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Technical guidelines for compliance testing

In the framework of Regulation (EU) No 10/2011 on plastic food contact materials

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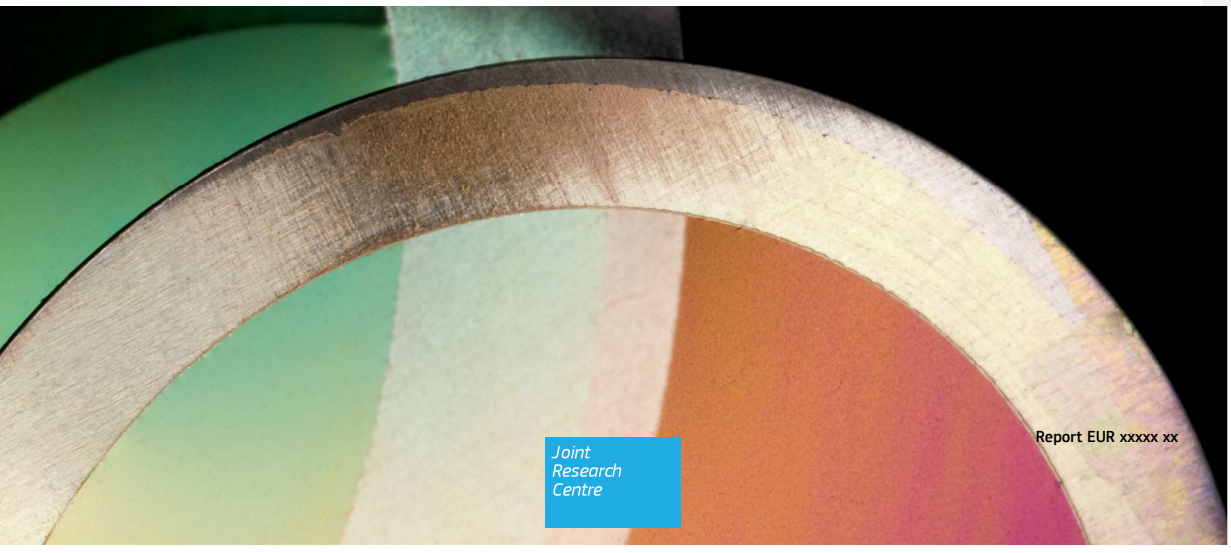

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Abstract

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Table of contents

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Table of contents of annexes in separate document

Abbreviations and definitions

For the purpose of this guideline, the relevant definitions laid down in Regulation (EC) No 882/2004, Regulation (EC) No 1935/2004 and in Regulation (EU) No 10/2011 shall apply.

Batch

is a defined quantity of starting material, packaging material, or product processed in a single process or series of processes so that it could be expected to be homogeneous. In the case of continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its homogeneity. A batch can be identified by a batch number (Simoneau et al., 2011).

FCM

food contact material or article

OM

overall migration

OML

overall migration limit

ND

Non-detectable

QMA

limit of residual concentration in the material per area

Sample

means an amount of material or the number of one article, set of articles, an already packed food commodity, or products from intermediate stages of their manufacturing that is taken from a batch with the aim to verify compliance (adapted from Simoneau et al., 2011).

Sampling for analysis

means taking a sample from a batch in order to verify compliance with Regulation (EU) No 10/2011 through analysis.

Set

means a number of articles (same or different) that are only sold together (Simoneau et al., 2011).

SM

specific migration

SML

specific migration limit

Test specimen

means a piece of a material or one article or one item of already packed food commodity of a sample on which a test can be performed (adapted from CEN EN 1186-1, 2002)

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Test piece

Means a part of the test specimen (adapted from CEN EN 1186-1, 2002)

1 Introduction

In yellow are those items that need attention of the editor

In grey are those items that depend on the foreseen change in the Regulation 10/2011

2 Sampling

This chapter describes the considerations for a correct sampling of materials and articles which are used in experimental testing for compliance purposes. Testing, and therefore sampling, is done by different stakeholders: enforcement authorities as well as customs, business operators and third party laboratories. Distinction needs to be made between testing for verification of compliance by enforcement authorities and testing to screen for compliance by industry. In what follows, certain aspects common to both approaches are given first, followed by more specific provisions for each of them.

2.1 Common provisions for sampling

2.1.1 Sampling strategy

A strategy for sampling should be defined, which enables an appropriate and representative selection of samples that will be taken. This includes at least, the type, amount or size and the characteristic properties of the sample.

2.1.2 Precautions to be taken

In the course of sampling and preparation of the samples, precautions should be taken to ensure the safety of the persons taking the samples and to avoid any changes of the samples, which would affect:

- the chemical composition of the material or article (residual content of a migrant, polymer structure).
- the physical constitution, e.g. density.
- the representativeness of the sample, e.g. scratches on the surface
- the composition of food for already packed samples, e.g. microbiology, sensory properties and humidity
- the organoleptic characteristics of the sample.

2.1.3 Labelling of samples

Relevant information permitting the sample to be identified unambiguously (sample ID and/or batch number), should be marked on the sample or its packaging, together with any additional information likely to be of assistance to the analyst (e.g. the side to be tested). Note that this labelling of the sample shall not affect the migration testing.

2.1.4 Packaging and transmission of samples

It is recommended to wrap the sample in plain aluminium foil (beware of cases where aluminium is an analytical parameter) to prevent any relevant interaction with its surroundings during transport. If this is impossible due to the physical characteristics of the sample, it should be placed in a clean, inert container offering adequate protection from contamination and against damage during transport. Precautions should be taken to avoid any change in or damage to the sample, which might arise during transportation or storage. The time of transport should be kept to a minimum. Sensitive (e.g. unstable) samples should be transported at appropriate temperatures.

2.2 Sampling in the context of official controls.

2.2.1 Scope

Sampling shall be done in the scope of Regulation (EU) No 10/2011 and in line with chapter I of the related Union Guidelines (EU, 2014).

Sampling for verification of compliance in the context of official controls shall follow Regulation (EC) No 882/2004 on official controls on feed and food.

This section 2.2 details the sampling requirements of Regulation (EC) No 882/2004 and Regulation (EC) No 10/2011. Samples thus obtained shall be considered as representative of the batch from which they are taken. Compliance laid down in Regulation (EC) No 10/2011 in articles, materials and foodstuffs shall be assessed on the basis of the levels determined in the laboratory samples.

Sampling can be performed

- in all stages of the supply chain of food contact material
- in the food industry
- at the point of entry in the EU
- at the point of distribution
- at retailers.
- Member State's legal rules on sampling shall be respected.

2.2.2 Provisions

2.2.2.1 Personnel

Sampling should be performed by an authorised and/or instructed person.

2.2.2.2 Material or article to be sampled

Each batch which is to be examined should be sampled separately. Large batches can be subdivided into sub-batches which can then be sampled separately.

The sample should always represent the worst case situation. For an already packed food commodity this means e.g. the worst place (highest expected storage temperature) or closed to the best before date. If the sample is intended to represent a range of materials of different brands or grades, then it should be assured that material is selected that will represent the worst case situation in the migration testing, e.g. the highest concentration of additive or co-monomer or thickness of the sample. If the substance is used in different kinds of polymers then, in principle, each type of polymer should be tested. However if it is properly argued only migration tests with the polymer representing worst case can be acceptable. For example for an additive used in all types of polyolefins tests with LDPE may suffice (EFSA, 2008).

When samples are taken from the manufacturer relevant Declaration of Compliance and supporting documentation shall be available on request (EU, 2013)

2.2.2.3 Sealing of samples

Each sample taken for compliance analysis shall be sealed at the place of sampling and identified following the rules of the Member State.

2.2.2.4 Sampling protocol

A detailed record shall be kept of each sample taken. As a minimum the following details should be recorded for each sample:

- Date and time of sampling
- Place of sampling (i.e. full address of facility/retail outlet from which the sample was taken)
- Spot of sampling (e.g. detailed description of the stage in the production batch, location in the stack of a given material or article or location within a reel of film from which the sample was taken; a photographic record could be helpful)
- Type of sample (e.g. material, article, starting substance, product from an intermediate stage of the manufacturing process, food)
- Labelling information according to Regulation (EC) No 1935/2004
- Number of samples taken
- Amount and/or size of each sample
- Sample identification: detailed description of sample (e.g. material type(s))
- Sample storage conditions from production up to and including the point of sampling (indicate whether or not lag-time or set-off could have occurred)
- Reason for sampling
- Name and signature of the responsible person and sampler

For each sampling of a batch, an appropriate sampling protocol form shall be prepared, which needs to be filled during the sampling. This sampling protocol shall be issued to the relevant stakeholders according to national procedures. Examples of stakeholders are (i) the inspector, (ii) the enforcement laboratory, (iii) the business operator on sampling location and (iv) the producer of the corresponding FCM or article. The sampling protocol shall be forwarded to the business operator in order to be included into the supporting documents according to article 16 of the Regulation. An example of a sampling protocol template is given in Annex 1.

2.2.2.5 Quantity of material to be sampled for laboratory analysis

Test samples are taken for enforcement (primary analysis), dispute (in case of dispute the analysis should be repeated) and reference (in case of lack of agreement after the analysis of the enforcement and trade samples, the analysis should be performed by a different laboratory for confirmation) purposes, unless such a procedure conflicts with Member States' rules for sampling and rights of the business operator. Deviations can also be made in the framework of Article 11 (6) of Regulation (EC) No 882/2004 "In particular, they shall ensure that feed and food business operators can obtain sufficient numbers of samples for a supplementary expert opinion, unless impossible in case of highly perishable products or very low quantity of available substrate".

Due to the fact, that materials and articles could be heterogeneously distributed, care must be taken to always have a representative quantity of test samples.

For official control it is recommended to take one test sample for the identification of the polymer type and one test sample for the surface area calculation. If samples for dispute and reference are considered relevant six samples are needed.

For compliance testing, i.e. migration or residual content, the recommended minimum amount of test samples for articles and sets of articles is three, based on

one combination of SM or OM in aqueous food simulants, food/food simulant and time-temperature condition. Similarly the recommended minimum amount of test samples for OM in vegetable oil is nine, i.e three samples per migration contact time.

NOTE: One sample is sufficient in cases where it can be demonstrated that the material or article is homogeneous.

The amount of samples may be multiplied by 3 to obtain also the test samples necessary for testing migration of residual concentration for dispute and reference. So in total a minimum of 9 test samples are recommended for SM or OM in aqueous food simulants and and 27 test samples for OM in vegetable oil. For each additional substance, food/food simulant or test condition these numbers are added.

For materials such as foils, wraps, nets, strings, casings and skins, the recommended minimum amount of test sample for enforcement depends on the area necessary for sample identification and migration test in triplicate. This amount needs to be multiplied by 3 to obtain also the test samples necessary for dispute and reference. For each additional substance, food/food simulant or test condition three times the amount necessary for migration tests in triplicate needs to be added.

Note: discarding the first layer of the bobbin of a foil/film may be necessary if changes or reactions of the foil or film occur in order to get a representative sample.

At the retail stage sampling of food contact materials and articles and already packed foodstuffs and kitchen and tableware shall be done where possible in accordance with the above sampling recommendations. Where this is not possible, other effective sampling procedures can be used provided that they ensure sufficient representativeness. Sampling of food contact materials and articles as parts/components of industry production plants (e.g. flat conveyor; tubes, sealing) shall be done where possible in accordance with the above sampling provisions. If needed, the corresponding food for testing (before and/or after contact with the questioned food contact material and article) shall be sampled in such a way as to guarantee both their legal and analytical validity.

2.3 Sampling for compliance testing at/by industry

2.3.1 Introduction

This chapter gives the main considerations for sampling plastic materials and articles for screening of compliance with OML and SML. Ultimately sampling only has purpose if it is linked to testing, therefore in what follows some of the considerations made relate more to the reasons for testing (or for not testing) than the actual sampling. Depending on the purpose of the testing, a specific testing and sampling strategy can be devised, in which the testing that has been done previously can also be taken into account.

The business operator should document his considerations on sampling and testing in his supporting documentation.

2.3.2 Basic aspects of sampling

Common provisions on sampling are given in section 2.1 earlier in this chapter.

To the extent that food contact materials and articles are produced in accordance with the requirements on GMP laid down in Regulation 2023/2006 and have a consistency in their properties and composition, any sample taken can be representative for any batch of that product irrespective of the number of production runs, until such time as a relevant change in product composition or its

manufacturing parameters gives cause to re-examining its migration behaviour. If consistency is achieved and documented then re-testing can be done at lower frequency.

To determine the appropriate timing for sampling, the business operator should take into account the presence of any material in his product that has not yet reached its definitive physical or chemical state immediately after production. For example, inks may need to dry, two component adhesives are subject to a chemical curing process, or plastics can re-crystallise after extrusion. These processes should be allowed to come to equilibrium before taking the sample. So the critical time for e.g. a final packaging material is when the article leaves the FCM producing company when it is for sale and can be used in contact with food. This sets the lower limit for timing when to sample an FCM.

The upper limit is set by the maximum age of the FCM at which it is still suitable for use. In between, consideration needs to be given to the following aspects (in particular for SM testing):

- set-off can affect the amount of substance present on the food contact side of the FCM that has to be tested;
- equilibration between the layers of a multilayer FCM can be addressed either by .
  - waiting for the material to come to equilibrium, or
  - using a more severe test condition according to the provisions of the Regulation, or
  - pre-conditioning the sample in the laboratory prior to testing (e.g. storing for 10 days in an oven at 40°C). .
- the previous two points would not be relevant for just-in-time deliveries where the user of the FCM does not store the FCM for any length of time.

Notwithstanding any pre-conditioning, the sample should remain part of the product for as long as is practical. For example if a normal production run involves producing stacks of cups that are kept in storage as stacks for a number of months, it makes no sense to isolate a single cup for sampling immediately after production.

The physical place where the sample is taken out of the material produced, can be important in certain cases. For example when producing a material that is wound on a reel, and sampling the outer winding of the reel to test for migration of a volatile substance, it can be expected that the substance has escaped. If it cannot be ruled out that the volatile substance also escapes in the actual use of the material, then it's better to sample deeper in the reel. Any similar aspects (e.g. set-off) should be given due consideration when deciding where and how to sample.

In case of sampling plastic intermediates (granules, flakes, powder) it is best to transform the sampled intermediate material into a test specimen applying the appropriate processing conditions for the material. The test specimen is typically a film or sheet or other article with defined thickness and shape. Alternatively, for migration modelling or calculation of total transfer it is possible to determine a substance concentration directly in the sampled plastic intermediate. In this case the results for volatile substances are going to be an over-estimate compared to a test specimen that has undergone its intended processing into an article.

At the time of sampling, a record should be kept of the relevant points allowing to unambiguously link the sample taken to the production run of the product and the raw materials used, as well as any other parameter considered relevant for the test at hand and the interpretation of the results.

Depending on the conditions in storage of the FCM and transport of the sample, the sample may need to be pre-conditioned upon arrival in the lab i.e. brought to a standardised temperature and relative humidity, if relevant.

2.3.3 **Family approach**

If there is a need, the business operator can attempt to reduce the number of samples to be tested to a more manageable number. For this purpose, the business operator manufacturing materials and articles will look for similarities in their composition and structure to justify selecting one or more individual products out of a larger group, the "product family", as the representative samples for that group. This justification for the decision to put products in one family should be part of the supporting documents.

The precise details of these considerations are impossible to describe in full detail in this document, as ultimately they will depend on the range of materials used by the manufacturer, on his product portfolio, on the various processes used in manufacturing, on the types of end use applications, etc. These considerations therefore are part of the manufacturer's supporting documentation.

2.3.4 **Testing frequency**

From a legal point of view, compliance testing is part of the supporting documentation (see Article 16.2 of the Regulation) needed to justify the information given in the Declaration of Compliance (DoC) (see Article 15 and Annex IV). Article 15.3 relates the interval at which the DoC needs to be renewed to substantial changes in the product's composition or production which change its migration characteristics. The test frequency shall be based on GMP and thus on the knowledge of the producer concerning the relation of the manufacturing parameters and the test results.

The business operator should consider the statistical significance of a test result obtained on any given product, and how that affects his testing frequency. An overview of the historical track record of test results on that product or its product family will show whether or not there is sufficient consistency to conclude on sustained compliance. On the other hand a single isolated test implies greater uncertainty. If the test result is not lower than the migration limit minus the analytical uncertainty additional tests for confirmation of compliance are needed.

There are a number of considerations that can be made on change control that are relevant to testing (i.e. the need for sampling), of which the following are some examples:

- Changes in the manufacturing process can be assessed either directly by investigating the relevant properties of the material produced, or indirectly by investigating its migration properties, or both.
- For SML compliance any change in composition that introduces a new substance with SML or substantially changes the amount present, would give rise to a new compliance assessment (whether by testing or any other method).
- When following a "family approach" in establishing compliance for a group of products (see 2.3.3), any new or reformulated product may already fit within an existing product family definition and would then not require additional testing.

Note that in addition to the above, the testing may need to be repeated when the legal provisions on compliance testing change.

2.3.5 **Alternatives to testing i.e. reasons not to sample**

For OM, there is no alternative to testing, but the provisions on family approach (section 2.3.3) and on testing frequency (section 2.3.4) fully apply. It needs to be noted that the Regulation does not require OM testing in every stage of the supply chain, nor does it require that only the finished material or article can be tested. The manufacturer of the final material or article has the legal obligation to confirm compliance with the OML. This *may* be based on testing done by an upstream supplier if the manufacturer of the finished material or article can justify (in his supporting documentation) that there is no substantial difference in the migration characteristics of his finished material or article compared to the semi-finished material received from his supplier.

For SM, there are a number of alternatives to testing provided in section 2.2 of Annex V of Regulation (EU) No 10/2011. In addition there are certain business practices related to the exchange of information relevant for compliance with SML. Thus it is possible for a business operator to assess the compliance of an SML without testing – if his supplier has e.g. disclosed the concentration of the substance (which feeds into worst case calculation or migration modelling), or has confirmed compliance on relevant samples, or for certain use conditions or for certain layer thicknesses or blend concentrations, etc. In these cases the only thing that remains to be done by the business operator receiving this information – apart from any calculations or modelling – is to make sure that his use of the product received as well as the end uses in contact with food, are covered by the conditions described by his supplier. Nevertheless self-monitoring of the business operator is also part of GMP.

3 Materials and articles already in contact with food or using food as a simulant – testing for specific migration

Testing foodstuffs to determine compliance with specific migration limits can be carried out in two situations:

(i) Packaged foodstuffs. If the food is already in contact with the material/article, determining the concentration of the substance in the foodstuff is the only way to assess compliance and non-compliance with specific migration limits.

(ii) Materials and articles not yet in contact with food. Verification of compliance with a specific migration limit for a material or article can be demonstrated using food in a migration test rather than a food simulant (Regulation EU No. 10/2011 Annex V, Chapter 2). Article 18.6 of Regulation EU No. 10/2011 states: The results of specific migration testing obtained in food shall prevail over the results obtained in food simulant and by screening tests.

NOTE: the use of foods for specific migration testing of materials and articles not yet in contact with food, may pose practical constraints, i.e. food composition change during testing, and analytical difficulties.

3.1 Packaged foodstuffs

For testing compliance of specific migration from a plastic packaging material or article already in contact with food the general rules laid down in Chapter 1 of Annex V of the Regulation apply.

Chapter 1 of Annex V of Regulation (EU) No 10/2011 states:

1.1 Sample preparation

"The material or article shall be stored as indicated on the packaging label or under conditions adequate for the packaged food if no instructions are given. The food shall be removed from contact with the material or article before its expiration date or any date by which the manufacturer has indicated the product should be used for reasons of quality or safety."

Therefore the packaged food should be stored according to the instructions given and the food should be separated from the packaging before the expiration date or any date by which the manufacturer has indicated the product should be used for reasons of quality.

If a foodstuff is tested at any point before the expiration date and the SML for the substance being tested is exceeded the food is not compliant. It is up to the MS Competent Authority to take a risk management decision and it is up to the retailer to establish the source of the migrants(s), i.e. food, packaging, packaging used for the ingredients or processing/preparation equipment.

When the migration result is close to the specific migration limit, and the sample has been analysed before its expiration date, there may be a risk of exceeding the limit by the end of the shelf life. This will depend on whether or not the migration equilibrium has been reached at the time of testing and so should be considered on a case-by-case basis. For tests in which the migration value approaches the SML, it is recommended that a follow-up investigation should be carried out with the food packaging manufacturer, for instance, through the examination of the supporting documentation. Where applicable migration modelling may be used to demonstrate that the migration has reached equilibrium and as such an increased storage time

will not be expected to result in an increase in the migration value (see Chapter 5.2.4 on modelling migration). Where this cannot be confirmed then the possibility of retesting at the end of the expiration date should be considered.

Removal of the foodstuff from the packaging should mimic that of the consumer, assuming the worst case. Care should be taken to remove any food adhered to the surface of the material and to homogenise it with the rest of the content prior to analysis.

Chapter 1 of Annex V of Regulation (EU) No 10/2011 states:

1.2 Conditions of testing

"The food shall be treated in accordance with the cooking instructions on the package if the food is to be cooked in the package. Parts of the food which are not intended to be eaten shall be removed and discarded. The remainder shall be homogenised and analysed for migration. The analytical results shall always be expressed on the basis of the food mass that is intended to be eaten, in contact with the food contact material."

Therefore if instructions are given that the foodstuff should be heated in-pack then these should be followed before removing the food from the packaging, homogenising and testing. For some foodstuffs more than one means of heating may be described on the packaging materials, e.g. heating in a microwave and in an oven. In such cases the worst case conditions should be selected for the preparation of the food. If it is not clear from the instructions given which is the worst case then the temperature at the food/packaging interface should be determined according to CEN standard EN 14233[1]. Taking into account the contact time and temperature at the interface of each method of in-pack preparation then the worst case test conditions should be determined. Alternatively, all indicated heating conditions are tested and the highest result is used to assess compliance.

The use of accelerated testing conditions is not recommended when testing food because of possible alteration of the state of the food. For example at higher temperatures the fat in the food may move to the surface thereby providing more intimate and more fatty contact with the packaging material.

Parts in food, e.g. bones that are not intended to be eaten, should be removed prior to homogenising and testing. The liquid media of packaged foods should only be removed if this is explicitly indicated on the label. In such cases the mass of food for determination of concentration is the mass intended to be eaten.

For some foodstuffs the product is subjected to further processing prior to consumption, e.g. dilution with water, use as an ingredient, boiling in water (not in the packaging), etc. For these foodstuffs the concentration in the food should be determined prior to these sample preparation steps, i.e. on removal from the packaging and without further preparation. The mass of the food used for the determination of the concentration is the mass of the packaged foodstuff.

The analysis of the migrated substances is dealt with in Chapter 6 of these guidelines. Specific points to be considered for testing foodstuffs are to ensure that the migrant is separated from any interfering substances in the analytical

[1] This standard refers still to former plastic food contact legislation. However this standard can still be used when "Council Directive 82/711/EEC" is read as "Regulation (EU) No 10/2011" and "Table 3 of EN 1186-1:2002" is read as "Annex V of Regulation (EU) No 10/2011".

determination. Foodstuffs are more complex matrices than food simulants and as such the potential for the presence of interfering substances is greater.

A schematic representation of the procedure when testing for specific migration from material/articles already in contact with food, is given below:

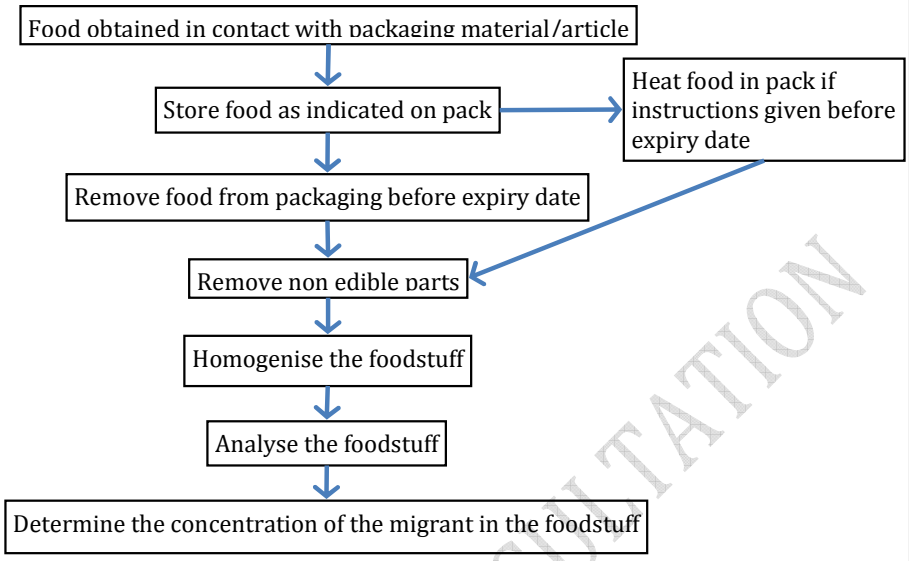

Figure 1 A schematic representation of the procedure when testing for specific migration material/articles already in contact with food

NOTE: The analysis of a packaged foodstuff represents the sum of contamination from all materials and articles with which it has come into contact during production, e.g. packaging used for the ingredients, processing and preparation equipment as well as the final food packaging material. Further, background levels of some contaminants may be present in the foods themselves. This applies in particular to substances such as phthalates (FCM substances 157, 159, 283, 728, 729) that are ubiquitously distributed. In such a situation while exceeding the SML, the food is not compliant. It is up to the MS Competent Authority to take a risk management decision and it is up to the retailer to find out what the source(s) of the phthalates is(are). When taking a risk management decision on the compliance of the food, the relevant provisions of the food law (Regulation (EC) No 178/2002) have to be applied, in particular Article 14.

3.2 Materials and articles not yet in contact with food

Migration testing using foodstuffs can be envisaged for the following situations:

Where the foodstuff is water, e.g. mineral water or flavoured water.

Where the representativeness of the food simulant is in doubt.

When a migration test into a food simulant fails, e.g. unacceptable quality assurance or when testing with a food simulant is more analytically challenging than testing with the foodstuff itself.

Where the material/article is intended to come into contact with a single and well defined foodstuff or a given food type for which a representative worst case foodstuff can be selected.

Chapter 2 of Annex V of Regulation (EU) No 10/2011 states: 2.1 Verification method "Verification of compliance of migration into foods with the migration limits shall be carried out under the most extreme conditions of time and temperature foreseeable in actual use taking into account paragraphs 1.4, 2.1.1, 2.1.6 and 2.1.7."

