Review of the Industry Guideline for the Compliance of Paper & Board Materials and Articles for Food Contact

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Copies of two Peer Reviews of the Industry Guideline for the Compliance of Paper and Board Materials and Articles for Food Contact conducted by PIRA International and commissioned by CEPI, the Confederation of European Paper Industries.

PART 1: Peer review of the Industry Guideline pre-publication version (2009)
PART 2: Updated review of the Industry Guideline as amended (2010)

Pira Review Report

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0. Executive Summary

Pira have reviewed version pre4 of the Industry Guideline for the Compliance of Paper & Board Materials and Articles for Food Contact and carried out a comparison of these Guidelines with Council of Europe Resolution RESAP (2002) on Food Contact Paper/Board and also with the national legislation that is currently in place in Germany, the Netherlands, France and Italy. The aim of the review was to assess how effective each of these systems are in implementing for paper/board the requirements of the EC Framework Regulation on Materials and Articles in Contact with Foods (EC Regulation 1935/2004).

The four sets of national legislation reviewed all aim to ensure compliance with the Framework regulation. However, in our opinion, none of them fully meet these requirements, with the most significant gaps relating to how they treat recycled fibres, multilayer structures and the lack of provisions for declarations of compliance. Additionally, the resulting differences between their approaches mean that compliance across Europe can be fraught with difficulty and it is difficult to argue that the different sets of national legislation are consistent with the aim of the Framework Regulation to foster a harmonised EU market for food contact paper/board.

Council of Europe Resolution RESAP (2002) set out to address some of the key weaknesses in the pre-existing member state legislation, and offers an approval process for food contact substances which is harmonised with EU protocols together with a more rigorous framework for the approval of recycled fibres which takes into account a wider range of contaminants than current member state legislation. However, there are several key issues which detract from the usability of the Council of Europe Resolution and these are related to (a) the lack of clarity in the positive list where many substances have not yet been assessed, (b) an overestimation of consumer exposure and (c) a complex system of approval for recycled fibres.

In our opinion, the current draft of Industry Guideline has built successfully on a number of themes drawn out from pre-existing member state legislation and the Council of Europe Resolution., with its key strengths being the clear rules it offers for the use of recycled fibres and multilayer materials. It also benefits from containing provisions relating to Good Manufacturing Practice and a Declaration of Compliance. We have additionally highlighted a number of areas where we feel that future versions of these Guidelines could be enhanced to bring them more closely into line with EC Regulation 1935/2004.

1.0 Background

There is currently no harmonised EU legislation on paper and board articles and materials for food contact applications beyond the general requirements laid out in the Framework Regulation 1935/2004. This means that to demonstrate compliance with the general safety requirements of Article 3 of the Framework Regulation, the paper and board food packaging supply chain rely on the national legislation for paper and board published in Netherlands, Italy and France or BfR Recommendation XXXVI published in Germany. These national regulations and recommendations are not always well aligned which can create some confusion and uncertainty, further compounded by the existence of a Council of Europe Resolution on Paper and Board Materials and Articles for Food Contact Uses which has not been adopted by any member state.

In response to this situation the European paper and board food packaging supply chain, comprising CEFIC[1], CEPI[2], CITPA[3] and FPE[4] representing the paper chemical producers, the paper industry, packaging converters and flexible packaging manufacturers have co-operated to develop an Industry Guideline for the compliance of paper and board materials for food contact. The aim of this document is to provide a single text which can be used by all operators in the paper and board packaging supply chain to establish compliance with Regulation 1935/2004 for materials and articles intended to come into contact with food.

The aim of this review is to provide an independent opinion of the effectiveness of the version pre4 of the Guideline in meeting the requirements of Regulation 1935/2004 and compare that effectiveness with that given by:

- Council of Europe Resolution RESAP (2002) 1 and its 6 Technical Documents, as published in Version 2 (13th April 2005);
- The national legislation of France – Notes d'Informations of DGCCRF N° 2004-64 et N° 2006-156.
- The German BFR Recommendation XXXVI.
- The national legislation of Italy – Ministerial Decree of 21 March 1973 as amended.
- The national legislation of the Netherlands – Ministerial Regulation of 25 January 1980 as amended.

2.0 Review of Applicable EU Legislation

2.0.1 The Framework Regulation; Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food

The most fundamental law relating to the marketing and safety of food-contact materials in the European Union is Regulation (EC) No. 1935/2004, which is generally referred to as the 'Framework Regulation'. This came into force in November 2004 [5] and replaced two previous Directives governing the use of food contact materials, 80/590/EEC and 89/109/EEC. The Framework Regulation applies to all materials or articles which, *'in their finished state: (a) are intended to be brought into contact with food; or (b) are already in contact with food and were intended for that purpose; or (c) can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.'* [6]

The Framework Regulation sets out the general requirements for the marketing of food contact materials and gives the European Commission (EC) authority to establish more specific measures (e.g. Directives, Regulations or Decisions) for these products, where they believe that this would be beneficial to either the safety of the consumer or to eliminate technical barriers to trade. To date, no such specific harmonised measure has been brought forward by the EC for food contact paper and board.

In essence, regardless of whether one of these specific measures is in place (as in the case of food contact plastics which are covered by EC Directive 2002/72/EC and its amendments), or not (as in the case of paper and board materials), all food contact materials are ultimately covered by the scope of the Framework Regulation and the aim of any specific measures, legislative proposals or codes of practice that are put in place should ultimately be to provide a route to demonstrate compliance with the requirements of the Framework Regulation.

This review will therefore focus primarily on addressing the way in which existing items of national legislation, Council of Europe Resolution RESAP (2002) and the Industry Guidelines address the basic requirements of the Framework Regulation and as an introduction to this, the remainder of this section details what in our opinion are the key elements from the Framework Regulation which should be dealt with by any legislation or legislative proposal.

2.1.1 General Requirements of the Framework Regulation - Article 3

The essential safety requirement of the Framework Regulation is enshrined in the general provisions set out in Article 3, which require that *'materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could: (a) endanger human health; or (b) bring about an unacceptable change in the composition of the food; or (c) bring about a deterioration in the organoleptic characteristics thereof'*.

The language of Article 3 is quite deliberate, because it deals with the issue of the transfer of substances from food packaging materials into foods and requires a demonstration that the concentration of the substances in the food is at a level which will not pose a risk to the health of the consumer. It is the way in which this requirement has been written in the Framework Regulation and its two preceding Directives that has set the philosophy of migration testing which has been applied to plastics. This also means that any compositional limit (e.g. a maximum use level for a substance in a food contact paper or plastic) needs to be linked in some way to an estimate of the level of the substance passing into foods. This is certainly the philosophy behind the use of residual limits (QM and QMA) within the plastics in contact with foodstuffs legislation[7]. Any national legislation or legislative proposal should therefore aim to relate maximum use levels of substances in food contact papers to safe levels in the foods coming into contact with those papers and this would be a key test of whether the measure was controlling risk to an acceptable level under Article 3.

One respect in which the wording of Article 3 leaves room for debate is the requirement that constituents are not transferred to foods in '*quantities which could… endanger human health'.* This has conventionally been assessed for plastics using measurement of migration, behind which lie the assumptions that (a) consumers eat 1 kg of packaged food every day, (b) that this food would always be packed in the material under consideration and that (c) this food would come into contact with 6 dm^2 of packaging. These are clearly very cautious requirements and an EU project (FACET) has recently been launched to develop a more sophisticated exposure based model for packaging materials in contact with foods. Given the lower exposure profile of food contact paper in contact with foods and the tentative acceptance of the exposure principle from regulators the exposure concept (where supported by data) may be able to be built into any assessments of safe levels of substances. However, a key test of whether this met the requirements of Article 3 would be the scientific rigour of any exposure estimates.

Significantly, Article 3 also contains a requirement for the use of ' Good Manufacturing Practice' (GMP) in the manufacture of food packaging materials and articles. Further details of what is meant by GMP in this context will be described in a later section on the GMP regulation, but clearly this is an important element of complying with the requirements of the Framework Regulation.

2.1.2 Authorization Procedure for Food Contact Substances; Articles 8 to 12

A further critical element to the Framework Regulation and one which is closely related to the general safety requirements outlined in Article 3 is the systematic procedure for authorization of new food contact substances for inclusion on the positive lists in specific measures and a mechanism for removal of substances from these lists. The bones of this procedure are laid out in Articles 8 to 12 of the Framework Regulation and it has been most widely used for the addition of new monomers and additives to the Plastics Directive. The current authorization procedure [8], involves an evaluation by the European Food Safety Authority (EFSA), based on an assessment of (a) the migration level of the substance into foods and (b) the toxicology of the substance.

In the absence of any harmonised EU legislation on paper in contact with foodstuffs, EFSA are not currently open to submissions for the authorization of substances intended solely for use in food contact papers. Despite this, a number of national authorities such as the BfR in Germany do maintain such positive lists and operate an approval process based on the EFSA procedure. These national approval processes will be discussed more fully in the section describing national legislation, but clearly it would desirable if such national approvals were modelled as closely as possible on the EFSA procedures. In principle, this should also mean that national approvals could be easily transposed into harmonised EU legislation, if and when this should be brought forward. The approval process will therefore form an important part of our assessment of whether national legislation and legislative proposals are aligned with the Framework Regulation.

2.1.3 Written Declarations of Compliance and Traceability; Articles 16 and 17

Article 16 of the Framework Regulation requires that where a class of food contact material is governed by a ' specific measure,' when it is placed on the market it must be accompanied by a written declaration stating that the product complies with the requirements of this legislation and passing on to the end user sufficient information to ensure that the product is used correctly and that they can establish their position under the measure. Following the introduction of the Framework Regulation several of the pre-existing items of European legislation have been amended to detail the requirements for declarations of compliance [9]. The information to be included in these statements varies according to the food contact material type and the specific item of legislation, but would typically include suitable food types, maximum permitted temperature and time in contact with foods, presence and identity of substances with restrictions and the presence/identity of dual-use additives. Additionally, there is a requirement to include the identity and address of the operator responsible for putting the material onto the market. Additional supporting documentation in the form of test work and calculations backing up the claim of compliance must also be available to the ' competent authorities' on request.

The presence of a clearly defined format for a Declaration of Compliance will therefore form an important part of our assessment of whether national legislation and legislative proposals are aligned with the Framework Regulation.

Following a number of packaging-related food scares in the EU, a much greater emphasis has been placed on traceability in the Framework Regulation than was the case in the previous two Framework Directives. Article 17 therefore introduced a requirement for traceability at all stages in the food packaging supply chain, to make it possible to control materials, to recall defective products, to provide information to consumers, and to attribute responsibility in the event of a problem with the food article or any of its components. Systems must therefore be in place to ensure that the business operator can trace their products one level up and one level down the supply chain. It should be mentioned that the Directives and Regulations do not currently include significant information on the documentary requirements of quality systems to comply with the traceability requirements. With this in mind, the UK Food Standards Agency is currently developing a Guidance Note dealing with these requirements and how they relate to the requirements of the GMP Directive.

The existence of a practical code of practice or good manufacturing guide for production of food contact papers and the control of traceability will therefore form an important part of our assessment of whether national legislation and legislative proposals are aligned with the Framework Regulation.

2.1.4 Labelling; Article 15

Article 15 of the Framework Regulation specifies that food-contact materials that are not already in contact with food when placed on the market must be labelled *'for food contact'* or with some indication of their intended use. One useful means of indicating suitability for food contact is by use of the symbol given in Annex II of the Regulation, which appears in the figure below.

Although reference to this symbol is not explicitly mentioned in the specific measures which have been introduced to present date, it would clearly be advantageous to include it in any proposal.

2.1.5 National Specific Measures; Article 6

Article 6 of the Framework Regulation states that; *'in the absence of specific measures…. this Regulation shall not prevent Member States from maintaining or adopting national provisions….'* In essence, this means that Member States are permitted to have their own national laws pertaining to food-contact materials, but only provided that these materials are not subject harmonized legislation at the EU level. In the case of paper and board which is not yet subject to any such harmonized legislation, this means that the member states of the EU are perfectly entitled to maintain their own legislation in this area.

The Industry Guidelines would therefore have to be sensitive to these national requirements which would still remain legally enforceable in each country where they are applied.

2.2 The Good Manufacturing Practice Regulation; Regulation (EC) No 2023/2006 for materials and articles intended to come into contact with food

Commission Regulation (EC) 2023/2006 on good manufacturing practice (GMP) came into force on 1 August 2008[10]. It sets out some general rules on GMP for materials and articles intended to come into contact with food, and applies to all the groups of materials identified in Annex I of the Framework Regulation, regardless of whether they are subject to specific measures such as Directives or Regulations. It also apples to combinations of those materials and articles and to recycled materials and articles used in those materials and articles. It therefore clearly applies to paper and cardboard and to multilayer structures containing paper and cardboard.

The GMP Regulation applies to all stages of manufacture, processing, and distribution of materials and articles but excludes the production of starting substances. The Regulation sets out the general rules on GMP, such as the establishment of quality assurance and quality control systems and the adequate documentation of those systems. Annex I of the Regulation outlines detailed requirements for processes involving printing inks.

One of the most significant elements in the GMP regulation is the requirement that starting materials must be selected to comply with pre-established specifications that will ensure compliance of the material or article with the rules applicable to it. In our opinion, this has two significant consequences for manufacturers of food contact paper and board in that any guidance document or legislative proposal would need to include some control on the selection of paper chemicals and also given the nature of the paper industry some agreed measures to ensure the safety of recycled fibres. How well any item of legislation or guidance document deals with these two requirements will be a significant factor in determining how well it addresses the requirements of the GMP and Framework Regulations. This will therefore form a key strand of our assessment of the existing legislation and the Industry Guideline.

To comply with the GMP Regulation, a business operator must also establish, implement, and ensure adherence to an effective and documented quality assurance system which must take into account factors such as the adequacy of personnel, their knowledge and skills, and the organization of the premises and equipment, as necessary, to ensure that finished materials and articles comply with the rules applicable to them. In addition, a business operator must establish and maintain appropriate documentation (in paper or electronic format) with respect to specifications, manufacturing formulae, and processing, which are relevant to compliance and safety of the finished

material or article. The documentation must be made available to the competent authorities upon request. These requirements are clearly very general and little specific guidance is offered in the GMP regulation of what is required to demonstrate that the requirements have been met. As mentioned previously, the UK Food Standards Agency is currently developing a Guidance Note dealing with these requirements, but clearly it would be useful to have a generally agreed code of practice or good manufacturing guide for production of food contact papers and ideally this should include some guidance on the control of traceability to ensure consistency with Article 17 of the Framework regulation. This will therefore form an important part of our assessment of whether national legislation and legislative proposals are aligned with the GMP Regulation.

2.3 Multilayer, Multimaterial Laminates

Paper is frequently used in multilayer materials in which the layer which actually comes into contact with the food is commonly plastic. These types of structures are currently not covered by the scope of the Plastics in Contact with Foodstuffs Directives, but there are active proposals to bring these materials under the scope of the legislation via what is currently known as the Plastics Implementing Measure. Under the current version of this document[11], it is proposed that;

'1. In a multi-material multi-layer material or article, the composition of each plastic layer shall comply with this Regulation.

2. By derogation from paragraph 1, a layer which is not in direct contact with food and is separated from the food by a functional barrier, may be manufactured with substances other than those included in this Regulation or in the national lists concerning the plastic materials and articles intended to come into contact with food.

3. The substances referred to in paragraph 2 shall not belong to either of the following categories:
(a) substances classified as proved or suspect "carcinogenic", "mutagenic" or "toxic to reproduction" substances in Annex I to Council Directive 67/548/EEC ;
(b) substances classified under the self-responsibility criteria as "carcinogenic", "mutagenic" or "toxic to reproduction" according to the rules of Annex VI to Directive 67/548/EEC;
3. The plastic layer shall comply with the restrictions for vinyl chloride monomer laid down in Annex I.'

There key definition of a *'functional barrier'* under this part of the legislation depends on the demonstration that migration of non-listed substances from non food contact layers shall not exceed 10 ppb into foods. It should therefore be noted that for many substances, the analytical studies required to demonstrate that this requirement has been met are highly complex and as a result this provision has not yet been widely applied.

2.4 Assessment Criteria Used in this Review

From the forgoing discussion of the Framework Regulation and the GMP regulation, it is clear that there are a number of critical elements which must be addressed within any national legislation, proposals for legislation or codes of practice if the document is to be shown to meet the requirements of this legislation. The review carried out in the rest of this document is therefore based on the following elements, which we consider to be critical.

1. There should be clear rules on the selection of paper chemicals for use in food contact paper and cardboard and these should be backed up by a suitable positive list.

2. Any limits specified for paper chemicals should take into account an assessment of the migration of that substance into foods and whether this can be demonstrated to satisfy the requirements of Article 3 of the Framework Regulation (i.e. does the limit control the migration to levels known to be safe).

3. The mechanism by which paper chemicals are entered onto the positive list and limits set should be harmonized to as great an extent as possible with the EFSA approval process which has been applied to food contact additives from plastics. This will make it easier to support the positive lists developed under 1. and 2. above and also to incorporate the positive lists into any future EU legislation (should it be developed).

4. There should be a clear way of demonstrating the safety of recycled fibres that incorporates measures to establish the process control of systems for the collection and recycling of reclaimed fibres. Within this, it would clearly be preferable if the system adopted for categorising reclaimed fibre was harmonized with the system most commonly operated by the recycling industry (EN 643). Monitoring of known and contaminants, selection of technologies and demonstration must, however, remain key elements in showing safety as EN643 is not a toxicological standard.

5. There should be clear guidance for the content of a Declaration of Compliance.

6. There should be a code of practice for GMP of food contact paper and board (or reference to an external document) which can be used to demonstrate compliance with the GMP Regulation.

7. On an interim basis, until the adoption of the plastics implementing measure, there should be clear advice on how to demonstrate safety for multilayer/multimaterial laminates including paper and cardboard. These are expected to be drawn under the scope of the Plastics Directives in future amendments and clearly this legislation will take precedence, but in the meantime it is our opinion that industry would benefit from a clear and pragmatic approach to multilayer materials.

3.1 Germany; BfR Recommendation XXXVI and the LFBG

German BfR Recommendation XXXVI[12] is the most widely recognised existing standard within the EU for food contact testing of papers and is the means most commonly used (in those member states without their own legislation) to demonstrate compliance of food contact paper and board with the safety requirements of the Framework Regulation. Within Germany, its role can be seen as a means of demonstrating compliance with the requirements of the German Food Law (the LFBG[13]).

The recommendation is split into 4 sections;

- XXXVI Paper and board for food contact
- XXXVI/1 Cooking Papers, Hot Filter Papers and Filter Layers
- XXXVI/2 Paper and Paperboard for Baking Purposes
- XXXVI/3 Absorber pads based on cellulosic fibres for food packaging

Of these 4 sections, the part which most closely correlates to the scope of the Industry Guideline is the first of these and this will therefore form the basis for the discussion in this section. The remaining 3 sections deal primarily with niche applications for paper and cardboard and follow a similar format to BfR Recommendation XXXVI, but generally have smaller lists of approved substances and differing extraction conditions to reflect the more intimate nature of the food contact in these applications.

BfR Recommendation XXXVI consists principally of a non-binding[14] positive list of raw materials approved for use in food contact papers and a number of tests to be carried out on finished papers. The positive list is split up according to the intended function of each approved constituent starting with fibrous materials and then working through various categories of paper chemicals segregated on the basis of functionality (e.g. fibres, sizing agents, retention aids, wet strength agents etc).

3.1.1 Rules for Selection of Paper Chemicals

For the greater part, BfR Recommendation XXXVI contains a good practical positive list for paper chemicals which may safely be used in the manufacture of food contact paper and cardboard. However, as mentioned previously, the list is formally non-binding and when carrying out an assessment of paper

formulations, it soon becomes apparent that not every chemical which is used in the manufacture of food contact paper and board is included in this positive list. The explanation for this is that the list focuses on functional chemicals which are intended to remain in the paper in its finished format in order to exert a technical effect. Despite the non-binding nature of the Recommendation, for these types of chemicals there is a general expectation that the substance should be listed if the manufacturer is to claim compliance. If, however, a paper chemical is only intended for use in the manufacturing process and is water-soluble (and therefore expected not to be present at significant levels in the finished paper), there would be no particular expectation that it would have to be listed, although this would be favourable.

There are of course grey areas when the above interpretation is applied and the positive list does contain a number of categories of process chemicals such as dispersion and flotation agents and defoamers which are clearly not intended to remain in the finished paper, but where a decision has been taken to list these substances, presumably on the basis that they may be carried over to the finished paper. This lack of clarity of whether substances need to be listed means that some degree of interpretation can be required to assess whether individual paper formulations meet the requirements of BfR Recommendation XXXVI.

In our opinion, this means that BfR Recommendation XXXVI partly meets the requirements of the GMP regulation with regard to having clear guidelines for selection of paper chemicals. It would be a significant improvement to the clarity of the Recommendation if it were to contain some clear guidance on when a paper chemical is expected to be listed and when it would not be expected to be listed.

3.1.2 Restrictions on Paper Chemicals

Where a paper chemical is listed in BfR Recommendation XXXVI, it is often listed subject to (a) a maximum use level and/or (b) an extraction restriction. For example, listed under the wet strength agents one can find the following two entries;

'Melamine- formaldehyde resins. Extract of the finished product must not contain more than 1.0 mg formaldehyde per dm^2' and

'Cross-linked, cationic polyalkylene amines (compare B. III. 3.), in total maximum. 4.0 %'

This second set of substances is subject to the following additional requirement;
'No ethyleneimine must be detectable in the resin (detection limit 0.1 mg/kg). 1,3-Dichloro-2-propanol must not be detectable in water extract of the finished product (detection limit 2 µg/l). The transfer of 3-monochloro-1,2-propanediol into the water extract of the finished products must be as low as technically achievable, a limit of 12 µg/l must not be exceeded in any case.'

