

ECMA STATEMENT ON TESTING CONDITIONS

April 2024

This statement reviews ways to test the migration of cartons stored for a long term (> 6 months) at room temperature.

Recently, this topic, has been discussed at length within the ECMA Food Safety Committee and with the various experts from European associations representing the materials used by carton makers, including FEICA (Adhesives and Sealants Industry), EuPIA (Printing Ink Association) and CEPI (Confederation of Paper Industries) and, has also been raised with the Joint Research Centre, the Belgian public research institute Sciensano and in the Packaging Ink Joint Industry Task Force.

Appropriate testing, among other means of assessing compliance, is part of the process flow of producing food-safe cartons.

As described in early ECMA GMP documents, this testing can be efficiently performed for so-called packaging systems, combinations of a well-defined substrate, ink and adhesive for a particular type of application. Once such a specific combination has been thoroughly tested, the packaging system can be used safely for many customers.

The Plastics Regulation (EU) No 10/2011 does not apply to paper and cardboard packaging, but in view of the misconception among some customers and laboratories that cartons should anyway be tested according to the requirements for plastics, the existing publications from the authorities and the guidelines of industry associations were carefully reviewed.

The level of safety should be the same for all packaging materials, although the material's intended use, properties and migration behaviour may differ greatly.

For the vast majority of cartons with no plastic barrier coating, tests with liquid simulants are, for example, not representative of migration from cartons.

In principle, testing migration into the packed food itself prevails, but if a simulant is used, modified polyphenylene oxide (MPPO) is suitable for assessing migration from cartons.

A recently developed alternative method is testing into infant powder, which is used as a kind of worst-case migration-sensitive type of food.

Which conditions to use?

Based on the Plastics Regulation, as indicated, some customers tend to require for long-term storage at room temperature, testing for 10 days at 60°C.

Apart from the fact that this legislation is not applicable, those conditions are also not representative of the effective use of cartons. As specified in Annex V "Compliance Testing" of the Plastics Regulation, such test conditions "cover storage for more than 6 months at room temperature and below, including hot filling and/or heating up to 70-100°C for - varying with the temperature - 15 minutes (100 °C) to 2 hours (70°C)."

These higher temperature conditions (associated with, for example, the pasteurisation process and hot filling), do not occur in the processing of regular cartons.

As no specific harmonised EU legislation exists for paper and board articles, the only material specific authorities' reference is the Council of Europe Resolution CM/Res (2020) 9, and the Technical Guide on paper and board used in food contact materials and articles. [1]

In the section on "Conditions of testing" it is stated "The worst foreseeable conditions of contact of the test specimen (paper or board material or article) with food are to be chosen for testing".

The Council of Europe publication refers (out of the scope of this note) for contact with liquid foods or beverages to the JRC publication "Guidelines on testing conditions for articles in contact with foodstuffs (with a focus on kitchenware)" and provides guidance on the testing conditions for baking and microwave oven applications.

Aside the review of those official references, the ECMA Food Safety Committee has had discussions and exchanges with leading food safety experts from the European associations representing the suppliers of the FCM materials, carton makers are using and with experts involved in the Packaging Ink Joint Industry Taskforce.

In a meeting with FEICA, their publication "Migration testing of adhesives intended for food contact materials" (Version 10/05/2023) was discussed [2] and the section "Accelerated tests at elevated temperature" states, "for certain types of adhesive applications, a change of physical properties will take place at temperatures of 60 °C. The observed migration will in such cases be substantially different from the real long-term migration at room temperature or even at 40 °C. In these cases, the migration results obtained may not be valid."

This same observation related to the physical and chemical changes which may happen to the migrating compounds was also part of the discussion with EuPIA and is well covered in the "EuPIA Guidance on migration test methods for the evaluation of substances in printing inks and varnishes for food contact materials". (Version 03/05/2023)". [3]

The EuPIA publication contains in the section "Selecting migration parameters" a table with testing conditions based on the difference between dry and liquid/moist food, the contact time and the food contact temperature. For dry foods used below 40 °C, this table is indicating MPPO testing at 40 °C. for 10 days. Based on a recent EuPIA migration study conducted at Fraunhofer IVV, it has however been stated by experts from the ink industry, it may be appropriate to prolong the testing time to 30 days to compensate the lower testing temperature.

In fact, the derogation of testing at a lower temperature is also well included in the Plastics Regulation itself.

Annex V paragraph 2.1.3 (i) contains the wording: "If it is found that carrying out the tests under the combination of contact conditions specified in the tables causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place."

Based on these various publications and discussions, ECMA assumes that it is appropriate to perform compliance tests for regular cartons stored for a long term (> 6 months) at room temperature, at 40 °C. In accelerated tests a pragmatic approach may be, to test at this temperature for 30 days unless there is scientific evidence that the migration of the present substances reaches equilibration at a different testing time.

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[1] <https://freepub.edqm.eu/publications/PUBSD-115/detail>

[2] https://www.feica.eu/information-center/all-information-centre/preview/1214/feica-guidance-paper-2023-migration-testing-adhesives-intended-food-contact-materials?id=d2ea314b-3e4a-4cae-bd85-bbf5a44f3ddd&filename=GUP-EX-F03-010_v2+FEICA+Migration+testing+for+non-plastics.pdf

[3] <https://www.eupia.org/key-topics/food-contact-materials/migration-testing/>