Therefore the migration test conditions should be the most extreme conditions of time and temperature foreseeable in actual use. For example if a packaging material can be used in a range of food contact applications (e.g. 1, 2, 3 or 4 h at 100°C) with a given food type then only the most severe conditions (in this example 4 h at 100°C) need to be tested with that food type.

For a material or article that may be subjected to several consecutive contact conditions these shall be carried out in succession using the same portion of food. For example a plastic bowl may be used to serve a hot food and then the food may be stored at ambient temperature for a period of time.

When testing migration into foods in this way the migration results determined are applicable to the specific foodstuff investigated and any other foods of the same type for which the food used in the migration test can be considered the worst case.

The migration test using foods should be carried out in a representative way, i.e. the extent of the contact and the test temperature should be the same as that found in real use. Any variability in contact should be taking into account when considering the uncertainty of the migration result. Alternatively more strict test conditions (i.e. at elevated temperature) could be used to assess compliance, if it has been demonstrated that under those conditions higher migration values are obtained and that the elevated contact temperature does not alter the state of the food or the contact between the food and the packaging.

Section 3.1 for packaged foodstuffs describing removal of the food from the packaging, removal of non-edible parts, homogenisation and testing given above is also applicable here. The same holds for foods that need reconstitution before consumption.

For articles that are intended to be used repeatedly then the migration test into food should be carried out three times and for each test a fresh portion of food should be used. The specific migration may not increase from the first to the third migration contact. The concentration of the analyte(s) of interest in the exposed food derived from the third migration test is then compared with the SML to determine compliance. For substances with a SML of non-detectable (ND), there is an exception and the result from the first test shall already be non-detectable.

4 Verification of compliance with migration limits using food simulants

4.1 Introduction

Verification of compliance serves two aims:

1. To check for the compliance of the specific migration of individual substances against the specific migration limit, and
2. To check for the compliance of the inertness of the material or article against the overall migration limit.

This guideline refers to individual substances as those being in Annex I and II of Regulation (EU) No 10/2011 as well as those covered by Art. 19.

Verification of compliance of the migration of individual substances into food has been described in Chapter 3. Verification of compliance of the specific migration of individual substances may also be shown using food simulants set out in Annex III of Regulation (EU) No 10/2011 and using test conditions described in section 2.1 of Annex V of the Regulation. However, the results of specific migration testing obtained in food shall prevail over the results obtained in food simulant (Art. 18.6 of Regulation EU No. 10/2011).

To verify compliance with the relevant restriction, migration experiments shall be performed taking into account the most severe contact conditions of the material with food under foreseeable conditions of use (time/temperature conditions). The representative conditions shall be taken from Annex III (selection of proper food simulant) and V (time/temperature conditions) of the Regulation. Specific cases are foreseen, e.g. storage above 30 days, combinations of contact times and temperatures or repeated use.

A demonstration of the inertness of the material, the so-called overall migration, is only feasible in food simulant and not in real foods. Test conditions shall be selected from Table 3 of Annex V of the Regulation that defines the test conditions and gives explanations about the real life conditions covered by the prescribed test conditions.

Occasionally the determination of the migration into the listed food simulants A, B, C, D1 and/or D2 may not be feasible for chemical or physical reasons, e.g. chemical reaction with the food simulant or incompatibility of the plastic with the food simulant. The Regulation specifies only in these cases the use of a replacement for food simulant D2 (iso-octane, 95% ethanol or poly(2,6-diphenyl-p-phenylene oxide) for verification of compliance. Although food simulant E is assigned, in accordance to Table 2 of Annex III, as a food simulant to determine specific migration of substances into dry foods, food simulant E is also assigned as a replacement for food simulant D2 for the determination of overall migration only in case of high temperature (≥175°C) applications.

4.2 Food simulants

4.2.1 Food simulant A, C and D1

The food simulants A (ethanol 10% (v/v), C (ethanol 20% (v/v) and D1 (ethanol 50% (v/v) are prepared by making a suitable dilution of ethanol with water (volume/volume) taking into account the initial concentration of ethanol.

4.2.2 Food simulant B

The food simulants B (acetic acid 3% (w/v)are prepared by making a suitable dilution of acetic acid with water (mass/volume) taking into account the initial concentration of the acetic acid.

4.2.3 Food simulant D2

Food simulant D2, the food simulant for fatty foods is vegetable oil. The composition of vegetable oil varies from its origin. Vegetable oil composes of a range of glycerol esters, free fatty acids, waxes and essential oils and similar substances.

Specific migration

For verification of the specific migration limits the composition of the vegetable oil is generally of limited influence on the migration behaviour.

Before starting a specific migration experiment with vegetable oil, it is recommended to establish that the oil is free of interfering substances. The oil shall be analysed and the interferences shall not exceed a level 10% of the SML. Otherwise another oil shall be selected or a more selective analytical method shall be applied.

Overall migration

Vegetable oil that is used for the determination of overall migration shall be rectified and contain less than 1% of unsaponifiable matter[2] (waxes and essential oils). Particularly with polyolefins, the waxes and essential oils will be adsorbed preferentially and that changes the composition of the absorbed oil significantly compared to the initial composition. Underestimation of overall migration or even negative values will be the result. On the other hand the presence of a relatively high amount of free fatty acids in the oil should be considered a worst case food simulant for polyolefins and similar highly diffusive polymers. Free fatty acids will penetrate significantly faster into a polyolefin due to the smaller molecular size, thereby causing an increase of migration.

For the reasons outlined above, vegetable oil intended for testing overall migration, needs to be refined properly. The refining process will remove interfering substances and unsaponifiable matter and free fatty acids. In general oil containing less than 1% of unsaponifiable matter and/or free fatty acids will be suitable for all migration experiments provided the oil is stored in the dark at refrigerated or frozen conditions. The method to determine the presence of interfering substances in the determination of overall migration is given in Annex 7.1.6.1.

Example of consequences of wax content above 1%:

The overall migration into vegetable oil is determined by the difference between the mass of the test specimen before and after contact with oil plus the mass of absorbed oil (see Annex 7). The difference between the mass of polyolefin test

[2] Rectification or refining is a treatment of vegetable oil to remove most of the non-triglycerides present in vegetable oils obtained by cold or hot pressing or extraction. The oil may be de-acidified, bleached and/or steamed to remove substances such as waxes, essential oil, free fatty acids, peroxides and chlorophyll. For determination see EN ISO 3596:2001 and 18609:2001

specimen before and after contact with oil is e.g. -90 mg. If the measured mass of adsorbed oil is e.g. 100 mg, then the measured overall migration is 10 mg. Since the oil complies with the requirement of less than 1% of unsaponifiable the influence on the results due to preferential absorption is negligible.

However, if the oil contains e.g. 2% of paraffin wax, the concentration of the paraffin wax in the absorbed oil increases to e.g. 10% due to preferential absorption. Then the real mass of adsorbed oil plus the increased paraffin wax is actually 108.9 mg (100 (98 mg oil + 2 mg wax) + 8.9 mg (additional 8% wax)). The real overall migration from the polyolefin is 18.9 mg (-90 +108.9) instead of the measured overall migration of 10 mg[3].

A second issue is the interference of substances that can be both present in olive oil that is most frequently used as the vegetable oil, and the polymer. For example, substances such as oleamide, fatty acids and their derivatives, are frequently used as antistatic agent, emulsifier or release agent, prevent a proper quantification of the absorbed olive oil and lead to an overestimation of the overall migration. In these cases olive oil has to be replaced by another vegetable oil being within the specifications of food simulant D2.

NOTE: The overestimated OM result in olive oil can be used to show compliance in the context of screening (see section 5).

Example:

In the case of no interfering substances the difference between the mass of the test specimen before and after contact with olive oil is e.g. -100 mg. If the measured mass of adsorbed olive oil is e.g. 110 mg, then the overall migration is 10 mg.

In another case a similar test specimen contains an interfering substance, e.g. 100 mg of oleamide. If e.g. 20 mg of oleamide migrates during contact with olive oil, the remaining 80 mg of oleamide will be determined as adsorbed oil. The measured mass of adsorbed olive oil will be 190 mg instead of 110 mg and the overall migration is consequently measured as 90 mg instead of 10 mg.

There may also be an interference eluting together with oleic acid peak. Then an oil with a high content on linoleic acid, e.g. sunflower oil or soybean oil, may be used. If vegetable oil with a fatty acid pattern close to olive oil does not solve the problem of interferences then a saturated oil with short fatty acids, e.g. coconut oil or palm kernel oil, which are rich of lauric and myristic acid (C_{12} and C_{14}), may be used. Migration from polyolefins using short chain triglycerides may slightly increase the migration behaviour and should be considered a more severe food simulant compared to long chain unsaturated triglycerides. However with polystyrene the migration may be slightly lower and, as differences are minor, the short chain saturated fatty acid oils are considered equal to unsaturated oils.

[3] Detailed solution: The measured absorbed mass of oil of 100 mg would, without preferentially absorption, contain 2 mg of wax (2%). The real absorbed mass of oil (y) is equal to the measured absorbed mass of oil plus the extra preferential absorbed wax (x): y=100+x. The concentration of the preferential absorbed wax in the oil is 10%: (x+2)/y=0.1. from these two equations it follows that x=8.9 mg and y=108.9 mg

4.2.4 **Food simulant E**

Food simulant E is a highly porous polymer (poly(2,6-diphenyl-p-phenylene oxide)) with a large specific surface and therefore strong absorbing properties. It has specified particle and pore size characteristics of 60-80 mesh and 200 nm, respectively, and is commonly referred to by the trade name Tenax® TA or modified polyphenylene oxide (MPPO) adsorbent. Note that MPPO also refers to a blend of polyphenylene oxide and polystyrene. To avoid confusion this term and its abbreviation is not used. The polymer can be cleaned using cleaning procedures (Annex 3) and reused.

From many experiments (Alnafouri and Franz, 1999; Jickells and Castle, 1993; Mountfort et al., 1994, 1996; Piringer et al., 1993) where migration into dry foods versus food simulant E was compared under same or very similar contact conditions it was shown that the adsorption to food simulant E is in general higher than to dry foods. This is the case for the full contact temperature range relevant for specific migration testing. It is therefore used for verification of compliance with specific migration limits in case of contact with dry foodstuffs.

In contrast to SM testing where volatile migrants adsorbed onto food simulant E can be analysed specifically without losing them, for OM testing a gravimetrical determination is applied. Problem with this method is that 1) an organic solvent is never able to completely extract all the substances that migrated to food simulant E and 2) migrants previously adsorbed to food simulant E are largely lost again during evaporation of the organic solvent. Therefore foods, for which only food simulant E is prescribed by the Regulation, are not subject to OML testing.

In case the determination of the overall migration into olive oil for 2 h at 175°C (OM7) is not feasible for technical reasons (see section 4.2.5) then this test shall be substituted by OM8 or OM9. OM8 is for high temperatures only and OM9 if for high temperatures including long term storage at room temperature. Both OM 8 and OM9 consists of two separate tests, one for 2 h at 175°C with food simulant E (OM8 and OM9) and another for 2 h at 100°C (OM8) or 10 d at 40°C (OM9) with food simulant D2 using a new test specimen for each test. The analytical results of food simulant E and D2 shall both comply with the OML.

4.2.5 **Situations where use of food simulant D2 is not feasible**

Tests for verification of compliance should be performed using the listed food simulants A, B, C, D1, D2 and/or E taking into account the nature of the foods intended to come into contact with the plastic. The Regulation makes an exception for the following situations.

- Annex III specifies 95% ethanol as a food simulant for food type 01.04, undenaturated ethyl alcohol, instead of food simulant D2. Actually this could be considered contact with the real food.

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- In Annex I of the Regulation a few substances are marked in column (11) indicating that verification of compliance for contact with fatty foods shall be performed with a specified food simulant. The substance with FCM 822 requires the use of a saturated fatty food simulant, whereas FCM 498 prescribes the use of isooctane as the replacing fatty food simulant D2.

Food simulant D2 is a very complex mixture. Some substances e.g. primary amines, may react with one or more of the components present in food simulant D2. In those cases verification of compliance with the SML will not be feasible with food simulant D2. There are also substances in Annex I, e.g. dimerised fatty acids (SML 0.05 mg/kg food), which have great similarity in chemical and physical properties with food

simulant D2 and which, from an analytical point of view, cannot simply be separated and quantified in food simulant D2.

Only in cases where it is demonstrated that for technical reasons the verification of compliance with an SML is not feasible in any vegetable oil within the specification of food simulant D2 the approach below can be applied to perform verification of compliance for fatty foods.

Technical reasons that have to be demonstrated and documented, are the following:

- In the determination of the overall migration
  - excessive absorption of oil (e.g. expanded polymers), i.e. when the expanded analytical measurement uncertainty of the result is higher than the analytical tolerance;
  - difficulties to recover the absorbed oil with any of the known methods (Annex 7.4). This may occur in some high temperature applications.
  - presence of interfering substances in the recovery and determination of the absorbed oil
  - difficulties to determine of the accurate mass of the sample before and after contact with the oil
  - physical changes in the test sample (e.g. delamination)
  - substitute test OM 8 and/or OM 9 are not suitable according to the selected test conditions

- In the determination of the specific migration "technical reasons or reaction" include the following reasons:
  - reaction of the substance with the food simulant (e.g. primary amines with oil)
  - physical or chemical properties of the substance that prevent isolation of the substance from the oil. (e.g. dimerised fatty acids, polymeric substances with SML of 0.05 mg/kg food, waxes (FCM 93) etc.)
  - unavoidable interferences from the food simulant D2
  - Insufficient analytical detection limit of the substance in vegetable oil

4.2.5.1 Specific migration

The simulants that should be applied in such a situation are iso-octane, 95% ethanol and food simulant E. For safety reasons the maximum temperature applied to iso-octane and 95% ethanol is restricted to 60°C. Therefore, in case of high temperature contact conditions of the material with food, a migration tests with food simulant E shall be performed as well to simulate high temperature conditions (≥100°C). A precondition of using any of the above simulants is that the material or article withstands the test conditions at or above 100°C that would otherwise be used with food simulant D2. Before starting a test it should be demonstrated visually that the test sample can withstand the intended temperature. For that purpose a test specimen is immersed in vegetable oil under the appropriate temperature condition for a period of at least 1 h. If the physical properties of the sample are not changed (e.g. melting, deformation) then the test conditions in Table 1 and Table 2 can be applied using new test specimens. If this test fails then the material has to be tested using the appropriate food and the worst foreseeable conditions of use (see Ch 3.2).

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Deleted: Table 1

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For plastic multi-layers, the layer in contact with food determines which table to use for the selection of time-temperature conditions using isooctane, ethanol 95% and food simulant E.

Test specimens have to be tested in conditions described in all the columns of Table 1, and Table 2, for the respective contact time and temperature row normally foreseen with food simulant D2. The highest value found in any of the test conditions shall comply with the restriction. Reason for this requirement is the great variety in the polymer properties as well as the physical properties of substances that may migrate. The test conditions are adapted for the fact that swelling of the polymer may occur and thus accelerate migration from such polymers. Polymers with a non-polar character, e.g. polyolefins, will, when tested with iso-octane, usually show comparable migration results to those tested with vegetable oil. However, for polar substances contained in polyolefin poor solubility in the non-polar iso-octane may result in an underestimation compared to their migration in vegetable oil. The opposite situation may occur for polar polymers such as PET. A polar polymer will usually show comparable migration results in 95% ethanol when compared to vegetable oil.

Deleted: Table 1

Deleted: Table 2

The test conditions described in Table 1, and Table 2, will generally result into reliable data for verification of compliance. It is emphasized that small deviations, both underestimation as well as overestimation, from migration in vegetable oil are to be expected.

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Deleted: Table 2

The most frequently used test conditions with food simulant D2 are given in Table 1, and Table 2, For test conditions not included in the table, the worst of the two closest test conditions has to be selected.

Deleted: Table 1

Deleted: Table 2

Table 1, is relevant for non-polar polymers such as polyolefins and polymers containing only carbon and hydrogen atoms. Table 2, is relevant for non-polyolefines and polymers containing more type of atoms. In case the polymer to be tested is not specified in Table 1, or Table 2, the time/temperature conditions of the polymer category specified in the tables which is closest to that under consideration should be taken. For example polymers which are predominantly of olefin nature, i.e. it contains less than 5% co-monomer bearing hetero atoms, fall under the polyolefins category. In case of blends the nature of the continuous phase polymer defines which table is applicable. In case of coextruded polymers the nature of the food contact layer defines which table is applicable..

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NOTE The conditions of 10 d at 60°C are considered the worst case situation. In case of combined contact conditions e.g. 2 h at 121°C followed by 10 d 60°C then the test should not be performed for 18 d at 60°C but only for 10 days at 60°C.

4.2.5.2 Overall migration

Regulation (EU) No 10/2011 gives the alternatives OM8 and OM9 in case it is not technically feasible to use OM7. In case it is not technically feasible to use vegetable oil in OM1 to OM6 then the procedure in section 4.2.5.1 shall be used.

Table 1 **Polyolefines (only containing carbon and hydrogen) (LDPE, LLDPE, HDPE, PP (homo, random, rubbery), PS, SBS): conventional test conditions and food simulants that has all to be performed when testing in food simulant D2 is technically not feasible**

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food simulant D2	ethanol 95%	iso-octane	food simulant E
10 d at 5°C	same t/T conditions as for food simulant D2	0.5 d at 5°C	no
1 d at 20°C	same t/T conditions as for food simulant D2	2.5 h at 20°	no
3 d at 20°C	same t/T conditions as for food simulant D2	8 h at 20°C	no
10 d at 20°C	same t/T conditions as for food simulant D2	1 d at 20°	no
1 d at 40°C	same t/T conditions as for food simulant D2	5 h at 20°C	no
3 d at 40°C	same t/T conditions as for food simulant D2	16 h at 20°C	no
10 d at 40°C	same t/T conditions as for food simulant D2	2 d at 20°C	no
10 d at 50°C	same t/T conditions as for food simulant D2	5 d at 20°C	no
10 d at 60°C	same t/T conditions as for food simulant D2	10 d at 20°C	no
2 h at 70°C	4 h at 60°C	0.5 h at 40°C	no
0.5 h at 100°C	12 h at 60°C	0.5 h at 60°C	same t/T conditions as for food simulant D2
1 h at 100°C	1 d at 60°C	1 h at 60°C	same t/T conditions as for food simulant D2
2 h at 100°C	2 d at 60°C	1.5 h at 60°C	same t/T conditions as for food simulant D2
0.5 h at 121 °C	2 d at 60 °C	1.5 h at 60 °C	same t/T conditions as for food simulant D2
1 h at 121 °C	4 d at 60 °C	2.0 h at 60 °C	same t/T conditions as for food simulant D2
2 h at 121 °C	8 d at 60 °C	2.5 h at 60 °C	same t/T conditions as for food simulant D2
0.5 h at 130 °C	3 d at 60 °C	2.0 h at 60 °C	same t/T conditions as for food simulant D2
1 h at 130 °C	6 d at 60 °C	3 h at 60 °C	same t/T conditions as for food simulant D2
2 h at 150 °C	10d at 60 °C	8.0 h at 60 °C	same t/T conditions as for food simulant D2
2 h at 175 °C	10 d at 60 °C	30 h at 60 °C	same t/T conditions as for food simulant D2

NOTE: The simulants and test conditions listed in the Tables are not necessarily applicable for screening purposes. For screening tests more severe test conditions or the conditions given in Chapter 5 may be applied.

Table 2 Non-polyolefines (containing also other atoms than carbon and hydrogen) (PET, PBT, PEN, PA6, PA66, PA12, PVC (rigid), PC, PMMA): conventional test conditions and food simulants that has all to be performed when testing in food simulant D2 is technically not feasible

food simulant D2	ethanol 95%	iso-octane	food simulant E
10 d at 5°C	0.5 d at 5°C	same t/T conditions as for food simulant D2	no
1 d at 20°C	2.5 h at 20°	same t/T conditions as for food simulant D2	no
3 d at 20°C	8 h at 20°C	same t/T conditions as for food simulant D2	no
10 d at 20°C	1 d at 20°	same t/T conditions as for food simulant D2	no
1 d at 40°C	5 h at 20°C	same t/T conditions as for food simulant D2	no
3 d at 40°C	16 h at 20°C	same t/T conditions as for food simulant D2	no
10 d at 40°C	2 d at 20°C	same t/T conditions as for food simulant D2	no
10 d at 50°C	5 d at 20°C	same t/T conditions as for food simulant D2	no
10 d at 60°C	10 d at 20°C	same t/T conditions as for food simulant D2	no
2 h at 70°C	0.5 h at 40°C	4 h at 60°C	no
0.5 h at 100°C	0.5 h at 60°C	12 h at 60°C	same t/T conditions as for food simulant D2
1 h at 100°C	1 h at 60°C	1 d at 60°C	same t/T conditions as for food simulant D2
2 h at 100°C	1.5 h at 60°C	2 d at 60°C	same t/T conditions as for food simulant D2
0.5 h at 121 °C	1.5 h at 60 °C	2 d at 60 °C	same t/T conditions as for food simulant D2
1 h at 121 °C	2.0 h at 60 °C	4 d at 60 °C	same t/T conditions as for food simulant D2
2 h at 121 °C	2.5 h at 60 °C	8 d h at 60 °C	same t/T conditions as for food simulant D2
0.5 h at 130 °C	2.0 h at 60 °C	3 d at 60 °C	same t/T conditions as for food simulant D2
1 h at 130 °C	3 h at 60 °C	6 d at 60 °C	same t/T conditions as for food simulant D2
2 h at 150 °C	8.0 h at 60 °C	10d at 60 °C	same t/T conditions as for food simulant D2
2 h at 175 °C	30 h at 60 °C	10 d at 60 °C	same t/T conditions as for food simulant D2

NOTE: The simulants and test conditions listed in the Tables are not necessarily applicablefor screening purposes. For screening tests more severe test conditions or the conditions given in Chapter 5 may be applied.

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Typical examples of technical reasons for deviation from food simulants/procedures for specific migration

Example 1.1

Isocyanates may migrate into food simulants. However these substances are not stable in any of the listed food simulants. Therefore it is necessary to determine the potential migration by extracting the plastic with an inert solvent and then determining the amount of the substance in the plastic.

NOTE: Isocyanates are converted into amines in food simulant B (acetic acid 3%). This can be used as a screening method provided that the reaction yields of the individual isocyanates are known.

Technical reasons for deviation from food simulants/procedures for overall migration

Example 1.2

An expanded polystyrene tray is used for storage at room temperature for less than 30 days (test conditions are 10 d at 40°C). During contact with food simulant D2 the amount of oil absorbed is excessive, i.e. about 1 g/dm². The analytical error in the determination of the amount of oil absorbed is between 10 and 40 mg/dm². This analytical error prevents an accurate determination of the overall migration in food simulant D2. In this case the verification test can be done in isooctane (2 d at 20°C) and 95% ethanol (10 d at 40°C) to determine the overall migration applicable to fatty foods.

Example 1.3

An article made of polyamide with a thickness of e.g. 5 mm will show problems while determining the mass of the test sample. If the sample mass, using any of the conditioning conditions, cannot be established due to fluctuations in humidity above 2 mg/dm², then an alternative food simulant may be used to determine the overall migration.

4.3 Selection of food simulants

Annex III of the Regulation gives the rules on the selection of food simulants for overall and specific migration testing.

Some additional provisions are laid down in Annex V on compliance testing.

Next to the rules laid down in Annex III and V, a generally accepted principle is that a test can always be replaced by another test which is at least as severe.

Specific migration

The following procedures are all valid options in selecting the appropriate food simulants for testing specific migration:

1. for one or more specific foods, select the food simulant(s) indicated in Table 2 of Annex III taking into account the provisions of Annex III, section 3 of the Regulation; if the specific food is not listed, select the closest food based on chemical-physical properties.

2. for broad categories of non-specific foods, i.e. “dry”, “aqueous”, “acidic”, “alcoholic” or “fatty” food types[4], select the food simulants according to section 2 of Annex III of the Regulation.
3. for compliance for “all types of food” in general, select food simulants A, B and D2 (see section 2.1.2 of Annex V of the Regulation).
4. for all types of foods, when testing for substances that react with acidic food simulant or with acidic foods, select food simulants A and D2 (see section 2.1.2 of Annex V of the Regulation).
5. based on scientific arguments, in specific cases testing may be reduced to a single food simulant, from among those selected according to points 1-4, which is known to be the most severe for that particular substance and/or material.

Overall migration

The following procedures are all valid options in selecting the appropriate food simulants for testing overall migration:

1. for one or more specific foods within a food category, select the food simulant(s) indicated in Table 2 of Annex III taking into account the fact that food simulant E does not apply to OML (see Article 18.4 and section 2 of Annex III of the Regulation); See however section 4.2.4 of this guidelines on the use of food simulant E for OML testing in a specific case.
2. for broad categories of non-specific foods, i.e. “aqueous”, “acidic”, “alcoholic” or “fatty” food types[4], select the food simulants according to section 4 of Annex III of the Regulation. OML testing is not required for “dry” foods.
3. for compliance for all types of food in general, select food simulants A (or water), B and D2 (see section 4 of Annex III of the Regulation).
4. based on scientific arguments, in specific cases testing may be reduced to a single food simulant, from among those selected according to points 1-3, which is known to be the most severe for that particular material.

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4.4 Test conditions for verification methods

The philosophy of the Regulation 10/2011 is that the tests shall reflect the worst foreseeable conditions of use. If the result has to be expressed in mg/kg food, the highest foreseeable surface-to-volume needs to be tested.

4.4.1 Specific migration test conditions

To verify compliance with the SML’s conventional established time-temperature conditions and food simulants (see section 4.2 and 4.3) have to be applied representing the worst foreseeable conditions.

[4] Standard EN 14481:2003 specifies a test method to determine whether there is fatty contact between the food and the plastic. NOTE This standard refers still to former plastic food contact legislation. However this standard can still be used when “Council Directive 85/572/EEC” and “EN 1186-1 and EN 13130-1” are read as “Regulation (EU) No 10/2011”.

Only if the conventional test conditions cause physical or other changes in the test specimen that do not occur under conditions of worst foreseeable real use, then use test conditions may be applied that do not cause the changes in the test sample.

4.4.1.1 Conditions specified in Tables 1 and 2 of Annex V

Table 1 and Table 2 in Annex V of the Regulation provide test contact conditions which shall be chosen based on the actual contact conditions of the food with the FCM. FCMs may be exposed to a combination of time-temperature conditions when coming in contact with food. In those cases each test contact condition shall be selected from the tables and the materials shall be submitted to those conditions in tandem following the same sequence of conditions and the same portion of food simulant.