These restrictions on paper chemicals can be viewed in one of two ways. They are, in essence, residual limits on the substance in food contact papers and can therefore be viewed as compositional limits which are easier for industry to comply with than specific migration limits would have been. However, since the restrictions are nowadays assigned on the basis of migration studies and known toxicology for the substance (see the section 3.1.3) and underpinning this process are some reasonable assumptions to relate migration levels in food to the level in paper, it can also be viewed that these compositional limits are in effect controlling the level of migration of paper chemicals (and/or their constituents and contaminants) into foods in line with the requirements of Article 3 of the Framework Regulation.

On this basis, we can conclude that, where specified, the limits within BfR Recommendation XXXVI are based on an assessment of the migration of substances into foods and are capable of controlling that migration in line with the requirements of Article 3 of the Framework regulation.

3.1.3 Approval Process for Inclusion on Positive List

It is generally accepted that the most useful way of getting approval for a new paper chemical in Europe is to get it listed on the German BfR Recommendation XXXVI and hence this is the route adopted by most paper chemical manufacturers. Although, as previously discussed, this is not a fully comprehensive list of paper chemicals and is not binding, it does have

widespread acceptance and using the principles of ' mutual recognition' can be used in a wide range of EU Member States outside of Germany.

To gain German BfR listing of a new chemical in Recommendation XXXVI a dossier including migration and toxicological data is submitted to the expert panel[15]. In addition to this, detailed information on the new chemical must be provided in a format laid down by the EFSA (European Food Safety Authority) in the ' Note for Guidance[16]. These data are classified under the main headings:

1. Identity of substance including manufacturing details, impurities etc.
2. Physical and chemical properties
3. Intended application of substance
4. Authorisation of substance (other national authorisations)
5. Data on migration of substance (food or food simulants)
6. Data on residual content of substance in the food contact material
7. Microbiological properties of substance (only applicable to biocides)
8. Toxicological data

If the new chemical is a mixture this must be classified as ' defined' or ' non defined' where a defined mixture is the result of a reproducible production process. A non defined mixture is one that varies from batch to batch and may be of natural origin. Additional data are needed on mixtures, such as starting substances, identification and proportion of constituents, molecular weight distribution and substances formed.

The Note for Guidance document is primarily intended for application to new substances used in plastics. For paper and board materials some substances are washed out in the paper making process. If the residual level of the chemical in the paper is very low then migration testing may not be needed. A permitted approach in these circumstances is to calculate 100% migration to food instead of migration testing. Then if the calculated ' worst case' migration works out at less than 50 ppb, then only a reduced toxicological package will be needed in the dossier, see below.

For new substances that are polymeric additives, additional data on the molecular weight distribution are needed, including the fraction < 1000 Daltons. This threshold of 1000 Daltons is important as EFSA have conventionally assumed in their assessments of plastics starting materials that above this molecular weight, substances are not absorbed by the body and therefore may be excluded from any calculations of migration.

If the new substance is hydrolysed at a level of > 95% to innocuous substances or substances which are already listed (and have toxicological data available) by simulated gastro-intestinal fluids then migration and toxicological data may not be needed.

No provision at the moment is available to present migration data in dry foods which accounts for many of the applications of paper and board. The generally accepted food simulants used to obtain migration data on all food types are water, 3% acetic acid, 10 % ethanol and a fatty food simulant. The Council of Europe has proposed migration tests using Tenax as a dry food simulant and this approach should be considered in cases where only contact with dry foods is likely.

The threshold of regulation[17] concept is not currently accepted in Europe, therefore any submission to BfR must be accompanied by 3 negative mutagenicity studies even when no migration is calculated or detected. There is also no provision at the moment for taking into account the ' packaging use factor' for paper and board materials and the assumption that a 60 kg person eats 1 kg of food packaged in the same type of packaging every day for a lifetime is still used.

The level of migration (or calculated migration) dictates the level of toxicological data needed for the submission so that migration:

- < 50 ppb requires 3 mutagenicity tests
- > 50 ppb but < 5 ppm requires 3 mutagenicity tests, 90 day rat feeding study plus data on bioaccumulation
- > 5 ppm requires all the above plus a further 90 day feeding study on a second species plus long term studies on reproduction on one species and

developmental toxicology on two species. Studies on absorption, distribution, metabolism and excretion are also needed.

A recent amendment to the Plastics Directive 2002/72/EC[18] allows the use of a fat consumption reduction factor (FRF) so that any migration results obtained with olive oil can be divided by a factor of 5 to allow for the fact that the consumer will not eat 1 kg of fat every day and that 200 g is a maximum. This factor is only applicable to strongly lipophilic substances and where migration is << 100%. This FRF can be used in submissions for new substances in plastics, so it should also be applicable to paper and board, where appropriate.

A specification may be proposed on the levels of impurities found to be present in the new substances based on measurements. After evaluation by the expert panel there may be a limit imposed on the use level of the substance in the paper and board.

On this basis, we can therefore conclude that the process for assessment of chemicals under BfR Recommendation XXXVI is currently a robust one which is well aligned with the requirements of Articles 8 to 12 of the Framework Regulation.

It is, however, worth noting that the BfR started listing paper chemicals before the current version of the EFSA protocol was put in place (ca. 1991). Prior to the adoption of this system, the BfR did have in place a clearly-defined process for assessing applications for new paper chemicals and this process was reviewed periodically. The process was based on a combination of migration/extraction testing coupled with toxicological assessment and so shared some common themes with the EFSA process, although since it was a forerunner to the EFSA process, it was not perfectly aligned. This means that many of the historical approvals on this list were not based on the current EFSA-harmonised approval process and so could still be open to question, depending on any position which the regulators or member states choose to adopt. Whether regulators would actually choose to question all these previous approvals is not certain as the BfR have reviewed a number of historical approvals since their harmonization with the EFSA protocols and on occasions have chosen not request additional dossier information[19], but

inevitably this means that there is some residual doubt in relation to the contents of the positive list in BfR Recommendation XXXVI and legislators outside Germany may still choose to review at least some of these approvals at a later date.

3.1.4 Recycled Fibre Requirements

BfR Recommendation XXXVI specifically permits the use of fibre material from a relatively wide range of sources including;

1. Natural and synthetic cellulose fibres, bleached or unbleached.

2. Fibres of synthetic high polymers, provided they comply with the corresponding BfR Recommendations.

3. Wood pulp, bleached or unbleached.

4. Recycled fibres from the manufacture and processing of paper or paperboard and from returned paper[20], provided that the products manufactured from these fibres comply with the requirements of this Recommendation. For contact with dry, non-fatty foodstuffs (e.g. flour, semolina, rice, sugar, salt, peas, lentils and the like) and with foodstuffs that are normally washed and/or peeled before being eaten (e.g. fruit, vegetables), other raw materials may also be used as a source of fibre, provided that the requirements of this Recommendation are otherwise complied with[21].

The Recommendation therefore clearly permits the use of recycled fibres, but this approval is subject to the compliance of the finished product with the full provisions of the recommendation and there is also a requirement that the content of diisopropylnaphthalene (DIPN) must be as low as technologically possible. It is also clear that the Recommendation does contain some control on the sources of fibre, although the categories included are not harmonised with those described in the EN 643 standard which is most commonly used in the recycling industry. Although Recommendation XXXVI clearly deals to some extent with the issue surrounding the source of recycled fibres, in our opinion, its usability is hampered by the choice of paper categories.

Additionally, it should be noted that the GMP regulation requires that;

'printing inks applied to the non food-contact side of materials and articles shall be formulated and/or applied in such a manner that substances from the printed surface are not transferred to the food-contact side:
(a) through the substrate or;
(b) by set-off in the stack or the reel,in concentrations that lead to levels of the substance in the food which are not in line with the requirements of Article 3 of Regulation (EC) No 1935/2004.'

Since a significant portion of recycled fibre has at some point been printed, this has led to some debate amongst parts of the scientific community as to whether the use of recycled fibre from printed sources in food contact applications is acceptable, since it is difficult to exclude exposure to traces of ink chemicals in recycled fibres. This confusing situation is exacerbated due to a lack of universally-accepted guidelines to assess when exposure to a printing chemical is at safe levels within the definition of Article 3 of the framework regulation.

To present date, there has been no ban from the BfR on the use of recycled fibres. However, given the continued high profile of the issue of food contact safety and the periodic identification of contaminants in recycled fibre (see the recent guidance note from the BfR on the level of di-isobutylphthalate which is used in some adhesives[22]), it is our opinion that a greater degree of care than that currently specified in BfR Recommendation XXXVI is required to quantify known constituents in reclaimed fibre sources and also possibly some means of broadband screening for additional constituents.

In summary, BfR Recommendation does offer some guidance on the use of recycled fibres in food contact applications, but in our opinion, this guidance stops some way short of providing sufficient information to fully satisfy the requirements of the Framework and GMP Regulations.

3.1.5 Declaration of Compliance

BfR Recommendation XXXVI does not currently contain any guidance on the contents of a Declaration of Compliance.

3.1.6 Code for Good Manufacturing Practice

There is no current Guidance on GMP either within the Recommendation or incorporated by reference.

3.1.7 Rules for Multilayer Materials

BfR Recommendation XXXVI does contain some general advice on multilayer materials containing paper and cardboard. In the preamble, it is stated that;

'In a composite, multi-layered or coated material, if the layer which comes into contact with the foodstuff is made of paper or paperboard it must comply with this Recommendation. Also, except for traces that are harmless to health and have no effect on taste or smell of the foodstuff, there must be no migration of substances from other layers into foodstuffs or on their surface,' and;
'If plastics or other polymers are used to coat paper or paperboard on the side that will come into contact with the foodstuff, only substances in compliance with the corresponding BfR Recommendations and the conditions stipulated therein may be used.'

In a section on coatings, the following additional advice is given in the Recommendation;
'Plastics (films, melts, solutions, lacquers, dispersions), provided they comply with the corresponding BfR Recommendations. Plastic coated paper or paperboard, in which from normal use only the layer of plastic comes into contact with the foodstuff and in which there can be no migration of substances from the paper or paperboard to the foodstuff, should not be evaluated after this Recommendation, but after the BfR Recommendation for the corresponding plastic.'

It is worth noting that the *'corresponding BfR Recommendations'* for plastics have for a number of years been increasingly taking a secondary role compared to EU plastics in contact with foodstuffs regulations. They certainly contain a reference to compliance the German Commodities Regulation[23] and in this manner clearly incorporate for plastics coatings the full range of migration limits which would apply to plastics when used in a monolayer structure. The position of the BfR can therefore be summarised as follows;
(a) any paper layers should comply with the requirements of

Recommendation XXXVI and (b) plastics layers should also comply with the composition rules and migration limits which apply to them under EC Directive 2002/72/EC and its amendments. In this respect, it is apparent that BfR Recommendation is currently consistent with the proposed approach contained in the current draft of the plastics implementing measure and at the moment probably exceeds these requirements since it does not confine its residual monomer requirements to vinyl chloride.

The one potential gap in BfR Recommendation XXXVI is in respect of the presence of some substances that are subject to Specific Migration Limits (SMLs) under the plastics directive, but are also used as (or present in) paper and board. For instance, formaldehyde, which is subject to an SML of 15 mg per kg in foods under EC Directive 2002/72/EC and also an extraction limit of 1 mg/dm^2 when used in paper and cardboard. If the substance is used in an underlying paper layer and the food contact layer is plastic, it is not clear which limit would apply. In this case, working from the standard EU assumptions (for plastics materials) of 6 dm^2 per kg of food, the paper limit is clearly more stringent as this leads to an inferred SML of 6 mg per kg and this is below the SML from plastics legislation, but this anomaly clearly creates room for confusion. This situation could be exacerbated if, as expected, later versions of the plastics implementing measure draw paper chemicals under the scope of plastics SMLs (where they apply).

In our opinion, BfR Recommendation clearly deals with the issue of paper in multilayer products and in our opinion is already aligned at least to the requirements of the proposed Plastics Implementing Measure. However, some clarification on restrictions that apply to chemicals where they are used in plastics and paper layers and subject to conflicting restrictions would be advantageous.

3.1.8 Testing Requirements under BfR Recommendation XXXVI

One of the key features of BfR Recommendation XXXVI are the testing requirements placed on finished papers and cardboards. Since a significant number of the tests required under BfR recommendation XXXVI are also required under one or other of the other sets of member state law which we will discuss in the following sections, we have included a summary of these BfR test requirements here.

Under BfR Recommendation XXXVI, the tests which would need to be carried out on most samples can be split into 2 categories; (a) tests which apply regardless of which paper chemical have been used and (b) tests which apply only where certain specified chemicals have been used in the paper.

Tests applying to all papers;

- Pentachlorophenol (PCP) content
- No visible migration of antimicrobials constituents when tested by EN 1104
- Heavy Metals Pb, Cd, Hg, Cr(VI) by ENV 12497 and ENV12498.
- Organoleptic Inertness EN 1230 parts 1 and 2

Tests which apply only when certain paper chemicals are present include the following[24].

- Migration of Fluorescent Whitening Agents when measured by EN 648
- Colour Migration by EN 646 (only be needed for coloured papers)
- Formaldehyde in a cold water extract by EN 1541
- Glyoxal in a cold water extract (BfR Method)
- 3MCPD/DCP by BfR Method (only where Kymene type wet strength agents have been used)
- Where recycled paper is used, the BfR require tests for the level of di-isopropyl naphthalene (DIPN)
- A temporary limit on di-isobutyl phthalate (DIBP) is currently in place

3.2 Netherlands Legislation 'The Warenwet'

At the most general level, food packaging materials are regulated in the Netherlands under a Decree of 1 October 1979 on Packaging and Articles of Daily Use *'Verpakkingen- en Gebruiksartikelen- besluit'*. This decree is implemented by a Ministerial Regulation of 25 January 1980 *'Regeling verpakkingen en gebruiksartikelen,'*, which is periodically amended and maintained. The compilation of these regulations and decrees is most commonly known as the Warenwet and provides what is essentially a volume of positive lists for starting substances in different types of food contact substances (e.g. Plastics, Paper and board, Rubber etc). In this respect, the Warenwet partly acts as a means to incorporate harmonised EU legislation as it is brought forward (e.g. the plastics directives), but it also provides a summary of the Netherlands legislation in areas which are not yet subject to harmonised EU legislation.

The Dutch legislation for food contact paper and cardboard is given in the Warenwet (*'Hoofdstuk II Papier en Karton'*). This legislation consists primarily of a listing of approved starting materials for use in food contact papers and by contrast to BfR Recommendation XXXVI, it should be noted that this is a binding positive list[25].

3.2.1 Rules for Selection of Paper Chemicals

The listing for paper chemicals is split up according to the application of the chemical and includes both paper chemicals (intended to remain in the paper) and process chemicals (which are not). The list also gives upper use limits and technical specifications for some chemicals. Additionally, it is permissible to ' read across' approvals from other chapters of the Warenwet. This has the effect of extending the positive list beyond the list of substances given in Chapter II and is particularly useful in assessing the use of dyes, paraffin waxes and other coatings. Any restrictions contained in the approvals incorporated by cross reference (e.g. SMLs, QMs and purity criteria) are still applicable when they are used in paper/board.

The binding nature of the positive list should in principle mean that checking compliance is a more straightforward matter than compliance with the requirements of the BfR recommendation. The downside of this clarity is that there is a lesser range of substances (and particularly process chemicals)

which may be used in food contact papers than is the case under the non-binding BfR Recommendation.

The current basis for inclusion of a chemical on the positive list of the Warenwet is discussed in Section 3.2.3, but it should be pointed out that, as for BfR Recommendation XXXVI, there are many substances on the list which were assessed prior to the adoption of EFSA style approval processes.

In our opinion, the Warenwet can therefore be argued to meet the requirements of the GMP regulation with regard to having clear guidelines for selection of paper chemicals. However, as pointed out above, strict application of the list is more restrictive than the German BfR Recommendation bearing in mind that this does not deal with all process chemicals.

3.2.2 Restrictions on Paper Chemicals

The positive list given in the Warenwet is largely structured around substances which are approved subject to maximum use limits. For instance, *'polyamide-epichlorohydrin resins produced through the reaction of the condensation product of adipic acid and bis(2-aminoethyl) amine and epichlorohydrin or with a mixture of epichlorohydrin and ammonia'* are approved for use as wet strength agents subject to a maximum use level of 1.5%. Additionally contained later in the positive list is a requirement that the specific migration of 3-monochloropropanediol (3MCPD, a by-product of epichlorohydrin and a known contaminant in this class of wet strength agents) does not exceed 0.01 mg per kg based on the conventional migration testing protocols for plastics. This should be compared with the German limit of 12 µg per kg of water in a cold water extract (produced from 40 g of paper per kg of water). Working from a 100 gsm paper, this limit is equivalent to 0.3 µg per dm^2, or an SML of 1.8 µg per kg in the food (based on 6 dm^2 of packaging per kg of food). In this case, the German limit is demonstrably tighter than the Warenwet limit.

This does seem to be a general pattern within the Warenwet which tends to contain slightly less tight restrictions than the BfR Recommendation. If one also considers formaldehyde, it is subject to an SML of 15 mg/kg under the Warenwet (identical to the limit in the plastics legislation). This should be

compared with the German limit of 1.0 mg per dm^2, which using the same assumptions as the previous section is equivalent to an SML of 6 mg per kg in the food.

Despite the above anomalies, what is clear is that the restrictions for recently approved paper chemicals are now commonly based on EFSA standard migration studies and known toxicology for the substance (see section 3.2.3 on the approval process) and the Warenwet has also implemented (where appropriate) the same limits as those used for plastics. It can therefore be clearly argued that the Warenwet is controlling migration of paper chemicals into foods in line with the requirements of Article 3 of the Framework Regulation.

On this basis, we can conclude that, where they are specified, the limits within the Warenwet are based on an assessment of the migration of substances into foods and are capable of controlling that migration in line with the requirements of Article 3 of the Framework regulation.

3.2.3 Approval Process for Inclusion on Positive List

In all its most important details, the approval process for inclusion of a chemical onto the Warenwet positive list is identical to the process for BfR listing. All that needs to be done is to submit the same migration and toxicological to the Dutch authorities as one would submit to the BfR. In this respect, once the work has been carried out for a BfR listing, the application should also just be submitted for Warenwet listing.

On this basis, we can therefore conclude that the process for assessment of chemicals under the Warenwet is currently a robust one which is well aligned with the requirements of Articles 8 to 12 of the Framework Regulation. As for BfR XXXVI, it is worth noting that many of the approvals on this list pre-date the current approval process and so could still be open to question in the same way that we described for the BfR approvals.

3.2.4 Recycled Fibre Requirements

The Warenwet permits a wide range of plant based fibre including wood dust and paper and paperboard.

- *Natural cellulose fibres.*
- *Wood pulp*
- *Paper and Paperboard fibres*
- *Plastics subject to them complying with the relevant regulation for that plastic described elsewhere in the Warenwet (Chapters I and X).*
- *Regenerated cellulose in compliance with chapter VIII*
- *Textile fibres in compliance with Chapter VII*

There are no restrictions set out within the Warenwet on the recovered paper groups which are permitted in food contact papers or for the purity or control of recycled fibre in food contact paper. However, finished papers must clearly comply with the wider requirements of Chapter II of the Warenwet, as would be the case for any other papers. On this basis, it is difficult to make a case that use of the Warenwet, without the back up of a suitable code of practice, provides a suitable Framework to establish the safety of recycled fibre under either the Framework Regulation or GMP regulation.

3.2.5 Declaration of Compliance

The Warenwet does not currently contain any detailed guidance on the contents of a Declaration of Compliance.

3.2.6 Code for Good Manufacturing Practice

There is no current Guidance on GMP either within the Warenwet or incorporated by reference.

3.2.7 Rules for Multilayer Materials

The use of a wide range of plastic coatings is permitted under Chapter X of the Warenwet. However, Chapter 2 (Paper and Cardboard) of the Warenwet also makes it clear that where a plastic coating has been applied, the overall migration limit and any specific migration limits that might apply to the plastic in its own right also apply to the multilayer structure. The testing regime applied to the finished article is incorporated into Chapter 2 by reference to the section relating to plastics. In this respect, the testing is therefore aligned

to the testing protocols for plastics in contact with foods, despite some of the known problems of carrying out overall migration tests on multilayer materials based on paper.

The position of the Warenwet for multilayer materials containing paper can therefore be summarised as follows; (a) any paper layers should comply with the requirements of Chapter 2 and (b) plastics layers should also comply with the composition rules and migration limits which apply to them under Chapter I (which itself is increasingly aligned with EC Directive 2002/72/EC and its amendments). In this respect, it is apparent that Warenwet is currently consistent with the proposed approach contained in the current draft of the plastics implementing measure and at the moment probably exceeds these requirements.

3.2.8 Testing Requirements under Warenwet Chapter II

In addition to the requirements relating to coated papers, there are also some testing requirements detailed in the Warenwet Chapter 2 for uncoated papers. These include measurements of overall migration into aqueous and fatty foods which should be carried out according to conventional migration testing protocols for plastics or equivalent (or more severe methods of test). In general the following two sets of tests are carried out to give upper estimates of the level of migration into aqueous and fatty foods;

- Water extractable material with the water extract prepared according to EN 647 (hot) and the extractable material determined according to EN 920, , and
- Measurement of overall migration into iso-octane using method EN 1186-15.

