protact were screened by Bluescreen® and other bioassays. The results of the NIAS screening showed no activity, demonstrating that Protact is indeed a very clean coated material, providing further evidence of the food safety of the product.

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