NOTE: the contact temperature may considerably differ from the temperature set at the oven or microwave. To determine the contact temperature, which is relavent for Regulation (EU) No 10/2011, CEN standard EN 14233 (2002) can be used (see footnote 1 on page 18).

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Table 2 in Annex V of the Regulation (EU) No 10/2011 is extended by two temperature ranges. For temperatures above 175°C food simulant E shall be used covering the real contact temperature.

Contact temperature	test contact temperature
130°C < T ≤ 150°C	175°C (*)
150°C < T ≤ 175°C	175°C (**)
175°C < T ≤ 200°C	200°C (**)
T > 200°C	225°C (**)

(*) This temperature, measured at the interface with the food, shall be used only for food simulants D2 and E. For applications heated under pressure migration testing under pressure at the relevant temperature may be performed. For food simulants A, B, C or D1 the test may be replaced by a test at 100°C or at reflux temperature for duration of four times the time selected according to the conditions in Table 1.

(**) Materials and articles used at contact temperatures exceeding 150°C, after adjustment to the real temperature at the interface with the food, shall be tested using only food simulant E.

NOTE: a closed pressurized system requires a sterilizer with requlated counter pressure (using N_2) to avoid "explosion" of the ethanol filled article. This system can even be used for a single side migration cell.

By derogation from the test conditions provided in Table 1 and 2, if the plastic material or article may in actual use be employed for periods of less than 15 minutes at temperatures of 70°C<T≤100°C (e.g. 'hot fill') and is so indicated by appropriate labelling or instructions, only the 2 hours test at 70°C shall be carried out. However if the material or article is intended to be used also for storage at room temperature or below, the above mentioned test is replaced by test conditions according to Table 1 and 2 or section 2.1.4 of Annex V of Regulation (EU) No 10/2011 depending on the duration of storage.

Verification test conditions need to take into account the conditions of use specified for the material or article according to the provisions of Art 15 of Regulation (EC) No 1935/2004 on labelling of the FCM and item 8 in Annex IV of Regulation (EU) No 10/2011 on the Declaration of Compliance. The provisions require that FCM shall be

properly labelled to assure food safety. Labelling should be in conformity with the claimed use but it should also cover the worst foreseeable conditions of use related to the functionality of the FCM.

One issue of labelling at the retail stage is that the label is often not fixed to the article so that the user is not reminded during every usage. This problem is even more pronounced when there are more users in a household or when the article changes property by e.g. a reuse market. A second issue of labelling is that the restriction of use mentioned on the label at retail stage is sometimes not coherent with foreseeable foods to be in contact with and the worst foreseeable conditions of use (i.e. contact time and temperature) in the Regulation. The combination of these two issues may cause a safety issue of FCM. Two examples encountered by enforcement authorities illustrate this situation.

1. A bowl made of melamine was labelled as salad bowl on the packaging at retail stage, but on the same label it was stated that it could not be used for acidic foods.
2. A Kitchen spoon made of melamine was labelled "not for cooking" but the foreseeable use is that such spoon might be used for cooking.
3. A Kitchen spoon made of melamine was labelled "max. 20 seconds in a hot pan" but in foreseeable use such spoon might be used for longer time.

In both examples the labelling is inappropriate. It makes no sense to label a bowl as suitable for salads while assuming that there will be no acid in the salad dressing. Therefore the foreseeable use is with acidic foods and the manufacturer should anticipate to this foreseeable use and shall assure that the bowl is suitable for contact with acidic foods. The same principle is valid for the kitchen spoon. If it is foreseeable that a kitchen spoon will be used for cooking then the spoon should be safe under cooking conditions. In conclusion, labelling indication shall not be taken into account if it is not in line with normal or foreseeable conditions of use.

Some typical examples of verification test conditions for specific migration

1 *Food is packed and stored for 2.5 months at ambient temperature.*

Test condition selected from Table 1 and section 2.1.4 of Annex V of Regulation (EU) No 10/2011 is 10 days at 50°C.

2 A *cup is filled with hot soup (± 90°C). The temperature of the soup will decrease within 15 minutes to a temperature of ± 60°C.*

In accordance with Table 1 and 2 of Annex V of Regulation (EU) No 10/2011 the test conditions of 0.5 h at 100°C could be established. However some materials are not resistant to temperatures of 100°C but can be used for hot fill applications where the initial temperature is 100°C or close to it and cools down in less than 15 minutes to a temperature of 70°C or below. Therefore the test at 100°C is allowed to be replace by a test using the condition of 2 h at 70°C on condition that the plastic material or article may in actual use be employed for periods of less than 15 minutes at temperatures between 70 °C and 100 °C (e.g. 'hot fill'). The actual use should be clear from the labelling of the material.

However if the material or article is intended to be used also for storage at room temperature or below, the above mentioned test is replaced by a test for 10 days at a temperature depending on the storage period (see 4.4.1.2).

3 *Ovenable packaging is filled with food, and heated in an oven at 200°C for 25 minutes.*

Selection of the contact time according Table 1 of Annex V of the Regulation (EU) No 10/2011 is 0.5 hour. The actual contact temperature at the interface of the food and the packaging may be more difficult to establish. Methods are available to determine the temperature at the interface but it will certainly be related to the composition of the food. Foods containing a significant portion of water, will not exceed a temperature of 100°C and testing with aqueous food simulants ((A, B, C or D1) can be performed for 2 h at 100°C or under reflux. If the food contains a significant amount of oil or fat, starch or sugar at the surface then the temperature at the interface food/packaging may be significantly higher than 175°C. CEN standard EN 14233 (2002) can be used (see footnote 1 on page 18) to determine the real contact test temperature of e.g. 180°C. Testing for 0.5 h at 200°C using food simulant E only, is considered a representative test condition. Only if it can be demonstrated that the contact test temperature is up to or equal to 175°C the migration test can be performed at 175°C.

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If the applied test condition causes physical changes (e.g. deformation) that do not occur in real use then the test conditions may be considered too severe. Milder conditions should be selected that do not cause the physical changes.

4 A packaged food is stored for maximum 2 years at room temperature

If the contact time is longer than 30 days Table 1 of Annex V of the Regulation (EU) No 10/2011 refers to special conditions. Section 2.1.4 of Annex V of the Regulation specifies that accelerated test shall be performed for a maximum of 10 days at 60°C. This approach is further discussed under item 4.4.1.2.

5 A spatula sold as a kitchen utensil

Utensils such as kitchen equipment are often used at a broad range of conditions of contact time and temperature. For such materials worst case conditions should be selected that covers not only the intended conditions, but also foreseeable worst case conditions. E.g. a spatula will be used for many different manipulations but use during baking and frying will be the worst case. Temperatures at the interface may easily go up to 175°C for limited contact time, i.e less than 0.5 h. In such case the spatula needs to be tested using food simulant D2 for 0.5h @ 175°C. However, in some cases even higher temperatures can be reached. Temperatures up to maximum 225 °C may be extreme but are not unlikely. For such extremely high temperatures the contact time will be limited. Migration testing should therefore be performed for conditions of 0.5 h at 225°C with food simulant E. A spatula is a repeated use article and the spatula should be tested as such.

Elaborate on polyamide and PAA

4.4.1.2 Special conditions for contact times above 30 days at room temperature and below

Many packaged foodstuffs have a shelf-life over 30 days while stored at room temperature or at refrigerated or deep frozen conditions. Long term storage conditions need adapted test conditions to guarantee food safety. Migration conditions should be related to the actual contact conditions. However, it is unrealistic to test packaging materials for a very long period of contact. Migration modelling has shown that test conditions of 10 days at 40°C may not always cover

long term storage at room temperature. Accelerated test conditions, based on the Arrhenius equation given in section 2.1.4 of Annex V of the Regulation (EU) No 10/2011, shall be used for verification of compliance with the specific migration limits. The Arrhenius equation can only be used for plastics where the migration is controlled by diffusion and the polymer properties are not greatly affected by increasing temperature. So if hydrolysis of a plastic, e.g. melamine or polycarbonate takes place at the foreseen conditions of use, the Arrhenius equation cannot be used.

In the following table specific test conditions are given covering a large range of applications. These test conditions are calculated based on the Arrhenius equation and followed by a decision by convention. For other contact conditions the Arrhenius formula can be applied. 5°C and 25°C are used as frozen/refrigerated and room temperature, respectively.

Table 3

Test condition	Types of application
10 days at 20°C	any time at frozen condition Food packaged when frozen and defrosted outside the packaging
10 days at 40°C	1. any time at refrigerated or frozen conditions including hot fill conditions and/or heating/cooling up to 100°C for maximum 15 minutes: any time at refrigerated or frozen conditions hot filling followed by refrigerated or frozen storage for unlimited time heating up to 100°C for maximum 15 minutes followed by refrigerated or frozen storage for unlimited time refrigerated or frozen storage for unlimited time followed by heating up to 100°C for maximum 15 minutes E.g. Food packaged, pasteurised in the package and after cooling stored in a freezer of refrigerator for any shelf life, Food packaged at room temperature, then stored for any time in a refrigerator or deep freezer and final defrosted and heated in a microwave for less than 15 minutes. Food packaged by hot filling and stored in refrigerator or freezer. 2. any time at room temperature provided it can be demonstrated that migration of a substance is at equilibrium after 10 days at 40°C. Thin films made of high diffusive polymers, e.g. polyethylene
10 days at 50°C	storage times up to 6 months at room temperature:
10 days at 60°C	long term storage above 6 months at room temperature, including hot fill conditions and/or heating/cooling up to 100°C for maximum 15 minutes: • Storage for any time at room temperature • hot filling followed by storage at room temperature

	for unlimited time • heating up to 100°C for maximum 15 minutes followed by storage at room temperature for unlimited time • storage at room temperature for unlimited time followed by heating up to 100°C for maximum 15 minutes E.g. Foods packaged, pasteurized (<70°C for max 2 h) in the package and stored for more than 6 months at room temperature. E.g. some beverages, dry foodstuff

The increased contact temperature in the test compared to the worst case contact temperature should not cause any physical changes such as phase transition. Phase transition may cause an excessive increase in migration. In those cases a lower temperature should be chosen in combination with a longer contact time. To find the proper conditions the acceleration factor can be calculated using the Arrhenius equation and calculation of an extended contact time by means of that acceleration factor.

For storage at room temperature testing time can be reduced to 10 days at 40 °C if there is scientific evidence that migration of the respective substance in the polymer has reached equilibration under this test condition.

4.4.1.3 Specific conditions for combinations of contact times and temperature

Materials may be used for different applications, e.g. for long term storage at refrigerated conditions (10 days at 40°C) or for long term storage at room temperature (10 days at 60°C). In this example testing for 10 days at 60°C covers both applications and testing for 10 days at 40°C can be skipped, as the 10 days at 60°C covers all relevant conditions. In general the more severe test conditions can be established using the Arrhenius equation.

A material or article can also be subject to two or more successive time-temperature conditions. In such cases the test specimen shall undergo the same sequence of time-temperature conditions using the same portion of food simulant.

Example 1

A food is sterilised at 130°C for 2 h. After that it is stored for a maximum of 25 days at room temperature.
Test condition for food simulant D2 is 2 h @130°C followed by 10 d @40°C. Test conditions of food simulants A, B, C, D1 can be either be 2 h @130°C under pressure or 8 h @100°C followed by 10 d @40°C.
If the food is a dry food then the test should use food simulant E: 2 h @ 130°C followed by 10 d @40°C

Example 2

A tray is filled with hot food at 85°C, cooled down within 25 minutes, stored for maximum 20 days under refrigerated conditions (4-8°C) and subsequently heated in a microwave oven for 4 min at 100°C. The tray may be filled with all types of food.

For testing we need to subject the food (simulant) for 0.5 h @ 100°C followed by 10 d @ 20°C and 5 min @ 100°C

4.4.1.4 Repeated use articles

Utensils and food production equipment are frequently applied in repeated use applications. Generally migration will reduce upon successive uses because the migration is determined by diffusion. Occasionally the migration may increase upon successive uses, e.g. migration of formaldehyde from phenol-formaldehyde or melamine-formaldehyde articles may increase due to hydrolysis in addition to diffusion. Therefore repeated use articles e.g. a food storage box or a bowl or plate should be tested in three successive contact periods, using a new portion of food simulant for each contact period. The specific migration may not increase from the first to the third migration contact. Conventionally the migration found in the third migration experiments shall comply with the relevant specific migration limit.

Performing three contact periods may be time consuming. If the migration in the first contact period is in compliance with the SML and it is known that the migration does not increase in the second and third migration period as documented in the supporting documentation, then the results obtained in the first experiments are accepted to demonstrate compliance with the restriction(s).

Materials containing substances assigned with a specific migration limit of ND (not detectable) in Annex I and II or substances that are not authorised because they are used behind a functional barrier are of special concern. Migration of such substances shall not be detectable already in the first migration period. These substances are required to be ND in all three migration tests. Only if it is known that migration will not increase in the second and third test, the successive tests may be omitted. Otherwise the migration in the third migration experiment shall also be determined.

Determination of the migration from a repeated use article does not deviate from the procedure followed for single use articles. However establishing the right contact conditions of time and temperature as well as actual surface to volume ratio may be more complex.

Some typical examples are given below. Not the examples themselves but the principles used to arrive to a conclusion should be considered and used to extrapolate to other repeated use articles.

Example 1 Plastic household cutting board

The cutting board has an area of 30 x 40 cm. It will be used with all types of food. Quantity of food in contact will vary from 20 g/dm^2 to 500 g/dm^2. Contact periods will vary from a few minutes to several hours at temperatures comparable to hot fill conditions (<100°C for <15 min.) down to room temperature. In between uses it will be cleaned. Life-time of the board is 5 years.

Based on the above use conditions the most severe conditions of contact could be established as 2 h at a temperature representing hot fill conditions that should be simulated by test conditions of 2 h at 70°C. Being repeat use articles then three successive contacts should be carried out.

If however the article contains a substance assigned with a SML of "not detectable" then the first migration period should already comply with the restriction.

The amount of food in contact with the board cannot easily be established. Therefore the cutting board is an example of an article that falls under Art. 17.2(b) and is the surface-to-volume ratio set at 6 dm^2/kg.

Example 3 Conveyor belt for bakery products

A conveyor belt is intended to be used in a bakery. The belt has a length of 60m with a width of 0.6 m. The belt has a life time of 3 years. The belt is intended to be used to transport cakes from the oven to the packing department. Belt is running at 0.36 km/h. At the start the cakes will have a temperature of 90°C and at the end they will be cooled down to 20°C. The cakes have a size of 8 cm diameter and a mass of 100 g each. The average production is 10,000 cakes an hour. According to good hygiene practice the belt is cleaned at least at the end of the day.

From the above information it appears that the contact time is 10 minutes (60 m/360 m/h * 60 min). The temperature decreases from 90°C to 20°C within 15 minutes. This is comparable to hot fill conditions. The contact area is 5 dm^2/kg food ($0.4^2 \cdot \pi$ dm^2/100 g). However, the quantity of food in contact with the total surface area of the conveyor belt is not clear, which justifies to use the conventional surface to volume ratio of 6 dm^2/kg. Three successive migration experiments may be performed applying conditions of 2 h at 70 °C.

4.4.2 Overall migration test conditions

Annex V, Table 3 sets the standardized conditions for the determination of the OM in various food simulants. It is a simplification of previous legislation because a need was identified by stakeholders. OM1 up to OM4 are applicable to all food simulants. OM2 is more severe than OM3. OM 4 requires a test temperature of 100°C. Because the boiling point of water/ethanol mixtures is about 80°C, reflux conditions are not appropriate. This implies that OM4 tests with food simulant A, C and D1 shall be performed in a closed (pressurized) system to allow the food simulant to reach a temperature of 100°C.

NOTE: a closed pressurized system requires a sterilizer with requlated counter pressure (using N_2) to avoid "explosion" of the ethanol filled article. This system can even be used for a single side migration cell.

In contrast with OM4, the condition OM5 does allow testing at reflux temperature. The test for 1 h at 121°C is conventionally defined as being equivalent to the test condition of 2 h at 100°C for vegetable oil or at reflux temperature for food simulant A, B, C and D1. OM5 is the test condition which is relevant for high temperature applications, more specifically:

- When testing materials with a non-polyolefin food contact layer, OM5 allows to clear the material for use conditions up to 121°C.
- When testing materials with a polyolefin food contact layer, OM5 allows to clear the material for any use condition even exceeding 121°C (within the limits of technical suitability and SML compliance). The reason is that from an inertness point of view (which is what OM is testing) OM5 is considered the worst case test condition to which these materials should be subjected.

OM6 is the worst case test condition for migration into food simulants A, B, C and D1 from materials having a non-polyolefin food contact layer. It allows clearing these materials for any use conditions even exceeding 100°C (within the limits of technical suitability and SML compliance) for contact with all foods where these food simulants are prescribed.

OM7 is the worst case test condition for migration into food simulant D2 for materials having a non-polyolefin food contact layer. It allows to clear these materials for any use conditions even exceeding 175°C (within the limits of technical suitability and SML compliance) for all foods where food simulant D2 is prescribed.

OM8 and OM9 are substitute test conditions for OM7 in case the test in oil is not technically feasible. An example of "non-feasible" (see also Section 4.2) is when a multi-layer food contact material delaminates during the contact time necessary for the migration test. When this happens the original shape of the multi-layer material is lost during the test, and internal layers of the multi-layer structure can come in contact with the food simulant.

Apart from the fact that food simulant E can be used as a substitute food simulant in OM8 and OM9, food simulant E is not relevant for overall migration in general. This food simulant is especially designed for testing migration of volatile substances and volatile substances are excluded from the overall migration limit.

The following table gives examples of actual conditions of packaging usage that are covered by the tests for overall migration conditions described Table 3 of Annex V.

If the material or article contains volatile substances then the test specimen need to undergo the vacuum conditioning method (see Annex 7.1.6.2) before the migration test is carried out.

Table 4

Test reference	Type of application
OM1 10 d at 20°C	All storage of foodstuffs in fridges, at either frozen or refrigerated temperature, for any time
OM2 10 d at 40°C	Long-term storage at room temperature of any food; Hot filling followed by cooling in the package and long-term storage, e.g. molten cheese, soups, tomatoes etc.; De-freezing and/or re-heating of food (e.g. ready meals) in microwave oven Flash pasteurization >70°C (time less than 15 min) or pasteurisation less than 70°C up to 2 hours, followed by long term storage at room temperature. Other short-time high-temperature treatment such as shrink of films followed by long term storage at room temperature.
OM3 2 h at 70°C	Hot filling for immediate consumption (e.g. coffee or tea cups; take away food) serving utensils and tableware intended to be used in hot food for 2 hours or less Articles intended for repeated usage in very short contact (< 5 minute) with food at room temperature; example: slicers, cutters, mincers.
OM4 1 h at 100°C	Pasteurization in the packaging (time longer than 15 min at 100°C or longer than 2 hours at 70°C) Cooking of food (e.g., cooking of ham in moulds, pre-cooked

	seafood, boil-in-bag ready meals etc.) up to 1 hour. Cooking in microwave oven (time >15 min) when the temperature does not exceed 100°C. Reheating longer than 15 min at 100°C
OM5 2 h at 100°C or at reflux or alternatively 1 h at 121°C	Cooking of food (e.g., cooking of ham in moulds, pre-cooked seafood, boil-in-bag ready meals etc.) Cooking in microwave oven when the temperature can exceed 100°C; Sterilization in the packaging, e.g. heat sterilization of broths and soups Cooking of food entailing long-term storage. It represents worst case conditions for all food simulants in polyolefins. cooking utensils
OM6 4 h at 100°C or at reflux	Cooking of food entailing long-term storage. It represents worst case conditions for food simulants A, B, C and D1 in non-polyolefins.
OM7 2 h at 175°C	High temperature oven-ability, e.g. dual-ovenable packaging for fatty foods such as bread, and home cooking trays, Microwave susceptors

Where a material or article is intended to come into repeated contact with foods, the migration test shall be carried out three times on a single sample using another sample of the food simulant on each occasion.

Its compliance shall be checked on the basis of the level of the migration found in the third test. However, if there is conclusive proof that the level of the migration does not increase in the second and third tests and if the overall migration limit is not exceeded on the first test, no further test is necessary.

4.4.3 Contact conditions in migration testing

To determine the migration (specific or overall) the test specimen is brought into contact with food simulants. In real life materials and articles are normally only in contact with the food on one side of the material. Only exceptionally materials are used by immersion, e.g. kitchen utensils. In Annex 7.1.5 various ways to put a test specimen in contact with food simulant has been given. A test specimen is preferably in contact with the food simulant at one side. For articles that can be filled this is rather straightforward as the article can be filled with food simulant and stored for the proper contact time and temperature and then the migration is determined. For films and other flat test specimen migration cells have been developed to achieve one sided contact. Alternatively a pouch can be made of a film which can then be filled.

For articles for which the S/V is difficult to estimate (such as kitchenware) you also need to take into account the S/V in addition to the time-temperature conditions. This means that you may have several approaches depending of the foreseeable use of the article

Example 2 Plastic gloves used in meat processing industry

Plastic gloves, containing approximately 25 % of plasticizer, are used during a shift period of 2 hours, before they are discarded. Contact with an individual piece of meat of 150 g is about 4 seconds. Temperature of the meat is approx. 1°C. Contact area with the meat is about 1 dm².

Based on the above information it can be calculated that 1 kg meat is in contact with 1 dm² of the glove for 27 seconds at a temperature of 1°C. Using the tables 1 and 2 in Annex V it may be concluded that proper test conditions would be three tests for 5 minutes at 5°C. However, the glove itself will be at body temperature and thus close to 37°C. Therefore the contact temperature to be selected should be 40°C. In addition there is a risk that a film of fat will be formed on the glove at these foreseeable use conditions. So three successive migrations for 5 minutes at 40°C shall be performed to demonstrate compliance with migration restrictions if the gloves are only used for the mentioned purpose.

The amount of food in contact with the gloves cannot easily be established. Therefore the gloves are an example of an article that falls under Art. 17.2(b) and is the surface-to-volume ratio set at 6 dm²/kg.

Another approach may be that you estimate that the gloves are used for at least 1 h with a maximum of 2 h; this is reasonable because you may work assuming a time schedule of 2 h work – break – 2 h work - lunch – 2 h work – break – 2 h work – home. When you pack, 0.15 kg of meat comes in contact with 6 dm²/kg food (Art. 17.2(b)) or 0.9 dm²/0.15 kg food. However this 0.9 dm² will be in contact with a multiple amount of 0.15 kg. In this case 4.5 kg in 2 h which means the S/V is 0.9 dm²/4.5 kg = 0.2 dm²/kg food. So this means that you need to test (or recalculate your test result) using a S/V of 0.2 dm²/kg food (instead of 6 dm2/kg food). Since you throw away the gloves after 2 h this use should be is considered as single use and you would test one time for2 h at 40°C using a S/V of 0.2 dm²/kg food.

Example 4 Tubing in milk machine

The plastic tubing is part of a unit of a milk machine and has an inside diameter of 15 mm and a wall thickness of 1.5 mm. Length may vary from 1 – 2.5 m. The temperature of the milk in the tubing is 30 °C. Each cow is connected to the machine for 15 minutes and delivers 10 l of milk on each occasion, twice a day. Life time of the tubing is guaranteed for 1 year, but will only be replaced after two years. The unit has a maximum capacity of 10 cows/milking session. Tubing is cleaned with hot water before first use and in between two milking sessions.

Some facts:

- Contact area:

Area calculated for the worst-case situation assuming a length of 2.5 m tubing with a diameter of 15 mm. The inside surface area is 11.78 dm²

- contact time:

The volume of the tube is 0.4418 l. The flow of the milk is 0.6667 l/min. so the real contact time of milk is 0.66 min.

- Ratio of S/V

However, during the use of the tube the migration of the substance during the real contact time will decrease while more milk has flowed through the

tube. Therefore an integrated volume that has been in contact with the surface area of the tube, need to be considered, i.e. a batch of milk or just one litre of milk. The volume of milk is inversely proportional to the S/V ratio (Figure 2). A lower S/V ratio requires a larger volume and thus a longer test period.

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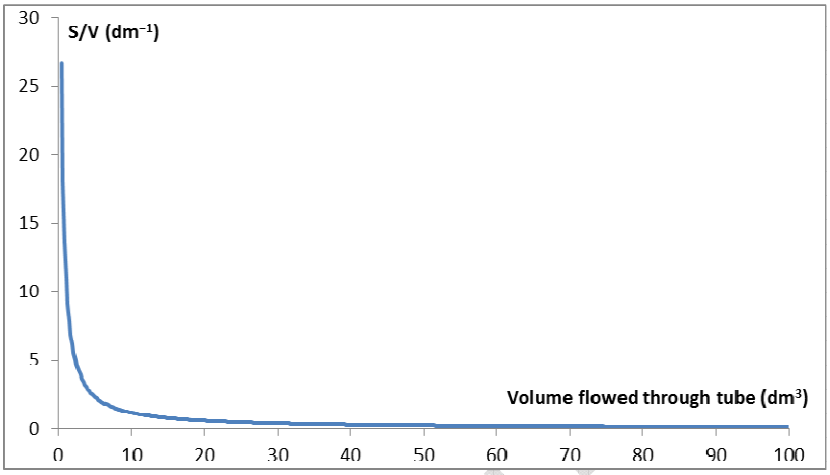

Figure 2 the relation between the volume flowed through the pipe and the S/V ratio

For one litre of milk the surface to volume ratio is 11.78 dm^2/l (11.78 dm^2/1 l) and the integrated contact time 1.5 min (1 l/0.6667 l/min). Adoption of this situation would lead to a test condition of 5 min at 40°C (repeated use conditions).

For 10 l of milk the surface to volume ratio is 1.18 dm^2/l and the integrated contact time 15 min. Adoption of this situation would lead to a test condition of 0.5 h at 40°C (repeated use conditions).

For 100 l of milk the surface to volume ratio is 0.12 dm^2/l and the integrated contact time 2.5 h. Adoption of this situation would lead to a test condition of 6 h at 40°C (repeated use conditions).

If there is no information given about the intended use of the tube then 5 min at 40°C using a realistic surface to volume ratio of 26.67 dm^2/l are selected as repeated use test conditions. However, if it is clear from the description of the use of the tube that it will be in contact with 100 l milk per milk session then the repeated use test conditions are 6 h at 40°C using a realistic surface to volume ratio of 0.12 dm^2/l.

For substances with a restriction "not detectable" the condition of 6 h at 40°C is the worst case as these substances shall be measured after the first contact time.

NOTE: if the article has multiple uses then the final result needs to reflect the worst case foreseeable contact surface-to-volume ratio.

NOTE: filling can be done with any volume as long as the surface-to-volume is known and the migration result can be recalculated to the real surface-to-volume ratio according to section 7.1.