Additionally, under the Warenwet, a short list of substances used in paper chemicals are subject to specific migration limits and in general, these are substances which are approved for use in paper and cardboard and the SMLs are harmonized with the limits in the Plastics legislation.

3.3 French Legislation

The French Legislative Framework for papers in contact with foodstuffs has been developed over many years and started in 1912 with measures which were put in place to control arsenic based compounds which were being used in colourants in food contact papers[26]. This legislation also had the effect of banning the use of print in direct contact with foods, which is a position which remains in place today. In later years, the legislation was developed through a series of circulars, instructions and circular letters which had the effect of approving a number of paper chemicals and setting standards for finished food contact papers in a relatively ad-hoc manner and these were incorporated in legislative documents which contained details of a number of different food contact materials. These approvals are drawn together in a single volume in Brochure 1227 which details all the French legislation relating to food contact materials[27]. However, the information contained is structured according to the original legislative texts with the provisions relating to paper mingled with those for other food contact materials and hence this is not the most convenient manner of accessing the French legislation on food contact paper and board.

A more convenient description of the French legislation is given in *'DGCCRF Information Note 2004/64'* which draws together all of the provisions of the French legislation and compiles them into a single document with the provisions segregated according to food contact material type[28]. This document is also supported by *'DGCCRF Information Note* 2006-156', which provides an explanation of the rules in relation to coated papers and cardboards[29]. Also referenced from within these documents and thereby forming part of the French legislative framework is a guide to good manufacturing practice the *'Guide de bonnes practiques de fabrication des papiers et carton',* which is most commonly known as the GDBP[30].

3.3.1 Rules for Selection of Paper Chemicals

There is currently no comprehensive or binding French positive list for substances which can be used in food contact papers (although amongst the list of substances approved there is a list of approved optical brighteners). For the greater part, NI 2004/64 instead refers manufacturers to the GDBP for further details of selection criteria. The *'guide de bonne practiques'* acknowledges the suitability of chemicals for use in food contact papers

provided that they are approved under BfR XXXVI or the Regulations contained in USA FDA 21CFR §176.170 and §176.180[31]. For this reason, auditing of the formulations against French legislation is generally confined to checking the status of optical brighteners under French legislation with all other chemicals generally being assessed under Recommendation BfR XXXVI, or when the substance is not listed there by reference to FDA regulations. This de-facto recognition of the value of the FDA regulations has the effect that it removes some of the grey areas left by the BfR distinction between paper and process chemicals and provides some clearer rules to justify the use of process chemicals based on FDA regulations. However, these FDA approvals have not necessarily been granted on the basis of petitions which would conform with the EFSA approval process, and hence there is the possibility that they would not always be accepted universally across the EU as some member states with more prescriptive and binding positive lists would be at liberty to adopt their own position on such chemicals.

In our opinion, this means that despite the absence of a comprehensive positive list, the French legislation meets the requirements of the GMP regulation with regard to having clear guidelines for selection of paper chemicals. Its adoption of the FDA list of approved paper chemicals could, however, lead to conflict with member states with more binding positive list requirements such as the Dutch Warenwet.

3.3.2 Restrictions on Paper Chemicals

The same restrictions that are under place in the FDA regulations or BfR recommendations (maximum use levels or residual levels) are also implemented under the French legislation.

On this basis, and given the foregoing discussion about the BfR recommendations, we can conclude that, under the French legislation, where the chemicals are selected according to the BfR list and its limits, the migration of substances into foods will be in line with the requirements of Article 3 of the Framework regulation.

3.3.3 Approval Process for Inclusion on Positive List

Since there is no comprehensive or actively maintained French positive list and the French approval system relies largely on the BfR lists (and therefore its underlying approval process), the French system is subject to the same strengths and weaknesses as those described for the BfR Recommendation above.

3.3.4 Recycled Fibre Requirements

The requirements for fibres are described in the GDBP, which permits the use of virgin fibres (bleached or unbleached) obtained by mechanical, thermochemical, semi-chemical or chemical processes. It also permits the used of fibres manufactured from regenerated cellulose or from high polymers where they meet the requirements of relevant EU legislation. The GDBP also permits the use of recycled fibres apart from the following classifications of recycled papers defined according to EN 643.

'A 0 Mixed waste paper (unsorted), thus designated "mixed waste paper (unsorted) including unsorted consolidated materials from households, no guarantee of absence of unusable materials.

A 12 "Shredded office waste paper (unsorted)"
B 11 "White carbonless copy paper"
B12 " Coloured carbonless copy papers"
Thermocopy papers are also to be excluded.'

In general, the GDBP permits without further authorisation, a wide range of fibres reclaimed from the manufacturing process, converting process and from public services, industries and retailers. Additionally, there is an approval process for fibres which do not meet this definition and a requirement for the submission of dossiers to the DGCCRF.

Additionally, and of relevance to recycled fibre in particular, the GDBP specifies a limit of 2 mg per kg for the level of PCBs in food contact paper and cardboard. This limit was clearly harmonised with the limit specified in BfR Recommendation XXXVI. The BfR removed this restriction in 2001. The reason for this withdrawal of the limit arose from the phase out of PCBs in carbonless copy papers and a number of other applications. Following a

series of studies in the late 1990s, it was concluded by the BfR that the level of PCBs in recycled fibres had fallen to such an extent that they were no longer of concern, and the BfR felt able to remove this restriction. The limit in the French legislation can therefore be seen as a throwback to this earlier version of the BfR recommendations, but it should nonetheless be respected as it clearly forms part of the French legislation.

In common with the BfR recommendation, because there is no detailed set of instructions about how to demonstrate the safety of recycled fibre in general and printed recycled fibre in particular, the French guidelines do leave operators open to being caught out when printing chemicals are found in their papers. Because the French framework does not include DIPN or DIBP within the list of contaminants to be controlled, it could be argued that it offers a slightly lesser degree of control, although these would merely be two potential contaminants. In our opinion, the French guidelines would definitely be improved by the incorporation of a longer list of contaminants subject to restrictions and possibly some form of broad band test with the goal of establishing that the recycling process is functioning properly.

In summary, the French legislative texts do offer some guidance on the use of recycled fibres in food contact applications, but in our opinion, this guidance stops some way short of providing sufficient information to fully satisfy the requirements of the Framework and GMP Regulations.

3.3.5 Declaration of Compliance

The French legislative documents do not currently contain any detailed guidance on the contents of a Declaration of Compliance.

3.3.6 Code for Good Manufacturing Practice

A clear advantage of the French legislative framework by comparison to the BfR Recommendation or the Warenwet is the Code for GMP described in the GDBP. In essence, this provides a set of guidelines for;

- Selection of raw materials including fibres and paper chemicals
- Description of acceptable manufacturing and converting technologies
- A description of likely risks and hazards associated with these processes and their likely impact on food contact issues including means of protection, inspection and follow up/documentation.
- Restrictions on the level of certain chemicals and contaminants present in papers.

The GDBP clearly predated the GMP regulation and therefore its wording is not perfectly-aligned. However, in our opinion, it is a strength of the GDBP that it recognises that the paper industry is highly-dependent on a wide range of raw materials and defines a framework for control of these materials. This was quite far-sighted and came some considerable time before similar requirements were put in place by the EU through the GMP regulation. However, the wording of the document has now been superseded to some extent by the GMP regulation and there is potential for confusion between these two documents. Additionally, the requirements of the GDBP can be viewed as top line quality objectives rather than a detailed road map showing how to implement a suitable quality system. Industry and those carrying out audits would benefit greatly from a more focussed set of requirements.

In our opinion therefore the French legislative Framework clearly offers a partial set of guidance along the lines of the GMP regulation, but would benefit from being updated to bring it in line with the GMP regulation and to provide more industry-focussed guidance.

3.3.7 Rules for Multilayer Materials

Rules for coated papers in contact with foods are laid out in Information Note 2006/156 which deals with paper and cardboard coated with *'wax, wax with additives, paraffins, paraffins with additives, silicones and polymeric emulsions that in the finished product state are designed to come into contact*

with foodstuffs.' Other types of multilayer structures based on plastic coated or laminated papers are legislated under the ' Composites' section of Information Note 2004/64.

For the types of products covered by Information Note 2006/156, there is a general requirement that the underlying paper meets the requirements of the French Legislation. Means of demonstrating compliance with the compositional requirements of the legislation for the coating include compliance with a number of items of French legislation and the Framework regulation. There is an additional reference to compliance with the legislation of other regulators including the BfR, the FDA and also the council of Europe Resolution on coatings in contact with foods[32]. There are additional requirements for the migration testing of finished products.

For laminates and plastic coated papers, there is a requirement that the paper layers shall comply with the requirements of the French legislation and that the plastic layer shall meet the compositional requirements of the plastics in contact with foodstuffs legislation. Additionally, there is a requirement that the finished product shall meet the Overall and Specific migration limits that would have applied if it had been a plastic monolayer

The position of the French legislation for multilayer materials containing paper can therefore be summarised as follows; (a) any paper layers should comply with the requirements that apply to paper, (b) wax coatings should comply with French legislation and/or the Framework Regulation and the Council of Europe Resolution on coatings and (c) plastics layers should also comply with the composition rules and migration limits which apply to them under EC Directive 2002/72/EC and its amendments). In this respect, it is apparent that the French Legislation is currently consistent with the proposed approach contained in the current draft of the plastics implementing measure and at the moment probably exceeds these requirements.

3.3.8 Testing Requirements under Information Note 2004/64

One of the key strengths of Information Note 2004/64 is that it offers a very clear summary of the testing requirements for papers in contact with foods which is not offered in either BfR Recommendation XXVI or the Warenwet, where to some extent the testing requirements are scattered throughout what

is essentially a positive list. This gives a great advantage in readability to the French legislation. These tests are primarily based on the same schedule as BfR Recommendation XXXVI and include;

- No visible migration of antimicrobials constituents when tested by EN 1104
- Organoleptic Inertness EN 1230 parts 1 and 2
- Pentachlorophenol (PCP) content
- Heavy Metals Pb, Cd, Hg, Cr(VI) by ENV 12497 and ENV12498.
- Formaldehyde in a cold water extract by EN 1541
- Glyoxal in a cold water extract (BfR Method)
- Migration of Fluorescent Whitening Agents when measured by EN 648
- Colour Migration by EN 646 (only be needed for coloured papers)

Additionally, there are some further tests required under the French legislation which are not already covered by BfR XXXVI are including;

- Measurement of PCBs by EN ISO 15318
- Water extractable material with the water extract prepared according to EN 647 (hot) and the extractable material determined according to EN 920
- Fluorine content

In contrast to BfR recommendation XXXVI, the French Information Note specifies different tests to be carried out according to the end use of the paper (i.e. dry foods, wet or fatty foods, cooking and hot filtration). In essence, these different tests focus effort on applications where the contact with the food is most intimate and the temperature is highest and it is in these circumstances where the migration of substances into foods would be expected to be highest.

3.4 Italian Legislation

The Italian legislation on paper and contact with foods was first put forward in 1973[33] within a general document on food contact materials (DM 21.3.1973) and this legislation has been amended on a number of subsequent occasions[34]. The most significant of these amendments dates from 2001[35] in which the legislation was altered to permit the use of fluorescent whitening agents and to bring the testing requirements partly in line with the requirements other EU member states for the non migration of these substances.

3.4.1 Rules for Selection of Paper Chemicals

The legislation as originally published in 1973 consisted primarily of a relatively short binding positive list of substances. In a number of amendments, this list has been expanded, but at present date , we do not believe that this list covers the full range of substances that are commonly used in the manufacture of food contact paper and board (the list is certainly shorter than the approved lists in either BfR Recommendation XXXVI or the Warenwet).

The positive list authorises the use of a number of fluorescent whitening agents (FWAs) in food contact paper and cardboard at levels up to 0.3%, subject to a requirement that they do not migrate into foods. The contents of this list and the upper use are all consistent with the requirements of BfR Recommendation XXXVI, although it should be mentioned that the Italian list specifies a greater range of FWAs than are currently listed in the Warenwet.

In our opinion, the Italian legislation meets the requirements of the GMP regulation with regard to having clear guidelines for selection of paper chemicals, but the list as it is currently structured is somewhat shorter than the positive lists in place in either Germany or the Netherlands and may not offer a sufficient range of substances to meet industry's requirements. There is also scope for conflict between the positive lists given in the Italian legislation and that of other member states, particularly with respect to FWAs. This is not an ideal situation given that one of the principal aims of the Framework Regulation was to harmonise national measures.

3.4.2 Restrictions on Paper Chemicals

Where a food contact substance is listed in the Italian positive list it is often listed with a maximum use limitation and/or a specific migration limit, and this may need to be tested in food simulants under conditions which replicate the end use of the paper. In principle this is in line with the requirements of Article 3 of the Framework regulation, but given that the positive list is not actively maintained to the same extent as the German or Dutch positive lists, in our view this could be viewed as an unnecessary complication as it brings no significant advantage over the approach adopted under BfR XXXVI whilst only going part of the way to offer the consumer the same degree of protection.

In our opinion therefore, the limits that are in place under the Italian legislation only partly meet the requirements of Article 3 of the Framework Regulation.

3.4.3 Approval Process for Inclusion on Positive List

Additional substances can be added to the Italian positive list by application to the Minister of Health using a procedure which is briefly referred to in Article 4 of the DM 21.3.1973. In practice, the process relies on previous assessments made for submissions under the plastics legislation and in principle should therefore be aligned with the EFSA. However, the legislation itself does not clearly set out the required information which should be submitted to the Minister of Health. It is, therefore, hard to argue that the current system as operated fully meets the requirements of Articles 8 to 12 of the Framework Regulation with regard to having clear rules for the approval process.

3.4.4 Recycled Fibre Requirements

The Italian legislation contains no comprehensive set of requirements for the levels of contaminants in recycled fibres when compared to virgin fibres, apart from the imposition of a limit of 2 mg per kg for the level of PCBs in the finished paper. This limit is also present in the French legislation, but was deleted from BfR Recommendation XXXVI following research which showed that PCBs were no longer present in fibres following a reduction in the use of these chemicals.

It is, however, worth noting that a 1993 amendment to the legislation contains a requirement that articles manufactured from recycled fibres should not be used in contact with foods for which migration testing would normally be required. The interpretation of this clause is that recycled fibre should not be used in contact with moist or fatty foods. This requirement clearly aimed to minimise the exposure of consumers to contaminating chemicals by restricting the use of recycled papers and boards to foods with low extracting power. However, from surveillance work carried out in the UK[36], it is known that chemicals such as diisopropylnaphthalenes (DIPNs) can migrate at significant levels from recycled board into dried foods (such as breakfast cereals), even when there is an intermediate layer of plastic between the card and the food. In the light of these findings, which came after the Italian legislators adopted their position on dried foods, it is hard to argue that the Italian legislation as it is currently framed is capable of controlling the migration of contaminating chemicals from recycled paper and cardboard and it would certainly benefit from monitoring a wider range of potential contaminants.

In our opinion therefore, the Italian legislation does not currently offer sufficient guidance to fully satisfy the requirements of the Framework and GMP Regulations with regard to the use of recycled fibres.

3.4.5 Declaration of Compliance

DM 21.3.1973 contains a requirement for a Declaration of Compliance, but the document does not currently contain any detailed guidance on the contents of such a Declaration of Compliance and this seems to be a gap compared to current EU practice in relation to other food contact materials.

3.4.6 Code for Good Manufacturing Practice

There is a general requirement under Article 27 of DM 21.3.1973 that GMP should be exercised to ensure to the presence of technological adjuvants is only at trace levels. However, in our opinion, this does not constitute detailed Guidance on GMP as would now be desirable to meet the requirements of the Framework and GMP regulations.

3.4.7 Rules for Multilayer Materials

The Italian legislation offers no specific or comprehensive guidance on multilayer /multimaterial structures based on paper/board in combination with plastics and/or metal layers. In our opinion, it therefore does little to clarify the requirements of Article 3 of the Framework Regulation in this area. There is, however some guidance on the use of cardboard multilayer materials and additional requirements on adhesives, colourants and waxed papers.

3.4.8 Testing Requirements under Italian Legislation

In addition to the specific migration restrictions described in an earlier section which apply when certain paper chemicals have been used, the Italian legislation also contains a requirement for 2 generic tests on food contact papers and cardboards.

- FWAs by EN 648
- PCBs by EN ISO 15318

The first of these is required under both BfR Recommendation XXXVI and the French Legislation, so in general, no additional work is required to establish compliance with the Italian legislation, if the paper/board already complies with German and French requirements. Experience tells us that the local enforcement agencies in Italy are particularly diligent in examining the transfer of FWAs into simulated foodstuffs.

3.5 Summary of National Legislation on Food Contact Paper and Board

In summary, we have seen that each of the pieces of National legislation reviewed has gone at least some way to satisfying key requirements of the Framework and GMP regulations. Each set of legislation has strengths and weaknesses and none fully meet the success criteria we identified for legislation to meet the requirements of the Framework and GMP regulations and the principal strengths and weaknesses.

German BfR Recommendation XXXVI

Key Strengths

- Clear practical positive list backed up by rigorous approval process that is now in line with EFSA protocols.
- Limits contained in the legislation at least reflect the level of chemicals to which consumers would be exposed.

Key Weaknesses

- No definition of requirements of a Declaration of Compliance
- No description of GMP requirements

Possible areas for improvement or partial gaps

- Positive list depends in part on historical approvals of chemicals carried out under protocols which are not well-aligned with current EFSA practice.
- Approach for recycled fibres is fragmentary and could be improved.
- Positive list is non-binding and hence there is a lack of clarity about whether some process chemicals should be listed.
- Multilayer structure rules do not allow for paper chemicals with SMLs under plastic legislation.

Dutch Warenwet

Key Strengths

- Clear practical positive list backed up by rigorous approval process that is now in line with EFSA protocols.

- Limits contained in the legislation reflect the level of chemicals to which consumers would be exposed and are to some extent harmonised with limits in the plastics legislation.

Key Weaknesses

- No definition of requirements of a Declaration of Compliance
- No description of GMP requirements
- No clear guidance on recycled fibre content.

Possible areas for improvement or partial gaps

- Positive list depends in part on historical approvals of chemicals carried out under protocols which are not well-aligned with current EFSA practice.
- Multilayer structure rules do not allow for paper chemicals with SMLs under plastic legislation.

French Legislation and the GDBP

Key Strengths

- No full positive list, but recognises the BfR and FDA positive lists.
- Limits contained in the BfR lists reflect the level of chemicals to which consumers would be exposed.
- Useful summary of GMP detailed under the GDBP.

Key Weaknesses

- No definition of requirements of a Declaration of Compliance
- Very little guidance on recycled fibre content.

Possible areas for improvement or partial gaps

- Positive lists incorporated by cross-reference depend in part on historical approvals of chemicals carried out under protocols which were not well-aligned with current EFSA practice.

Italian Legislation

Key Strengths

- Clear positive list for fluorescent whitening agents.

Key Weaknesses

- No clear definition of requirements of a Declaration of Compliance.
- No clear code for GMP
- No specific rules for multilayer/multimaterial structures.

Possible areas for improvement or partial gaps

- The positive list of approved substances is a little short and would benefit from updating and extension, to cover a greater number of the substances cleared under BfR XXXVI and the Warenwet.
- Clearer explanation of the rules for approval of new substances would be beneficial.
- There is only partial guidance on the contaminants in recycled fibres.

Clearly, within each of these four member states, these items of legislation must be respected, but the different positive lists and differing restrictions mean that ensuring compliance in all four states is very far from being a straightforward exercise. For instance, if one used a fluorescent whitening agent in a food contact paper/board, one would have to ensure that it was included on each of the four positive lists, each of which are framed in slightly different ways. Furthermore, even when one set of legislation acknowledges the positive list of a separate member state (as is the case in the French recognition of the BfR XXXVI list), the testing requirements of the legislation can be different. We have summarised the key testing requirements of the different member states in table 3.5.1, but it is clear that there are a number of differences between the approaches of the different states and this creates many anomalies one of which is the persistence of restrictions on PCBs in the French and Italian test matrices, long after this test was deemed not to be necessary under the BfR system.

In conclusion, although each of the sets of national legislation reviewed here do at least aim to ensure compliance with the GMP and Framework regulation, none of them are perfect and differences in approach mean that compliance across Europe can be fraught with difficulty. In this light, industry would clearly benefit from harmonised legislation or standards provided that the approach taken was practical and proportionate to the risks involved. It was with these aims in mind that the CoE resolution and the Industry Guidelines were developed and we will now discuss each of those documents in more detail.

3.5.1 Summary of tests required against the requirements of individual EU member States

	Tests Required in member States			
Test	**Germany‡**	**France‡**	**Holland‡**	**Italy‡**
OBAs EN 648	Yes	Yes	-	Yes
Colour Migration EN 646	Yes	Yes	-	-
Formaldehyde EN 1541	Yes	Yes	-	Yes
Glyoxal BfR Method	Yes	Yes	-	-
PCP CEN Method	Yes	Yes	-	-
3MCPD/DCP BfR Method	Yes		-	-
Antimicrobials EN 1104	Yes	Yes	-	-
Heavy Metals Pb, Cd, Hg, CrVI ENV 12497 and ENV12498	Yes	Yes	-	-
Organoleptic Inertness EN 1230	Yes	Yes	-	-
PCBs EN ISO 15318	-	Yes	-	Yes
Water extractables EN 647 (hot) and EN 920	-	Yes	Yes	-
Heptane extractables			Yes	-

‡ Please note that the German, Dutch and Netherlands legislation all contain additional provisions related to the migration of certain additional substances (expressed as SMLs or extraction limits or residual limits). Determination of the limits which apply is dependent on the formulation of the paper/board. The above table is not designed to be a comprehensive description of all testing requirements.

