

NIAS

NON INTENTIONALLY ADDED SUBSTANCES

SAFE SUSTAINABLE SOLUTIONS



Analytical Approach to Determine NIAS Substances

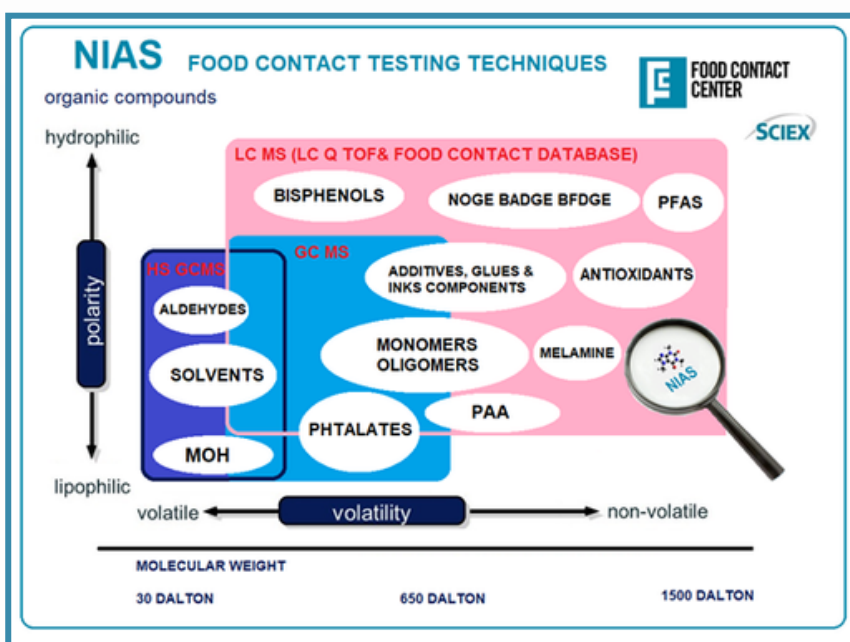
Food contact materials and articles (FCMs) contain substances that can migrate into foodstuffs. The assessment of their safety is not limited only to the control of intentionally added substances (IAS), such as the monomers used for the production of the material, or the additives used to improve the characteristics of the final article. In fact, FCMs can also contain unintentionally added substances (NIAS), such as impurities present in IAS, degradation products or reaction products that may be formed during the manufacture of the material.

Previously, compliance of plastic materials was demonstrated by testing only the finished product (**art. 19, Reg. 10/2011**). With the new amendments, the focus shifts to the supply chain, requiring control over the composition and purity of substances used, especially additives and dyes. **According to art. 3a of Regulation 2025/351**, a substance is deemed pure if:

- its components match the chemical identity in the Positive List,
- **NIAS** or contaminants are present only in irrelevant traces, and
- these traces are covered by regulatory authorization, risk assessment, exclusion of genotoxicity, or negligible migration.

Furthermore, according to Article 3 of the Framework Regulation (EU) No. 1935/2004, it must be ensured for every kind of material that the migration of these substances into food does **not endanger human health**.

The NIAS analysis can therefore be considered mandatory for all materials intended to come into contact with food.



Currently, there are no official guidelines on how to analyze and evaluate NIAS, but many discussions are also taking place in the technical tables.

What is finally clear is that screening test must be focused on a wide family of substances, lipophilic, hydrophilic, volatile and non volatile. **A GC-MS approach is not exhaustive, and the LC – MS screening is necessary**, coupled with a library, that must be produced by the laboratory, due to the lack in the scientific instrumental market.

Food Contact Center was involved in the ILSI Europe Task Force on Packaging.

The task force published a recent guideline, *An Overview of Approaches for Analyzing NIAS from different FCMs*

<https://doi.org/10.5281/zenodo.7828612>

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OUR SOLUTION

The Food Contact Center has been active for several years in the analysis NIAS, it is in fact the **FIRST LABORATORY in Europe to have developed NIAS (Not Intentionally Added Substances) screening methods with HS GC-MS, GC-MS and HR LC-MS techniques, coupled with an owned library built with major partners, and to have accredited these methods** according to the ISO 17025 standard.

The challenge for laboratories and research institutes is to access to sophisticated instrumentation, which is still limited in Europe, and to build a library for Food Contact Materials.

For polar and nonvolatile compounds, it is not sufficient to combine liquid chromatography with a high-resolution technique. A dedicated database is essential for the recognition of unknown compound.

- For the evaluation of the volatile and semi-volatile substances GC-MS refers to the NIST library, which the Food Contact Center constantly updates on the basis of its analyses of FCMs.
- For evaluation of non-volatile substances in LC-MS, in the absence of universal libraries for the identification of compounds, Food Contact Center in **collaboration with SCIEX, university institutions and CNR has developed, thanks to several years of research, a proprietary library of over 12,000 molecules.**



Our laboratory performs the evaluation of NIAS both with analysis by content but above all with migration tests in order to have results that are directly comparable with the mandatory legal limits. This is because if high concentrations of NIAS are found in the content tests, it will be necessary to do further migration tests. Such an approach would lengthen the analysis time and lead to increased costs and energy. Depending by substances identified, we adopt a toxicological risk assessment approach.

Food Contact Center has also participated in an **inter-laboratory circuit** on *Extractables & Leachables*, managed by Merck and produced in compliance with the ISO / IEC 17043:2010 standard, obtaining **excellent results**. In the past two years Food Contact Center has also performed **proficiency tests managed by DRRR** on NIAS Screening for GC-MS and LC-MS, again obtaining excellent results and confirming the reliability of the **results provided by the accredited NIAS methods**.

References

*Art. 20_ Commission Regulation (EU) No. 10/2011 of 14 January 2011

The Laboratory Management

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