NOTE: In some applications the packaged food may undergo a treatment, e.g. sterilisation by gamma radiation. The Documentation of Compliance and/or the

Supporting Documentation should address the effect of such treatment, e.g. the effect on the formation of non-intentionally added substance.

4.4.3.1 Mono-layers

Optionally, total immersion of the test sample may be applied. However it should be considered very carefully which contact area should be taken into account to calculate the final migration. For thin film e.g. 20 µm made of high diffusive material (e.g. polyolefins) used for long term storage at room temperature only one side of the test specimen should be taken into account for migration calculations as migration will most likely be complete (100%) exposing either one or two sides. For instance, when testing a 20 µm PP film one-sided this will give the same migration result compared to the full immersion testing for any migrant. However, at the same thickness a film made from a low diffusivity material (e.g. PET) may be tested by full immersion and, depending on the test conditions and molecular mass of the migrant (see Table 5), both sides of the test specimen can be taken into account for migration calculation. In these cases testing a 20 µm PET film by one side contact will give half of the migration result of the full immersion test.

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As a general rule it should be considered that migration from one side should be less than 50% of the initial content of a substance in the plastic in order to be able to test that test specimen by full immersion and to use the surface area of both sides when calculating migration. If one sided migration exceeds the 50% value then preferably only one side should be tested. If nevertheless a full immersion test is performed, then only one side of the sample shall be considered for calculating migration.

Determination of the actual thickness at which the 50% rule is fulfilled requires a preliminary test which is laborious and time consuming. The thickness at which the 50% rule is fulfilled depends on the diffusion properties of the polymer and the time/temperature conditions considered for migration testing and can be estimated if the diffusion properties of the material are known. Guidance for materials with known diffusion properties is given below.

If the thickness of the sample is equal to or higher than the layer thickness given in Table 5 (see also Annex 4) the migrating amount can be related to the area of both sides of the sample tested. Otherwise the migrating amount in [mg] will be related only to the area of one sample side. In the case of overall migration testing the thickness recommendations for the molecular mass range 501-750 g/mol apply.

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Table 5 Layer thickness L (in µm) above which both side of the sample can be considered for calculation of migration if tested by full immersion at different contact conditions for four different molecular mass ranges

Polymer type	time/Temp	layer thickness L in [µm] for			
molecular mass of migrant (g/mol)		100-250	251-500	501-750	751-1500
LDPE, PP rubbery[5]	10 d at 60°C	none	none	9600	3840
	10 d at 40°C	none	12000	3680	1440
	10 d at 20°C	10000	3520	1200	480
	2h at 100°C	none	16000	4880	1920
HDPE	10 d at 60°C	none	13700	4200	1680
	10 d at 40°C	11800	4800	1320	540
	10 d at 20°C	3200	1200	400	168
	2h at 100°C	none	8600	2640	1040
PP isotactic/homo PP random	10 d at 60°C	20000	6800	2080	840
	10 d at 40°C	5840	2200	680	288
	10 d at 20°C	1600	620	220	80
	2h at 100°C	11700	4320	1320	540
PET, PBT, PEN	10 d at 60°C	160	60	20	8
	10 d at 40°C	52	20	8	4
	10 d at 20°C	12	8	4	2
	2h at 100°C	100	40	12	6
PS	10 d at 60°C	220	84	28	12
	10 d at 40°C	80	40	20	8
	10 d at 20°C	28	12	8	4
	2h at 100°C	108	40	20	12
SBS	10 d at 60°C	none	none	7200	3000
	10 d at 40°C	none	9200	2800	1140
	10 d at 20°C	8400	3000	940	400
	2h at 100°C	none	12400	3800	1500
PA 6 (not swollen: e.g. direct contact with food simulant D2 and iso-octane)	10 d at 60°C	364	132	40	16
	10 d at 40°C	136	52	16	8
	10 d at 20°C	44	20	8	4
	2h at 100°C	176	68	24	12
PA 6,6 (not swollen: e.g.	10 d at 60°C	980	360	108	44

[5] Rubbery PP is a heterophasic PP consisting of random PP surrounded by isotactic PP

direct contact with food simulant D2 and iso-octane)	10 d at 40°C	360	136	44	20
	10 d at 20°C	116	44	16	8
	2h at 100°C	480	180	56	24
PA 12 (not swollen: e.g. direct contact with food simulant D2 and iso-octane)	10 d at 60°C	1320	500	148	60
	10 d at 40°C	500	180	56	20
	10 d at 20°C	160	60	20	12
	2h at 100°C	660	240	76	32
PVC, rigid	10 d at 60°C	220	84	28	12
	10 d at 40°C	80	40	20	8
	10 d at 20°C	28	12	8	4
	2h at 100°C	108	40	20	12

4.4.3.2 Plastic multi-layers

Plastic multi layer materials include materials having inorganic coatings of e.g. aluminium, aluminium oxide or silicium oxide.

Platic multilayers shall in principle be brought into contact only single sided as migration from the non-food contact side to food (simulant) may be higher than in the one-sided test and would therefore not necessarily be relevant.

Some clarifications are needed to account for the multi-layer nature of certain materials and articles on the market.

Specifically, it needs to be realized that for multi-layers there is usually no single "worst case" material that represents the ideal testing sample: a thin direct food contact layer is the worst case for the contribution of migration from the other layers, while a thick direct food contact layer is the worst case for the migration from that layer itself. Of course these thickness considerations depend on the polymer type (see section 4.4.3.1).

Additionally, consideration needs to be given to the fact that countless numbers of multi-layer FCM are put on the market so that it is not practical to test each and every one of them.

Therefore compliance work usually focuses on identifying relevant samples, instead of testing every product. The available information, including the margin between test results and migration limits, then needs to be considered in verifying compliance for the other products in the product family.

It is generally recognized that migration from plastic multi-layers is mainly driven by the composition of the food contact layer. Nevertheless all layers starting from the food contact side of the material or article up to a functional barrier layer, if present, will in principle contribute to some extent to the specific and overall migration. For specific migration, set-off also needs to be considered.

NOTE: Substances behind the functional barrier may migrate in retardation and may migrate after the three successive migration tests. The Documentation of Compliance and/or the Supporting Documentation should address the efficiency of the functional barrier to fulfil the requirements of Art. 13 of Regulation (EU) No 10/2011 during its lifetime.

4.4.3.3 Multi-material multi-layers

The use of multi-material multi-layers, e.g. plastic multilayers containing an aluminium layer, in contact with food is governed by the Framework Regulation (EC) No 1935/2004 and in particular Article 3 which gives the general safety requirements, as well as the GMP Regulation 2023/2006. The detailed requirements on OML and SML are not applied to multi-material multilayer FCM in Regulation (EU) No 10/2011 and therefore this Guidance does not address their testing. There is one exception. The absence of vinylchloride needs to be verified at a SML of "non-detectable". Migration can be tested following the previous section (4.4.3.1).

NOTE: vinyl chloride shall also comply with the QM restriction.

4.4.3.4 Multi-component or assembled articles

Multi-component articles consists of components of different plastics or components of multi-materials that are assembled together. The plastic compounds need to be compliant with Regulation (EU) No 10/2011. For testing the migration from plastic components there are two extreme approaches:

1. Test the individual plastic components. Correct the specific migration according to section 7.1 using the real contact area of the component and the volume of the assembled article.
2. Test the assembled article by filling it.

Plastic parts of machinery that have a very small surface area-to-volume contribution to the complete machine, such as (part of) taps or other parts in a machine (e.g. a coffee machine) are also falling under Art. 17.3 and 4. Producers of such parts only need to test the overall/specific migration per article. The assembler of the machine needs to recalculate the overall/specific migration using the total S/V. Repeated use test conditions are necessary depending on the use of the parts.

4.5 Verification by residual content

Where necessary, substances have been assigned an SML in Table 1 of Annex I of Regulation (EU) No 10/2011. However some substances are reactive with the food simulants or an analytical method to determine the migration is not available. In those cases the substances carry a note (note 1, 8-10, 13 and 17) in column 11 of the table. For some substances Table 1 has set QMA values. For other substances this is not the case and then it is assumed (as a worst case) that all residual content will migrate to the food simulant. The determination of the residual content in section 5.2.2 shall be followed. Depending on the wording of the note in column 11, the ratio of actual surface to volume may be taken into account.

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Example

Isocyanates or epoxy groups may migrate into food simulants. However these substances are not stable in any of the listed food simulants. Therefore it is necessary to determine the potential migration by extracting the plastic with an inert solvent and then determining the amount of the substance.

The results are expressed as a residual content in mg/6 dm² (see section 2.1.8 of Annex V). E.g. the residual content of octadecyl isocyanate (FCM no 274) from an epoxy coating (thickness 50 µm) is determined as 0.05 mg/dm² material. The restrictions are 1 mg of NCO moiety per kg material (note 10 in column 11 of Table 1 in Annex I). However (note (17) in column (9) of Table 1 in Annex I) requires that the migration

*shall not be detectable expressed as NCO. As the substance is not stable in food simulants note 10 in column 11 of Table 1 in Annex I requires that verification of compliance shall be determined by the residual content per surface area (section 2.1.8 of Annex V). That means that the residual content shall not exceed 0.01 mg NCO*V/S for Art 17.1 articles or 0.01 mg NCO/6 dm² for Art 17.2 articles. Taking the above residual content of 0.05 mg octadecyl isocyanate/dm², the amount of octadecyl isocyanate is 0.3 mg/6 dm². For comparison with the restriction, the residual content needs to be recalculated for the amount of NCO: 0.043 mg of NCO moiety/6 dm² (0.3 mg/6 dm² · 42 g/mol / 295.5 g/mol). So the material is not compliant.*

NOTE: Isocyanates are converted into amines in food simulant B (acetic acid 3%). This can be used as a screening method provided that the reaction yields of the individual isocyanates are known.

Phthalates form a specific case. Box 1 shows the restrictions of the phthalates. A technical support agent has normally a lower concentration in a plastic material compared to a plasticiser and is therefore limited by its residual concentration in the polymer. Since the concentration in the plastic material is easier to determine compared to the SML official laboratories prefer starting with the verification of compliance of the residual content of the technical support agent. If this is compliant, the compliance with the SML shall be verified. In order to facilitate the work of the enforcement authorities concerning the restrictions of phthalates, Table 6, has been developed specifying the parameters, i.e. specific migration limit or maximum permitted residual content in the material relevant to these substances.

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Box 1 Legislation citations on phthalates

Regulation (EC) No 10/2011 provides a set of restrictions and specifications for the use of a number of phthalates in food contact materials (Table 1 of Annex I):

Phthalic acid, benzyl butyl ester (FCM substance no 159; ref. no. 74560; CAS no. 000085-68-7) to be used only as:

(a) plasticizer in repeated use materials and articles;

(b) plasticizer in single-use materials and articles contacting non-fatty foods except for infant formulae and follow-on formulae as defined by Directive 2006/141/EC) and processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC;

(c) technical support agent in concentrations up to 0.1 w/w % in the final product.

SML = 30 mg/kg food simulant.

Phthalic acid, bis (2-ethylhexyl) ester (FCM substance no 283; ref. no. 74640; CAS no. 000117-81-7) to be used only as:

(a) plasticizer in repeated use materials and articles contacting non-fatty foods;

(b) technical support agent in concentrations up to 0.1 w/w % in the final product.

SML = 1.5 mg/kg food simulant.

Phthalic acid, dibutyl ester (FCM substance no 157; ref. no. 74880; CAS no. 000084-74-2) to be used only as:

(a) plasticizer in repeated use materials and articles contacting non-fatty foods;

(b) technical support agent in polyolefines in concentrations up to 0.05 w/w % in the final product.

SML = 0.3 mg/kg food simulant.

Phthalic acid, diesters with primary, saturated C8-C10 branched alcohols, more than 60% C9 (FCM substance no 728; ref. no. 75100; CAS no. 068515-48-0 and 028553-12-0) to be used only as:

(a) plasticizer in repeated use materials and articles;

(b) plasticizer in single-use materials and articles contacting non-fatty foods except for infant formulae and follow-on formulae as defined by Directive 2006/141/EC) and processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC;

(c) technical support agent in concentrations up to 0.1 w/w % in the final product.

Table 6 Restrictions and critical parameters for the "classical" phthalates for control in enforcement work

Ref. no.	Substance	Use	SML	QM	Parameter to control in ***single use*** Food Contact Material *			Parameter to control in ***repeated use*** Food Contact Material		
			mg/kg food	w/w % in plastic	Fatty food	Infant food@	Non-fatty food	Fatty food	Non-fatty food	Infant food (non-fatty)
159 74560	Phthalic acid, benzyl butyl ester (BBP)	Plasticiser	30	n.r.	n.a.		SML	SML		
		TSA	30	0.1	QM(+SML)&					
283 74640	Phthalic acid, bis(2-ethylhexyl) ester (DEHP)	Plasticiser	1.5	n.r.	n.a.			n.a.	SML	
		TSA	1.5	0.1	QM(+SML)&			QM(+SML)&		
157 74880	Phthalic acid, dibutyl ester (DBP)	Plasticiser	0.3	n.r.	n.a.			n.a.	SML	
		TSA	0.3	0.05 #	QM(+SML)&			QM(+SML)&		
728 75100	Phthalic acid, diester with C8-C10 (DiNP)	Plasticiser	9 $	n.r.	n.a.		SML	SML		
		TSA	9 $	0.1	QM(+SML)&					
729 75105	Phthalic acid, diester with C9-C11 (DiDP)	Plasticiser	9 $	n.r.	n.a.		SML	SML		
		TSA	9 $	0.1	QM(+SML)&					

* Packaging made from glasses with lid containing a plasticized gasket is usually considered as a single use material; # only permitted in polyolefins; $ SML(T) is sum of DiNP and DiDP; & if QM complies, the SML needs to be tested; @ infant formulae and follow-on formulae as defined by Directive 2006/141/EC) and processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC

n.a., not allowed; n.r., not relevant; QM, maximum permitted quantity of the residual substance in the material; SML, specific migration limit; TSA, technical support agent

5 Screening

5.1 Introduction to screening approaches

"Screening tests"[6] is the new term according to Regulation 10/2011 for alternative compliance test approaches for overall and specific migration. Screening tests can be based on experimental-analytical testing methods or on theoretical migration estimations via calculation or migration modelling. Furthermore, in certain cases overall migration results can be used for evaluation of specific migration limits.

NOTE; Screening can only establish compliance. Non-compliances needs to be established by verification.

The reasoning for screening is given in preamble 32 of Regulation 10/2011: "As migration testing is complex, costly and time consuming it should be admissible that compliance can be demonstrated also by calculations, including modelling, other analysis, and scientific evidence or reasoning if these render results which are at least as severe as the migration testing." This consideration opens up a way forward to more rapid and economic strategies of compliance testing compared to verification testing.

As a matter of principle, screening approaches need always to be at least as conservative as the verification method. Therefore, test conditions which are at least as severe, should be applied. For estimation of migration conservative theoretical considerations which overestimate migration are needed. As a logical consequence, screening tests can only be conclusive in that they demonstrate compliance but they cannot demonstrate non-compliance. In case of exceeding a migration limit by screening, compliance may be checked then by using a more appropriate verification test using food simulants or even foodstuffs. Since, from experience, screening results will be in most cases conclusive concerning positive compliance declaration, screening tests offer advantages over verification methods with regard to time and costs.

Screening tests can be applied stepwise within a tiered approach system starting from the assumption of total mass transfer via very quick and cheap extraction tests of food contact materials determining the residual content to more refined tests and migration considerations thus approaching more and more the verification method.

5.2 Screening approaches for specific migration

According to Annex V Chapter 2.2 of the Plastics Regulation 10/2011: "To screen if a material or article complies with the migration limits any of the following approaches can be applied which are considered at least as severe as than the verification method described in section 2.1". Four screening principles for specific migration are listed.

5.2.1 Replacing specific migration by overall migration

The Regulation states in section 2.2.1 of Annex V: "To screen for specific migration of non-volatile substances, determination of overall migration under test conditions at least as severe as for specific migration can be applied".

As only a limited number of overall migration test conditions are defined in Regulation 10/2011 then to replace specific migration by overall migration it must be shown that contact under the overall migration test conditions (time and temperature) would result in migration equal to or

[6] Note that the term "screening" is also used as first tier for the identification of a range of substances in a sample, especially unknown substances. This meaning is not used in this chapter, but may be used in chapter 6.

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higher than would be observed under the appropriate specific migration test conditions. For diffusion controlled migration this can be demonstrated applying the Arrhenius calculator.

In case the overall migration testing carried out using oil, this approach can also be used to screen for the specific migration of volatile substances provided the method in oil does not include a vacuum treatment of the plastic material.

This means that it is possible to check in certain cases the compliance with the SML through the determination of the overall migration by recalculation of the OM result (in mg/dm^2) into a concentration value (in mg/kg food) using either the surface-to-volume ratio of the actual application or the conventional EU cube ratio of 6 dm^2/kg food for the materials and articles not intended for infants and young children mentioned in Art 17.2.

5.2.1.1 Screening for substances with a generic SML of 60 mg/kg food

According to Article 11 of the Regulation a generic specific migration limit of 60 mg/kg food applies to all substances for which no specific migration limit or other restrictions are provided in Annex I of the Regulation. The main intention of this provision is to provide to enforcement the possibility to react to problems caused by excessive migration of one of these substances. It is not the intention that the specific migration of these substances should be generally tested as a compliance requirement. Specifically, it is considered to be a reasonable assumption without need for further investigation that the substances subject to the generic SML of 60 mg/kg food are in compliance in the following situation:

a. the FCM complies with the OML in the test conditions and food simulants applicable for OM compliance (Table 3 of Annex V of the Regulation) provided that the testing conditions required for the specific migration test, were covered by the testing conditions of the overall migration test.; therefore non-volatile substances when tested in aqueous food simulants or in vegetable oil using the vacuum treatment, and non-volatile as well as volatile substances when tested in vegetable oil not using the vacuum treatment, are under control; and

b. in the context of good manufacturing practices, highly volatile substances (typically solvents) are kept under control by appropriate methods.

If the above reasonable assumption is shown to be incorrect, i.e. excessive migration of a substance with a generic SML takes place or is suspected, then a verification test on the specific substance is necessary.

5.2.1.1.1 Non-volatile substances

From an analytical point of view the overall migration into aqueous food simulants (A, B, C, D1) does not include volatile substances as the food simulant is removed by evaporation before weighing the residue. Volatile substances and substances that form an azeotrope with the food simulant vapours, will not be included in the final residue. If the overall migration is lower than the generic specific migration limit then it can be concluded that the non-volatile substances with a generic specific migration limit are compliant as long as the overall migration test conditions would result in migration equal to or higher than would be observed under the appropriate specific migration test conditions.

Migration into food simulant D2 is based on different principles. Various methods of determination have been described (Annex 7). The volatile substances are expected to be removed before contact with vegetable oil only when applying a method that includes a vacuum treatment of the test specimen; in other cases they remain included and will not be lost during determination of OM due to decomposition or volatility. If the overall migration is lower than the generic specific migration limit then it can be concluded that the substances with a generic specific migration limit are compliant as long as the overall migration test conditions would

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result in migration equal to or higher than would be observed under the appropriate specific migration test conditions.

5.2.1.1.2 Volatile substances

The specific migration of a volatile substance can be determined either by the determination of the individual volatile substance by GC-MS using specific migration test conditions or as a part of the overall migration determination in food simulant D2. The following two overall migration procedures are considered valid to demonstrate compliance with the generic SML for volatile substances.

Both methods are valid to demonstrate compliance, however it does not allow a demonstration of non-compliance. If the results show a migration that exceed the generic SML then further migration experiments shall be performed using appropriate test conditions, food simulants and specific analytical method to determine the migration of the individual volatile substances.

Vacuum method

Determine the mass of a 1 dm^2 (10 x 10 cm) test specimen and place the test specimen in a vacuum oven at 60°C ± 5°C, and reduce the pressure in the oven to 1.3 kPa or less. Leave the sample in the oven for 60 min ± 10 min. After that time transfer the test specimen from the vacuum oven to a desiccator containing self-indicating silica gel or anhydrous calcium chloride. Determine, after cooling for 60 min ± 10 min the mass of the test specimen. Calculate the difference between the mass of the test specimen before and after the one hour vacuum conditioning. If the difference between the masses of the test specimen is less than 2 mg/dm^2, then conditioning of the test specimens to be used in the test will not be necessary and the sample may be considered in compliance with the generic SML for volatile substances. More details can be found in Annex 7.

If the difference between the masses of the test specimen is greater than 2 mg/dm^2, then further conditioning of the test specimens will be necessary by replacing the test specimen in the vacuum oven under the same conditions but now for a period of 24 hours. Repeat this procedure until constant mass has been achieved. If the final mass difference is less than 10 mg/dm^2 then the sample is deemed to comply with the generic SML of 60 mg/kg food provided the conventional S/V ratio is 6 dm^2/kg is relevant, otherwise the actual or foreseeable S/V ratio should be taken into account. For thick materials like some utensils both sides of the test specimen may be taken into account. More details can be found in Table 5.

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The results of this method may be biased by the release of water, which is not subject to a generic SML or the OML. Depending on the polymer type and the physical dimensions of the test specimen (thick materials (polyamide) or some types of multilayers (EVOH or polyamide layer in the middle may not allow the intended method) a correction for the release of water may be necessary. If the sample contains water then the sample should be conditioned in a desiccator at a relative humidity of 50% until constant mass (W_1) has been achieved. Subsequently the test specimen is vacuum treated as described above. After constant mass has been achieved the test specimen should be re-conditioned at 50% relative humidity until constant mass has been achieved again (W_2). $W_1 - W_2$ should comply with the generic SML of 60 mg/kg food for volatile substances, after taking into consideration of the surface area of the test specimen and the relevant S/V ratio.

Overall migration method using food simulant D2

In principle the overall migration in food simulants is intended to demonstrate compliance with the OML of 10 mg/dm^2 as the sum of all non-volatile substances. But depending on the analytical method the OM determination in food simulant D2 may exclude or include the migration of volatiles.

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If the overall migration in food simulant D2 is determined applying the vacuum drying procedure described in Annex 7.1.6.2, then the volatile substances are excluded from the final results of the determination of the OM. But if the OM is determined using the moisture sensitivity conditioning procedure described in Annex 7.1.6.3 or in case no conditioning is required (according that Annex 7) then the migration of volatile substances is included in the final result. For substances with a boiling point of <300°C recovery in food simulant D2 should be demonstrated, i.e. the volatile substance of interest should be spiked into the food simulant and tested under the selected time and temperature conditions and its recovery demonstrated. A list of widely used substances and their recovery in different food simulants is reported in a study by Bradley et al. (2009) (see also Annex 5)

As with the vacuum drying method, if the OM is less than 10 mg/dm^2, then the migration of volatile substances cannot exceed the generic SML for volatile substances when taking into account the actual S/V or the conventional S/V ratio of 6 dm^2/kg. Therefore the sample is deemed to be in compliance with the regulation.

Example

A PP sample obtained from an emulsion polymerisation process may contain an amount of methanol. The migration of the methanol will not be included in the overall migration value obtained with aqueous food simulants (A-D1) so the vacuum method can be used for the determination of methanol. Migration of methanol will be included in the overall migration value in food simulant D2 when no vacuum conditioning step is involved before weighing the test sample. In the case that a vacuum drying step is applied before determination of the sample mass then the methanol will not be included in the overall migration value as the methanol will be removed from the sample before contact.

5.2.1.2 Restricted substances captured by overall migration

The approaches mentioned in sections 5.2.1.1.1 and 5.2.1.1.2 can also be used for substances with a specific migration limit lower than the generic SML of 60 mg/kg food. However, the following conditions shall be respected when replacing specific migration by overall migration:

a) Only substances with a SML greater than the analytical tolerance of the overall migration test can be used

- For food simulant D2 the analytical tolerance for overall migration has been observed to be 3 mg/dm^2. This means that compliance cannot be demonstrated in this way if the specific migration limit is less than 18 mg/kg food using the conventional surface-to-volume contact ratio of 6 dm^2/kg food, or corresponding value calculated from the real worst case surface-to-volume contact ratio.
- For migration into food simulants in which the overall migration is determined gravimetrically (A, B, C, D1), the analytical tolerance has been observed to be 2 mg/dm^2. This means that compliance cannot be demonstrated in this way if the specific migration limit is less than 12 mg/kg food using the conventional surface-to-volume contact ratio of 6 dm^2/kg food, or corresponding value calculated from the real worst case surface-to-volume contact ratio.

b) Substances that break down or react with the food simulant forming one or more volatile reaction products during the contact phase, are not suitable for the determination of compliance in this way. Stability of the specific migrant under the selected overall migration test conditions should be demonstrated.

c) Volatile substances cannot be determined by overall migration with volatile food simulants (A, B, C, D1) or other contact media according to Annex 8 and their compliance cannot therefore be demonstrated in these food simulants using overall migration. The same is valid for volatiles determined by the overall migration with food simulant D2 and using the vacuum treatment.

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d) Regulation (EU) No 10/2011 specifies a limited number of overall migration test conditions (OM1 to OM7). For compliance of the specific migration limit by determination of the overall migration the applied test conditions for overall migration testing must at least cover the conditions required for specific migration testing (as above). The Arrhenius converter provided in section 2.1.4 of Annex V of Regulation (EU) No 10/2011 may be used to demonstrate that the OM conditions cover the SM test conditions.

A list of possible substances for which points a, b and c have already been investigated, is given in Annex 5. This does not exclude the possibility to carry out those investigations for other substances as required. The list in Annex 5 notably does not list semi-volatile and volatile substances that could be assessed by the vacuum method or by screening the overall migration in food simulant D2 without the use of a vacuum treatment.