4 Council of Europe Resolution on Paper and Board in Contact with Foods; Resolution RESAP 2002(1) Version 3

The Council of Europe started work on the Paper and Board Resolution in 1987 with two main aims;

- Protection the health of the consumer
- Harmonisation of the approach taken towards paper and board food contact packaging materials.

The Council of Europe Resolution on paper and board was formally approved by the Committee of Ministers of the Council of Europe [CoE] on 18th September 2002 and has been subject to two subsequent revisions. The current text of the Policy Statement on *'paper and board materials and articles intended to come into contact with food'* (Version 3 - 11 December 2007[37]) is based around six documents. The first document contains the resolution itself with the remaining five being technical documents which are referenced from the main resolution and provide guidance on compliance with the resolution:

- Resolution ResAP (2002) 1 on *'paper and board materials and articles intended to come into contact with foodstuffs'*
- Technical document No. 1 – *'List of substances to be used in the manufacture of paper and board materials and articles intended to come into contact with foodstuffs'* (Version 2)
- Technical document No. 2 – *'Guidelines on test conditions and methods of analysis for paper and board materials and articles intended to come into contact with foodstuffs'* (Version 3)
- Technical document No. 3 – *'Guidelines on paper and board materials and articles, made from recycled fibres, intended to come into contact with foodstuffs'* (Version 2)
- Technical document No. 4 – *'CEPI Guide for good manufacturing practice for paper and board for food contact'* (prepared by CEPI)
- Technical document No. 5 – *'Practical Guide for users of Resolution ResAP (2002) 1 on paper and board materials intended to come into contact with foodstuffs'* (Version 2)

The resolution applies to all food-contact paper, including coated board and multilayer materials. Paper that is used in food-contact articles, but that is separated from the food by a functional barrier, non-woven materials, kitchen towels, napkins, and certain filter materials do not fall within the scope of the Resolution.

4.1 and 4.2 Rules for Selection of Paper Chemicals and Restrictions on Paper Chemicals

The part of the resolution where criteria for selection of raw materials are laid out is the inventory list given in Technical Document 1. This contains lists of Food Contact Substances (FCSs) permitted for use in food contact applications. Additives are divided between List 1 and List 2 substances.

- List 1 includes Additives evaluated by either (a) the SCF, (b) an EU Member State, or (c) by the US Food and Drug Administration, and (d) substances authorized as direct food additives. Inclusion in this part of the list requires the presence of a dossier which meets EFSA requirements and which allows the FCS to be classified in SCF Lists 0-4. List 1 therefore consists primarily of substances which have been assessed by EFSA in preparation of the plastics in contact with foodstuffs legislation.

- List 2 includes FCSs that do not meet the criteria laid down for List 1 substances. List 1 is further subdivided into Categories A and B;
    - Category A contains the list of authorized additives with the established restrictions
    - Category B contains a temporary list of additives authorized in Member States or approved by the US Food and Drug Administration, with restrictions to be fixed.

Monomers for use in the manufacture of polymeric additives are divided into three Appendices.

- Appendix A lists approved monomers approved at the European level with established restrictions
- Appendix B lists monomers authorized only in Member States or approved by US Food and Drug Administration, with restrictions to be fixed

- Appendix C lists monomers not yet assessed.
  In principle, because the approach adopted in compiling the inventory list was that adopted by EFSA, it is easy to argue that the list and its associated limits meet the requirements of Article 3 of the Framework regulation. However, the usability of the list as a tool for safety assessment of food contact chemicals, as required by the GMP regulation, is severely restricted by the large number of widely-used paper chemicals which are included on List 2 and therefore have not been through the EFSA approval process. For instance List 2 contains all the fluorescent whitening agents approved under National regulations and also glyoxal. Since none of these have previously been assessed by EFSA for use in plastics, the only comment next to their entry is that a restriction is yet to be fixed. It is therefore hard to argue that this element of the CoE Resolution will offer clear guidance on selection of materials without significant expenditure on the registration of these substances through EFSA or a national authority.

  Where restrictions are given in the lists, they are generally in the form of SMLs and these are based on the same assumptions as would be the case for plastics (i.e. consumers eating 1kg of food every day packed in the same material and in contact with 6 dm^2 of packaging material). It is questionable whether these assumptions are correct for most plastics in contact with foodstuffs. However, given the different usage ratio of paper/board in food contact and also the generally lower exposure of consumers to food packed in paper/board or coated paper/board, it is our opinion that these assumptions represent a significant overstatement of actual exposure risks to paper chemicals.

  One other point of confusion may arise from the common use of polymeric additives as paper chemicals. For instance, the kymene-type wet strength agents which are based on polyamine-epichlorohydrin type chemistry. These are listed according to the SMLs assigned to individual monomers and therefore have the potential to attract several SMLs for each wet strength agent rather than the relatively short list of extraction tests currently specified under BfR Recommendation XXXVI.

  Additionally, it is worth noting that under the Resolution, a None Detected SML (DL < 0.01 mg/kg) is assigned to epichlorohydrin, whereas under BfR

recommendation XXXVI a limit is instead placed on the level of DCP and 3MCPD (the hydrolysis products of epichlorohydrin) in a cold water extract (DCP < 0.002 mg/kg and 3 MCPD < 0.012 mg/kg). The BfR tests are carried out using an extract of 40 g of paper in 1 litre, hence for a 100 gsm paper, this is equivalent to 0.0003 mg of DCP per dm^2 of paper, which is equivalent to an SML of 0.0018 mg per kg using the conventional EFSA assumptions. It is therefore quite likely that BfR recommendation XXXVI is already controlling this risk to a greater extent than would be the case under the Resolution.

In summary, whilst the approach adopted in Technical Document 1 of the Resolution is clearly aligned to Article 3 of the Framework Resolution, its reliance on the existence of an EFSA assessment of the substance before any interpretation can be made of the suitability of the formulation means that it is quite likely that manufacturers would remain dependent on National Regulations to demonstrate suitability for many years until a large backlog of paper chemicals had been assessed. It is therefore hard to argue that it offers any clear rules that could be applied in the near future for the selection of raw materials to satisfy the requirements of the GMP regulation.

Additionally, in our opinion, given the lower exposure of foods to paper when compared with plastics, without incorporation of more sophisticated exposure modelling this is not likely to be a proportionate approach to controlling the risks. We therefore do not believe that the added level of complexity of the proposed system compared with that offered by the existing national lists would be justified.

4.3 Approval Process for Inclusion on Positive List

The proposed approval process for the incorporation of a substance on List 1 of the CoE resolution depends on the existence of a suitable dossier which has been assessed by EFSA. This approach is clearly aligned with the requirements of Articles 8 to 12 of the Framework Regulation. However, the EU do not currently have a harmonised regulation for paper in contact with foods, and so EFSA are not currently open to such applications.

If a decision were taken by the European Commission to adopt this approach, it would take a considerable amount of effort and expenditure to work through the EFSA approval process on those chemicals which have only been

assessed by the member states. This process could easily take 5 to 10 years based on the time that was required to develop the plastics legislation. There would almost certainly be a requirement for some clarification in the notes for guidance document to accommodate the different practical approaches which might be required to carry out migration studies on papers (e.g. agreed worst case extraction conditions etc).

4.4 Recycled Fibre Requirements

In our opinion, the Resolution offers a significantly enhanced Framework to demonstrate the safety of recycled fibres in contact with foodstuffs, when compared with the National Legislation described earlier in this report. The approach is based on three principles;

- The source of recovered paper and board
- The processing technologies used in the recovery/decontamination and
- The food types with which the recycled fibres may be used.

The general principle of the Resolution is that the cleaner the source of fibre, the less rigorous the cleaning process would need to be and the greater the range of foods with which the end product could be used (i.e. intimate contact with moist and fatty foods rather than just contact with foods to be peeled and/or washed).

Technical Document 3 also refers to the need for the use of GMP in the manufacture of paper and board in contact with foods. The requirements are laid out in more detail under Sections 3, 5 and 6 of Technical Document 3.

In the current version of the Technical Document, recovered paper/board is categorised into four Groups;

- Group 1 - Paper manufactured from food contact approved substances as defined in Technical Document 1. Unprinted, cuttings shavings etc from food contact paper.
- Group 2 - Paper with non-approved or unknown additives, unprinted, lightly printed or lightly coloured.

- Group 3 - Printed paper and board, corrugated board from supermarkets, paper and board from households and industry
- Prohibited waste paper; Hospital waste, paper/board that has been sorted from mixed household refuse, batches consisting mainly of carbonless copy paper, old archival papers etc.

Since these definitions are somewhat general, the Technical Document also clarifies Groups 2 and 3 using a number of standard paper types according to EN 643 which is widely used in the recycling industry.

Food types are defined as;

- Food type I; Aqueous and/or fatty foodstuffs
- Food type II; Dry, non-fatty foodstuffs
- Food type III; Foodstuffs which are shelled, peeled or washed before consumption.

A number of restrictions are then placed on certain contaminants known to be of concern in printed/recycled fibres;

[1] Di-isopropylnaphthalenes (DIPN); ' as low as reasonably achievable'.
[2] Partially hydrogenated terphenyls (HTTP); ' as low as reasonably achievable'
[3] Phthalates; see EC Directive 2002/72/EC and amendments for restrictions
[4] Solvents; ' as low as possible'
[5] Polycyclic aromatic hydrocarbons (PAHs); (SML = Not Detectable, Detection Limit 0.01 mg/kg in Food)
[6] Benzophenone; SML = 0.1 mg per dm^2 of paper
[7] Michler's Ketone (SML = Not Detectable, Detection Limit 0.01 mg/kg in Food)
[8] 4,4'-bis(diethylamino) benzophenone (DEAB), (SML = Not Detectable, Detection Limit 0.01 mg/kg in Food)
[9] Azo-colours; No detectable primary aromatic amines in the paper using a method with a detection limit of 0.1 mg/kg
[10] Primary aromatic amines suspected as carcinogens; same limit as given for Azo-colours
[11] Fluorescent whitening agents, no visible migration when tested by EN 648.

These test requirements do not apply when the source of the paper is purely from the collection of approved food contact papers (i.e. Group 1 Fibre), or when the finished article is intended for use only in contact with Food Type III. Items [1] to [6] apply to use of Group 2 and 3 papers in contact with all other food types. Items [7] to [11] only apply to the use of Group 2 paper in contact with aqueous and fatty foods. Group 3 Fibre is not permitted in contact with aqueous or fatty foods.

The above approach certainly goes beyond that adopted in any of the sets of member state legislation in identifying more compounds of risk which are likely to be present in and also in providing a framework which links the source of the fibre to the degree of care that is required both in the decontamination of the fibres and also in the extent of testing that is required. There is after all little practical benefit in testing unprinted fibre for residues which are most likely to be present in printed fibres.

Where the proposed guideline leaves something of a gap is in the establishing the efficacy of decontamination methods for recycled fibres. There is certainly potential for a wide range of contaminants to be present apart from those covered by the tests [1] to [11] and this clearly leaves the finished products open to the periodic discovery of new contaminants and consequent scare stories (for example, ITX and 4 methyl benzophenone). This is not an entirely dissimilar situation to that which presented itself to the plastic recycling industry, where plastics can clearly pick up contaminants in use. The solution evolved to support the use of recycled plastics in food contact is described in the recent EU Regulation on recycling of plastics EC Regulation 282/2008[38]. Regulation 282/2008 is essentially set up as an amendment to the GMP regulation and a key requirement is that the holders of a process should be able to demonstrate that it is capable of removing contaminants to an extent that they are considered not to pose a risk to health. The mechanism for this proof is through what is known as a challenge test[39] whereby known amounts of specified contaminants are fed into the recycling process and then the output of the process analysed to demonstrate safe removal. The challenge testing process was clearly designed with plastics recycling in mind and is almost certainly not appropriate for the paper and cardboard industry where paper mills operate on a much larger scale, but

it does demonstrate that an approach where there is imperfect knowledge about the precise content of the raw materials (and hence finished products) can be acceptable under Article 3 of the Framework Regulation and the GMP Regulation. The key issues that would need to be demonstrated for this to be accepted would be (a) the existence of an adequate GMP system with control points properly identified and (b) some means of demonstrating removal of contaminants.

Additionally, it should be noted that some of the clarity of this approach is compromised by the text in the consolidated testing matrix which contains a number of provisos which state that there is a requirement for specified clean up processes unless they are ' not necessary'. There is no explanation of when the processes might not be necessary and this leaves significant room for misinterpretation of the Resolution.

In our opinion, the Resolution clearly offers an improved approach towards the demonstration of the safety of recycled fibre than is present in any of the member state legislation and in our opinion goes a significant way towards satisfying the requirements of Article 3 of the Framework Regulation and the GMP Regulation. However, one area which might require further thought is what steps could be taken to demonstrate the safe removal of contaminants which are not included in the test schedule of the Resolution.

4.5 Declaration of Compliance

The Council of Europe Resolution does not currently contain any detailed guidance on the contents of a Declaration of Compliance and in our opinion, due to the complex interaction of fibre source, process technologies and tests that we have described in Section 4.4 above, it would be particularly important to communicate clearly which types of food could be used in contact with the finished recycled papers.

4.6 Code for Good Manufacturing Practice

A relatively brief description of the requirements of a GMP system Technical Document No. 4 which was prepared by CEPI in 1999. In essence, this provides a set of guidelines for;

- Selection of raw materials including fibres and paper chemicals (by reference to Technical Documents 1 and 3)
- Description of acceptable manufacturing and converting technologies
- A description of likely risks and hazards associated with these processes and their likely impact on food contact issues including means of protection, inspection and follow up/documentation. The is similar in structure to the French GDBP.
- Restrictions on the level of certain chemicals and contaminants present in papers contained in the other Technical Documents are incorporated by cross-reference.

Technical Document No 4 clearly predated the GMP regulation and therefore its wording is not aligned perfectly, but it does put in place a partial framework for Good Manufacturing Practice in the paper industry. However, since the wording of the document has now been superseded to some extent by the GMP regulation and there is clearly potential for confusion between these two documents.

In our opinion therefore Technical Document 4 offers a partial set of guidance along the lines of the GMP regulation, but would benefit from being updated to bring it in line with the GMP regulation and to provide more industry-focussed guidance. We understand that a revised GMP document is being prepared in support of the Industry Guidelines described later in this review.

4.7 Rules for Multilayer Materials

In principle, the Resolution specifies that paper layers should comply with the resolution itself and also states that when a plastic coating is present, it should be formulated in accordance with the plastics in contact with foodstuffs legislation. If any substances are present in the structure which are subject to restrictions (either QM, QMA or SML), regardless of which layer they are present in, they would be subject to that restriction in the finished product as a whole. This would mean that where a melamine-formaldehyde wet strength agent is used in a paper layer, the finished structure would be subject to the SMLs for formaldehyde (15 mg/kg) and melamine (30 mg/kg), regardless of whether the paper actually comes into contact with the food or not.

Where a functional barrier can be demonstrated, it would be possible to argue that you do not require to demonstrate compliance with the SMLs, but demonstration of the efficacy of functional barriers is not a simple matter in itself.

In our opinion, therefore, the CoE Resolution clearly deals with the issue of paper in multilayer products and in our opinion is already aligned at least to the requirements of the proposed Plastics Implementing Measure and already allows application of SMLs for non food contact layers which may be brought forward in future amendments of the Plastics Implementing Measure. It can therefore be viewed as satisfying the requirements of Article 3 of the Framework Regulation for this important category of materials.

4.8 Testing Requirements under Council of Europe Resolution

Due to the requirements associated with the use of recycled fibres, it is clear that there is potential for a significant volume of testing to demonstrate compliance with the Resolution. On the following page, we have detailed the tests which must be carried out on all paper materials and also where recycled fibres might be present. Additionally, there are a good number of common paper chemicals which might have SMLs. Testing of finished paper and board would therefore be relatively complex under the Resolution.

To mitigate this, the resolution offers clear guidelines on how to convert from SMLs to QMA type limits. However, these use the conventional ratio of 6 dm^2 of packaging material to each kg of food which is applied to plastics and may not be appropriate to papers. Additionally, the resolution permits the use of worst case extraction conditions in the demonstration of compliance. However, these steps cannot completely dilute the complexity of the compliance framework.

Limits Applying to All Food Contact Paper and Board

Substance	Limit	Method
Cadmium	0.02 mg/dm^2 paper & board	In an aqueous extract according to EN 12498
Lead	0.03 mg/dm^2 paper & board	In an aqueous extract according to EN 12498
Mercury	0.03 mg/dm^2 paper & board	In an aqueous extract according to EN 12497
Pentachlorophenol	0.15 mg/kg paper& board	In an aqueous extract according to EN 15320
Antimicrobial Substances	Paper and Board shall not release substances in quantities which have an antimicrobial effect	EN 1104
Dyes and colorants (where used)	no bleeding	EN 646

Limits Applying only When Recycled Fibre is Present		
Michler's ketone	Not detectable in foodstuffs (detection limit 0.01 mg/kg)	
4, 4'-bis (diethylamine) benzophenone	Not detectable in foodstuffs (detection limit 0.01 mg/kg)	
DIPN	As low as reasonably achievable	
HTTP	As low as reasonably achievable	
Phthalates	Limits taken from EC Directive 90/128/EC with guidance on conversion between SMLs and residual limits.	
Solvents	As low as possible	
Primary aromatic amines (PAAs)	Not detectable in foodstuffs (detection limit 0.01 mg/kg) Testing required for Food Type 1 only.	
Azo colourants (which may cleave to form PAAs)	Primary aromatic amines not detectable in foodstuffs (detection limit 0.01 mg/kg) Testing required for Food Type 1 only.	
Polycyclic Aromatic Hydrocarbons (PAH)	Not detectable in foodstuffs (detection limit 0.01 mg/kg)	
Benzophenone	Specific migration limit of 0.1 mg/dm^2 of paper	

4.9 Summary of Council of Europe Resolution

In summary, we have seen that the council of Europe Resolution set out to address some of the key weaknesses in the pre-existing member state legislation, but still it has distinct areas of strength and weakness.

Key Strengths

- Rigorous approval process for chemicals which sets out to be harmonised with EFSA protocols, and therefore limits are based on specific migration levels and are consistent with the approach previously taken for plastics.
- A top level GMP code is contained within the Resolution.
- A significantly more rigorous framework for the approval of recycled fibres when compared to national legislation including fibre source, clean up processes and testing protocols, but this comes at the price of complexity.
- Clear rules on multilayer materials.

Key Weaknesses

- The positive list contains a large number of substances which have not been fully assessed by an EFSA protocol and therefore the list does not currently offer sufficient guidance to determine whether their use is safe. Significant additional work would be required to assess the remaining substances.
- Specific migration limits where they are specified are based on consumption and exposure factors that are not realistic for paper/board.
- No definition of requirements of a Declaration of Compliance

Possible areas for improvement or partial gaps

- GMP Guidance would need to be brought into line with the requirements of the GMP regulation.

In our opinion, the key issues which detract from the usability of the Council of Europe Resolution are related to (a) the lack of clarity in the positive list, (b) the overestimation of consumer exposure and (c) the complex system of approval for recycled fibres based on the consolidated matrix. These would be key points that should be addressed in the preparation of any future legislation or Industry Guideline.

5 Industry Guideline for the Compliance of Paper & Board Materials and Articles for Food Contact

The Industry Guideline for the Compliance of Paper & Board Materials and Articles for Food Contact has been prepared by a working group formed of members from CEFIC, CEPI, CITPA and FPE with the aim of producing a more practical and consistent framework to ensure the safety of food contact paper and board than is currently offered by national legislation or in the CoE Resolution. In doing this it picks up on many strands from these other documents and develops them. In discussing the Industry Guideline, we have therefore adopted the same strategy as our review of these other documents and most of the details of the Guideline are discussed in sections 5.1 to 5.8.

There are, however, two important new concepts contained in the Industry Guideline which we would like to introduce before starting this review; correction factors and biological testing.

We would also acknowledge at this point the statement in section 1b of the Industry Guideline which reminds users that even if they comply with this document, they are still bound by the requirements of national legislation in the member states until such a point that the EU brings forward harmonised legislation. This has a number of consequences that should be considered carefully including the differences between positive lists for fluorescent whitening agents and some different tests which are required between countries.

5.0.1 Correction Factors

Annex 5 of the Industry Guideline introduces the concept of correction factors when assessing compliance with any restrictions for paper chemicals. These aim to provide a method to take into account the less intimate manner in which food often comes into contact with paper when compared to plastics and also to fulfil the role taken in the Council of Europe Resolution by the consolidated matrix.

The correction factors apply to;

- The limits given in Annex 1 (i.e. the substances approved under BfR recommendation XXXVI and therefore including substances such as formaldehyde etc), and
- Table 1 (i.e. the contaminants potentially originating from recovered fibres) with the exceptions of PCP which must comply with the uncorrected limit and any contaminants with a non-detectable limit.

The way in which this correction factor is intended to work is to multiply 2 factors; (a) a food type factor (1 for dry and fatty foods, 1.5 for dry non-fatty foods and 10 for washed and peeled foods) and (b) a temperature factor (1 for T>10ºC, 2 for 0ºC<T<10ºC and 5 for T<0ºC. The two factors would then be multiplied together to give a total correction factor which would be used to adjust the restriction for substances in papers.

It is worth pointing out that the document in its current version states that there is not sufficient data available to fully justify this approach, so the correction factor will be set to 1 until this data has been provided. The derivation of these factors has been very well described in the final report of the Biosafepaper project[40], where for benzophenone they compare the results of food surveillance data[41] on the level of this substance in foods and compare this with the level of the substance in the packaging. This has demonstrated that for benzophenone, this approach is feasible.

In our opinion, if it could be shown that this approach also works for a wider range of chemical substances (covered by restrictions under the Industry Guideline) and a wider range of exposure temperatures (to reflect for instance fast food storage), there would be a very good case to support the argument that the correction factors are consistent with Article 3 of the Framework regulation. When more data is available it is quite possible that the correction factors will be different to those given above. Until the data is available, we think the approach of setting the factor to 1 by default is a prudent one.

It is worth noting that in the current draft of the Industry Guideline, there are a number of references to the ratio of packaging material to food and the conventional assumption of 6 dm^2 per kg of food. Since the factors proposed

in Annex 5 and Table 2 do not correct for the exposed surface area of packaging, we would suggest that Annex 5 should be edited to just focus on the issue of correction factors without mention of the surface area, so as to prevent confusion with clause 7 which does include some references to correction for exposed surface area.

One key strength of this approach, assuming it is supported by further data, is that it would be possible to quote a minimum correction factor for a paper/board to ensure compliance and then users could determine very easily whether their application meets these requirements.

5.0.2 Biological Testing

Under clause 5 of the Industry Guideline, there is provision to use the methodology developed under the Biosafepaper project to demonstrate safety of food contact papers. This methodology is discussed very fully in the final report of this project, and a brief summary is given in Figure 4 of the Industry Guideline, so we do not intend to discuss this in detail here. However, in essence the methodology involves carrying out extraction tests (akin to migration tests or BfR extraction tests) on finished papers and then subjecting the extracts to a number of biological assays (Ames test, Acute Cytotoxicity, Comet assay and RNA synthesis inhibition). The method can therefore be viewed as being an abbreviated version of the toxicity tests which are carried out by EFSA with the tests carried out on extracts of the finished paper and therefore taking into account a wide range of substances including paper chemicals and contaminants from the recycling process which may have been present in the paper.

Currently, although there is some ongoing work in relation to provision of additional biological end-points (e.g. endocrine disruption), there does seem to be agreement between research institutes, legislators and industry that the approach could be used as part of the battery of tests for studying the food contact safety of paper/board and hence it has been included in the Industry Guideline. What is not currently included in the Industry Guideline, however, is an indication of the circumstances under which the Biosafepaper methodology should be used.

In our opinion, although the Biosafepaper methodology is extremely powerful, it is not well-suited to replace the routine type of testing that is today carried out against BfR recommendations. Principally, this is because the methodology is quite involved and hence expensive. The methodology also relies heavily on biological assays which can give ambiguous results and therefore would not be suited to routine compliance testing of the type usually required by end customers such as McDonald's and where simpler tests may be more appropriate. In later sections (5.1. and 5.4) we have identified two key areas where we think the methodology could help resolve problems faced by the paper industry, with regard to the use of recycled fibres and paper chemicals which have not been fully assessed. When and how this test methodology should be employed is clearly a key issue to be addressed within a later edition of the Guideline and in our opinion, Industry should seek to reach a clear consensus of what it is hoping to achieve from the method, so that it can get the best value from this novel approach.

5.1 Rules for Selection of Paper Chemicals

By contrast to the CoE Resolution, the Industry Guideline proposes to rely primarily on BfR Recommendation XXXVI in the selection of appropriate paper chemicals for food contact paper/board. A separate approach is suggested for the selection of fibres. Furthermore, the Industry Guideline states that any restrictions applying to substances under BfR Recommendation XXXVI should be applied (e.g. the restrictions on DCP/3MCPD, formaldehyde, glyoxal etc and also maximum use limits specified in the BfR Recommendation XXXVI). The Industry Guideline also mentions that other substances which are subject to other approvals may be acceptable provided that their use can be shown to be in line with the requirements of Article 3 of the Framework Resolution. Specifically, the Industry Guideline mentions USA FDA Regulations 176.170 and 176.180 relating to paper in contact with aqueous and fatty or dry foods respectively[31].

Although the Dutch Warenwet list is a binding list of approved substances and forms National legislation within the EU, it is not mentioned specifically in the Industry Guideline, even though by inference it can be taken to meet the general requirements of the Guideline. Given that the underlying processes behind the Warenwet are similar to those used by the BfR, one could make an argument that the Warenwet should be included in the Guideline on at

least an equal footing with the FDA legislation. Given the fragmentary and sometimes incomplete nature of the French and Italian National lists, in our opinion there would be little benefit if they were included specifically.

The approach described in the Industry Guideline clearly has an advantage of usability over the CoE Resolution in that it provides clearer guidelines for the selection of paper chemicals and that most commonly used paper chemicals are on one of these lists and have at some point been assessed. For a great number of such chemicals, the CoE Resolution just states that a restriction is yet to be fixed and hence does not form a useful guideline for the selection of raw materials or in identifying suitable tests on finished products. However, because the Guideline adopts the lists from National legislation, it also reflects all the problems and inconsistencies of these National lists. Specifically;

- Where a substance has been approved under the BfR system, there is an issue of whether that assessment has been carried out recently under processes which are well-aligned to EFSA protocols, or historically in which case the linkage will not be so strong. In the first case, it is easy to argue that the use of the chemical is supported by the Framework Regulation in the second case it could be more difficult.

- There is a clear potential for conflicts between restrictions for individual substances given in (a) BfR XXXVI, (b) The Warenwet and (c) FDA Regulations. For instance take the case of glyoxal which is approved under BfR XXXVI for use as a wet-strength agent subject to an extraction limit of 1.5 mg per dm^2. Under the Warenwet, it is approved for use as *'an insolubilising agent in glucose-based layer. Level not to exceed 1 % by weight of the glucose content. Only for non alcoholic foods and beverages'*. To confuse matters further, the same substance is approved under FDA regulations *'for use only as an insolubilizing agent in starch- and protein based coatings that contact nonalcoholic foods, and limited to use at a level not to exceed 6 percent by weight of the starch or protein fraction of the coating solids.'* Having a clear set of rules for resolving these conflicts within the guideline would be helpful (e.g. by identifying which limit is most restrictive), but in this case the approval of the substance would still be restricted to different applications under the different sets of legislation. In our opinion, for glyoxal

the BfR approach makes the most sense. After all, the human metabolism doesn't know which type of additive has transferred the glyoxal into its food. There is logically either a safe limit, or it is not safe. However, clearly the Warenwet will remain in force in the Netherlands and therefore its use restriction must be respected.

- When the FDA regulations have been used to support the selection of a chemical, there is a clear potential that the assessment will have been carried out using a protocol that is significantly different from that used by EFSA. This will especially be the case where the approval is historical, bearing in mind that FDA approvals in some cases stretch back 50 years. In the case of substances which have been approved more recently under the Food Contact Notification Programme (since 2000), or under the Food Additive Petition process (from 1993 when it was partially harmonised with the EFSA procedure) there is a better argument that the approval can be used to support selection of the chemical.

  Clearly, by relying on BfR Recommendation XXVI as the primary list, it can be argued that the Industry Guideline offers at least the same degree of assurance that is currently in place throughout Europe where this approach is widely accepted. However, one clear question that comes out of the above discussion is how to cope with the criticism that the approvals have been granted over a long period of years and were not always well-aligned to current EFSA protocols. This criticism applies equally to some of the historical approvals under BfR or FDA regulations and leaves at least some question mark over the use of some of the substances on these lists as it is not possible to argue unequivocally that their use has been shown to be in line with Article 3 of the Framework regulation.

  One possible solution would be to adopt the line of the CoE Resolution and to re-evaluate a great number of individual substances using the standard EFSA protocols. This would be consistent with the Framework Regulation, but would have the disadvantage of cost and the length of time taken to work through this process which we have previously discussed. Additionally, given the known lower exposure to food contact paper and board compared to that for plastics, it is arguable that this would not be proportionate to the risks.

Another possible solution to this problem would be to make use of the methodology used in the Biosafepaper project and segregate paper chemicals approved under BfR XXXVI, Warenwet and USA FDA 21CFR into two categories;

1. Substances which have been assessed recently under protocols which are well-aligned to current EFSA practice.
2. Substances which were previously assessed and which were subject to less stringent assessment.

For the first group of substances, the National approval could be taken directly. For the second group of substances, a review could be carried out of the original dossier and if any significant gaps in information are identified (i.e. if there are any doubts that the substance would be approved by the BfR today without any further supporting data), further supporting evidence could be produced by using the Biosafepaper methodology to establish that no harmful levels of substances are migrating into foods from finished samples of paper containing the substances. Only if the materials did not clear this battery of biological tests would there be a need to go further down the EFSA approval process. In our opinion, this would make it significantly easier to argue that the Industry Guideline was aligned to the requirements of the Framework and GMP Regulations for the selection of paper chemicals.

In our opinion, this means that The Industry Guideline partly meets the requirements of the GMP regulation with regard to having clear guidelines for selection of paper chemicals, at least to the same extent as BfR Recommendation XXVI. It would be a significant improvement to the clarity of the Recommendation if it were to contain some clear guidance on priorities when BfR XXXVI, The Warenwet and FDA conflict in the restrictions they assign to individual chemicals.

5.2 Restrictions on Paper Chemicals

For the greater part, under the Industry Guideline, it is expected that restrictions on the use of chemicals would be taken from BfR Recommendation XXXVI and hence could be viewed in the same manner and it is likely that they would be subject to (a) a maximum use level and/or (b) an extraction restriction.

As explained in the section relating to BfR Recommendation XXXVI, these restrictions on paper chemicals can be viewed in one of two ways. Whilst at first glance, many of these limits are expressed as extraction limits into water they can also be viewed as residual limits on the substance in food contact papers and can therefore also be seen as compositional limits which are easier for industry to comply with than specific migration limits. The restrictions can also be converted between QM, QMA and SML figures using simple arithmetic and conventional assumptions about the weights of paper, the amount of paper in contact with each kg of food and complete transfer of substances. The transfer of chemicals from paper to foods is, after all, not likely to be diffusion-limited (as is often the case in plastics) and there therefore seems little merit in becoming mired in the differences between QMA and SML limits, which should be equivalent.

However, since the restrictions set for recently approved substances are based on migration studies and known toxicology for the substance and have been set using reasonable assumptions to relate migration levels to the level in paper, it can be viewed that they are in effect controlling the level of migration of paper chemicals (and/or their constituents and contaminants) into foods in line with the requirements of Article 3 of the Framework Regulation.

It should also be noted that the Industry Guideline aims to apply the correction factors described in section 5.0.1 to the assessment of compliance with the limits specified for individual chemicals. Pending further experimental data, the correction factor has been set at as 1, but it is envisaged that this would be a central feature of the final edition of the guideline and in our opinion (subject to further supporting data), the approach would be consistent with the requirements of Article 3 of the Framework Regulation.

On this basis, we can conclude that, where specified, the limits within the Industry Guideline (largely by incorporation from BfR Recommendation XXXVI) are based on an assessment of the migration of substances into foods, and are at least partly capable of controlling that migration in line with the requirements of Article 3 of the Framework regulation.

5.3 Approval Process for Inclusion on Positive List

Under the current version of the Industry Guideline it is not proposed to develop an approval process outside of the BfR process. The Guideline can therefore be considered to meet this requirement to the same extent as the BfR Recommendation or the Warenwet.

5.4 Recycled Fibre Requirements

The issue of how to demonstrate the safety of paper/board manufactured from recovered fibre is essentially a matter of how one chooses to manage the risks associated with a variable feedstock of recovered fibre which may be contaminated with inks, adhesives, residues of substances picked up in use and bacteria or moulds picked up in handling during the time which the paper/board spends in a domestic environment and is out of control of the manufacturer or converter. The approach adopted within the Industry Guideline to ensure the safety of paper/board produced from recovered fibre is based on several key elements;

- Selection of recovered paper of an appropriate quality
- Selection of appropriate processing technologies
- Operation of Good Manufacturing Practice
- Testing of finished products to ensure that a number of known potential contaminants are absent from the recycled paper/board.

The problem can be viewed to some extent as a similar challenge to that faced by the recyclers of food grade plastics and covered by the recent regulation on the recycling of plastics for food contact applications[38]. The plastics recycling regulation is structured as an amendment to the GMP regulation and deals with a very similar problem to paper recycling (i.e. variable and contaminated feedstock) and seeks to ensure that appropriate systems are put in place to select raw materials, demonstrate process efficacy and identify critical control points which can be used in the quality control systems of those companies operating recycling plants. The approach taken within the plastics industry to demonstrate efficacy and identify critical control parameters is through what is known as a challenge test. Under this methodology, known amounts of contaminants spanning a range of physicochemical properties are introduced to the waste stream

entering the recycling process and the output is analysed to assess the removal efficiency. This approach was developed within the plastic industry and hence is tailored to the recycling processes used for plastics. Given the relatively large scale of paper mills compared to individual plastics recycling lines and also the nature of the relative technologies, it is unlikely that such an approach would be practicable in the recycled paper industry. However, it does demonstrate the point that by using good manufacturing processes which are aligned to the requirements of the GMP regulation and by defining some measure to demonstrate that the clean up has been effective, the European Commission have felt comfortable enough to put in place an approval process for recycled plastics despite the fact that no-one can be 100% certain of the precise composition of the recycled material. Given the differing technologies involved in recycling paper/board when compared to plastics and lower exposure of consumers to food contact paper/board, it is very likely that the practical means to demonstrate clean up would be different to those in the plastics industry.

5.4.1 Control of Feedstock

This is clearly a key issue and the Industry Guideline firstly adopts the same policy as that taken under the Council of Europe Resolution by excluding mixed waste from refuse sorting stations or from multi-material recycling systems. Additionally, a number of other categories of fibre are excluded from use in food contact paper and board including hospital waste, batches consisting mainly of carbonless copy paper, old archival papers etc.

The Industry Guideline refers to a system whereby recovered paper and manufacturing industries would use a system to identify batches of paper supplied to paper mills based on the supplier reference and the EN 643 classification of each batch of paper. In our opinion, this would be aligned to the requirements of the Framework Regulation for backwards traceability (at least by one step).

Backing this system up is the CEPI Guideline on responsible sourcing of fibre [42] and guidance on the selection/rejection of unusable fibre sources. These documents all provide useful controls in the manufacture of recycled papers, but when viewed alongside the GMP Code of practice which we have reviewed in Section 5.6 , they form a slightly confusing set of documents

which would benefit from being compiled into a single document rather than the current position where they are cross-referenced.

In common with the national legislation previously described and the CoE Resolution, the above approach does have two blind spots which leave open the possibility of criticism;

- It is not possible to guarantee that all paper/board taken into the recycling process was manufactured only using substances approved for food contact. There will inevitably be some intermingling of non-food contact paper/board in the collection process.

- In use, the paper/board may have been printed and or used in conjunction with adhesives. These classes of materials are not subject to specific EU legislation and this means that the feedstock for the recycling process will have potentially been exposed to a wide range of poorly-regulated and unknown contaminants which will probably have been removed to some extent by the recycling process. However, it is also highly likely that some residues remain in the recycled paper/board and these leave the manufacturers open to periodic scare stories arising from analyses of food packed in recycled paper/board either by enforcement agencies or non-governmental organisations campaigning against the packaging industry.

  One possible solution to the above two problems would be to use the Biosafepaper methodology to demonstrate that the finished product of the recycling process is safe and that the process is being operated with correct controls in place to ensure that the finished paper/board meets the safety requirements of Article 3 of the Framework Regulation. This may still take a little further development work to the Biosafepaper methodology using additional endpoints until the majority of regulators accept the approach. However, in our opinion, the Biosafepaper project clearly has the potential to offer an extremely powerful means to demonstrate the efficacy of the recycling systems in place at recycled paper manufacturers and could therefore be used as part of an authorisation procedure for paper recycling processes.

5.4.2 Selection of appropriate processing technologies and Operation of Good Manufacturing Practice

From communications with CEPI, we understand that a revised GMP Guide for Paper is currently being prepared and have been provided with a draft copy of the document. In our opinion, it appears to be aligned well with the wording of the Framework and GMP regulations and has clearly been structured to reflect best practice in the paper industry. For simplicity and the prevention of conflict between different documents, consideration should be given to incorporating the CEPI guideline on responsible sourcing within this document (or as an appendix).

In our opinion, therefore the approach taken within the Industry Guideline towards selection of process technologies and GMP is therefore aligned with the GMP regulation, subject to the drafting process being completed.

5.4.3 Testing of finished products

We will discuss the testing requirements of the Industry Guidelines more fully in Section 5.8 below, but it is worth noting that the list of contaminants tested for under the Industry Guideline takes as a starting point the list of substances under the full testing set of the CoE resolution. The list is based on known contaminants (from inks adhesives etc) in recycled fibres. There are a few differences between the lists in the CoE Resolution and the Industry Guideline. For instance, there is no requirement for testing of solvent residues or HTTP under the Industry Guideline whereas these were listed in the CoE Resolution. Care should be taken to ensure that there is a rational argument for leaving these substances out of the list.

It is also worth noting that under the Industry Guideline, many of the limits which applied only to recycled paper under the CoE Resolution have been extended to cover virgin paper too although we know that the contaminants are likely only to be present in recycled fibres. We will comment on this later in section 5.8 on testing requirements, but it is clear that it reduces complexity in the approach compared to the CoE Resolution at the expense of additional testing for virgin paper/board.

It is also worth noting that the limits given in the Industry Guideline have mostly been expressed in the form of QMA limits rather than SMLs as was the case in the CoE resolution. The two sets of limits are essentially equivalent and in our opinion, for practical reasons, it makes more sense to measure the residues of these substances than to control them by measuring migration into food simulants. In reality, the CoE resolution also provided this option, but by explicitly stating that the limit is a QMA, the Industry Guideline points its users in the most practical direction.

In our opinion, the approach taken offers a more rigorous approach to the control of contaminants in recycled paper than is the case under National Regulations and therefore goes a very long way towards meeting the requirements of Article 3 of the Framework Regulation in controlling these contaminants.

5.4.4 Summary of Recycled Fibre Requirements

From the forgoing discussion, we can conclude that the approach which has been put in place goes a very long way towards meeting the requirements of the Framework and GMP regulations with regard to the selection of recycled fibres, recycling process and ensuring that the finished fibre is of an appropriate quality. The two key issues we would suggest that are developed further would be;

- Use of the Biosafepaper methodology in validation of recycling processes
- Further work on a more specific GMP Guidance Document

In summary, it is our opinion that the Guideline puts in place the beginnings of an approach which is both practical and aligned with the requirements of the Framework and GMP Regulations. In doing so, it is very easy to argue that it provides a more useful set of Guidelines for the safe use of recycled fibres than is currently in place under any of the National Regulations.

5.5 Declaration of Compliance

Unlike any of the pieces of National legislation or the CoE Resolution reviewed in earlier sections, the Industry Guidelines contain some very clear guidance about the contents of a Declaration of Compliance. The contents described in the suggested format include most of the points required under

Article 16 of the framework regulation and would, in our opinion form a very useful set of guidance in informing an end user of the paper/board what the product can safely be used for. This is ultimately the point of a Declaration of Compliance.

The format of the Declaration is additionally well-aligned with the general methodology adopted under the Industry Guideline, particularly in item 4.5 where 2 options are given for communicating the acceptable end uses for the products (a) quoting suitable food types and temperatures or (b) quoting a minimum Correction Factor (see discussion in section 5.0.1). In our opinion, the two approaches are broadly equivalent with the correction factor approach being slightly more elegant, but if it is used in a statement, such a Declaration would benefit from a short table giving a partial list of the most common food types/temperatures and the correction factors associated with them.

One absence from the Declaration of Compliance is a statement on *'dual use'* or *'multiple function'* additives. These are additives which would have a use in paper and also have a use as direct food additives. Under EC Directive 2002/72/EC and its amendments, manufacturers of plastics have an obligation to declare when they have such an additive present, so that end users can ensure that they do not accidentally contravene any separate restrictions under general food law. We would strongly suggest the inclusion of a statement about ' dual use' additives in the standard Declaration. This could be backed up with an agreed list of what the industry regards as dual use additives.

Additionally, we would like to highlight point 4.6 in the Guideline which deals with substances in paper which are subject to separate SMLs under EC Directive 2002/72/EC and its amendments. The aim of making such a statement is undoubtedly to inform users of the paper in multilayer laminates that they should test their finished products in line with any SMLs under either the Industry Guideline or the Plastics Implementing Measure when this is brought forward. This would apply to a relatively short list of substances which have uses in paper **and** plastics. There is already a working list of these within the Warenwet. For reasons of clarity and openness, we would generally tend to recommend the approach of making a straight declaration of these substances and their associated restrictions without requiring users to

enter into a confidentiality agreement. After all, there is little intellectual property in knowing that paper often contains additives containing formaldehyde which is subject to an SML of 15 mg/kg in foods. We would suggest that confidentiality is only invoked relatively infrequently when there is a genuine need to protect an innovative product.

If by calculation from the residual level of such a substance, it can be shown that the finished paper will not exceed this limit under any circumstances, an additional comment should be included in the statement, so that the producer of the multilayer product knows that they need not carry out any further work.

One additional point we would like to highlight is that of validity period for the Declaration. For many years, it has been common practice to incorporate a validity period of two years on statements of compliance with BfR Recommendation XXXVI. There is no mention of this validity period within the Recommendation itself, so this has been added externally. There are a number of questions associated with including a validity period;

- What should happen if the legislation is amended at some point after the issue of the statement and prior to renewal?