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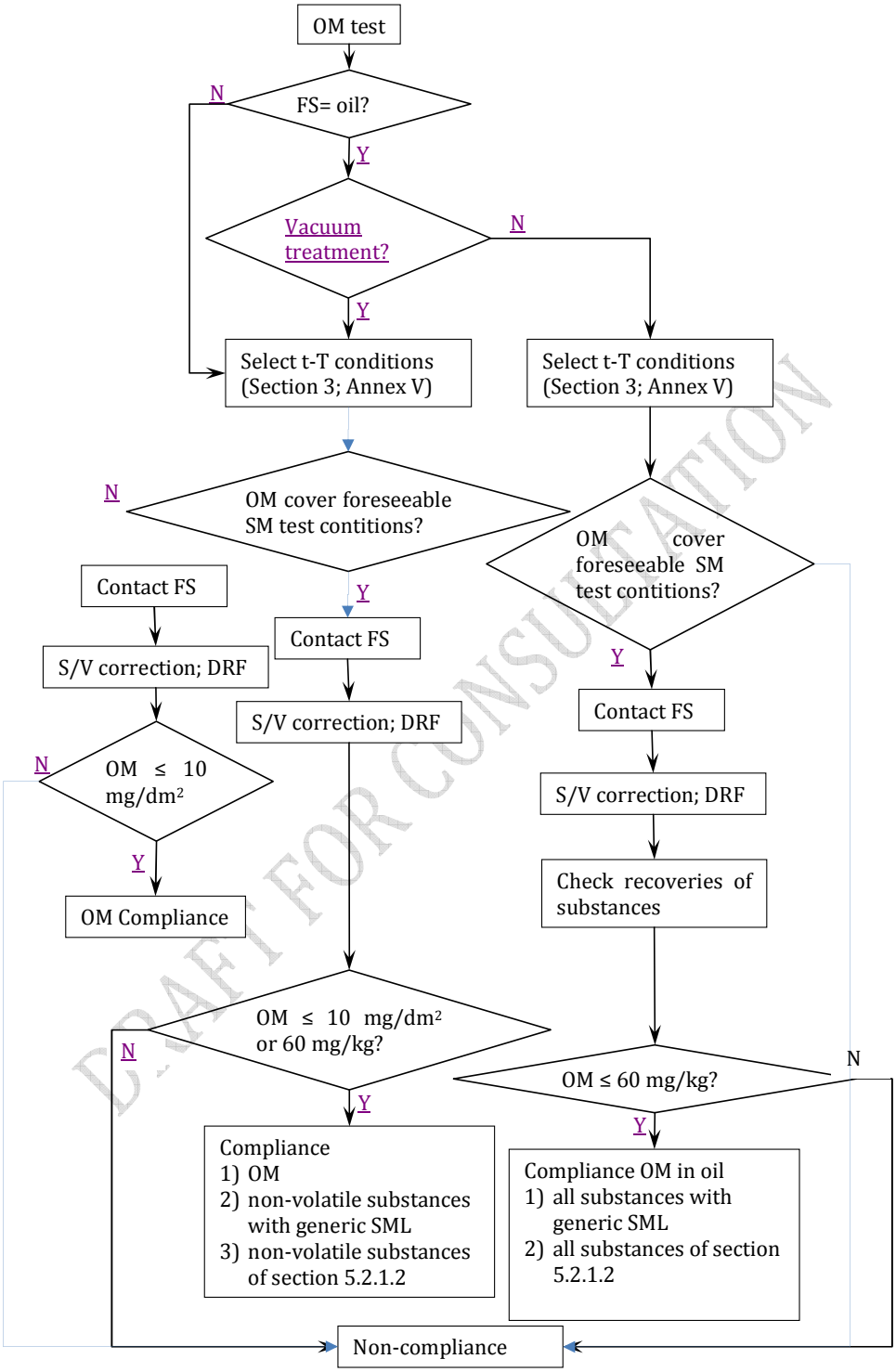

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5.2.2 Screening for volatile substances with a generic SML migrating from plastic materials in contact with dry food only

Plastic materials that are in contact with dry food only, are not tested for OM. Screening for the migration of volatile substances with a generic SML can be done by the application of the vacuum method (see section 5.2.1.1.2). Altenatively a GC-MS screening in food simulant E can be done or a generic headspace method can be applied.

5.2.3 Screening by residual content

The Regulation states "To screen for specific migration the migration potential can be calculated based on the residual content of the substance in the material or article assuming complete migration".

If the content of a substance in the material or article is known, e.g. nominal concentration[7] of an additive, or has been determined by an appropriate method, then maximum migration can be calculated by assuming total migrant transfer for the given material thickness at the appropriate surface-to-volume ratio. In case a range of concentrations under otherwise identical conditions is given by the supplier, the highest nominal concentration is used for this calculation as worst case. In case a range of thicknesses is foreseen with a constant concentration, the highest thickness is taken into account. Consideration of the full layer thickness of the material or article for the worst case calculation is the first basis for calculation. More refined considerations on layer thickness is given in Table 7.

The 'area related concentration' c_A (understood as mass of migrant per dm^2 of food contact area) is obtained from the concentration c_P in the polymer by multiplication with the polymer density ρ (kg/dm^3) and the thickness l of the layer (dm).

$$c_A \left[\frac{mg}{dm^2}\right] = c_P \left[\frac{mg}{kg}\right] \times \rho \left[\frac{kg}{dm^3}\right] \times l \, [dm]$$

In case the substance is present in more than one layer of a multilayer, the area related concentrations per layer have to be summed up for those layers that are before the functional barrier if present.

From c_A the total mass transfer migration M_{total} is obtained by multiplication with the ratio of the real contact surface area A and the food mass m_F (Note: density of food is assumed to be 1 kg/dm^3) or the conventional surface-to-volume ratio of 6 dm^2/kg in cases according to Art. 17.2 of the Regulation:

$$M_{total} \left[\frac{mg}{kg}\right] = c_A \left[\frac{mg}{dm^2}\right] \times \frac{A \, [dm^2]}{m_F \, [kg]}$$

Total mass transfer migration as calculated in this way is often referred to as 'maximum' or 'worst-case' migration.

Based on advanced scientific knowledge for a limited number of polymers one could set the borderline thickness by migration modelling from which realistic total mass transfer may occur by taking into account (i) the diffusion properties of the particular polymer and (ii) the molecular size or mass of the migrant. Furthermore, exhaustive migration depends also on the time-temperature contact conditions. In Table 7 (see also Annex 4) a list of thicknesses is given for a variety of polymers as a function of molecular mass ranges of migrants for several time-temperature conditions.

[7] concentration that one can assume to be the one in the polymer because it is the intentionally added amount without taking into account losses

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It should be noted that all thickness values are related to the non-swollen state of the polymer under conditions of use. In practical applications this may not always be the case. For instance polyamides can be swollen when in contact with aqueous foods thus leading to enhanced diffusion characteristics. However in the case of PA/PE multilayers where the PE layer is in contact with the food (simulant) PA will not swell. Direct contact with oil and iso-octane will also not lead to swelling.

The initial concentration is one of the main parameters for the migration. Therefore an accurate determination of the initial concentration in the polymer using a validated analytical method is necessary. Depending on the physical properties of the migrant, mainly its volatility, different general methods are applicable.

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259 **Table 7 Layer thickness L (in µm) for which total mass transfer assumption can be made at**
260 **different contact conditions for four different molecular mass ranges**

Polymer type	time/Temp	layer thickness L in [µm] for molecular mass of migrant (g/mol)			
		100-250	251-500	501-750	751-1500
LDPE, PP rubbery[8]	10 days at 60°C	Full L	Full L	2400	960
	10 days at 40°C	Full L	3000	920	360
	10 days at 20°C	2500	880	300	120
	2h at 100°C	Full L	4000	1220	480
HDPE	10 days at 60°C	Full L	3425	1050	420
	10 days at 40°C	2950	1100	330	135
	10 days at 20°C	800	300	100	42
	2h at 100°C	Full L	2150	660	260
PP isotactic/homo PP random	10 days at 60°C	5000	1700	520	210
	10 days at 40°C	1460	550	170	72
	10 days at 20°C	400	155	55	20
	2h at 100°C	2925	1080	330	135
PET, PBT, PEN	10 days at 60°C	40	15	5	2
	10 days at 40°C	13	5	2	1
	10 days at 20°C	4	2	1	0.5
	2h at 100°C	25	10	3	2
PS	10 days at 60°C	55	21	7	3
	10 days at 40°C	20	10	5	2
	10 days at 20°C	7	3	2	1
	2h at 100°C	27	10	5	3
SBS	10 days at 60°C	Full L	Full L	1900	750
	10 days at 40°C	Full L	2300	700	285
	10 days at 20°C	2100	750	235	100
	2h at 100°C	Full L	3100	950	375
PA 6 (not swollen: e.g. direct contact with food simulant D2 and iso-octane)	10 days at 60°C	91	33	10	4
	10 days at 40°C	34	13	4	2
	10 days at 20°C	11	5	2	1
	2h at 100°C	44	17	6	3
PA 6,6 (not swollen: e.g. direct contact with food	10 days at 60°C	245	90	27	11
	10 days at 40°C	90	34	11	5

[8] Rubbery PP is a heterophasic PP consisting of random PP surrounded by isotactic PP

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simulant D2, and iso-octane)	10 days at 20°C	29	11	4	2
	2h at 100°C	120	45	14	6
PA 12 (not swollen: e.g. direct contact with food simulant D2, and iso-octane)	10 days at 60°C	330	125	37	15
	10 days at 40°C	125	45	14	5
	10 days at 20°C	40	15	5	3
	2h at 100°C	165	60	19	8
PVC, rigid	10 days at 60°C	55	21	7	3
	10 days at 40°C	20	10	5	2
	10 days at 20°C	7	3	2	1
	2h at 100°C	27	10	5	3

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5.2.4 Screening by migration modelling

Chapter 2.2.3. of Annex V of this Regulation states that migration modelling can be applied as screening tool as long as the method is considered more severe than the verification method:

"To screen for specific migration the migration potential can be calculated based on the residual content of the substance in the material or article applying generally recognised diffusion models based on scientific evidence that are constructed such as to overestimate real migration".

Article 18.3 regulates the compliance check using migration models:

"For materials and articles not yet in contact with food screening of compliance with the specific migration limit can be performed applying screening approaches in accordance with the rules set out in Chapter 2, Section 2.2 of Annex V. If a material or article fails to comply with the migration limits in the screening approach a conclusion of non-compliance has to be confirmed by verification of compliance in accordance with paragraph 2".

A generally recognised model must be based on scientific evidence. During the last two decades numerous scientific investigations have demonstrated that migration from food contact materials, in particular from plastics, into food and food simulants are predictable physical processes which obey in most cases to Fick´s laws of diffusion. Hence, in addition to experimental screening methods, theoretical migration estimations can be carried out. For the use of migration modelling for compliance checking, the reader is referred to the "Practical guidance document on the implementation of diffusion modelling for the estimation of specific migration in support of Regulation (EU) No 10/2011".

As residual content of a substance in the material or article the nominal concentration can be taken or, in case of a concentration range, the highest nominal concentration is used for this calculation. Alternatively the concentration can be determined by an appropriate method (see section 5.2.2).

As with other screening approaches, it should be noted that if a material or article fails to comply with the specific migration limits using migration modelling, a final conclusion on compliance can only be derived from a verification test (see Chapter 4).

It is self-evident that migration modelling has the potential to allow compliance evaluation in a highly time- and cost-saving way. Beyond this, migration modelling can be a check for and supportive to experimentally measured values.

A useful application of migration modelling can be seen in the reversed approach. This means starting from a given SML value it can be back-calculated which maximum content would be allowed in the polymer without risk of exceeding the SML. For PET polymer, for instance, it was shown (Störmer et al., 2004) in this way that SMLs of the monomers EG, DEG and terephthalic

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acid can never be exceeded. The same holds true for the overall migration. In conclusion these tests are in principle not needed any longer when the evidence is given that the polymer is made of PET.

5.2.5 Screening food simulants

Section 2.2.4. of Annex V of the Regulation states: "To screen for specific migration, regulated food simulants can be replaced by screening food simulants if it is based on scientific evidence that the screening food simulants overestimate migration compared to the regulated food simulants".

5.2.5.1 Severity ranking of food simulants

The selection of the most severe regulated or screening food simulant depends on the nature of the migrating substance(s), the dissolving power of the food simulant for the migrant(s), the stability of the migrant in the food simulant, the degree of interaction of the food simulant with the packaging material and the contact conditions (time-temperature) of the contact between food simulant and FCM.

From the point of view of the solubility or adsorption properties of various foodstuffs the following general assignment of food types to regulated food simulants can be made:

- Foods with hydrophilic and acidic character with pH<4.5 => acetic acid 3%
- Foods with hydrophilic and acidic character with pH≥4.5 => ethanol 10%; ethanol 20%
- Foods with hydrophilic character that contain relevant amounts of organic ingredients that render the food more lipophilic => ethanol 20%; ethanol 50%
- Foods with hydrophilic and alcoholic character => ethanol 20%; ethanol 50%; (ethanol 95%)
- Foods with lipophilic character, oil-in-water emulsion character => ethanol 50%
- Foods with lipophilic character, free fat character at the contact surface => vegetable oil
- Foods with dry character => food simulant E

For screening, a food simulant that is considered more severe than the above assigned conventional food simulants can be selected per food category if desired. Alternatively, to cover more than one category and for economic reasons even more severe screening food simulants (such as 95% ethanol or iso-octane) than required per food category may be used. A compilation of most severe food simulants for each food category is given in the following table.

Food category	More severe regulated food simulant	Most severe screening food simulant
hydrophilic and acidic (pH<4.5) food	acetic acid 3%	Acetic acid 3%
hydrophilic food (pH≥4.5)	ethanol 20%	Ethanol 50%
hydrophilic foods containing relevant amounts of organic ingredients	ethanol 50%	Ethanol 95%

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hydrophilic and alcohol containing food	ethanol 50%	Ethanol 95%
lipophilic food with an oil in water emulsion character	ethanol 50%	Ethanol 95% vegetable oil
lipophilic food with free fat at the surface	vegetable oil	Vegetable oil; 95% ethanol; iso-octane*
dry food	food simulant E	Vegetable oil; 95% ethanol; iso-octane*

*Concerning selection of the appropriate most severe food simulant for lipophilic food with free fat at the surface and dry food considerations made above in section 5.2.5 and further down in section 5.3.2 should be consulted.

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There are foods for which testing with more than one food simulant is required according to Table 2 in Annex III of the Regulation. For screening purposes the number of tests may be reduced to a single food simulant if it can be demonstrated that this food simulant will give the highest migration result. The following rules should be taken into account:

1.) Specific migration

- The food simulant in which the migrant has the highest solubility, i.e. gives the highest migration result, is in general the worst case. Data about solubility can be found in literature. This approach ignores the potential effect of swelling by food simulants. It is assumed that swelling effects do not occur in contact with the actual food.
- Food simulant B is the worst case for metals and inorganic compounds and for organic substances which are soluble in acidic media, e.g. by protonation such as amines.

2.) Overall migration

- In case of polyolefins the migrants contributing significantly to the OM are mainly oligomers (non-polar character),for which food simulant D2 would be expected to result in the highest migration, slip agents for which iso-octane would be expected to result in the highest migration and antistatic additives for which ethanol 95% would be expected to result in the highest migration. Further guidance in selecting the most severe simulant is given in section 5.3.2.
- For materials that contain inorganic matter that is solvable in acid, food simulant B should be used.
- In general food simulant D1 can be considered to be the most severe aqueous food simulant for hydrophilic non-acidic foods.

Migration of primary amines (linear and aromatic) can be determined using 3% acetic acid as the worst case food simulant. Therefore determination of the migration into another food simulant may be omitted (see Industrial guideline "Determination of PAA Migration in Laminates.docx", Simoneau et al., 2011)). Polymers containing a primary amine cannot be tested with food simulant D2 due to reaction of the primary amine with aldehydes present in the oil..

5.2.5.2 Screening food simulants for lipophilic foods

In many cases vegetable oils are in practice unfavourable for specific migration testing of non-volatile substances because

a. the test procedure to be applied according to existing standards is complex and time consuming.

b. Analytical quantification of many substances subject to restrictions is laborious and in general linked with poor detection limits and low precision.

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c. In some cases vegetable oils cannot be used for specific migration testing due to chemical reaction between the migrant and substances in the vegetable oil.

Therefore in many cases, application of screening tests using suitable screening food simulants under appropriate test conditions may be preferable or even necessary.

This section intends to give scientific guidance in selection of screening food simulants for vegetable oil taking into account the legal requirement that the result of specific migration tests with the screening food simulant must be at least as high as compared to the test results with vegetable oils, i.e. the migration test with the screening food simulant is at least as severe as compared to that with vegetable oils.

This implies that the solubility of the migrants in the screening food simulant is at a minimum as high as in vegetable oils. In combination with the use of conventional time and temperature conditions as applicable for vegetable oil, in general migration test results will be obtained that are at least as severe as the verification method.

When the screening food simulant is selected in such way that the solubility of the migrant in the screening food simulant is at least as high as in vegetable oils and the selected screening food simulant will cause swelling of the polymer, i.e. accelerate migration, it might be feasible to deviate from the conventional time and temperature conditions based on scientific evidence, i.e. select shorter times and/or lower temperatures for testing, to account for the swelling effect. Because there is limited knowledge available on the swelling effect with respect to all possible solvent-polymer combinations, no generally applicable recommendation can be given for selection of adequate time/temperature conditions.

General recommendation for selection of screening food simulant

According to the scientific considerations (Feigenbaum et al., 2000) esters built from C2 to C8 acids with C2 to C8 alcohols and mixtures of these with aliphatic hydrocarbons with C6 to C8 carbon atoms can generally be recommended as screening food simulants for migration testing (specific and overall), which most likely will satisfy the requirement that the solubility of the migrants in the screening food simulant is as high as in vegetable oils, due to similar polarity of the screening food simulant with vegetable oil. In some cases this general approach may not work due to swelling of the polymer. This is the reason that other screening food simulants may be used provided the solubility of the migrant in the screening food simulant is still as high as in food simulant D2.

Screening food simulants selection for specific migration testing

The recommendation on the selection of screening food simulants is based on the rule "similar solves similar", i.e. the closer the polarity of the migrant and the screening food simulant is, the better the solubility of the migrant will be in the screening food simulant. As a measure of polarity the octanol to water partition coefficient ($K_{O/W}$) can be used because plenty of scientific literature is in place and numerous estimation procedures including software tools exist. Annex 6 describes the background of this approach.

The condition for the selection of the screening food simulant is:

$$ratio^{K} = [K_{O/W}(sim) - K_{O/W}(mig)] / [K_{O/W}(oil) - K_{O/W}(mig)]$$

and

$$\mathbf{-1 < ratio^{K} < 1}$$

Where $K_{O/W}(sim)$ is the $K_{O/W}$ of the screening food simulant, $K_{O/W}(mig)$ the $K_{O/W}$ of the migrant and $K_{O/W}(oil)$ is the $K_{O/W}$ of the oil.

If the above $ratio^{K}$ is above -1 and below 1 the screening food simulant can be considered to be an screening for vegetable oil. If the above $ratio^{K}$ is between -1.5 and -1 respectively 1 and 1.5

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the screening food simulant may be a reasonable screening for vegetable oil, but a certain risk of underestimation exists.

The condition "-1 < ratio^K < 1" is a strong requirement if migration comes close to equilibrium concentration. For -1.5 < ratio^K < -1 or 1 < ratio^K < 1.5 no underestimation is expected if:

- the migrating amount of the substance will be significantly lower than its equilibrium concentration, or
- the migrant is sparingly soluble in vegetable oil and as sparingly soluble in the screening food simulant.

The selection of a screening food simulant requires first consideration of $K_{O/W}$ of the migrant (experimental or estimated value) and calculation of ratio^K with respect to the screening food simulant under consideration. It is recommended to start evaluating ethanol 95% as a suitable screening food simulant. If the ratio^K requirement is fulfilled, the time/temperature conditions for testing can be selected according to Table 8. If not, a less polar solvent should be considered in the following order, e.g. isopropanol, n-butyl acetate,isooctane. Due to lack of knowledge on the swelling effect with respect to all possible solvent-polymer combinations no general applicable recommendation can be given for selection of refined time/temperature conditions.

The benefit of the ratio^K approach is, that only one screening food simulant is to be used instead of food simulant D2, compared to previous approaches where at least two and under high temperature conditions even three screening food simulants had to be used.

If ethanol 95% or isooctane fulfil the ratio^K requirement, which is not necessarily the case, Table 8 gives an overview of time-temperature conditions recommended for the screening food simulants 95% ethanol and isooctane. It should be noted that depending on the polymer type, the applicable t/T conditions deviate from the conventional ones that are used for vegetable oil, when swelling (accelerated migration) occurs .

In case the polymer to be tested is not specified in Table 8 the time/temperature conditions of the polymer category specified in the table which is closest to that under consideration may be taken. In case of doubt the conventional time and temperature conditions as applicable for food simulant D2 should be taken.

Food simulant E can be considered as a screening food simulant for high temperature applications because it is generally considered that for the most migrants the adsorption ability of food simulant E is as high as their solubility in food simulant D2. Food simulant E is to be used as screening food simulant in combination with the use of conventional time and temperature conditions as applicable for vegetable oil (no swelling effect).

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468 **Table 8 test conditions for screening food simulants compared to vegetable oil for**
469 **specific migration**

plastic	vegetable oil	ethanol 95%	iso-octane	food simulant E
LDPE, LLDPE PP random PP rubbery	@ ≥ 100°C			same t/T conditions as for vegetable oil
	10d @ 60°C	10d @ 60°C	2d @ 40°C	
	10d @ 40°C	10d @ 40°C	2d @ 20°C	
	10d @20°C	10d @ 20°C	1d @ 20°	
	–	–		
HDPE	@ ≥ 100°C			same t/T conditions as for vegetable oil
	10d @ 60°C	10d @ 60°C	1d @ 60°C	
	10d @ 40°C	10d @ 40°C	1d @ 40°C	
	10d @20°C	10d @ 20°C	1d @ 20°	
PP isotactic	@ ≥ 100°C			same t/T conditions as for vegetable oil
	10d @ 60°C	10d @ 60°C	1d @ 60°C	
	10d @ 40°C	10d @ 40°C	1d @ 40°C	
	10d @20°C	10d @ 20°C	1d @ 20°	
PET, PBT, PEN	@ ≥ 100°C			same t/T conditions as for vegetable oil
	10d @ 60°C	1d @ 60°C	10d @ 60°C	
	10d @ 40°C	1d @ 40°C	10d @ 40°C	
	10d @20°C	1d @ 20°C	10d @ 20°	
PS	@ ≥ 100°C			same t/T conditions as for vegetable oil
	10d @ 60°C	1d @ 60°C	1d @ 60°C	
	10d @ 40°C	1d @ 40°C	1d @ 40°C	
	10d @20°C	10d @ 20°C	1d @ 20°	
SBS	10d @ 60°C	10d @ 60°C	1d @ 60°C	
	10d @ 40°C	10d @ 40°C	1d @ 40°C	
	10d @20°C	10d @ 20°C	1d @ 20°	
PA 6, PA 6.6	@ > 100°C			same t/T conditions as for vegetable oil
	10d @ 60°C	1d @ 60°C	10d @ 60°C	
	10d @ 40°C	1d @ 40°C	10d @ 40°C	
	10d @20°C	1d @ 20°C	10d @ 20°	
PA 12	@ > 100°C			same t/T conditions as for vegetable oil
	10d @ 60°C	1d @ 60°C	10d @ 60°C	

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	10d @ 40°C	1d @ 40°C	10d @ 40°C	
	10d @20°C	1d @ 20°C	10d @ 20°	
PVC, rigid	@ > 100°C			same t/T conditions as for vegetable oil
	10d @ 60°C	1d @ 60°C	10d @ 60°C	
	10d @ 40°C	1d @ 40°C	10d @ 40°C	
	10d @20°C	1d @ 20°C	10d @ 20°	

5.2.6 Use of Arrhenius

If the material or article is intended for a food contact application where it is successively subject to a combination of two or more times and temperatures, a single migration contact test time can be defined based on the highest contact test temperature from section 2.1.3 and/or 2.1.4 by using the Arrhenius equation as described in section 2.1.4.

Example 1

A food is sterilised at 130°C for 2 h. After that it is stored for a maximum of 25 days at room temperature.

1. Test condition for food simulant D2 is 2 h @130°C followed by 10 d @40°C. Test conditions of food simulants A, B, C, D1 can be either be 2 h @130°C under pressure or 8 h @100°C followed by 10 d @40°C.
2. Test condition of food simulant D2 for 2h15min @130°C (15 min recalculated from 10 d @40°C). Test condition of food simulants A, B, C or D1 for 2h15min @130°C under pressure or 9h45min @100°C (1h45min recalculated from 10 d @40°C)

If the food is a dry food then the test should use food simulant E:

1. 2 h @ 130°C followed by 10 d @40°C
2. 2.2 h @130°C (0.2 h recalculated from 10 d @40°C)

Example 2

A tray is filled with hot food at 85°C, cooled down within 25 minutes, stored for maximum 20 days under refrigerated conditions (4-8°C) and subsequently heated in a microwave oven for 4 min at 100°C. The tray may be filled with all types of food.

Here we have two possibilities for testing:

1. Subjecting food (simulant) for 0.5 h @ 100°C followed by 10 d @ 20°C and 5 min @ 100°C
2. Subjecting food (simulant) for 46 min @100°C (12 min recalculated from 10 d @20°C)

5.2.7 Functional barrier considerations

Definition (13) in Article 3 of the Regulation (EU) No 10/2011 states that a functional barrier may consist of one or more layers of any material type when it ensures that the final material complies with the general requirement of Article 3 in EC Regulation 1935/2004 and that the level of migration complies with the specific provisions of the Regulation (EU) No 10/2011. This means that a functional barrier prevents e.g. substances mentioned in Annex I and II of the Regulation (EU) No 10/2011 and present in a layer behind the functional barrier from migrating above the SML. More specifically, the Regulation (EU) No 10/2011 states in Article 13 that migration of not listed substances from a layer separated by the food contact layer from the food should not be detectable at 10 µg per kg food or food simulant.

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It should be noted that in case of multi-layer structures not only the food contact layer itself but also any other layer located between a layer that contains a potential migrant (including the layer that contains the migrant) and the food can exhibit a migration reducing effect. This can be due to a very slow diffusion process in this barrier layer or even due to a very favourable partitioning effect, for instance achieved by extremely low solubility of a migrant in this barrier layer. According to migration theory the degree of this migration reducing effect will be determined by the structural details of the multilayer, the size and type of the potential migrant, the food type and the time-temperature history of the material during storage and contact with food. It is obvious that a thicker barrier layer, a larger migrant, a lower temperature, a shorter contact time as well as a lower solubility of a migrant in a food will lead as an end effect to a lower or even no migration scenario. This means that the degree of migration is a function of the details of whole packaging-migrant-food system. Therefore the term functional barrier is appropriate to describe these cases. In those cases, where zero-migration would occur the term 'absolute barrier' is applicable.

From the usual tiered approach concept for migration evaluation from FCMs into foods the first question would address 'What are absolute barriers'? Which materials at which thickness would exclude any permeation of potential migrants from outside into the food at any foreseeable contact condition for packed foods. Here the following examples can be considered:

- Glass of any thickness (not: SiOx layers)
- Metal cans and lids
- Aluminium foils at thickness when pinholes or other damages can be excluded
- plastic layers for substances in dependency of their molecular mass and in relation to defined time/temperature conditions (compare Table 9)

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Practically this means that in these cases potential migrants present in any layer behind the functional barrier such as outer labels, markers and sleeves or in print layers does not migrate into foods through the packaging material.

Another understanding of absolute barriers is related to the non-permeability of plastics for particular migrants or groups of migrants. Polymers used in the food packaging are impermeable for inorganic pigments, inorganic salts or nanoparticles.

Based on the migration theoretical considerations from which the values given in Table 7 were derived, also functional barrier thicknesses can be derived for various polymers and as a function of the molecular mass of the migrant for worst case test conditions of 10 days at 60°C (Annex 4). No migration of molecules of the specified molecular mass range can be expected for the FB thicknesses listed in Table 9. In this table polyolefins are only marginally covered due to their generally recognized failure as FB materials for organic substances.

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548 **Table 9 Functional barrier layer thickness L^{FB} (in µm) of various polymers through which no**
549 **migration can be expected at different contact conditions for four different molecular**
550 **mass ranges**

Polymer		FB layer thickness (µm)			
Molecular mass range of migrant (g/mol)		100-250	251-500	501-750	751-1500
LDPE, PP rubber	10 days at 60°C	no FB	no FB	7000	2600
	10 days at 40°C	no FB	8800	2640	1000
	10 days at 20°C	7000	3000	800	340
	2 hours at 100°C	no FB	10000	3240	1360
HDPE	10 days at 60°C	no FB	9000	3300	1080
	10 days at 40°C	8500	3000	960	400
	10 days at 20°C	2280	800	280	130
	2 hours at 100°C	no FB	6400	1800	700
PP homo/isotactic; random	10 days at 60°C	no FB	4600	1400	580
	10 days at 40°C	3900	1480	500	220
	10 days at 20°C	1080	440	160	70
	2 hours at 100°C	8000	3000	900	380
PET, PBT, PEN	10 days at 60°C	91	35	12	5
	10 days at 40°C	31	14	4	2
	10 days at 20°C	9	4	2	1
	2 hours at 100°C	61	23	7	3
PS	10 days at 60°C	127	49	16	6
	10 days at 40°C	46	18	6	3
	10 days at 20°C	17	7	3	1
	2 hours at 100°C	65	26	8	4
SBS	10 days at 60°C	no FB	no FB	4600	1900
	10 days at 40°C	no FB	5800	1750	700
	10 days at 20°C	5000	1900	600	280
	2 hours at 100°C	no FB	7600	3300	1000
PA 6	10 days at 60°C	210	82	25	10
	10 days at 40°C	80	32	11	5
	10 days at 20°C	26	11	4	2
	2 hours at 100°C	105	40	14	6
PA 6.6	10 days at 60°C	565	225	70	28
	10 days at 40°C	220	65	26	13
	10 days at 20°C	76	28	10	5
	2 hours at 100°C	300	120	36	16

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PA 12	10 days at 60°C	810	300	91	37
	10 days at 40°C	420	114	34	15
	10 days at 20°C	100	44	13	6
	2 hours at 100°C	400	147	46	19
PVC, rigid	10 days at 60°C	127	49	16	6
	10 days at 40°C	46	18	6	3
	10 days at 20°C	17	7	3	1
	2 hours at 100°C	65	26	8	4

A higher degree of differentiation and further refinements can be achieved by migration modelling when the detailed parameters such as the exact molecular mass and concentration of the migrant in the releasing polymer layer and the structural specifications of the application are known or can reasonably be assumed. It can then be derived for a given migrant whether or not the barrier layer would be a functional barrier, i.e. would prevent migration from exceeding of the respective SML or another acceptable migration limit.

Other materials than those mentioned in Table 9 can act as functional barrier as long as it has been demonstrated at the worst case foreseeable conditions of use that the relevant potential migrants are not migrating above the limit of 0.01 mg/kg food.

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Besides the barrier properties achieved solely by a monolayer polymer other very thin barrier layers can be placed on usual carrier polymers to achieve excellent barrier effects by the whole composite, e.g. acrylic or PVDC coated PP films.

Within a comprehensive research project (Annex 2) the barrier properties of 24 different flexible packaging films were studied by permeation measurements across these films using 12 different test permeants with molecular mass between 90 and 400 g/mol at temperatures between 20°C and 80°C with core test conditions for all films of 40°C and 60°C up to 47 days, respectively 14 days.

As a result, a list of general functional barriers which would always be efficient in reducing for migrants with molecular mass equal to or higher than 90 g/mol any migration from behind to levels below of 10 ppb for test conditions of 10 days at 60°C was established (Table 10). In addition, a list of relative functional barriers which would provide this barrier performance when used for long term storage at room temperature (see Regulation (EU) No 10/2011, Annex V, section 2.1.4) was also defined (Table 11).

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Table 10 Barrier films which act as a general FB in reducing any migration down to levels below of 10 ppb at test contact conditions of 10 d @ 60°C.

Film structure	Base polymer	Barrier material
36 µm O-PET corona treated	PET	PET
12 µm PET metallised	PET	metallisation
12 µm PET-SiOx 80 nm *)	PET	SiOx
12 µm PET-SiOx 50 nm Ormocer-Laquer*)	PET	SiOx / Ormocer
12 µm PET / SiOx*)	PET	SiOx
12 µm PET / AlOx / adhesive / 30 µm PP	PP	PET-AlOx
6 µm aluminium)*		*Aluminium*
6 µm aluminium) / PE*	*PE*	*Aluminium*

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*) It should be noted that this is only the case when no pinholes or other damages are present.

Table 11 Barrier films which act as a FB in reducing any migration down to levels below of 10 ppb when used for long term storage at room temperature.

Film structure	Base polymer	Barrier material
15 µm OPA*)	PA	PA
12 µm PET	PET	PET
12 µm PVDC coated transparent Polyester film	PET	PVDC
PE / EVOH 3 µm / PE total 30 µm	PE	EVOH

*) This efficiency is only ensured when no swelling occurs

Specific migration testing for potential migrants present behind the films, for instance from other outer layers such as polymers, adhesives, printing inks, coatings, paper and board or secondary packaging is not needed at all for the general functional barriers (Table 10) unless the migration target value would be much lower than 10 ppb or an issue with set-off has been identified. The analogous conclusion can be made for barrier films listed in Table 11 for long term storage at room temperature contact applications.

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For applications at higher temperatures than 60°C, the barrier properties have to be checked and verified.

5.3 Screening approaches for overall migration

According to Annex V Chapter 3.4 of the Plastics Regulation 10/2011: "To screen if a material or article complies with the migration limits any of the following approaches can be applied which are considered at least as severe as than the verification method described in sections 3.1 and 3.2". Two screening principles for overall migration are listed.

5.3.1 Screening by residual content

Provided that for a final material or article or for all raw material used for manufacturing of a material or article the total non-volatile extractable amount (TNE = residual content of migratable substances) in the food simulants is known by experimental determination through complete extraction with the food simulant, a worst case overall migration can be calculated based on its composition/recipe under assumption of the total transfer to food of the TNE respectively TNE fraction according to the recipe (as for specific migration).

5.3.2 Screening food simulants

Section 3.4.2. of Annex V of the Regulation states: "To screen for overall migration food simulants can be replaced if based on scientific evidence the substitute food simulants as least as severe as migration compared to the regulated food simulants".

Under the assumption, that the nature of the migrating substances contributing to the overall migration from the plastic is known, the considerations in section 5.2.5 are applicable as well.

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The two solvents ethanol 95% and iso-octane span the polarity range of migrants from plastics encountered in practice. Substituting the overall migration test with vegetable oil requires testing with both solvents under consideration of the highest result for compliance evaluation. Regarding ethanol 95% its polarity is much higher compared to vegetable oil, reason for which solubility of non-polar migrants in ethanol 95% is expected to be lower compared to olive oil and as a consequence contribution of non-polar migrants (e.g. polyolefin oligomers or typical antioxidants) to overall migration may be underestimated. Regarding isooctane its polarity is lower compared to olive oil, reason for which solubility of polar migrants in isooctane is expected to be lower compared to vegetable oil and as a consequence contribution of polar

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migrants (e.g. polyamide oligomers or residual monomers) to overall migration for may be underestimated.

To minimize the risk of underestimation testing with both screening food simulants is required and the highest migration result needs to be considered for compliance evaluation.

Based on the above conclusion the following time/temperature conditions for overall migration testing with screening food simulants are recommended:

Table 12 Test conditions for screening food simulants compared to vegetable oil for overall migration

plastic	vegetable oil	ethanol 95%	iso-octane
LDPE, LLDPE PP random PP rubbery	OM2	OM2	2d @ 20°C 1d @ 40°C
	OM1	2d@40°C	1d@20°C
HDPE	OM2	2d@60°C	1d@40°C
	OM1	2d@40°C	1d@20°C
PP isotactic	OM2	2d@60°C	1d@40°C
	OM1	2d@40°C	1d@20°C
PET, PBT, PEN	OM2	1d@40°C 1d @ 50°C	OM2
	OM1	1d@20°C	2d@40°C
PS	OM2	1d@40°C	1d@40°C
	OM1	1d@20°C	1d@20°C
SBS	OM2	2d@60°C	2d@20°C 1d @ 40°C
	OM1	2d@40°C	1d@20°C
PA 6, PA 6.6	OM2	1d@40°C	2d@60°C
	OM1	1d@20°C	2d@40°C
PA 12	OM2	1d@40°C	2d@60°C
	OM1	1d@20°C	2d@40°C
PVC, rigid	OM2	1d@40°C	2d@60°C 1d @ 40°C
	OM1	1d@20°C	2d@40°C

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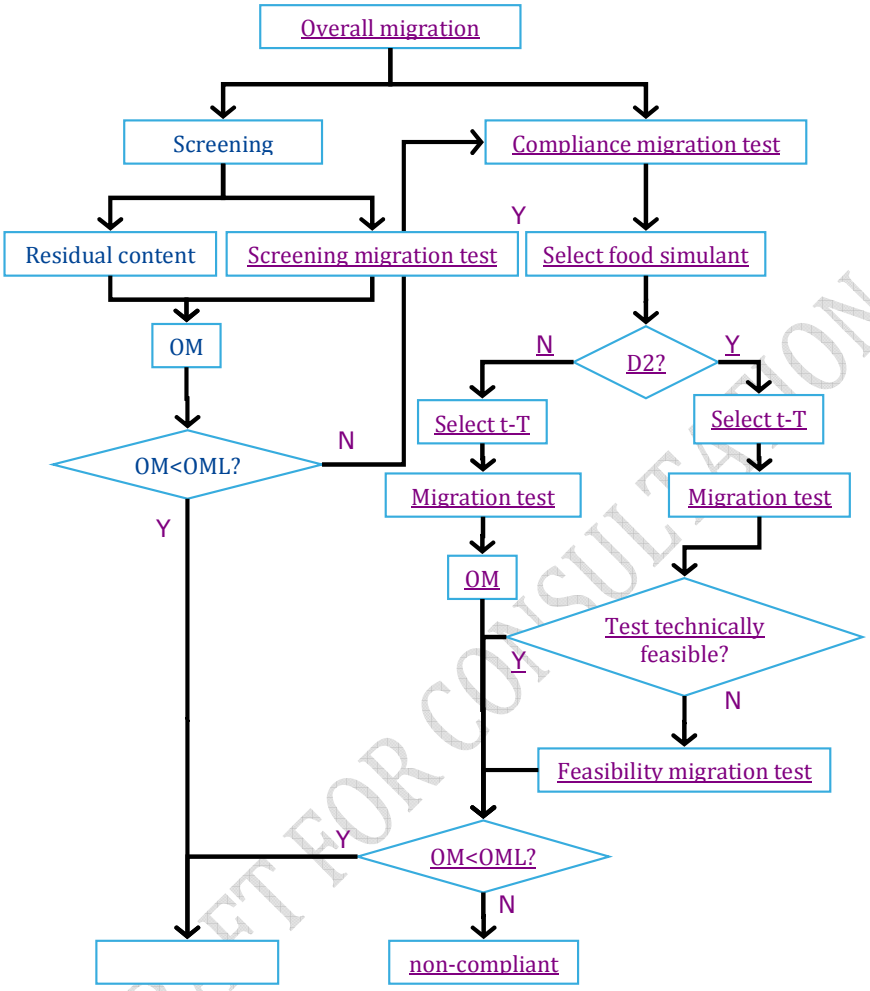
Overview of checking materials and articles that are not yet in contact with food for compliance with overall and specific migration.



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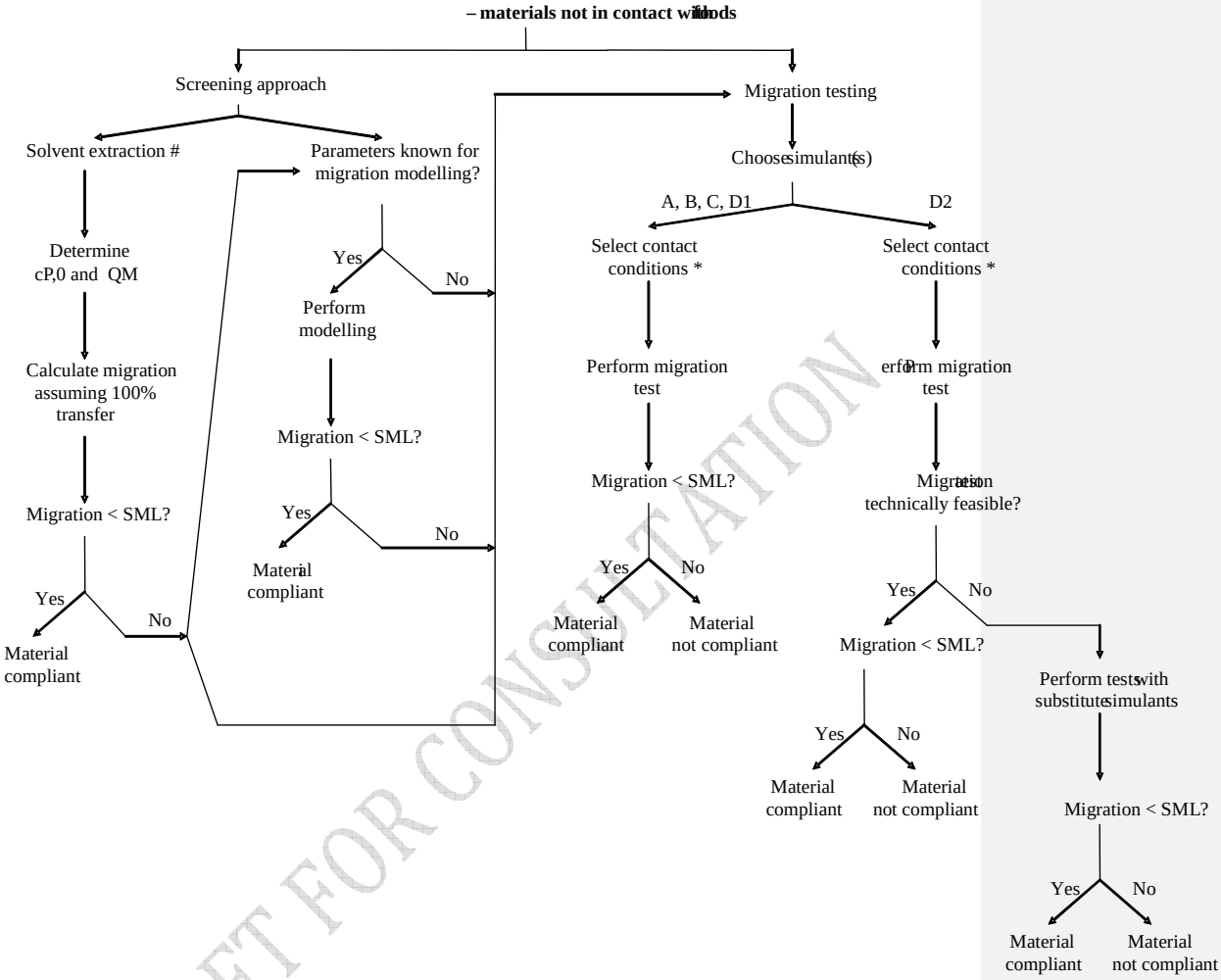

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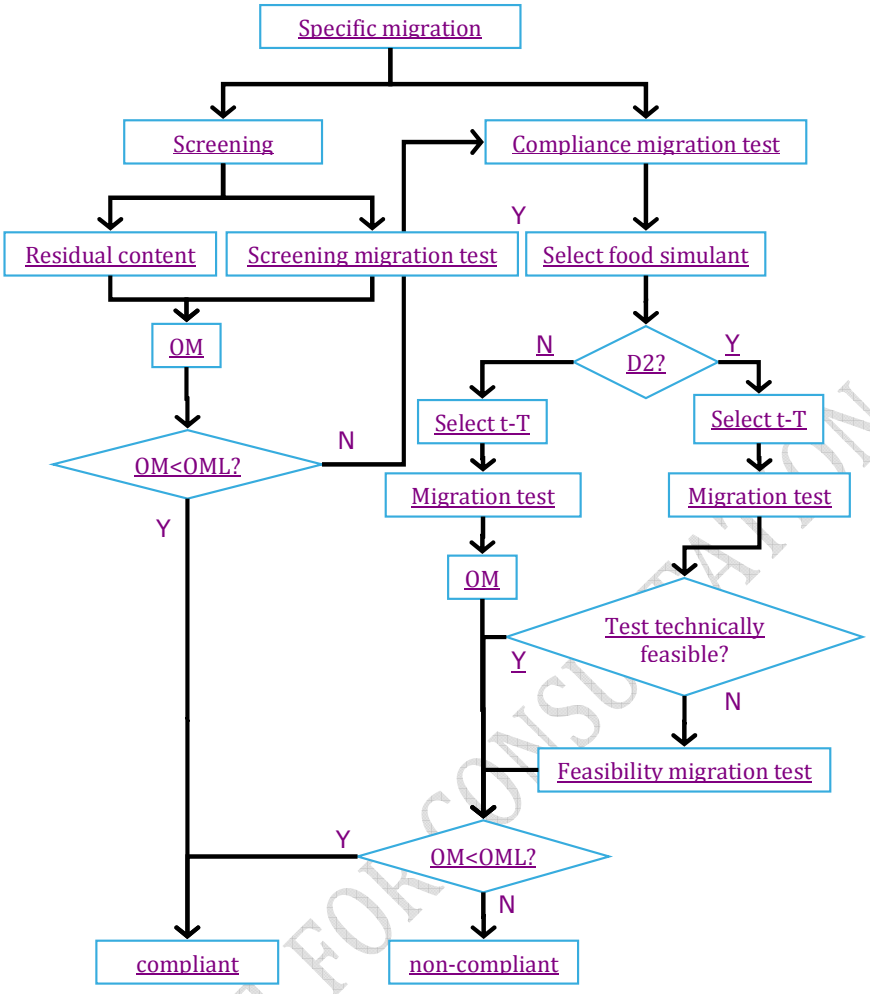

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6 Analytical determination of migrants

Sections 1.3 and 2.1.7 of Annex V of Regulation (EU) No 10/2011 give indications about analysis of migrants. This Regulation refers to Article 11 of the Regulation (EC) No 882/2004 on official food and feed controls.

6.1 Scope of analysis

The aim of this chapter is to describe two types of analytical methods:

1) Methods for to confirm the identity of the polymer
2) Methods for the analysis of the migrant:
   a) the determination of the residual concentration of the migrant in a material or article
   b) The determination of the migrant concentration in a food or a food simulant after a migration experiment
   c) The determination of the migrant concentration in a packaged food that has been sampled on the market. Note: analysis of a packaged food assesses the overall contamination of a substance originating from all sources such as environment, food processing (food ingredients, equipment) and food packaging.

6.2 Methods for the determination of the migrant

6.2.1 Hierarchy of methods

Methods in EU legislation

In the case of food contact materials, there are no European Union methods. There were two methods for vinyl chloride migration and residual vinyl chloride that detailed the analysis, However these Commission Directives have been repealed by the Regulation. Council Directive 78/142/EEC that states that vinyl chloride has to be analysed by headspace gaschromatography with a detection limit of 0.01 mg/kg food and that specifies that vinyl chloride is in principle determined in food and when it is technically impossible in food simulants, is replaced by Regulation (EU) No 10/2011.

CEN methods

Different CEN standard methodologies have been developed to test overall or specific migration from plastics within the frame of former EU legislation of plastic FCM materials. Methods for the determination of overall migration correspond to the CEN standard EN 1186 series. For specific migration the CEN standard EN 13130 series offers both standards and technical specification. All CEN standards that refer to the former EU legislation on plastic FCM are not valid anymore for Regulation (EU) No 10/2011. Only those standards and technical specifications that determine the residual content of a substance in the plastic can still be used.

Other methods

Most methods are validated for a single substance. The EURL has derived repeatability and reproducibility data for the determination of di-isodecyl phthalate (DIDP) in sunflower oil (Bratinova et al., 2010a), bisphenol A in ethanol 50% (Bratinova et al., 2010b) and for several migrants in spiked food simulant E (Beldì et al, 2012). The latter study obtained also repeatability and reproducibility data for the combination of the specific migration test using food simulant E and the determination of the migrants.

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6.3 Requirements for methods of analysis

Methods should be capable of either quantification of the substance in the material or article itself or quantification in food, or food simulants.

Method of analysis should comply with the following format (specimen examples may be seen in EN Methods for Food Contact Materials)

1. Scope
2. Principle
3. Sampling
4. Reagents (Safety precautions)
5. Apparatus
6. Procedure
7. Confirmation
8. Measurement uncertainty
9. Test report

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The box below represent a brief summary of how methods description for the analytical determination of migrants (EFSA, 2008).

1. SCOPE

Statement of types of materials and articles for which the method is applicable.

Statement of food simulants (or foods) for which the method is suitable.

Statement of the limit for which the method is capable of quantitative determination of the substance in the material and article or food simulant (or food).

2. PRINCIPLE

Statement of the principle that is employed for the determination (for example headspace GC, extraction followed by HPLC, extraction followed by colorimetric determination).

3. REAGENTS

Statement of safety requirements and any special precautions in handling reagents.

Statement of purity requirements of substance, internal standard and any special requirements for solvent or reagent purity.

Statement of primary and diluted calibrant solutions which should have a concentration range to span the QM or SML limit.

4. APPARATUS

Normal laboratory apparatus can be assumed but any instrument or special piece of apparatus or particular specification should be stated. The minimum performance of chromatographic methods should be stated in terms of the resolution of the substance to be determined from internal standard, solvent or other components. Examples of columns found to be suitable should be given.

5. SAMPLES

Statement of requirements for taking of representative samples of materials and articles for analysis. For testing with simulants the guide to the selection of conditions and methods of test is stipulated in an EN Method.

6. PROCEDURE

Statement in sufficient detail of how to carry out procedure which should include the manner of preparation of calibration curves, evaluation of data, and final determination graphically or by calculation. As quantitative extraction from materials and articles can never be fully demonstrated the method of standard addition should always be employed for calibration. For determinations of substances in food simulants an internal standard should always be employed for chromatographic procedures and calibration should be against blank food simulant fortified with the substance in question.

7. CONFIRMATION

The method of analysis must include details for confirmation of test results to be used in cases where the measured QM or SML values have been found to exceed the limits specified in Regulation EU No 10/2011 and subsequent amendments. The principle behind the confirmation step is that the technique used is sufficiently

different from that first used, that it confers additional assurance of identity and level of putative substance. Thus for example: For volatile substances where GC is employed then confirmation by GV/MS (scanning or selected ion monitoring) is appropriate polarity or derivative formation. For non-volatile substances using HPLC, confirmation can be carried out by GC/MS after formation of a suitable volatile derivative or by using at least one other HPLC column with differing separation characteristics and a different solvent system, and/or stopped-flow scanning UV or fluorescence studies.

8. PRECISION

Statement of the detection limit of the method of analysis and the limit of quantification. The analytical tolerance that will be applied to QM or SML limits will depend on the performance of the method and the calculation of a critical difference value that can only be obtained by inter-laboratory collaborative trial. However, the method should include a statement of the within-laboratory "repeatability" of the method obtained by the laboratory.

9. TEST REPORT

The test report should give the relevant information on the method used.

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6.4 *Choice of analytical method*

6.4.1 Overall migration.

As CEN standard series EN 1186 is not valid any more, they have been updated to be used in Annex 7 and 8

6.4.2 Specific migration

As CEN standard series EN 13130 concernin specific migration is not valid any more, they need an update.

The analytical approach for specific migration will be dependent on:

- the volatility of the substance(s)
- the polarity of the substance(s)
- the nature of the food or food simulant (e.g. aqueous or fatty)
- the level of determination (e.g. high or low)
- the functional groups of the substance(s) (considered to define the detection method)

The lowest specific migration limit required is 0.005 mg/kg food for FCM no 662. For a group of substances the lowest specific migration is the limit of detection of 0.01 mg/kg food, e.g. for primary aromatic amines (Annex II of Regulation) and a group of substances of similar properties behind a functional barrier. Many detectors can achieve this level, even if some concentration of the samples might be necessary. The most crucial in the case of the migrant from food contact materials has been recognised more as their extraction from the foodstuffs or food simulant and their quantification free of interferences. The Table 13 gives a generic classification of where food contact material components are more adequately analysed by one or another technique.

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Table 13 Examples of analytical approaches to determine specific migration

Type of substance	*Example*	*Predominant technique*
Volatile organics (bp< 150°C)	*Monomers, solvent residues (e.g. styrene)*	*Headspace, SPME, purge & trap and GC, with mostly FID or MS*
Semi-volatile organics (bp <300°C)	*Plasticisers, glycols, additives, MW <400-500 amu (e.g. phthalates)*	*Liquid injection (split, splitless, PTV, on-column etc) and GC with FID or MS*
Non-volatile organics	*Antioxidants, polymeric plasticisers, additives with M_W >400-500 amu (e.g. perfluorotelomers)*	*LC in majority reverse phase, with diode array, fluorescence or MS detection*
elements	*Ba, Co, Cu, Fe, Li, Mn, Zn*	*ICP-MS*

Note: GC, gas chromatography; FID, flame ionization detector; ICP, inductively coupled plasma; MS, mass detector; PTV, programmable temperature vaporizer; SPME, solid phase micro extraction; bp, boiling point, M_W, molecular mass

There are a variety of factors that influence the instrumental techniques that can be applied to the identification and the quantification of migrants from food contact materials. Among these factors, physical and chemical properties of the migrants themselves are very important. Substances used in food contact materials can range from non-polar (more often) to polar and from most volatile to non-volatile. As a common scientific consensus, substances concerned range generally up to a molecular mass of 1000 amu.