- Given that the results of tests against extraction limits are dependent on the variability of the product and statements are generally supported by only a single set of data without any long run of data to support the assumption that they are representative of the production as a whole, the best they can represent is a snapshot of production on a single day. To extrapolate a validity period on this basis is therefore not easy to justify. In reality it would never be possible to know whether the period selected is too long or indeed too short without repeated testing.

  For these reasons, we would not favour setting a validity period within the industry Guidelines. If individual operators have sufficient robust statistical information to feel confident in setting validity periods, this should not preclude them from doing so, but it would be difficult to generalise and we would tend to exclude it from the Guideline.

In our opinion, the format for the Declaration of Compliance offered in the Industry Guidelines is generally a good one and (with a few minor amendments) it is possible to make a very strong case that it meets the requirements of Article 16 of the Framework Regulation.

5.6 Code for Good Manufacturing Practice

As previously discussed in Section 5.4.2, a new version of the CEPI guideline for GMP is currently under preparation to supersede the version published in the CoE resolution and to bring its requirements into line with the GMP regulation. We have seen a draft copy of this document and it appears to deal with all of the requirements of the GMP regulation and the traceability requirements of the Framework regulation as well as having been written from a practical perspective providing guidelines for quality managers and auditors. We can therefore conclude that the Industry Guideline through this document (when it is published) will provide clear guidance on GMP.

Prior to its publication, we would suggest a careful reading of the CEPI GMP Guideline alongside the GMP regulation itself to ensure that all requirements of the GMP regulation have been dealt with clearly and in a manner which is well-aligned with operating practices in the paper/board industry.

5.7 Rules for Multilayer Materials

As previously discussed, the rules relating to multilayer materials under existing EU legislation are far from clear and hence form an important area which requires clarification. In our opinion, this could therefore be a very useful role for the Industry Guideline. We note, however, that the position of paper multilayer materials may well be affected by the expected plastics implementing measure and hence, this part of the guideline might be superseded or may need to be brought into line with EU legislation and should therefore be thought of as a draft for development. The following discussion is based on the current draft of the document and offers our opinion on the suitability of the approach and suggestions for further improvements.

The rules provided under Clause 7 relate to all multilayer structures manufactured using a paper/board layer and are split into 3 categories;

- **Category 1:** Multilayers with no plastic or aluminium layer between the paper/board and food; in which case the paper, in the same way as would be the case for a single layer material, and the other layer/s in the construction would have to comply with EU or national legislation.

- **Category 2:** Multilayers with at least one layer of plastic between paper/board and the food, but no aluminium foil; these pose a significantly more complex problem and are dealt with by a combination of migration tests and extraction tests with the results corrected by exposure factors and also the use of the correction factors described in section 5.0.1 as well as the conventional fatty food reduction factors taken from the plastics legislation.

- **Category 3:** Multilayers with aluminium foil between the paper/board and food (with or without additional layer(s) of plastic); in which case paper shall comply with the Guideline, but the highest correction factors shall be applied irrespective of end use. Other layers shall comply with applicable EU or National Standards.

Clearly, the area which has been most open to debate under existing legislation is how to ensure safety in use for Category 2 laminates, particularly since these products currently lie outside the scope of EC Directive 2002/72/EC and its amendments. The proposal within the Industry Guideline is that all layers shall comply with the compositional requirements that apply to them under National or EU legislation. This means that the plastic would need to be formulated solely from monomers and additives which are listed in EC Directive 2002/72/EC as amended. For the paper layer, the Industry Guideline is also quite clear in stating that this should comply with the requirements of the Guideline. However, the Industry Guideline also proposes a scheme for the assessment of the finished multilayer product to ensure that they comply with overall and specific migration limits.

For determination of overall migration, there are issues surrounding the selection of food simulants and test conditions, given that for practical

reasons; olive oil can not generally be used as a food simulant with these types of materials. There are additionally a number of issues which cause the testing of these laminates with aqueous and volatile migration to be less than straightforward, particularly when the plastic layer is thin[43]. The guidance within this document of how to cope with the problems of overall migration testing is not completely developed. In our opinion, therefore, there is some need for additional guidance (either within this document of an additional technical guideline) on how to carry out overall migration testing on these materials.

The approach described in the Industry Guideline of how to approach checking compliance with SMLs essentially allows for two approaches; (a) measurement of migration at the food contact surface or (b) calculation of migration based on the known level of substances in the paper and in the plastic.

Where specific migration is measured at the plastic surface, the result may be corrected by the conventional reduction factor PLRF (referred to in the plastics legislation as DRF and only applying to migration into fatty foods) and then to multiply this by an additional exposure correction factor (EXCF) to reflect the low amount of food which comes into direct contact with paper/plastic laminates.

In general, the EC have stated that they are not averse to the use of exposure data when it is scientifically justified and this is the background to the recently launched FACET programme which is supported by the EU and industry, so in our opinion this approach could be useful, provided it is supported by rigorous scientific data.

EXCF is a correction factor predicated on the basis that when conventional SMLs were set under the plastics legislation, this was on the assumption of 6 dm^2 of packaging material being in contact with 1 kg of food and the consumer eating 1 kg of this food (packed in the same packaging every day of their life). This is clearly a cautious method of estimating exposure even for plastics. Data within the Industry Guideline suggests that a consumer's exposure to plastic coated paper/board is even lower at only 0.8 dm^2 per day and therefore EXCF = 6/0.8 = 7.8 (i.e. the directly measured migration of a

substances can exceed the SML by a factor of 7.8 before it is actually considered to be a problem). The acceptability of this approach will therefore depend crucially on the robustness of this assumption.

Within the guideline, it is not entirely clear whether the daily exposure of 0.8 dm^2 of plastic coated paper represents a mean, median or cautious estimate of exposure[44]. In our opinion, the derivation of this figure should be expanded upon to help support the approach. In compiling this review, we have carried out some rough calculations to assess the validity of the assumed 0.8 dm^2 per day exposure estimate. Consider for example a 1 litre carton of fresh fruit juice constructed from a paperboard/PE laminate (no aluminium layer) with an internal surface area of approximately 6.6 dm^2. Such packs are widely available from major retailers in the UK. Take into account a consumer who might drink 250 ml of fruit juice each morning (usually from a very similar pack) and through this means alone (and without considering the rest of their diet) will receive an exposure to 1.65 dm^2 to these laminates every day. Whilst these assumptions might represent an above average exposure to these materials, it is hard to argue that they represent an extreme consumer. It is also easy to envisage circumstances where consumers might get even more exposure to these materials through fruit juice alone, since consumption of more than 250 ml of fruit juice per day is not that uncommon. It is therefore quite likely that this daily exposure figure would be viewed with some scepticism by regulators or member states and may need to be set with slightly more caution.

This above argument poses the important question of what level of exposure to laminate materials does one need to take into account in setting EXCF. Clearly by considering a very extreme consumer, one would be overestimating exposure for most consumers, but by basing EXCF on the average consumer, there would still be a large number of consumers exposed to significantly higher amounts of these materials.

By means of illustration of what legislators might find acceptable, consumption data has already been used within the plastics legislation where a daily fat consumption of 200 g was one of the key assumptions behind the introduction of fat reduction factors to the plastics legislation under EC Directive 2007/19/EC. Before fat reduction factors were adopted, an

extensive study was carried out using consumption data gathered across the EU and a figure of 200 g per day was agreed on, based on the 90th percentile of fat consumption of consumers across the EU (as an explanation, roughly only 10% of the population consume more fat than this). This would clearly seem to offer some guidance of what the EC consider to offer a reasonable worst case scenario in assessing exposure risk.

The acceptance of this argument for plastics was a significant advance, because until then the legislators had felt constrained to think about very extreme consumers and this position clearly shifted. For an exposure approach to be an acceptable means to provide a correction for the area of paper/plastics laminates, in our opinion more work would have to be carried out to establish a reasonable worst case exposure figure (probably based on the 90th or 95th percentile) and this could be used to revise the estimate of EXCF. This will probably move the factor down, but it still would offer a useful relief from the full application of the uncorrected SMLs.

Where specific migration is determined on the basis of calculation from the paper and board layer only, the correction factor PBRF (conventionally set to 1, pending further information) is to be multiplied by EXCF to give a combined correction factor which can then be applied to the measured migration level.

As a general summary, in our opinion this part of the guideline has certainly been drafted bearing in mind the important principle of Article 3 of the Framework Regulation that substances should not enter foods from multilayer materials at a level likely to pose a risk to the health of the consumer. In this respect, it is entirely within the spirit of the legislation. However, there are clearly two factors used within this section to provide some relief from specific migration limits and which in our opinion would almost certainly require further data to support them before they are accepted fully by legislators; PBCF and EXCF.

As an additional general comment, this particular section of the Industry Guideline would benefit from the inclusion of a number of worked examples of how to use the guidelines to demonstrate compliance with SMLs for a paper/plastics laminate. This would greatly improve the readability of the document and clarify the concepts in the mind of the users. As previously

mentioned, care should also be taken to ensure that this section of the Industry Guideline remains harmonised with the plastics implementing measure as this develops.

5.8 Testing Requirements under Industry Guideline

The testing requirements for paper/board under the Industry Guideline break down into two broad categories; (a) those associated with paper chemicals (i.e. the limits applied under national regulations such as BfR XXXVI) and (b) those applying to fibres (even though the measurements are largely carried out on finished paper/board).

The first thing to notice about the testing requirements relating to fibres under the Industry Guideline is that the list of contaminants which are to be tested is very similar to the list within the Council of Europe resolution. However, it is worth noting that within the CoE Resolution, certain tests for residues of inks, adhesives etc apply only when recycled fibre is used. Under the Industry Guidelines, these limits have been applied to all fibre types regardless of whether any recycled fibre is actually present. This was a conscious decision on the part of those drafting the Guideline and was partly founded on the assumption that (a) only a minority of paper/board contains 100% virgin fibre, (b) a desire to show that the approach was rigorous, and (c) an aim to reduce some of the complexity associated with the Council of Europe Resolution where testing requirements vary with fibre source. The aim of this is an entirely laudable one and is certainly consistent with the requirements of Article 3 of the Framework Regulation, although it could be argued to place an unfair burden on virgin paper/board manufacturers.

From discussions with CEPI members, it is apparent that frequent testing against these limits was not intended for virgin fibre products and that they only envisaged this being carried out once . This is backed up within the text of Clause 3 of the Guideline where it is stated that *'if for instance it can be shown from calculations, from a knowledge of the constituents, or from other information giving conclusive evidence, that a particular substance could never exceed its restriction in the material or article, then the very lowest testing frequency (one single test) would be appropriate'*. However, this position does appear to conflict slightly with the comments on frequency of testing given elsewhere under Clause 3 of the Guideline, where there is a

statement that frequency of testing should be determined statistically. One reading of Clause 3 would be that virgin fibre operators would each have to determine their own frequency of testing based on repeated testing for these contaminants which we know are only likely to be present alongside recycled fibres. Additionally, this section could also be construed in different ways by end users and auditors who would possibly require this work to be carried out annually. In our opinion therefore, some consideration should either be given to exempting virgin paper/board manufacturers from these restrictions, or to clarify the wording of this section so that the responsibilities of virgin paper/board suppliers are more clearly defined with respect to frequency of testing.

It is also worth noticing that there are differences between the limits and chemicals listed in the CoE Resolution and the Industry Guideline. Some chemicals previously listed in the CoE Resolution are absent from the list in the Industry Guideline and have been replaced with others. Consideration should be given to how these differences can be rationalised and supporting information should be collated. This information should not necessarily be presented within the Industry Guideline itself, but should be available to support the approach should legislators request justification.

What were previously expressed as SMLs within the Council of Europe Resolution have been replaced by QM or QMA limits in the Industry Guideline. In our opinion, this is a perfectly reasonable approach and entirely consistent with the aims Article 3 of the Framework Regulation and the mechanism put in place to support the plastics legislation. It is therefore perfectly acceptable and offers a more practical means of control than direct measurement of SMLs. For comparison with the limits contained in the Council of Europe Resolution under Section 4.8, the restrictions specified in the Industry Guideline for all papers are given in the following table.

Limits Applying to All Food Contact Paper and Board

Substance	Limit	Method
Cadmium	0.5 mg/kg paper & board	In an aqueous extract according to EN 12498
Lead	3 mg/kg paper & board	In an aqueous extract according to EN 12498
Mercury	0.3 mg/kg paper & board	In an aqueous extract according to EN 12497
Pentachlorophenol	0.15 mg/kg paper& board	In an aqueous extract according to EN 15320
Antimicrobial Substances	Paper and Board shall not release substances in quantities which have an antimicrobial effect	EN 1104
Dyes and colorants (where used)	no bleeding	EN 646
Fluorescent Whitening Agents (where used and in case of recycled fibres)	no bleeding	EN 648
Michler's ketone	0.0016 mg/dm^2 in paper & board (non-detectable)	See test quoted in Annex 3
4, 4' bis (diethylamine) benzophenone (DEAB)	0.0016 mg/dm^2 paper & board (non-detectable)	See test quoted in Annex 3
Benzophenone	0.1 mg/dm2 paper & board	See test quoted in Annex 3
DIPN	1.3 mg/dm^2 paper & board	EN 14719
Phthalates	Dibutylphthalate: 0.05 mg/dm^2 Di(2-ethylhexyl)phthalate: 0.25 mg/dm^2 Benzylbutylphthalate: 5 mg/dm^2 Diisononylphthalate: 1.5 mg/dm^2 Diisodecylphthalate: 1.5 mg/dm^2 Diisobutylphthalate: 0.17 mg/dm^2	In aqueous extract according to prEN quoted in Annex 3
Primary aromatic amines and azo colourants (which by reductive cleavage will form primary aromatic amines)	as primary aromatic amine 0.1 mg/kg	In aqueous extract according to prEN quoted in Annex 3
Polycyclic Aromatic Hydrocarbons (PAH)	0.01 mg/kg paper & board (non-detectable)	According to prEN quoted in Annex 3

5.9 Summary of Conclusions relating to the Industry Guideline

In conclusion, it is our opinion that the current draft of Industry Guideline has built very successfully on a number of strengths drawn out from pre-existing member state legislation and the Council of Europe Resolution. On this basis, we have concluded that the Industry Guideline provides a useful structure to demonstrate compliance with the requirements of the Framework Regulation and the GMP Regulation. In our opinion, the Industry Guideline has more strengths and fewer weaknesses than any of these previous documents.

Key Strengths

- Clear practical positive list primarily derived from BfR Recommendation XXXVI backed up by BfR approval process for chemicals which is now harmonised with EFSA protocols, and therefore limits associated with the positive list are clearly related to toxicological assessments.
- A practical GMP code will be referenced from the Guideline with relevant provisions relating to the manufacture of virgin and recycled paper/board.
- A significantly more rigorous framework is offered for the approval of recycled fibres when compared to national legislation including fibre source, clean up processes and testing protocols, with the advantage over the Council of Europe Resolution that some of the associated complexity has been reduced.
- Clear rules on multilayer materials.
- Clearly defined format given for a Declaration of Compliance

Key Weaknesses

- Reliance on the pre-existing approvals defined primarily in BfR Recommendation XXXVI has two key problems;
  (a) the BfR list contains many approvals which were granted under approval processes prior to the BfR aligning their process with EFSA. Although these approvals were granted under state of the art assessment procedures at the time, here is a possible need for some of these approvals to be reviewed.
  (b) the BfR positive list is non-binding and there are many commonly used process chemicals which are not currently listed. Some clearer practical guidance on how to deal with these non-listed substances through the use of other listings (e.g. FDA, BfR, Warenwet etc), as permitted by the Industry Guideline would be beneficial.

Recommendations for Possible Improvements in Future Drafts of the Industry Guideline

In reviewing the current draft of the Industry Guideline we have highlighted a number of areas where we think the document could be improved either to bring it more closely into line with the requirements of the Framework and GMP Regulations, or to improve its usability. Full details of these suggestions are given throughout Section 5 of this report, but we have summarised the key recommendations below

1. Further guidance should be given in the Guideline on how to apply the BfR and FDA positive lists particularly with regard to identifying when the approvals have or have not been granted on the basis of a process that is well-aligned to current EFSA approval process. Guidance should also be given on how to treat process chemicals which are not universally listed under BfR XXXVI.

2. Clarification should be given in the Guideline relating to when the Biosafepaper methodology should be used. We have highlighted two areas where it might provide solutions to contentious issues. Namely; (a) use of these tests to establish the efficacy of mill recycling operations in achieving food contact safety standards and (b) the use of these tests to validate pre-existing approvals for chemicals which were originally under approval systems which were not aligned to current EFSA practice.

3. Include in the Declaration of Compliance a comment on the presence (or absence of) of "dual use" or "multiple function" substances (i.e. substances present in the paper and board and also approved as food additives). This could be supported by a generally agreed list of multiple function substances which would be subject to this requirement.

4. It would be a useful addition to compile a generally-agreed list of papermaking substances which also have an SML under the plastics legislation so that these can be included on Declarations of Compliance issued to plastic laminators. If 100% migration of such substances will not result in the plastic SML being exceeded, a suitable statement should be made so that the laminator can make a robust decision of whether or not to test for migration of the substance.

5. We would not suggest the inclusion of a standard validity period in the Declaration of Compliance.

6. Include a requirement to use the "For Food Use" symbol or equivalent wording as required by the Framework Regulation.

7. Complete the work already started to develop a new GMP code of practice. Ideally, this should include appropriate elements of the CEPI Responsible Sourcing of recovered paper document, so that these can all be viewed in a single document. On completion, the new GMP code should be checked carefully to ensure it contains all the elements mentioned in Regulation 2032/2006.

8. For multilayer materials, more work is required to validate the PBCF factor. This work should focus on building up a larger data set to demonstrate the validity of the approach for a wider range of chemicals under different exposure conditions.

9. Care should be taken to ensure the wording of the section on multilayer materials remains in agreement with future drafts of the plastics implementing measure which is expected to include multilayer materials.

10. Further consideration should be given on how to develop the Exposure Correction Factor (EXCF) for coated paper/board with particular care taken to set the factor to be a cautious overestimate rather than basing it on mean consumption figures.

11. Consideration should be given to the inclusion of worked examples demonstrating how PBCF and EXCF are to be applied.

12. We would suggest some careful consideration of the position of virgin fibre producers with respect to the tests required to demonstrate compliance with Table 1 of the Guideline. The contaminants listed in Table 1 are primarily associated with recycled fibres and may not be appropriate to the virgin fibre sectors of the industry. The current version of the Guideline is open to misinterpretation in this area and could result in these producers being subject to requests from auditors for repeated testing of these contaminants, which in our opinion would be disproportionate. We would suggest that you possibly even consider exempting virgin paper manufacturers from testing against these requirements all together.

6 Final Conclusions

In our opinion, the current draft of the Industry Guidelines offers an extremely useful contribution towards the harmonisation of legislation on food contact paper/board and presents a more complete and practical package of measures to demonstrate compliance with the requirements of the Framework and GMP Regulations than has been the case under existing EU member state legislation or the Council of Europe Resolution. In particular, the Industry Guideline offers a significantly enhanced framework to demonstrate the safety of recycled fibres when compared to existing member state legislation and this is achieved without some of the complexity associated with the Council of Europe's suggested approach in this area.

Clearly until the Industry Guideline is either adopted by the EU as the basis of future legislation, or is otherwise adopted by individual member states, some care will be required to ensure compliance with the legislation in each of the member states as these are expected to remain in place for the foreseeable future. However, in our opinion, the Industry Guideline provides a useful model to form the basis of discussions with regulators about the future direction of harmonised legislation and it sets out a pragmatic approach to demonstrate compliance with the key requirements of the Framework and GMP regulations which is well-suited for paper and board in contact with foods.

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References

1 Cefic - European Chemical Industry Council

2 CEPI - Confederation of European Paper Industries

3 CITPA - Confederation of Paper and Board Converters in Europe

4 FPE - Flexible Packaging Europe

5 Regulation (EC) No. 1935/2004 of the European Parliament and of the Council, of 27 October, 2004 on materials and articles intended to come into contact with food and repealing Directive 80/590/EEC and 89/109/EEC).

6 *See* Article 1 of Regulation (EC) No. 1935/2004.

7 COMMISSION DIRECTIVE 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs (OJ L 220, 15.8.2002, p. 18) and its 5 amendments up to and including Commission Directive 2008/39/EC of 6 March 2008 (OJ L63, 7.3.2008, page 6)

8 Note for Guidance for Food Contact Materials, 30/07/2008, see http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902030817.htm

9 EC Directive 2007/19/EC gives the Declaration of Compliance Requirements for plastics food contact materials and similar requirements are in place for regenerated cellulose films (EC Directive 2007/42/EC), ceramics (EC Directive 2005/31/EC) and epoxy coatings (EC Regulation 1895/2005).

10 COMMISSION REGULATION (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food (OJ L 384, 29.12.2006, page 75)

11 COMMISSION SERVICES WORKING DOCUMENT IN PREPARATION OF A COMMISSION REGULATION relating to plastic materials and articles intended to come into contact with foodstuffs, EMB/1137, Brussels, 10.10.2008 SANCO/E/3/AS.

12 For details of BfR Recommendations XXXVI, XXXVI/1, XXXVI/2 and XXXVI/3, see the BfR web site at http://bfr.zadi.de/kse/faces/DBEmpfehlung_en.jsp.

13 Lebensmittel- und Futtermittelgesetzbuch in der Fassung der Bekanntmachung vom 26. April 2006 (BGBl. I S. 945).

14 Food Contact Legislation for EU Markets, 2nd Edition, Keller and Heckman LLP, Published by Pira International Ltd, 2008, Chapter 10 Page 61

15 BfR, Postfach 330013, D-14195 Berlin, Germany for the attention of Karla Pfaff karla.pfaff@bfr.bund.de

16 Note for Guidance updated 30/07/08 European Food Safety Authority.

17 Except where a barrier is present, migration is < 10 ppb from a non food contact layer and the substance is not authorised. The Council of Europe have proposed a threshold of regulation of 0.5 ppb in food but it is very difficult task to measure at this level.