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NOTE: In general, substances with a a molecular mass higher than 1000 amu are excreted rather than metabolised above this molecular mass, and therefore are of less toxicological concern. Nevertheless any substance used in plastic FCM needs a risk assessment.

The analytical determination of migrants includes three main steps: extraction, sample clean-up if necessary and determination (mainly by chromatographic techniques). The extraction and sample clean-up depend on how much substance is expected and its characteristics with respect to those of the matrix. The aim of the clean-up is to remove and discard any substance of the food or fatty food simulant that could interfere or obscure the signal of the analytes investigated. Another purpose is to remove major food component such as protein, carbohydrates or fats, which may burden and soil the analytical equipment. The elimination of these compounds improves the quantification.

A source of analytical methods covering more than 400 methods can be found on the from the European Union Reference Laboratory for Food Contact Materials.

6.5 Characterisation of materials

6.5.1 Characterisation of materials

The characterisation of a plastic material can give valuable information on its components, such as types of monomers or specific additives, and on what migration tests could be performed.

The first step in the characterisation of a material is the analysis the food contact layer and the outer layer. The qualitative characterisation of a material is most commonly performed by Fourier Transform Infrared Spectrometry (FT-IR). The samples are scanned through a wavelength range typically from 600 to 4000 cm^{-1}. Both the polymer itself and specific functional groups of monomers and additives will give out specific characteristics and absorbances that are indicators of their respective identities. A common and user-friendly technique is the use of Attenuated Total Reflectance (ATR). The correct identification depends on the quality of the spectral libraries (either commercial or produced in-house) and the interpretation by the user.

As a next step it is recommended to prepare a microtome section of the sample and to investigate it using a transmitted light microscope with polarized light. This will allow the visualisation of the layers in the sample and to have a first clue on the possible types of material in each layer.

The third step is to separate the different layers by either peeling off or using proper organic solvents or acids. It is possible to split laminated layers by dissolving the adhesive and to split samples that contain an aluminium layer. Each layer needs proper identification.

6.5.2 Residual concentration of substances in the material

In some cases, the limits imposed in the legislation are on the maximum quantity of a substance or group of substances permitted in a material (QM) rather than a migration limit into foods. This may be because the substance is volatile and so migration testing would have large uncertainties and measurement difficulties or that the substance readily reacts with foodstuffs or food simulants and thus, cannot be measured as such after migration.

The measurement of residual content requires the complete extraction of the target substance from the polymer. This can be achieved by headspace gas-chromatography mass-spectrometry (GC-MS) analysis for volatile substances or for less volatile substances by dissolving the polymer in a strong effective solvent and re-precipitating the polymer with a solvent that would not result in the substance being incorporated into the precipitate. It is widely accepted that the solvent used should both dissolve the target compound well and also swell or dissolve the polymer matrix. Polymer swelling data are readily available in the literature, but the solubility of the selected substances in potential extraction solvents are not always available and have sometimes to be estimated as a function of the analyte and of the extraction solvent. Several

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combinations of solvent/analyte/polymer have been studied. THF for example has been used to dissolve PVC. Other extraction procedures are Soxhlet or reflux or conditions that are the most severe (as defined in the legislation). The sample preparation usually involves pre-cutting the polymer or materials into small pieces or grinding to facilitate the extraction process.

For less organic volatile substances, the solvent extraction will possibly be followed by fractionation or derivatisation. The extract is first analysed with GC-MS in SCAN mode followed by SIM (Single Ion Monitoring) mode to verify the presence of additives eventually used. The Scan mode is generically chosen to identify the largest number of substances extracted, while the SIM mode targets specific ion fragments to check the presence of specific substances. An example is an ion selection at 530 and 515 amu to check the presence of octadecyl-3-(3,5-di-tert.butyl-4-hydroxyphenyl)-propionate (FCM 433). For some non-volatile substances, liquid chromatography mass spectrometry (LC-MS) can be a good alternative to GC-MS.

In the case of inorganic compounds, the polymer is digested and analysed by e.g. ICP-MS.

CEN has also generated standardised test methods:

- EN 13130-4:2004 Part 4: Determination of 1,3-butadiene in plastics
- EN 13130-6:2004 Part 6: Determination of vinylidene chloride in plastics
- EN 13130-8:2004 Part 8: Determination of isocyanates in plastics
- CEN/TS 13130-17:2005 Part 17: Determination of carbonyl chloride in plastics
- CEN/TS 13130-20:2005 Part 20: Determination of epichlorohydrin in plastics
- CEN/TS 13130-22:2005 Part 22: Determination of ethylene oxide and propylene oxide in plastics

6.5.3 Determination of surface area

For articles for which it is unpracticle to measure the volume of food that is in contact the surface of the article, the ability to determine the surface area in contact with food is important to apply article 17.2 of Regulation (EU) No 10/2011. The inter-laboratory comparison on the determination of the contact surface area of kitchen utensils (Mieth and Hoekstra, 2013) shows that the measurement uncertainty of the determination of the surface area needs to be taken into account in the total measurement uncertainty of the analytical result.

6.6 Indications of method according to nature of chemical and matrix

6.6.1 Volatile organic substances

Clean-up from most food matrices can be achieved effectively by headspace (static or dynamic), or purge and trap sampling techniques (e.g. poly(2.6diphenyl-p-phenylene oxide). The food sample is heated and the volatile components partitioned into the headspace gas leaving the main food components behind. An aliquot of the headspace is then injected into the GC column. In some cases solid phase micro-extraction (SPME) has been applied. GC-MS is often preferred due to the possibility to monitor specific ions which lead to an unequivocal identification of the target substances. Heating time and temperature are the major variable. The major drawback of headspace GC-MS is quantification, since headspace is based on a partitioning mechanism between the gas phase and the liquid phase. Each substance almost has its own partitioning characteristic. Therefore if internal standards are used they must be very close to the target substance, so close in fact that it has been suggested that standard addition of the same substance is a better option for quantification.

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6.6.2 Semi volatile and non-volatile organic substances

6.6.2.1 Aqueous or solvent matrix

The medium must be miscible with the LC solvent or be in a solvent that can vaporized easily for GC. Interferences should be absent.

6.6.2.2 Fatty matrix

Clean-up from the matrix can be attempted in a variety of ways for fatty matrix (simulant or food)

- Selective solvent extraction; the food sample is extracted with a solvent selected to dissolve the target substance but not the main food matrix.
- Solvent-solvent partitioning; the food extract is partitioned (washed) with a second solvent to remove potential interferences.
- Size exclusion chromatography (SEC) or gel permeation chromatography (GPC) can be used to determine and isolate the fraction containing the target substances which have a molecular mass typically below 1000 amu. The food extract is passed through a bed of gel with a controlled pore size. The separation is based on molecular size, and therefore, the shape of the target molecule has an influence beyond its molecular mass. The fraction containing the target substance is collected and the remainder is discarded.
- Solid phase extraction uses disposable cartridges. The target substances are absorbed effectively on a cartridge packaged with an active support and the unwanted materials are washed off. The target substance(s) is/are then eluted by a change in solvent.

The analysis of the extract containing the target migrant(s) can then be done by GC-MS or LC-MS.

6.6.3 Inorganic substances

A number of inorganic substances are regulated for migration due to their inherent toxicity. Some additives that are organometallic in nature as well as catalyst residues are also commonly regulated by the amount of the inorganic moiety permitted to migrate. Most methods for elements are similar to those used in food safety, i.e. using atomic absorption, atomic emission with various extraction and/or digestion techniques for sample pre-treatment. If the target analytes include several elements, inductively coupled plasma (ICP) MS is then a method of choice.

6.7 Calibrants

For the verification of compliance calibrants are necessary to verify the identity of the migrant and to quantify the migrant in the polymer or food or food simulant. Commercial analytical sources should be sought first in order to have the information on the exact purity for use as analytical standards and the safety data sheets (MSDS).

6.7.1 Quality of calibrants: Identity, purity, and storage of standards

"Pure" standards of analytes should be of known purity and each must be uniquely identified and the date of receipt recorded. They should be stored at low temperature, preferably in a freezer, with light and moisture excluded, i.e. under conditions that minimise the rate of degradation. Under such conditions, the supplier's expiry date, which is often based on less stringent storage conditions, may be replaced, as appropriate for each standard, by a date allowing for storage up to 10 years. The pure standard may be retained and a new expiry date allocated provided that it is checked by the appropriate date and its purity is shown to remain

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acceptable. Ideally, the identity of a freshly acquired "pure" standard should be checked if the analytes are new to the laboratory (EU, 2013).

For screening purposes only, the "pure" standards and derived solutions may be used after the expiry date, providing that the reporting level can be achieved. If the substance has been detected, a new or certified "pure" standard and calibration solution made thereof has to be used for quantification.

Purity of a calibrant, used to prepare a standard stock solution, should be greater than 95%. In this case the weighted amount of the calibrant can be taken to calculate its concentration in the standard stock solution.

6.7.2 Instability of substances including for calibration purposes

Whenever any standard is used beyond its expiry date its stability should be verified. Existing stock and working solutions may be tested against newly prepared solutions by comparing the detector responses obtained from appropriate dilutions of individual standards or mixtures of standards. The purity of an old "pure" standard may be checked by preparing a new stock standard and comparing the detector responses obtained from freshly prepared dilutions of old and new stock standards. Inexplicable differences in apparent concentration between old and new standards must be investigated.

The means from at least three replicate measurements for each of two solutions (old and new) should not normally differ by more than ±10%. The mean from the new solution is taken to be 100%. If the mean response of the old standard differs by more than ±10% from the new, storage time or conditions must be adjusted as necessary on the basis of the results and should be checked against a second solution independently prepared from the first one. The use of an internal standard may reduce the number of replicate injections required to achieve a ±10% difference.

Analyte stability in extracts should be investigated during method validation. Storage of extracts in a refrigerator or freezer will minimise degradation but potential losses at the higher temperatures of an autosampler rack should not be ignored.

6.7.3 Calibrants with different CAS numbers

For selected substances listed in Annex I of Regulation (EU) No 10/2011 two CAS numbers are given for a single entry due to different sources. For example the two CAS numbers are given for the mixture of isomers "phthalic acid, diesters with primary, saturated C8-C10 branched alcohols, more than 60% C9" (FCM No 728) and the two CAS numbers for "phthalic acid, diesters with primary, saturated C9-C11 alcohols more than 90% C10" (FCM No 729). To ensure accurate quantification of the concentration of these substances in a given material or article or foodstuff then the calibrant used for quantification should be the same as used in the manufacture of the material or article. If information detailing which of the two CAS numbers was used in the manufacture is not available through the Declaration of Compliance then, for these two sets of substances, this can be checked by comparing the chromatographic profile of the authentic standard with that of the extracted polymer.

Other substances included in Annex I of Regulation (EU) No 10/2011 for which more than one CAS number is given are:

FCM No.	Substance
110	α-tocopherol
551	poly(ethylenepropylene)glycol
598	calcium sulphoaluminate
728	phthalic acid, diesters with primary, saturated C8-C10 branched alcohols, more than 60% C9

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729 phthalic acid, diesters with primary, saturated C9-C11 alcohols more than 90% C10

752 bis(methylbenzylidene)sorbitol

790 poly(6-morpholino-1,3,5-triazine-2,4-diyl)-[(2,2,6,6-tetramethyl-4-piperidyl)imino)] hexa-methylene-[(2,2,6,6-tetramethyl-4-piperidyl)imino)]

999

1000 6.7.4 Calibrant with lower quality

1001 Some substances are not commercially available at sufficient purity, e.g. it is a mixture or it
1002 originates from a petitioner or an industrial source. Where a calibration standard is a mixture of
1003 isomers of the analyte, or has no CAS number, the detector response generally may be assumed
1004 to be similar, on a molar basis, for each component. The presence of interferences can be
1005 checked by using different analytical columns.

1006 Technical substance with a purity lower than 50% are not sufficient. In such a case, a clean-up
1007 step should be considered, except when the purity (of e.g. 30 %) is certified by the producer.

1008 **How to handle a calibrant with lower quality**.

1009 If it is not possible to get a calibrant in such a high quality the weighted amount used to prepare
1010 a standard stock solution needs to be corrected.

1011 M = m*P/100

1012 M = corrected mass in mg

1013 m= weighted amount of calibrant in mg

1014 P= GC-FID purity in (%)

1015

1016 Therefore the determination of the purity is necessary. That can be done in several ways:

1017 1) Identification and quantification of the impurities (exact method)

1018 2) Determination of the gas chromatographic purity by GC-FID

1019 3) HPLC

1020 4) NMR

1021 Since the first option is not always feasible the second option is broadly accepted. The GC purity
1022 (P) is defined as the quotient of the peak area of the calibrant and the total peak area (sum of
1023 peak areas of all peaks observed in the chromatogram except the solvent peak).

1024 P [%]= A*100/T

1025 A: peak area of the calibrant

1026 T: sum of peak areas of all peaks observed in the chromatogram except the solvent peak

1027 Note

1028 One should inject a solution of the calibrant under such conditions so that the calibrant peak is in
1029 about 75 to 90% of the scale. This can be achieved by setting concentration, sensitivity, range, split
1030 ratio and attenuation collectively.

1031 6.7.5 Substance without a CAS number

1032 Substance without CAS number have to be treated as in the sections before. Having an CAS
1033 number or not does not say anything about the purity of the substance.

1034 6.7.6 Quantification

1035 Where practicable, each detection system should be calibrated with all the targeted analytes for

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every batch of analyses. If this requires a disproportionately large number of calibrations, the determination system must be calibrated with a minimum number of representative analytes. Representative analytes must be chosen very carefully, to provide enough evidence that acceptable performance is achieved for all other analytes. The choice should be made according to the probability of finding the substance in the sample and the physico-chemical characteristics of the analytes i.e. analytes likely to give similar response factors than the target substance.

6.8 Method performance

When carrying out an analysis to determine the overall or specific migration from a plastic material or article or when determining compliance with any other restriction in the legislation it is important that any methods used are of suitable quality and that the performance of the methods used meets defined method performance criteria. Parameters to be determined to demonstrate the applicability and suitability of an analytical method for purposes of official controls include: selectivity for the analyte(s) of interest, stability of the analyte throughout the migration phase as well as the subsequent analysis, repeatability, reproducibility, recovery, working range, linearity of the calibration, limit of detection, limit of quantification, robustness and measurement uncertainty associated with the test result. These parameters and approaches to method validation are described in EU Report EUR 24105 EN which was prepared by the EURL-NRL network of laboratories: Guidelines for performance criteria and validation procedures of analytical methods used in controls of food contact materials (Bratinova et al., 2009).

6.8.1 Expanded measurement uncertainty

In the context of food contact materials, important sources of error are measuring the surface area of the test specimen, the performance of the migration test, and the quantification of the migrant in the food (simulant), each of them adding to the measurement uncertainty.

6.8.1.1 Overall migration

Analytical tolerances, i.e the expanded measurement uncertainty, associated with a given method may be determined during method validation taking into account the repeatability and reproducibility characteristics of the method. Analytical tolerances associated with the overall migration tests are no longer included in EU legislation. The tolerances are included in CEN standards. Although these standards have not been updated, the migration tests essentially remain the same (consisting of two parts - the contact of the test specimen with the food simulant and the analytical determination part) and so the established tolerances.

When establishing the overall migration methodology the laboratory has to validate the method and has to demonstrate its capability to comply with the analytical tolerances.

Aqueous food simulants

The following analytical tolerances are allowed: 12 mg/kg food or 2 mg/dm^2 for all aqueous food simulants and food simulant D1. The test result for each individual test specimen is valid if it differs from the mean of the triplicate test results by not more than the permitted analytical tolerance. If a minimum of three results is not within the analytical tolerance, then the test is repeated using fresh test specimens from the sample. If this repetition also does not meet the criteria, sample inhomogeneity may be the cause and shall be checked with the supplier.

Fatty food simulants for single use applications

The following analytical tolerances are allowed: 20 mg/kg food or 3 mg/dm^2 for all fatty food simulants and substitute test media. The tolerances are valid also after application of a reduction factor to the results of the test. If a reduction factor does not apply, valid results above 10 mg/dm^2 shall not differ by more than 30 % from the mean of the set of results.

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The determination of overall migration into the fatty food simulant is normally carried out in quadruplicate to allow three valid results to be obtained even if one determination is discarded. Where four results have been obtained from four determinations i.e. no single determination has been rejected because of an obvious manipulative error, all four results are valid if each individual result differs from the mean of the four results by not more than the analytical tolerance. If one of the four results is greater or less than the mean by an amount more than the analytical tolerance, then this result can be rejected and the mean recalculated on the remaining three results. If two results are greater or less than the mean by amounts more than the analytical tolerance, the result with the largest difference from the mean can be rejected and a new mean calculated from the remaining three results. The remaining three test results are valid if they are within the analytical tolerance. If a minimum of three results do not meet the above criteria of being within the analytical tolerance, then the test shall be repeated using fresh test specimens from the sample.

Fatty food simulants for repeated use applications

When repeated testing is used to determine the overall migration into a fatty food simulant the individual results for each set of the determinations (M1, M2 or M3) shall be deemed valid if at least three results are obtained in each set which do not differ from the mean for that set by more than 30% for results above 10 mg/dm² or by more than 3 mg/dm² for results below 10 mg/dm². Results which exceed this tolerance shall be discarded according to the procedure given for single use applications above.

6.8.1.2 Specific migration and determination of residual content

For those methods where there are no expanded measurement uncertainties set, such as for specific migration and determination of the residual content in the material, the "standard level" validation scheme described in Bratinova et al. (2009) should be followed. This document also describes approaches to determine expanded measurement uncertainty and is summarised below. The expanded measurement uncertainty (U) is a parameter associated with the result of a measurement that characterizes the dispersion of the values and could be regarded as a single expression of the accuracy of the analytical method.

Results should be expressed as:

$x \pm U$

where:

x = measured value

U = expanded uncertainty

The expanded uncertainty (U) can be calculated by multiplying the combined standard uncertainty (uc) by a factor k that associates to the uncertainty a determined

level of confidence.

$$U = k \cdot uc$$

A simplification is given by using k=2, which gives a level of confidence of about 95%.

When the test result is close to the legislative limit, it is crucial that the reported result is given with the measurement uncertainty to assess compliance.

It should be noted that the expanded measurement uncertainty refers only to the analytical measurements, performed on homogenous samples, and do not account for the possible inhomogeneity between samples (e.g. inhomogeneity has been found sometimes in replicate specimens of samples such as cutlery and dishes). The uncertainty due to inhomogeneity is normally greater than the expanded measurement uncertainty of the analytical measurement.

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6.8.2 Quality assurance

As with any analysis for compliance testing appropriate analytical quality assurance samples should be included in each batch, i.e. solvent blanks, procedural blanks, certified or other well characterised reference materials and/or spiked samples should be tested alongside the samples. Methods should include internal standards at best or external standardisation at worst, and care must be taken in avoid either loss of target volatile migrants or contamination, which can occur with ubiquitous substances such as some phthalate diesters.

The determination of compliance with SML, OML, QM and QMA restrictions requires various procedural steps e.g. sampling, migration tests with different experimental conditions (OML, SML) or extraction (QM, QMA) as well the analytical determination. Each of these steps is subject to certain variability and the overall variability will affect the value found by one laboratory (repeatability) or by more than one laboratory (reproducibility) when testing the same sample.

Official control laboratories are required to participate in inter-laboratory comparison exercises in order to check their analytical performance in an independent way.

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7 Reporting of the final migration test result

Several issues are involved in the reporting of the final migration test result and these will be addressed in this chapter:

1. correction for the difference between the experimental and worst case real contact surface to volume ratio
2. correction by the food simulant D2 reduction factor (DRF)
3. correction by the fat reduction factor (FRF)
4. expression of results and the selection of units
5. measurement uncertainty

Furthermore, in the interpretation of the results when comparing with migration limits, other issues such as the type of testing and the uncertainty of the measurement must be considered and are dealt with in this section.

Before comparing specific and overall migration test results with the migration limits, three corrections as mentioned above may apply in accordance with certain rules set out in the Regulation (EU) No 10/2011. This chapter also guides for the minimum information to be included in the analytical test report and gives information on quality assurance in official controls.

NOTE: density of food simulants. When comparing the results of the migration tests with the legislative limits, the specific gravity of the food simulants is conventionally assumed to be 1. Therefore the migration measured in milligrams of substance(s) released per litre of food simulant (mg/L) corresponds to milligrams per kilogram of food simulant and to milligrams per kilogram of food. The convention is that 1 kg food simulant is 1 kg food.

NOTE: For the expression of the migration results of a salt permitted under the derogation provided by Article 6(3)(a), the molar mass of the acid, alcohol or phenol or the cation needs to be used for this purpose. The risk assessment is based on the acid, alcohol or phenol or the cation and therefore only that mass should be used to determine compliance against the SML.

7.1 Correction of the migration test result for the surface-to-volume ratio from experimental to actual contact

The migration test results expressed in mg/kg must be corrected when the migration test has been performed under a different surface-to-volume contact ratio (S/V) than the foreseen or actual S/V. Correction for the S/V ratio does not apply in OM testing since results are expressed in mg/dm^2. This is the case, for instance, when tests are carried out on samples taken from the material or article or on samples manufactured for the purpose, and these samples are placed in contact with quantities of foodstuff or simulant that differ from the foreseen or actual S/V. This is always the case for materials and articles that are intended for contact with food for children.

NOTE: if the article has multiple uses then the final result needs to reflect the worst case foreseeable or actual contact surface-to-volume ratio.

The experimental migration test result shall be corrected by applying the following formulas:

$$M_{S/V} = m \times a_2 \times 1000/(a_1 \times q)$$

where:

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$M_{S/V}$ is the migration in milligrams per kilogram; M is the mass in milligrams of substance released by the sample determined by the migration test; a_1 is the surface area in square decimetres of the sample in contact with the food simulant/food during the migration test; a_2 is the surface area in square decimetres of the material or article intended to come into contact with foodstuff in real conditions of use; q is the quantity in grams of foodstuff in contact with the material or article in real conditions of use

or alternatively:

$$M_{S/V} = M_{test} \times S/V_{(actual)} / S/V_{(test)}$$

where:

$M_{S/V}$ is the migration in milligrams per kilogram; M_{test} is the mass in milligrams of substance per kg of food/food simulant released by the sample determined by the migration test; $S/V_{(actual)}$ is the surface to area ratio (dm^2/kg food) of the sample in contact with the food simulant/food under real conditions of use. $S/V_{(test)}$ is the surface to area ratio (dm^2/kg food) of the sample in contact with the food simulant/food during the migration test.

For some articles the migration test result is not corrected by the foreseen or actual S/V but by the S/V of the standard food cube of 6 dm^2/kg food. This is valid for the following articles:

- articles that are fillable and have a volume less than 500 ml or higher than 10 L.
- sheets and films that are not yet in contact with food
- sheets and films already in contact with food but only for a volume less than 500 ml or higher than 10 L
- for which it is not practical to estimate the relationship between the surface area of that article and the volume of food in contact therewith

the two formulas of above become then

$$M_{S/V} = m \times 6 / a$$

where:

$M_{S/V}$ is the migration in milligrams per kilogram; m is the mass in milligrams of substance released by the sample determined by the migration test; a is the surface area in square decimetres of the sample in contact with the food simulant/food during the migration test.

or alternatively:

$$M_{S/V} = M_{test} \times 6 / S/V_{(test)}$$

where:

$M_{S/V}$ is the migration in milligrams per kilogram; M_{test} is the mass in milligrams of substance per kg of food/food simulant released by the sample determined by the migration test; $S/V_{(test)}$ is the surface to area ratio (dm^2/kg food) of the sample in contact with the food simulant/food during the migration test.

7.2 food simulant D2 reduction factor

The food simulant D2 reduction factor (DRF) compensates for the higher extraction power of food simulant D2 in comparison with certain fatty foods and applies to both, overall and specific migration test results (section 4.2 of Annex V). The DRF cannot be applied to other food

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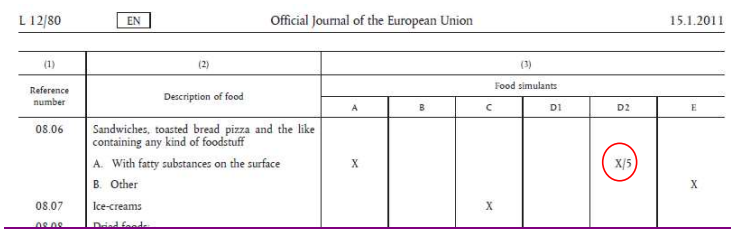
simulants than D2, but can be applied with alternative and screening food simulants replacing food simulants D2. The value of the DRF for various food categories are given in sub-column D2 of Table 2 of Annex III.



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(1)	(2)	(3)					
Reference number	Description of food	Food simulants					
		A	B	C	D1	D2	E
08.06	Sandwiches, toasted bread pizza and the like containing any kind of foodstuff						
	A. With fatty substances on the surface	X				X/5	
	B. Other						X
08.07	Ice-creams			X			
08.08	Dried foods						

Figure 3 A selected copy of Table 2 of Annex III showing a DRF of 5 for sandwiches with fatty substances on the surface

The DRF is a value between 1 and 5 by which the migration test result shall be divided before comparing with the migration limit:

$M_{DRF}=M_{S/V}$ / DRF

Where:

M_{DRF} is the overall or specific migration corrected by the DRF, in mg/dm² or mg/kg food; $M_{S/V}$ is the experimentally determined migration, possibly corrected to the foreseeable or actual S/V.

In contrast to the old legislation, the DRF can now be applied to specific migration of lipophilic substances from materials where the total mass of the substance migrated into food simulant D2 is higher than 80% of the mass of the substance in the finished materials or article.

This section is not applicable for substances

- behind a functional barrier,
- with a specific migration limit "*not detectable*"
- migrating from a cap, gasket, stopper or similar sealing article, for which the intended use is unknown.

Example 1

The overall migration found into food simulant D2 of a plastic material intended to package sandwiches with fatty substances on the surface is 15 mg/dm². Since the food category is 08.06 and a reduction factor of 5 is applicable, the final migration result would be 15/5 = 3 mg/dm², and therefore below the restriction limit of 10 mg/dm².

7.3 Fat Reduction Factor

The Fat Reduction Factor (FRF) takes into account the fact that the ingestion of fat per day by an adult, is 200 g instead of 1 kg which is the reference for setting the specific migration limits. The FRF applies only to the specific migration of certain lipophilic substances, when the food in contact or intended to be in contact contains more than 20% fat (Annex V, Section 4.1). The correction of the migration test result by the FRF is applicable when the following conditions are fulfilled:

- migration test result is obtained in food, food simulant D and, D2.and in alternative and screening food simulants replacing food simulant D2.