18 Commission Directive 2007/19/EC

[19] Di-alkyl(C10-C22)diketenes, BfR XXXVI, B. I, 12 which was reviewed to expand its usabikity and Acrylic retention aids covered under B. III, 2 which was rewritten to include a broader definition. Private communication with Dr B Podd of Kimberly-Clark.

[20] Only rejects from manufacturing and processing, or recycled paper of equivalent quality, may be used. The sorts of paper that are suitable are listed in "Wiedergewinnung von Papierfasern; Beschreibung des Verfahrens" published by the German Pulp and Paper Association (Verband Deutscher Papierfabriken e. V. - VDP) in its loose-leaf collection, "Untersuchung von Papieren, Kartons und Pappen für den Lebensmittelkontakt", Erich Goltze Verlag, Göttingen.

[21] What must not be used are sort A 00 in the German Pulp and Paper Association's "Liste der Deutschen Standardsorten und ihre Qualitäten", and paper and paperboard from sorting plants for general or mixed component waste.

[22] For further details on the BfR position on DIBP, see; http://www.bfr.bund.de/cm/230/di_isobutyphthalate_in_food_contact_paper_and_board.pdf

[23] Bedarfsgegenständeverordnung vom 10. April 1992 (BGBl. I S. 866), which incorporates the Framework Regulation and the complete (amended) Series of Plastics in Contact with Foodstuffs Directives into German law.

[24] This is a non exclusive list focussing on the most common chemicals used in the paper industry and subject to restrictions under BfR Recommendation XXXVI. In drawing up a testing programme for food contact papers, the full text of the Recommendation should always be consulted.

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[26] Arrêté du 28/06/1912 (articles 7) relatif à la coloration, à la conservation et à l'emballage des denrées alimentaires et boissons J.O. du 29/06/1912

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[30] Guide de bonnes pratiques de fabrication des papiers et cartons et des articles transformés en papier et carton destinés au contact des denrées alimentaires, approuvé le 09/09/97 par la section de l'Alimentation et de la Nutrition du CSHPF.

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[34] See http://ec.europa.eu/food/food/chemicalsafety/foodcontact/docs/ReferencesEurNatLeg_20080625.pdf for more details.

[35] DMH No. 267 of 30 maggio 2001(modifications to paper and boards) Regolamento recante aggiornamento del decreto ministeriale 21 marzo 1973, concernente la disciplina igienica degli imballaggi, recipienti, utensili destinati a venire in contatto con le sostanze alimentari o con sostanze d'uso personale. G.U. n.155 del 6.7.2001 pag. 12

[36] United Kingdom Ministry of Agriculture, Fisheries and Food, Food Surveillance Sheet No 169, January 1999, ' Diisopropylnaphthtahelenes in food packaging made from recycled paper and board.

[37] See http://www.coe.int/t/e/social_cohesion/soc-sp/public_health/food_contact/PS%20E%20PAPER%20AND%20BOARD%20Version%203.pdf

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[41] Food Additives and Contaminants, 2003, 20, 607-618.

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[44] The figure actually represents a per capita average daily exposure.

Pira Report

Review of the Industry Guideline for the Compliance of Paper & Board Materials and Articles for Food Contact

Prepared for CEPI

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0. Executive Summary

Pira have reviewed version pre4 of the Industry Guideline for the Compliance of Paper & Board Materials and Articles for Food Contact and carried out a comparison of these Guidelines with Council of Europe Resolution RESAP (2002) on Food Contact Paper/Board and also with the national legislation that is currently in place in Germany, the Netherlands, France and Italy. The aim of the review was to assess how effective each of these systems are in implementing for paper/board the requirements of the EC Framework Regulation on Materials and Articles in Contact with Foods (EC Regulation 1935/2004).

The four sets of national legislation reviewed all aim to ensure compliance with the Framework regulation. However, in our opinion, none of them fully meet these requirements, with the most significant gaps relating to how they treat recycled fibres, multilayer structures and the lack of provisions for declarations of compliance. Additionally, the resulting differences between their approaches mean that compliance across Europe can be fraught with difficulty and it is difficult to argue that the different sets of national legislation are consistent with the aim of the Framework Regulation to foster a harmonised EU market for food contact paper/board.

Council of Europe Resolution RESAP (2002) set out to address some of the key weaknesses in the pre-existing member state legislation, and offers an approval process for food contact substances which is harmonised with EU protocols together with a more rigorous framework for the approval of recycled fibres which takes into account a wider range of contaminants than current member state legislation. However, there are several key issues which detract from the usability of the Council of Europe Resolution and these are related to (a) the lack of clarity in the positive list where many substances have not yet been assessed, (b) an overestimation of consumer exposure and (c) a complex system of approval for recycled fibres.

In our opinion, the current draft of Industry Guideline has built successfully on a number of themes drawn out from pre-existing member state legislation and the Council of Europe Resolution., with its key strengths being the clear rules it offers for the use of recycled fibres and multilayer materials. It also benefits from containing provisions relating to Good Manufacturing Practice and a Declaration of Compliance. We have additionally highlighted a number of areas where we feel that future versions of these Guidelines could be enhanced to bring them more closely into line with EC Regulation 1935/2004.

1.0 Background

There is currently no harmonised EU legislation on paper and board articles and materials for food contact applications beyond the general requirements laid out in the Framework Regulation 1935/2004. This means that to demonstrate compliance with the general safety requirements of Article 3 of the Framework Regulation, the paper and board food packaging supply chain rely on the national legislation for paper and board published in Netherlands, Italy and France or BfR Recommendation XXXVI published in Germany. These national regulations and recommendations are not always well aligned which can create some confusion and uncertainty, further compounded by the existence of a Council of Europe Resolution on Paper and Board Materials and Articles for Food Contact Uses which has not been adopted by any member state.

In response to this situation the European paper and board food packaging supply chain, comprising CEFIC[1], CEPI[2], CITPA[3] and FPE[4] representing the paper chemical producers, the paper industry, packaging converters and flexible packaging manufacturers have co-operated to develop an Industry Guideline for the compliance of paper and board materials for food contact. The aim of this document is to provide a single text which can be used by all operators in the paper and board packaging supply chain to establish compliance with Regulation 1935/2004 for materials and articles intended to come into contact with food.

The aim of this review is to provide an independent opinion of the effectiveness of the version pre4 of the Guideline in meeting the requirements of Regulation 1935/2004 and compare that effectiveness with that given by:

- Council of Europe Resolution RESAP (2002) 1 and its 6 Technical Documents, as published in Version 2 (13th April 2005);
- The national legislation of France – Notes d'Informations of DGCCRF N° 2004-64 et N° 2006-156.
- The German BFR Recommendation XXXVI.
- The national legislation of Italy – Ministerial Decree of 21 March 1973 as amended.
- The national legislation of the Netherlands – Ministerial Regulation of 25 January 1980 as amended.

2.0 Review of Applicable EU Legislation

2.0.1 The Framework Regulation; Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food

The most fundamental law relating to the marketing and safety of food-contact materials in the European Union is Regulation (EC) No. 1935/2004, which is generally referred to as the 'Framework Regulation'. This came into force in November 2004 [5] and replaced two previous Directives governing the use of food contact materials, 80/590/EEC and 89/109/EEC. The Framework Regulation applies to all materials or articles which, *'in their finished state: (a) are intended to be brought into contact with food; or (b) are already in contact with food and were intended for that purpose; or (c) can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.'*[6]

The Framework Regulation sets out the general requirements for the marketing of food contact materials and gives the European Commission (EC) authority to establish more specific measures (e.g. Directives, Regulations or Decisions) for these products, where they believe that this would be beneficial to either the safety of the consumer or to eliminate technical barriers to trade. To date, no such specific harmonised measure has been brought forward by the EC for food contact paper and board.

In essence, regardless of whether one of these specific measures is in place (as in the case of food contact plastics which are covered by EC Directive 2002/72/EC and its amendments), or not (as in the case of paper and board materials), all food contact materials are ultimately covered by the scope of the Framework Regulation and the aim of any specific measures, legislative proposals or codes of practice that are put in place should ultimately be to provide a route to demonstrate compliance with the requirements of the Framework Regulation.

This review will therefore focus primarily on addressing the way in which existing items of national legislation, Council of Europe Resolution RESAP (2002) and the Industry Guidelines address the basic requirements of the Framework Regulation and as an introduction to this, the remainder of this section details what in our opinion are the key elements from the Framework Regulation which should be dealt with by any legislation or legislative proposal.

2.1.1 General Requirements of the Framework Regulation - Article 3

The essential safety requirement of the Framework Regulation is enshrined in the general provisions set out in Article 3, which require that *'materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could: (a) endanger human health; or (b) bring about an unacceptable change in the composition of the food; or (c) bring about a deterioration in the organoleptic characteristics thereof*'.

The language of Article 3 is quite deliberate, because it deals with the issue of the transfer of substances from food packaging materials into foods and requires a demonstration that the concentration of the substances in the food is at a level which will not pose a risk to the health of the consumer. It is the way in which this requirement has been written in the Framework Regulation and its two preceding Directives that has set the philosophy of migration testing which has been applied to plastics. This also means that any compositional limit (e.g. a maximum use level for a substance in a food contact paper or plastic) needs to be linked in some way to an estimate of the level of the substance passing into foods. This is certainly the philosophy behind the use of residual limits (QM and QMA) within the plastics in contact with foodstuffs legislation[7]. Any national legislation or legislative proposal should therefore aim to relate maximum use levels of substances in food contact papers to safe levels in the foods coming into contact with those papers and this would be a key test of whether the measure was controlling risk to an acceptable level under Article 3.

One respect in which the wording of Article 3 leaves room for debate is the requirement that constituents are not transferred to foods in '*quantities which could… endanger human health'.* This has conventionally been assessed for plastics using measurement of migration, behind which lie the assumptions that (a) consumers eat 1 kg of packaged food every day, (b) that this food would always be packed in the material under consideration and that (c) this food would come into contact with 6 dm^2 of packaging. These are clearly very cautious requirements and an EU project (FACET) has recently been launched to develop a more sophisticated exposure based model for packaging materials in contact with foods. Given the lower exposure profile of food contact paper in contact with foods and the tentative acceptance of the exposure principle from regulators the exposure concept (where supported by data) may be able to be built into any assessments of safe levels of substances. However, a key test of whether this met the requirements of Article 3 would be the scientific rigour of any exposure estimates.

Significantly, Article 3 also contains a requirement for the use of 'Good Manufacturing Practice' (GMP) in the manufacture of food packaging materials and articles. Further details of what is meant by GMP in this context will be described in a later section on the GMP regulation, but clearly this is an important element of complying with the requirements of the Framework Regulation.

2.1.2 Authorization Procedure for Food Contact Substances; Articles 8 to 12

A further critical element to the Framework Regulation and one which is closely related to the general safety requirements outlined in Article 3 is the systematic procedure for authorization of new food contact substances for inclusion on the positive lists in specific measures and a mechanism for removal of substances from these lists. The bones of this procedure are laid out in Articles 8 to 12 of the Framework Regulation and it has been most widely used for the addition of new monomers and additives to the Plastics Directive. The current authorization procedure [8], involves an evaluation by the European Food Safety Authority (EFSA), based on an assessment of (a) the migration level of the substance into foods and (b) the toxicology of the substance.

In the absence of any harmonised EU legislation on paper in contact with foodstuffs, EFSA are not currently open to submissions for the authorization of substances intended solely for use in food contact papers. Despite this, a number of national authorities such as the BfR in Germany do maintain such positive lists and operate an approval process based on the EFSA procedure. These national approval processes will be discussed more fully in the section describing national legislation, but clearly it would desirable if such national approvals were modelled as closely as possible on the EFSA procedures. In principle, this should also mean that national approvals could be easily transposed into harmonised EU legislation, if and when this should be brought forward. The approval process will therefore form an important part of our assessment of whether national legislation and legislative proposals are aligned with the Framework Regulation.

2.1.3 Written Declarations of Compliance and Traceability; Articles 16 and 17

Article 16 of the Framework Regulation requires that where a class of food contact material is governed by a 'specific measure', when it is placed on the market it must be accompanied by a written declaration stating that the product complies with the requirements of this legislation and passing on to the end user sufficient information to ensure that the product is used correctly and that they can establish their position under the measure. Following the introduction of the Framework Regulation several of the pre-existing items of European legislation have been amended to detail the requirements for declarations of compliance [9]. The information to be included in these statements varies according to the food contact material type and the specific item of legislation, but would typically include suitable food types, maximum permitted temperature and time in contact with foods, presence and identity of substances with restrictions and the presence/identity of dual-use additives. Additionally, there is a requirement to include the identity and address of the operator responsible for putting the material onto the market. Additional supporting documentation in the form of test work and calculations backing up the claim of compliance must also be available to the 'competent authorities' on request.

The presence of a clearly defined format for a Declaration of Compliance will therefore form an important part of our assessment of whether national legislation and legislative proposals are aligned with the Framework Regulation.

Following a number of packaging-related food scares in the EU, a much greater emphasis has been placed on traceability in the Framework Regulation than was the case in the previous two Framework Directives. Article 17 therefore introduced a requirement for traceability at all stages in the food packaging supply chain, to make it possible to control materials, to recall defective products, to provide information to consumers, and to attribute responsibility in the event of a problem with the food article or any of its components. Systems must therefore be in place to ensure that the business operator can trace their products one level up and one level down the supply chain. It should be mentioned that the Directives and Regulations do not currently include significant information on the documentary requirements of quality systems to comply with the traceability requirements. With this in mind, the UK Food Standards Agency is currently developing a Guidance Note dealing with these requirements and how they relate to the requirements of the GMP Directive.

The existence of a practical code of practice or good manufacturing guide for production of food contact papers and the control of traceability will therefore form an important part of our assessment of whether national legislation and legislative proposals are aligned with the Framework Regulation.

2.1.4 Labelling; Article 15

Article 15 of the Framework Regulation specifies that food-contact materials that are not already in contact with food when placed on the market must be labelled *'for food contact'* or with some indication of their intended use. One useful means of indicating suitability for food contact is by use of the symbol given in Annex II of the Regulation, which appears in the figure below.

Although reference to this symbol is not explicitly mentioned in the specific measures which have been introduced to present date, it would clearly be advantageous to include it in any proposal.

2.1.5 National Specific Measures; Article 6

Article 6 of the Framework Regulation states that; *'in the absence of specific measures…. this Regulation shall not prevent Member States from maintaining or adopting national provisions….'* In essence, this means that Member States are permitted to have their own national laws pertaining to food-contact materials, but only provided that these materials are not subject harmonized legislation at the EU level. In the case of paper and board which is not yet subject to any such harmonized legislation, this means that the member states of the EU are perfectly entitled to maintain their own legislation in this area.

The Industry Guidelines would therefore have to be sensitive to these national requirements which would still remain legally enforceable in each country where they are applied.

2.2 The Good Manufacturing Practice Regulation; Regulation (EC) No 2023/2006 for materials and articles intended to come into contact with food

Commission Regulation (EC) 2023/2006 on good manufacturing practice (GMP) came into force on 1 August 2008[10]. It sets out some general rules on GMP for materials and articles intended to come into contact with food, and applies to all the groups of materials identified in Annex I of the Framework Regulation, regardless of whether they are subject to specific measures such as Directives or Regulations. It also apples to combinations of those materials and articles and to recycled materials and articles used in those materials and articles. It therefore clearly applies to paper and cardboard and to multilayer structures containing paper and cardboard.

The GMP Regulation applies to all stages of manufacture, processing, and distribution of materials and articles but excludes the production of starting substances. The Regulation sets out the general rules on GMP, such as the establishment of quality assurance and quality control systems and the adequate documentation of those systems. Annex I of the Regulation outlines detailed requirements for processes involving printing inks.

One of the most significant elements in the GMP regulation is the requirement that starting materials must be selected to comply with pre-established specifications that will ensure compliance of the material or article with the rules applicable to it. In our opinion, this has two significant consequences for manufacturers of food contact paper and board in that any guidance document or legislative proposal would need to include some control on the selection of paper chemicals and also given the nature of the paper industry some agreed measures to ensure the safety of recycled fibres. How well any item of legislation or guidance document deals with these two requirements will be a significant factor in determining how well it addresses the requirements of the GMP and Framework Regulations. This will therefore form a key strand of our assessment of the existing legislation and the Industry Guideline.

To comply with the GMP Regulation, a business operator must also establish, implement, and ensure adherence to an effective and documented quality assurance system which must take into account factors such as the adequacy of personnel, their knowledge and skills, and the organization of the premises and equipment, as necessary, to ensure that finished materials and articles comply with the rules applicable to them. In addition, a business operator must establish and maintain appropriate documentation (in paper or electronic format) with respect to specifications, manufacturing formulae, and processing, which are relevant to compliance and safety of the finished

material or article. The documentation must be made available to the competent authorities upon request. These requirements are clearly very general and little specific guidance is offered in the GMP regulation of what is required to demonstrate that the requirements have been met. As mentioned previously, the UK Food Standards Agency is currently developing a Guidance Note dealing with these requirements, but clearly it would be useful to have a generally agreed code of practice or good manufacturing guide for production of food contact papers and ideally this should include some guidance on the control of traceability to ensure consistency with Article 17 of the Framework regulation. This will therefore form an important part of our assessment of whether national legislation and legislative proposals are aligned with the GMP Regulation.

2.3 Multilayer, Multimaterial Laminates

Paper is frequently used in multilayer materials in which the layer which actually comes into contact with the food is commonly plastic. These types of structures are currently not covered by the scope of the Plastics in Contact with Foodstuffs Directives, but there are active proposals to bring these materials under the scope of the legislation via what is currently known as the Plastics Implementing Measure. Under the current version of this document[11], it is proposed that;

'1. In a multi-material multi-layer material or article, the composition of each plastic layer shall comply with this Regulation.

2. By derogation from paragraph 1, a layer which is not in direct contact with food and is separated from the food by a functional barrier, may be manufactured with substances other than those included in this Regulation or in the national lists concerning the plastic materials and articles intended to come into contact with food.

3. The substances referred to in paragraph 2 shall not belong to either of the following categories:
(a) substances classified as proved or suspect "carcinogenic", "mutagenic" or "toxic to reproduction" substances in Annex I to Council Directive 67/548/EEC ;
(b) substances classified under the self-responsibility criteria as "carcinogenic", "mutagenic" or "toxic to reproduction" according to the rules of Annex VI to Directive 67/548/EEC;
3. The plastic layer shall comply with the restrictions for vinyl chloride monomer laid down in Annex I.'

There key definition of a *'functional barrier'* under this part of the legislation depends on the demonstration that migration of non-listed substances from non food contact layers shall not exceed 10 ppb into foods. It should therefore be noted that for many substances, the analytical studies required to demonstrate that this requirement has been met are highly complex and as a result this provision has not yet been widely applied.

2.4 Assessment Criteria Used in this Review

From the forgoing discussion of the Framework Regulation and the GMP regulation, it is clear that there are a number of critical elements which must be addressed within any national legislation, proposals for legislation or codes of practice if the document is to be shown to meet the requirements of this legislation. The review carried out in the rest of this document is therefore based on the following elements, which we consider to be critical.

1. There should be clear rules on the selection of paper chemicals for use in food contact paper and cardboard and these should be backed up by a suitable positive list.

2. Any limits specified for paper chemicals should take into account an assessment of the migration of that substance into foods and whether this can be demonstrated to satisfy the requirements of Article 3 of the Framework Regulation (i.e. does the limit control the migration to levels known to be safe).

3. The mechanism by which paper chemicals are entered onto the positive list and limits set should be harmonized to as great an extent as possible with the EFSA approval process which has been applied to food contact additives from plastics. This will make it easier to support the positive lists developed under 1. and 2. above and also to incorporate the positive lists into any future EU legislation (should it be developed).

4. There should be a clear way of demonstrating the safety of recycled fibres that incorporates measures to establish the process control of systems for the collection and recycling of reclaimed fibres. Within this, it would clearly be preferable if the system adopted for categorising reclaimed fibre was harmonized with the system most commonly operated by the recycling industry (EN 643). Monitoring of known and contaminants, selection of technologies and demonstration must, however, remain key elements in showing safety as EN643 is not a toxicological standard.

5. There should be clear guidance for the content of a Declaration of Compliance.

6. There should be a code of practice for GMP of food contact paper and board (or reference to an external document) which can be used to demonstrate compliance with the GMP Regulation.

7. On an interim basis, until the adoption of the plastics implementing measure, there should be clear advice on how to demonstrate safety for multilayer/multimaterial laminates including paper and cardboard. These are expected to be drawn under the scope of the Plastics Directives in future amendments and clearly this legislation will take precedence, but in the meantime it is our opinion that industry would benefit from a clear and pragmatic approach to multilayer materials.

3.1 Germany; BfR Recommendation XXXVI and the LFBG

German BfR Recommendation XXXVI[12] is the most widely recognised existing standard within the EU for food contact testing of papers and is the means most commonly used (in those member states without their own legislation) to demonstrate compliance of food contact paper and board with the safety requirements of the Framework Regulation. Within Germany, its role can be seen as a means of demonstrating compliance with the requirements of the German Food Law (the LFBG[13]).