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- the substance is indicated as "yes" in column 7 of Annex 1
- the food intended to be in contact has a fat content >20%
- the food intended to be in contact is not for infants and young children (< 3 years).
- it is not an article for which the relationship between the surface area and the quantity of food in contact cannot be estimated (Art. 17.2(b))
- the surface-to-volume corrected specific migration value in food is not above the generic specific migration of 60 mg/kg food (this guarantees that the overall migration limit in food is not exceeded)

The following formula is used to estimate the FRF:

FRF = (g fat in food/kg of food)/200 = (% fat × 5)/100.

The fat content can be taken from the labelled food declaration. The value of the FRF is in the range of 1-5, and the specific migration shall be divided by the calculated FRF before comparing with the specific migration limit:

$M_{FRF}=M_{S/V}$ / FRF

Where:

M_{FRF} is the specific migration corrected by the fat reduction factor, in mg/kg food; $M_{S/V}$ is the experimentally determined migration, possibly corrected to the foreseeable or actual S/V; FRF is the calculated fat reduction factor, with a maximum value of 5.

Example 2

the concentration of the substance FCM No 433 (SML = 6 mg/kg food), found in a migration test of a plastic article in food simulant D2 was 8 mg/kg food. The article with a food contact surface of 4 dm^2 is intended to contain 500 g of mayonnaise (food category 08.04) with a fatty content of 73%. The S/V in the migration test was 0.6 dm^2/100 ml food simulant.

Taking into account the requirements mentioned above, the FRF is applicable. The experimental migration result is first corrected to the real in use S/V ratio: M = 8 x (4/0.5)/6 = 10.7 mg/kg food. Then the FRF is calculated and the S/V corrected migration result is divided by the factor: FRF = (73 x 5)/100 = 3.65; M_{FRF} = 10.7/3.65 = 2.9 mg/kg food. The sample would be compliant for that intended use.

Example 3

The concentration of the substance FCM No 797 (SML (T) = 30 mg/kg food (group restriction no 31; SML (T) = 60 mg/kg food (group restriction no 32) found in a migration test of an elastomer type gasket in food simulant D2 was 65 mg/kg food. The gasket is intended to seal a 500 g container (diameter = 7 cm; height = 14 cm; S/V=6.4 dm^{-1}) for mayonnaise (08.04B; DRF=1) with a fatty content of 73%. The S/V in the migration test was the same as in real use. The overall migration test resulted in 14 mg/dm^2 tested under real S/V conditions.

The FRF is calculated to be 3.65. For a gasket with a known use the results need to be expressed based on the actual food content. The SM of FCM No 797 is calculated to be 65/1/3.65 = 17.8 mg/kg food which is compliant with both its SMLs. However, since the overall migration minus the analytical tolerance of 3 mg/dm^2 under real conditions is above the limit, the gasket is not compliant. If the overall migration test would have resulted in 11 mg/dm^2 then the gasket would have been compliant.

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7.4 Combination of correction factors, DRF and FRF, in specific migration

When testing the specific migration of a lipophilic substance, indicated in column 7 of Annex I of the Regulation, in food simulant D2, both DRF and FRF may be applicable if the conditions indicated under paragraphs 7.2 and 7.3 above are fulfilled (Annex V, Section 4.3). In this case, a total reduction factor (TRF) is estimated multiplying both factors, DRF and FRF. The resulting factor, with a maximum value of 5, is used to divide the specific migration result before comparison with the migration limit:

$TRF = DRF \times FRF \leq 5$

$M_{TRF} = M_{S/V} / TRF$

Where:

M_{TRF} is the specific migration corrected by the total reduction factor, in mg/kg food; $M_{S/V}$ is the experimentally determined migration, possibly corrected to the S/V applicable; DRF is the correction factor for food simulant D2; FRF is the fat reduction factor; TRF is the total reduction factor and cannot be higher than 5.

Figure 4 shows an overview of all the corrections applied to the specific migration test result. This overview is not valid for articles such as caps, gaskets, stoppers and similar sealing articles, when their intended use is unknown (Hoekstra et al., 2011). A calculator for the correction of the experimental specific migration for comparison with the legislative limit is available (Petersen and Hoekstra, 2011).

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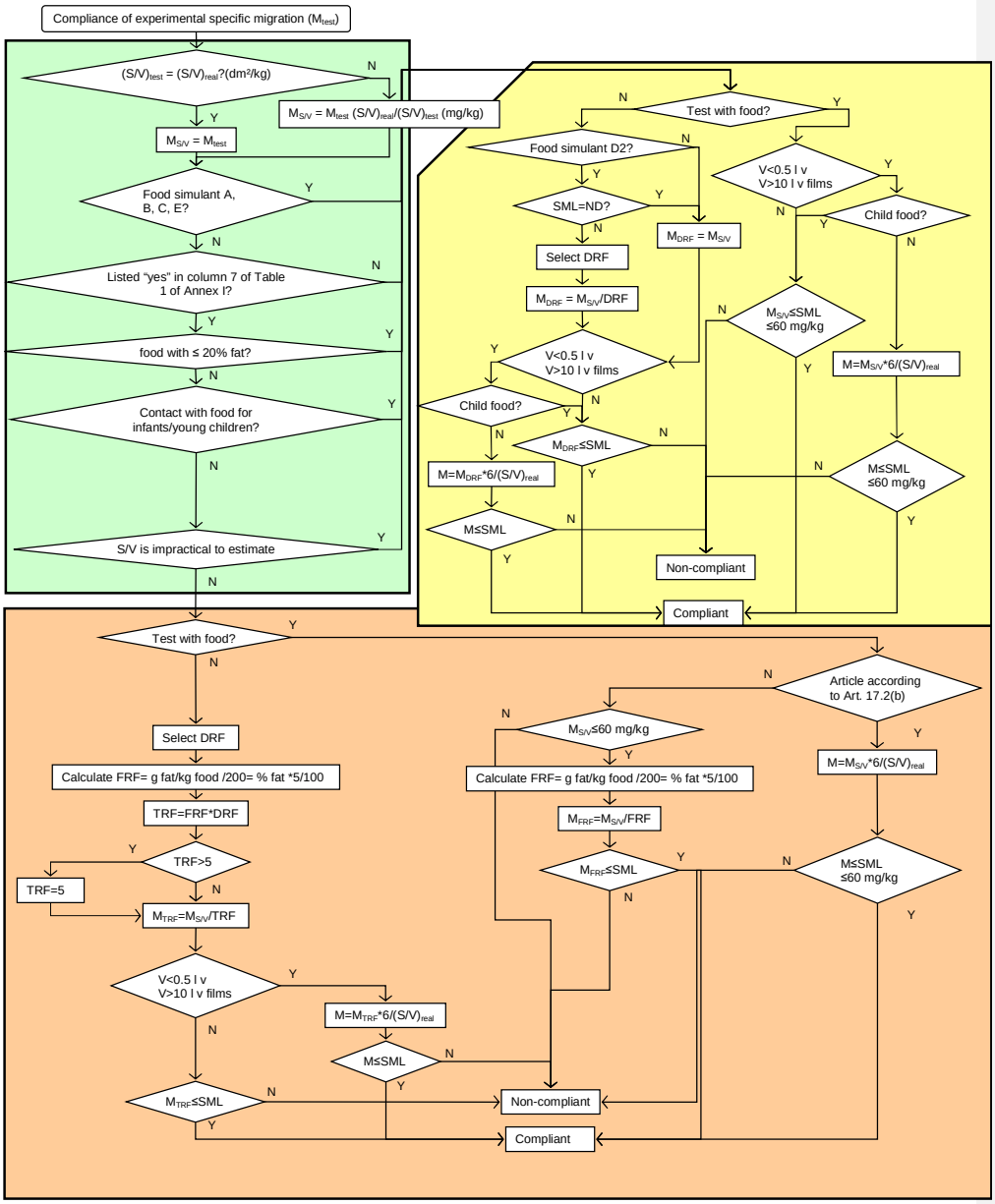

Figure 4 **overview of the corrections applied to the specific migration test result. This overview is not valid for articles such as caps, gaskets, stoppers and similar sealing articles, when their intended use is unknown. DRF, food simulant D2 reduction factor; FRF, fat reduction factor; M_{test}, specific migration determined in test; (mg/kg food); $M_{S/V}$, specific migration corrected for.$(S/V)_{real}$; M_{TRF}, migration corrected for S/V-ratio and TRF, M_{DRF}, migration corrected for S/V-ration and DRF; M_{FRF}, migration corrected for S/V-ration and FRF; M specific migration (mg/kg food); N, no; ND, not detectable; S, contact surface (dm^2); $(S/V)_{real}$, surface-to-volume ratio of food in contact with material/article; $(S/V)_{test}$, surface-to-volume ratio of food simulant in test; SML, specific migration limit (mg/kg food); TRF, total reduction factor (DRF * FRF ≤ 5); V, volume of article (litre); Y, yes. (Hoekstra et al., 2011)**

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7.5 Choice of units for migration test results

Plastics Regulation EU No 10/2011 has introduced different units for the expression of migration test results (Art. 17). The selection of the units depends on whether

- the result originates from an overall or specific migration test.
- the article is a cap, gasket, stopper or similar sealing article. or not
- the intended use of the article for the type of food(s) is known or not,
- the article is used for children's food or not

The following two sections describe the expression of migration test results for both overall and specific migration.

7.5.1 Overall migration

Overall migration is a measure of the inertness of the material and the results should be reported in mg per unit of food contact surface area: mg/dm² (Art. 12). Figure 5 depicts a flowchart that leads to the proper unit for an overall migration test result. The main rule holds for articles that are not caps, gaskets, stoppers or similar sealing materials and that are not intended to be in contact with food for children (0-3 years). In this case the migrated amount of substances is related to the actual or foreseen surface area of the article in contact with food. There are three exceptions on this general unit:

- Articles that are not caps, gaskets, stoppers or similar sealing materials and are intended to be in contact with food for children (0-3 years) (Art. 12.2)
- caps, gaskets, stoppers or similar sealing materials for which their intended use is known (Art. 17.4(a))
- caps, gaskets, stoppers or similar sealing materials for which their intended use is not known (Art. 17.4(b))

For the article that is not a cap, gasket, stopper or similar sealing material and that is used for contact with food for children the unit for the overall migration test is mg per unit of mass of food that is foreseeable as actual content.

Example 4

The value of overall migration of a material has been estimated in 2 mg/dm². It is intended to be used in contact with food for infants and young children at a S/V ratio of 2 dm²/250 g food. Then, the actual S/V in use is 8 dm²/kg food. The recalculated overall migration result is 16 mg/kg.

Example 5

The value of overall migration of a material has been estimated in 2 mg/dm². When the actual S/V is unknown, e.g. for a film, and the article is intended for infants and young children, the result shall be estimated assuming a S/V of 6 dm²/kg food, and this shall be indicated. The recalculated overall migration result is 12 mg/kg food. For verifing compliance with the overall migration limit, the user of the film shall correct the overall migration result for the actual S/V in use, if different from 6 dm²/kg food.

In the particular case of caps, joints, gaskets, corks and other closing systems, results are expressed in:

- mg/dm², applying the total contact surface (article + sealing article), if the intended use is known
- mg/article, if the intended use is unknown.

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This provision is based on the assumption that the migration from a small closure with a small surface would contribute only to a limited extent to the total migration of a substance into the food contained in the closed article. It is also why there is no special rule for being in contact for food for children. Therefore, it would not apply for those lids having a comparable contact surface to the container; in such a case the article should be treated in the same way as the container itself and the result expressed in mg/dm² applying only the lid contact surface. Figure 7 depicts some examples of closing systems that are considered as cap or not.

Example 6

The value of overall migration of a cap with 0.12 dm² contact surface has been estimated to be 1 mg/dm². the cap is intended for a 1 L milk bottle, the contact surface of which is 6 dm². The result of the cap is calculated taking into account the total contact surface of 6.12 dm² and would be 0.12 mg / 6.12 dm² = 0.020 mg/dm².

Note: for the verification of overall migration compliance of the combined articles, the contribution of both, cap and bottle, must be considered. For Example 6, assuming a migration of 5 mg/dm² from the bottle, the total overall migration is 0.02 + 5 = 5.02 mg/dm².

Example 7

The value of overall migration of a cap with 0.12 dm² contact surface has been estimated to be 1 mg/dm². The intended use is unknown. The result is expressed as 0.12 mg/article.

Note: The user of the cap in Example 7 shall follow Example 6 and its note in order to verify the overall migration compliance of the cap combined with the bottle or container for its intended use. The DRF shall be applied to the overall migration test result if applicable.

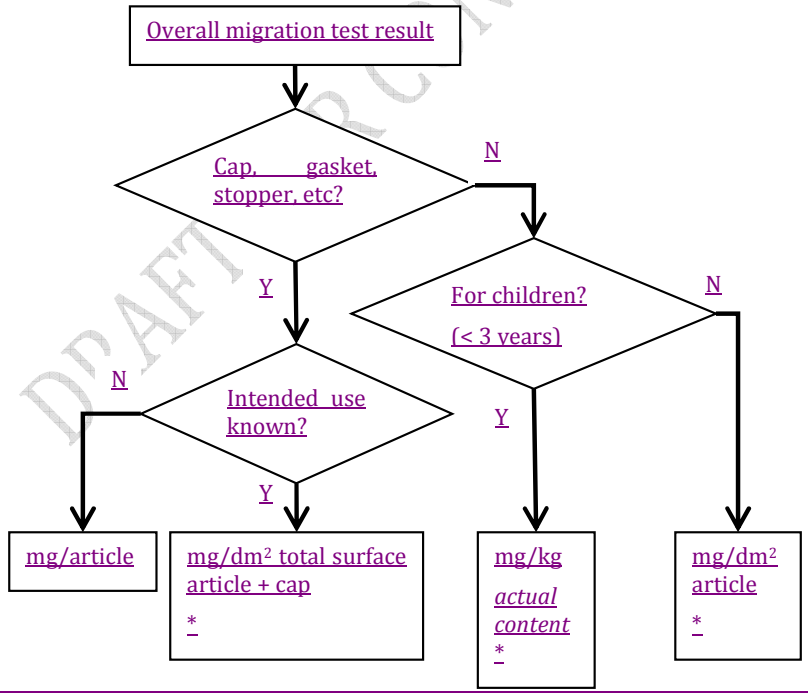

Figure 5 Reporting units for the overall migration depending on several criteria. N, no; Y, yes; * DRF may be applicable

OML compliance for food intended for infants and young children.

Article 12.2 provides that the OML is 60 mg/kg food if the plastic material and article is used in contact with foods formulated for particular nutritional use by infants and young children up to 3 years of age. The main clarification that is needed in this context, is that the wording is intended to imply that the actual surface/volume ratio of the package is considered instead of the conventional 6 dm^2/kg. However when the actual surface/volume ratio is less than 6 dm^2/kg it is certainly acceptable to do the compliance assessment assuming 6 dm^2/kg.

This has implications for OML compliance as the testing is done on a surface basis for most materials and articles, following the methods given in Annex 7 and 8. A problem then arises when the surface/volume ratio is very high, as explained in the following example.

Example 8

OML compliance is investigated for a package containing a 100 g portion of infant food in 3.5 dm^2 of packaging material. The actual surface/volume ratio is 35 dm^2/kg food. The overall migration in food simulant D2 is determined to be 1.5 mg/dm^2. The following considerations need to be made:

- *Upon first inspection it would appear that the material is in compliance with the OML as 1.5 mg/dm^2 x 35 dm^2/kg = 52.5 mg/kg and this is less than the 60 mg/kg limit. However this ignores the analytical tolerance..*
- *The analytical tolerance on an OM result in oil is 3 mg/dm^2. The test result is therefore 1.5 ± 3 mg/dm^2 and the 'fail limit' for the OML (assuming no reduction factor applies) is 10 + 3 = 13 mg/dm^2. Now 4.5 mg/dm^2 x 35 dm^2/kg food = 157.5 mg/kg food is higher than 13 mg/dm^2 x 6 dm^2/kg food=78 mg/kg food and therefore the article is not compliant.*
- *This example so far has considered only a single test result. For any material repeatedly manufactured there will be some variation on the test results that would be obtained if each batch were to be tested. Therefore some extra safety margin should be taken into account or else a statistical control of the OM results undertaken.*

From the calculation outlined in **Example 8**, it follows that even when the OM test result is 0.0 mg/dm^2, there is a limit on the surface/volume ratio that can be complied with on the basis of a 60 mg/kg food migration limit. For testing in aqueous food simulants where the analytical tolerance is 2 mg/dm^2, the upper OML is 12 x 6 = 72 mg/kg food. For testing in oil the upper OML is 13 x 6 = 78 mg/kg food.

This problem does not arise for foods for which the Regulation provides only food simulant E, or no food simulant at all, as these foods do not need to be tested for OML.

7.5.2 Specific migration

Specific migration limits should be reported in mg/kg food (Art 17.1 and 2). The surface-to-volume may differ being either the foreseeable or actual one or the standard food cube of 6 dm^2/kg food (Figure 6).

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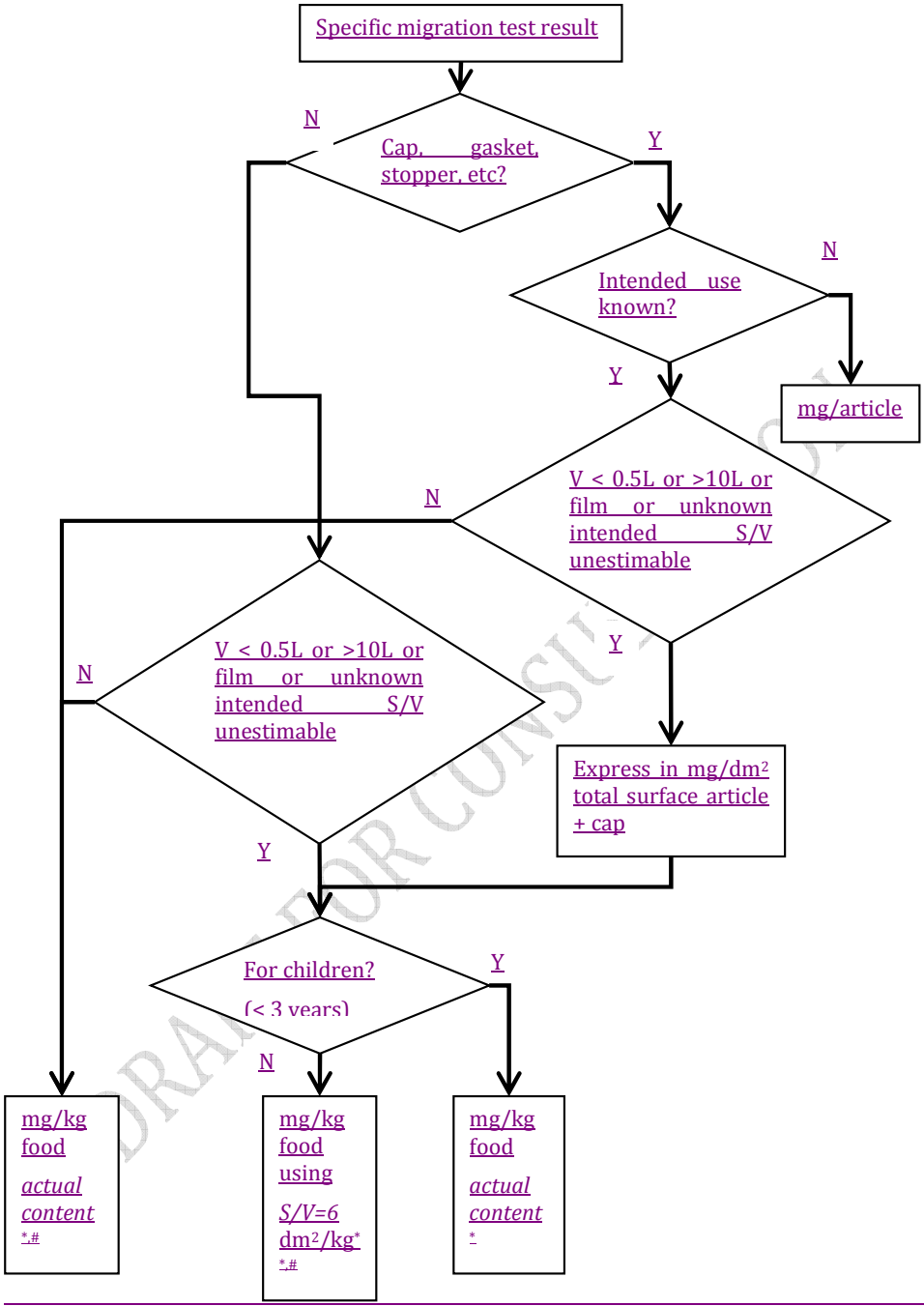

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1474 **Figure 6 Reporting units for the specific migration depending on several criteria.* DRF may be**
1475 **applicable provided restrictions section 4.2 in Annex V; # FRF may be applicable**
1476 **provided restrictions section 4.1 in Annex V**

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1478 Example 9

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The experimental specific migration of an additive from a plastic container has been estimated to be 1 mg/kg food. The article was tested by filling, under actual S/V ratio.

a) the container has a volume of 200 ml with 1.5 dm^2 contact surface. The S/V ratio during testing (by filling) was 1.5/0.2 = 7.5 dm^2/kg food. Since the article has a volume below 500 ml, the experimental value must be corrected for the S/V ratio of 6 dm^2/kg food, for comparison with the migration limit: (1 x 6)/7.5 = 0.8 mg/kg food.

If the container is intended for food for infants and children (<3 years), the real S/V contact conditions applies and the experimental result is directly compared with the specific migration limit.

b) the container has a volume of 500 ml with 3.5 dm^2 contact surface. The S/V ratio during testing (by filling) was 3.5/0.5 = 7 dm^2/kg food. Since the article has a volume of 500 ml, results are expressed taking into account the real in use S/V ratio (same as those used in testing); therefore, no correction of the experimental results is needed.

For caps, gaskets, stoppers and similar sealing articles, results are expressed in (Art 17.3):

- mg/dm^2, applying the total contact surface (article + sealing article) or mg/kg food actual content, if the intended use is known. If the article is to be used with a container intended for infants or small children, the results must be expressed in mg/kg food
- mg/article, if the intended use is unknown.

When the intended use of the closing system is known, the results are calculated as follows:

- If the container of the closing system is intended for a volume <500 ml or >10 L, the migration is calculated on the basis of the total contact surface, in mg/dm^2, in the same way as for the overall migration (see Example 6). With regards to comparison with the specific migration limit, the estimated valued in mg/dm^2 shall be first multiplied by 6, and corrected for applicable reduction factors.
- If the container of the closing system is intended for a volume ≥500 ml and ≤10 L, the migration is related to the actual food mass and the obtained value in mg/kg food is compared (after applying the possible correction factors) against the specific migration limit.
- If the closing system is for a container intended for food for children (≤ 3 years), the specific migration test result can only be calculated in mg/kg food related to the actual food mass content.

Example 10

The specific migration of an additive from a cap with 0.12 dm^2 contact surface has been estimated to be 0.12 mg/article.

a) the cap is intended for a 0.5 L milk bottle with a contact surface of 3.5 dm^2. The specific migration is related to the intended food mass of the container: 0.12 mg/0.5kg = 0.24 mg/kg food

Note: for the verification of the specific migration compliance of combined articles, the contribution of both, cap and bottle, must be considered. For example, assuming a migration of 0.4 mg/kg food (same additive) from the bottle, the total specific migration would be 0.24 + 0.4 = 0.64 mg/kg food. Correction factors (DRF and FRF) shall be applied to the migration test result if applicable, before comparison with the restriction limit.

b) the cap is intended for a 0.3 L milk bottle (not specifically intended for children under 3 years) with a contact surface of 3 dm^2. The specific migration is calculated taking into account the total contact surface (cap + bottle) of 3.12 dm^2: 0.12 mg/3.12 dm^2 = 0.038 mg/dm^2. This would be equivalent to 0.038 x 6 = 0.23 mg/kg food for comparison with the SML.

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Note: as in the example above, for the verification of the specific migration compliance of combined articles, the contribution of both, cap and bottle, must be considered, and possible reduction factors applied.

c) the intended use is unknown. The result is expressed as 0.12 mg/article.

Note: The user of the cap in Example 10c shall follow Example 10a and b and their notes in order to verify the specific migration compliance of the cap combined with the bottle or container for its intended use. The DRF and FRF shall be applied to the specific migration test result if applicable.

This provision is based on the assumption that the migration from a small closure with a small surface would contribute only to a limited extent to the total migration of that substance into the food contained in the closed article. Therefore, it would not apply for those lids having a comparable contact surface as the container; in such a case the article should be treated in the same way as the container itself and the result expressed in mg/dm^2 applying only the lid contact surface. This approach of lids also applies to small parts with small surface area in contact with the total mass of food in assembled products.

In Figure 7, some examples of closing systems are shown and the part of legislation applicable to them is indicated.

Figure 7 Examples for different closing and sealing systems whether they are considered as cap/sealing (Art 17.3 and 17.4) or not (Art. 17.2)

7.6 Minimum information in the test report

The test report should contain, as a minimum, the following:

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- Identification of the sample (i.e. consignment number, batch number, sample number);
- All information necessary for complete description of the sample, e.g. chemical
- type, trade mark, grade, dimensions, shape etc – pictures should be included together with a ruler.
- Date and method of sampling;
- Name of laboratory; Name of person responsible for analysis; Date of report;
- Analyte(s); A reference to the method(s) used.
- The type of the migration test (i.e. immersion or article fill, number of contacts);
- The duration and temperature;
- The surface area exposed and volume of food simulant used;
- The individual test results, expressed in the correct units. Expanded *measurement uncertainty should be reported*
- Any relevant comments on the test results;
- Details of any confirmation procedure(s), if any.
- Any deviations from the standards

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7.7 Interpretation of the results. Assessment of compliance with migration limits

Several aspects shall be taken into consideration in the interpretation of test results and assessment of compliance with the migration limits.

From an enforcement point of view, the individual test result minus the analytical uncertainty (expanded uncertainty of measurement) must be above the legislative limit, to deem a sample non-compliant. This is valid for both overall and specific migration.

For official controls of large batches of materials or articles it may difficult to prove statistically that the three samples taken for a certain compliance check, are representative for the whole batch. If the relative standard deviation of the average of the three results is reasonable low and one of the results is above the limit value it is reasonable to request the supplier to prove that their batch is compliant.

NOTE There are cases known where aging of materials has an influence on the migration. For example an article was compliant after production, but testing after one year showed non-compliance. These technical guidelines on compliance testing do not cover aging effects since it is considered as part of GMP, documentation of compliance and supporting documentation.

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