The recommendation is split into 4 sections;

- XXXVI Paper and board for food contact
- XXXVI/1 Cooking Papers, Hot Filter Papers and Filter Layers
- XXXVI/2 Paper and Paperboard for Baking Purposes
- XXXVI/3 Absorber pads based on cellulosic fibres for food packaging

Of these 4 sections, the part which most closely correlates to the scope of the Industry Guideline is the first of these and this will therefore form the basis for the discussion in this section. The remaining 3 sections deal primarily with niche applications for paper and cardboard and follow a similar format to BfR Recommendation XXXVI, but generally have smaller lists of approved substances and differing extraction conditions to reflect the more intimate nature of the food contact in these applications.

BfR Recommendation XXXVI consists principally of a non-binding[14] positive list of raw materials approved for use in food contact papers and a number of tests to be carried out on finished papers. The positive list is split up according to the intended function of each approved constituent starting with fibrous materials and then working through various categories of paper chemicals segregated on the basis of functionality (e.g. fibres, sizing agents, retention aids, wet strength agents etc).

3.1.1 Rules for Selection of Paper Chemicals

For the greater part, BfR Recommendation XXXVI contains a good practical positive list for paper chemicals which may safely be used in the manufacture of food contact paper and cardboard. However, as mentioned previously, the list is formally non-binding and when carrying out an assessment of paper

formulations, it soon becomes apparent that not every chemical which is used in the manufacture of food contact paper and board is included in this positive list. The explanation for this is that the list focuses on functional chemicals which are intended to remain in the paper in its finished format in order to exert a technical effect. Despite the non-binding nature of the Recommendation, for these types of chemicals there is a general expectation that the substance should be listed if the manufacturer is to claim compliance. If, however, a paper chemical is only intended for use in the manufacturing process and is water-soluble (and therefore expected not to be present at significant levels in the finished paper), there would be no particular expectation that it would have to be listed, although this would be favourable.

There are of course grey areas when the above interpretation is applied and the positive list does contain a number of categories of process chemicals such as dispersion and flotation agents and defoamers which are clearly not intended to remain in the finished paper, but where a decision has been taken to list these substances, presumably on the basis that they may be carried over to the finished paper. This lack of clarity of whether substances need to be listed means that some degree of interpretation can be required to assess whether individual paper formulations meet the requirements of BfR Recommendation XXXVI.

In our opinion, this means that BfR Recommendation XXXVI partly meets the requirements of the GMP regulation with regard to having clear guidelines for selection of paper chemicals. It would be a significant improvement to the clarity of the Recommendation if it were to contain some clear guidance on when a paper chemical is expected to be listed and when it would not be expected to be listed.

3.1.2 Restrictions on Paper Chemicals

Where a paper chemical is listed in BfR Recommendation XXXVI, it is often listed subject to (a) a maximum use level and/or (b) an extraction restriction. For example, listed under the wet strength agents one can find the following two entries;

'Melamine- formaldehyde resins. Extract of the finished product must not contain more than 1.0 mg formaldehyde per dm^2' and

'Cross-linked, cationic polyalkylene amines (compare B. III. 3.), in total maximum. 4.0 %'

This second set of substances is subject to the following additional requirement;
'No ethyleneimine must be detectable in the resin (detection limit 0.1 mg/kg). 1,3-Dichloro-2-propanol must not be detectable in water extract of the finished product (detection limit 2 µg/l). The transfer of 3-monochloro-1,2-propanediol into the water extract of the finished products must be as low as technically achievable, a limit of 12 µg/l must not be exceeded in any case.'

These restrictions on paper chemicals can be viewed in one of two ways. They are, in essence, residual limits on the substance in food contact papers and can therefore be viewed as compositional limits which are easier for industry to comply with than specific migration limits would have been. However, since the restrictions are nowadays assigned on the basis of migration studies and known toxicology for the substance (see the section 3.1.3) and underpinning this process are some reasonable assumptions to relate migration levels in food to the level in paper, it can also be viewed that these compositional limits are in effect controlling the level of migration of paper chemicals (and/or their constituents and contaminants) into foods in line with the requirements of Article 3 of the Framework Regulation.

On this basis, we can conclude that, where specified, the limits within BfR Recommendation XXXVI are based on an assessment of the migration of substances into foods and are capable of controlling that migration in line with the requirements of Article 3 of the Framework regulation.

3.1.3 Approval Process for Inclusion on Positive List

It is generally accepted that the most useful way of getting approval for a new paper chemical in Europe is to get it listed on the German BfR Recommendation XXXVI and hence this is the route adopted by most paper chemical manufacturers. Although, as previously discussed, this is not a fully comprehensive list of paper chemicals and is not binding, it does have

widespread acceptance and using the principles of 'mutual recognition' can be used in a wide range of EU Member States outside of Germany.

To gain German BfR listing of a new chemical in Recommendation XXXVI a dossier including migration and toxicological data is submitted to the expert panel[15]. In addition to this, detailed information on the new chemical must be provided in a format laid down by the EFSA (European Food Safety Authority) in the 'Note for Guidance'[16]. These data are classified under the main headings:

1. Identity of substance including manufacturing details, impurities etc.
2. Physical and chemical properties
3. Intended application of substance
4. Authorisation of substance (other national authorisations)
5. Data on migration of substance (food or food simulants)
6. Data on residual content of substance in the food contact material
7. Microbiological properties of substance (only applicable to biocides)
8. Toxicological data

If the new chemical is a mixture this must be classified as 'defined' or 'non defined' where a defined mixture is the result of a reproducible production process. A non defined mixture is one that varies from batch to batch and may be of natural origin. Additional data are needed on mixtures, such as starting substances, identification and proportion of constituents, molecular weight distribution and substances formed.

The Note for Guidance document is primarily intended for application to new substances used in plastics. For paper and board materials some substances are washed out in the paper making process. If the residual level of the chemical in the paper is very low then migration testing may not be needed. A permitted approach in these circumstances is to calculate 100% migration to food instead of migration testing. Then if the calculated 'worst case' migration works out at less than 50 ppb, then only a reduced toxicological package will be needed in the dossier, see below.

For new substances that are polymeric additives, additional data on the molecular weight distribution are needed, including the fraction < 1000 Daltons. This threshold of 1000 Daltons is important as EFSA have conventionally assumed in their assessments of plastics starting materials that above this molecular weight, substances are not absorbed by the body and therefore may be excluded from any calculations of migration.

If the new substance is hydrolysed at a level of > 95% to innocuous substances or substances which are already listed (and have toxicological data available) by simulated gastro-intestinal fluids then migration and toxicological data may not be needed.

No provision at the moment is available to present migration data in dry foods which accounts for many of the applications of paper and board. The generally accepted food simulants used to obtain migration data on all food types are water, 3% acetic acid, 10 % ethanol and a fatty food simulant. The Council of Europe has proposed migration tests using Tenax as a dry food simulant and this approach should be considered in cases where only contact with dry foods is likely.

The threshold of regulation[17] concept is not currently accepted in Europe, therefore any submission to BfR must be accompanied by 3 negative mutagenicity studies even when no migration is calculated or detected. There is also no provision at the moment for taking into account the 'packaging use factor' for paper and board materials and the assumption that a 60 kg person eats 1 kg of food packaged in the same type of packaging every day for a lifetime is still used.

The level of migration (or calculated migration) dictates the level of toxicological data needed for the submission so that migration:

- < 50 ppb requires 3 mutagenicity tests
- > 50 ppb but < 5 ppm requires 3 mutagenicity tests, 90 day rat feeding study plus data on bioaccumulation
- > 5 ppm requires all the above plus a further 90 day feeding study on a second species plus long term studies on reproduction on one species and

developmental toxicology on two species. Studies on absorption, distribution, metabolism and excretion are also needed.

A recent amendment to the Plastics Directive 2002/72/EC[18] allows the use of a fat consumption reduction factor (FRF) so that any migration results obtained with olive oil can be divided by a factor of 5 to allow for the fact that the consumer will not eat 1 kg of fat every day and that 200 g is a maximum. This factor is only applicable to strongly lipophilic substances and where migration is << 100%. This FRF can be used in submissions for new substances in plastics, so it should also be applicable to paper and board, where appropriate.

A specification may be proposed on the levels of impurities found to be present in the new substances based on measurements. After evaluation by the expert panel there may be a limit imposed on the use level of the substance in the paper and board.

On this basis, we can therefore conclude that the process for assessment of chemicals under BfR Recommendation XXXVI is currently a robust one which is well aligned with the requirements of Articles 8 to 12 of the Framework Regulation.

It is, however, worth noting that the BfR started listing paper chemicals before the current version of the EFSA protocol was put in place (ca. 1991). Prior to the adoption of this system, the BfR did have in place a clearly-defined process for assessing applications for new paper chemicals and this process was reviewed periodically. The process was based on a combination of migration/extraction testing coupled with toxicological assessment and so shared some common themes with the EFSA process, although since it was a forerunner to the EFSA process, it was not perfectly aligned. This means that many of the historical approvals on this list were not based on the current EFSA-harmonised approval process and so could still be open to question, depending on any position which the regulators or member states choose to adopt. Whether regulators would actually choose to question all these previous approvals is not certain as the BfR have reviewed a number of historical approvals since their harmonization with the EFSA protocols and on occasions have chosen not request additional dossier information[19], but

inevitably this means that there is some residual doubt in relation to the contents of the positive list in BfR Recommendation XXXVI and legislators outside Germany may still choose to review at least some of these approvals at a later date.

3.1.4 Recycled Fibre Requirements

BfR Recommendation XXXVI specifically permits the use of fibre material from a relatively wide range of sources including;

1. Natural and synthetic cellulose fibres, bleached or unbleached.

2. Fibres of synthetic high polymers, provided they comply with the corresponding BfR Recommendations.

3. Wood pulp, bleached or unbleached.

4. Recycled fibres from the manufacture and processing of paper or paperboard and from returned paper[20], provided that the products manufactured from these fibres comply with the requirements of this Recommendation. For contact with dry, non-fatty foodstuffs (e.g. flour, semolina, rice, sugar, salt, peas, lentils and the like) and with foodstuffs that are normally washed and/or peeled before being eaten (e.g. fruit, vegetables), other raw materials may also be used as a source of fibre, provided that the requirements of this Recommendation are otherwise complied with[21].

The Recommendation therefore clearly permits the use of recycled fibres, but this approval is subject to the compliance of the finished product with the full provisions of the recommendation and there is also a requirement that the content of diisopropylnaphthalene (DIPN) must be as low as technologically possible. It is also clear that the Recommendation does contain some control on the sources of fibre, although the categories included are not harmonised with those described in the EN 643 standard which is most commonly used in the recycling industry. Although Recommendation XXXVI clearly deals to some extent with the issue surrounding the source of recycled fibres, in our opinion, its usability is hampered by the choice of paper categories.

Additionally, it should be noted that the GMP regulation requires that;

'printing inks applied to the non food-contact side of materials and articles shall be formulated and/or applied in such a manner that substances from the printed surface are not transferred to the food-contact side:
(a) through the substrate or;
(b) by set-off in the stack or the reel,in concentrations that lead to levels of the substance in the food which are not in line with the requirements of Article 3 of Regulation (EC) No 1935/2004.'

Since a significant portion of recycled fibre has at some point been printed, this has led to some debate amongst parts of the scientific community as to whether the use of recycled fibre from printed sources in food contact applications is acceptable, since it is difficult to exclude exposure to traces of ink chemicals in recycled fibres. This confusing situation is exacerbated due to a lack of universally-accepted guidelines to assess when exposure to a printing chemical is at safe levels within the definition of Article 3 of the framework regulation.

To present date, there has been no ban from the BfR on the use of recycled fibres. However, given the continued high profile of the issue of food contact safety and the periodic identification of contaminants in recycled fibre (see the recent guidance note from the BfR on the level of di-isobutylphthalate which is used in some adhesives[22]), it is our opinion that a greater degree of care than that currently specified in BfR Recommendation XXXVI is required to quantify known constituents in reclaimed fibre sources and also possibly some means of broadband screening for additional constituents.

In summary, BfR Recommendation does offer some guidance on the use of recycled fibres in food contact applications, but in our opinion, this guidance stops some way short of providing sufficient information to fully satisfy the requirements of the Framework and GMP Regulations.

3.1.5 Declaration of Compliance

BfR Recommendation XXXVI does not currently contain any guidance on the contents of a Declaration of Compliance.

3.1.6 Code for Good Manufacturing Practice

There is no current Guidance on GMP either within the Recommendation or incorporated by reference.

3.1.7 Rules for Multilayer Materials

BfR Recommendation XXXVI does contain some general advice on multilayer materials containing paper and cardboard. In the preamble, it is stated that;

'In a composite, multi-layered or coated material, if the layer which comes into contact with the foodstuff is made of paper or paperboard it must comply with this Recommendation. Also, except for traces that are harmless to health and have no effect on taste or smell of the foodstuff, there must be no migration of substances from other layers into foodstuffs or on their surface,' and;
'If plastics or other polymers are used to coat paper or paperboard on the side that will come into contact with the foodstuff, only substances in compliance with the corresponding BfR Recommendations and the conditions stipulated therein may be used.'

In a section on coatings, the following additional advice is given in the Recommendation;
'Plastics (films, melts, solutions, lacquers, dispersions), provided they comply with the corresponding BfR Recommendations. Plastic coated paper or paperboard, in which from normal use only the layer of plastic comes into contact with the foodstuff and in which there can be no migration of substances from the paper or paperboard to the foodstuff, should not be evaluated after this Recommendation, but after the BfR Recommendation for the corresponding plastic.'

It is worth noting that the *'corresponding BfR Recommendations'* for plastics have for a number of years been increasingly taking a secondary role compared to EU plastics in contact with foodstuffs regulations. They certainly contain a reference to compliance the German Commodities Regulation[23] and in this manner clearly incorporate for plastics coatings the full range of migration limits which would apply to plastics when used in a monolayer structure. The position of the BfR can therefore be summarised as follows;
(a) any paper layers should comply with the requirements of

Recommendation XXXVI and (b) plastics layers should also comply with the composition rules and migration limits which apply to them under EC Directive 2002/72/EC and its amendments. In this respect, it is apparent that BfR Recommendation is currently consistent with the proposed approach contained in the current draft of the plastics implementing measure and at the moment probably exceeds these requirements since it does not confine its residual monomer requirements to vinyl chloride.

The one potential gap in BfR Recommendation XXXVI is in respect of the presence of some substances that are subject to Specific Migration Limits (SMLs) under the plastics directive, but are also used as (or present in) paper and board. For instance, formaldehyde, which is subject to an SML of 15 mg per kg in foods under EC Directive 2002/72/EC and also an extraction limit of 1 mg/dm^2 when used in paper and cardboard. If the substance is used in an underlying paper layer and the food contact layer is plastic, it is not clear which limit would apply. In this case, working from the standard EU assumptions (for plastics materials) of 6 dm^2 per kg of food, the paper limit is clearly more stringent as this leads to an inferred SML of 6 mg per kg and this is below the SML from plastics legislation, but this anomaly clearly creates room for confusion. This situation could be exacerbated if, as expected, later versions of the plastics implementing measure draw paper chemicals under the scope of plastics SMLs (where they apply).

In our opinion, BfR Recommendation clearly deals with the issue of paper in multilayer products and in our opinion is already aligned at least to the requirements of the proposed Plastics Implementing Measure. However, some clarification on restrictions that apply to chemicals where they are used in plastics and paper layers and subject to conflicting restrictions would be advantageous.

3.1.8 Testing Requirements under BfR Recommendation XXXVI

One of the key features of BfR Recommendation XXXVI are the testing requirements placed on finished papers and cardboards. Since a significant number of the tests required under BfR recommendation XXXVI are also required under one or other of the other sets of member state law which we will discuss in the following sections, we have included a summary of these BfR test requirements here.

Under BfR Recommendation XXXVI, the tests which would need to be carried out on most samples can be split into 2 categories; (a) tests which apply regardless of which paper chemical have been used and (b) tests which apply only where certain specified chemicals have been used in the paper.

Tests applying to all papers;

- Pentachlorophenol (PCP) content
- No visible migration of antimicrobials constituents when tested by EN 1104
- Heavy Metals Pb, Cd, Hg, Cr(VI) by ENV 12497 and ENV12498.
- Organoleptic Inertness EN 1230 parts 1 and 2

Tests which apply only when certain paper chemicals are present include the following[24].

- Migration of Fluorescent Whitening Agents when measured by EN 648
- Colour Migration by EN 646 (only be needed for coloured papers)
- Formaldehyde in a cold water extract by EN 1541
- Glyoxal in a cold water extract (BfR Method)
- 3MCPD/DCP by BfR Method (only where Kymene type wet strength agents have been used)
- Where recycled paper is used, the BfR require tests for the level of di-isopropyl naphthalene (DIPN)
- A temporary limit on di-isobutyl phthalate (DIBP) is currently in place

3.2 Netherlands Legislation 'The Warenwet'

At the most general level, food packaging materials are regulated in the Netherlands under a Decree of 1 October 1979 on Packaging and Articles of Daily Use *'Verpakkingen- en Gebruiksartikelen- besluit'*. This decree is implemented by a Ministerial Regulation of 25 January 1980 *'Regeling verpakkingen en gebruiksartikelen,'*, which is periodically amended and maintained. The compilation of these regulations and decrees is most commonly known as the Warenwet and provides what is essentially a volume of positive lists for starting substances in different types of food contact substances (e.g. Plastics, Paper and board, Rubber etc). In this respect, the Warenwet partly acts as a means to incorporate harmonised EU legislation as it is brought forward (e.g. the plastics directives), but it also provides a summary of the Netherlands legislation in areas which are not yet subject to harmonised EU legislation.

The Dutch legislation for food contact paper and cardboard is given in the Warenwet (*'Hoofdstuk II Papier en Karton'*). This legislation consists primarily of a listing of approved starting materials for use in food contact papers and by contrast to BfR Recommendation XXXVI, it should be noted that this is a binding positive list[25].

3.2.1 Rules for Selection of Paper Chemicals

The listing for paper chemicals is split up according to the application of the chemical and includes both paper chemicals (intended to remain in the paper) and process chemicals (which are not). The list also gives upper use limits and technical specifications for some chemicals. Additionally, it is permissible to 'read across' approvals from other chapters of the Warenwet. This has the effect of extending the positive list beyond the list of substances given in Chapter II and is particularly useful in assessing the use of dyes, paraffin waxes and other coatings. Any restrictions contained in the approvals incorporated by cross reference (e.g. SMLs, QMs and purity criteria) are still applicable when they are used in paper/board.

The binding nature of the positive list should in principle mean that checking compliance is a more straightforward matter than compliance with the requirements of the BfR recommendation. The downside of this clarity is that there is a lesser range of substances (and particularly process chemicals)

which may be used in food contact papers than is the case under the non-binding BfR Recommendation.

The current basis for inclusion of a chemical on the positive list of the Warenwet is discussed in Section 3.2.3, but it should be pointed out that, as for BfR Recommendation XXXVI, there are many substances on the list which were assessed prior to the adoption of EFSA style approval processes.

In our opinion, the Warenwet can therefore be argued to meet the requirements of the GMP regulation with regard to having clear guidelines for selection of paper chemicals. However, as pointed out above, strict application of the list is more restrictive than the German BfR Recommendation bearing in mind that this does not deal with all process chemicals.

3.2.2 Restrictions on Paper Chemicals

The positive list given in the Warenwet is largely structured around substances which are approved subject to maximum use limits. For instance, *'polyamide-epichlorohydrin resins produced through the reaction of the condensation product of adipic acid and bis(2-aminoethyl) amine and epichlorohydrin or with a mixture of epichlorohydrin and ammonia'* are approved for use as wet strength agents subject to a maximum use level of 1.5%. Additionally contained later in the positive list is a requirement that the specific migration of 3-monochloropropanediol (3MCPD, a by-product of epichlorohydrin and a known contaminant in this class of wet strength agents) does not exceed 0.01 mg per kg based on the conventional migration testing protocols for plastics. This should be compared with the German limit of 12 µg per kg of water in a cold water extract (produced from 40 g of paper per kg of water). Working from a 100 gsm paper, this limit is equivalent to 0.3 µg per dm^2, or an SML of 1.8 µg per kg in the food (based on 6 dm^2 of packaging per kg of food). In this case, the German limit is demonstrably tighter than the Warenwet limit.

This does seem to be a general pattern within the Warenwet which tends to contain slightly less tight restrictions than the BfR Recommendation. If one also considers formaldehyde, it is subject to an SML of 15 mg/kg under the Warenwet (identical to the limit in the plastics legislation). This should be

compared with the German limit of 1.0 mg per dm^2, which using the same assumptions as the previous section is equivalent to an SML of 6 mg per kg in the food.

Despite the above anomalies, what is clear is that the restrictions for recently approved paper chemicals are now commonly based on EFSA standard migration studies and known toxicology for the substance (see section 3.2.3 on the approval process) and the Warenwet has also implemented (where appropriate) the same limits as those used for plastics. It can therefore be clearly argued that the Warenwet is controlling migration of paper chemicals into foods in line with the requirements of Article 3 of the Framework Regulation.

On this basis, we can conclude that, where they are specified, the limits within the Warenwet are based on an assessment of the migration of substances into foods and are capable of controlling that migration in line with the requirements of Article 3 of the Framework regulation.

3.2.3 Approval Process for Inclusion on Positive List

In all its most important details, the approval process for inclusion of a chemical onto the Warenwet positive list is identical to the process for BfR listing. All that needs to be done is to submit the same migration and toxicological to the Dutch authorities as one would submit to the BfR. In this respect, once the work has been carried out for a BfR listing, the application should also just be submitted for Warenwet listing.

On this basis, we can therefore conclude that the process for assessment of chemicals under the Warenwet is currently a robust one which is well aligned with the requirements of Articles 8 to 12 of the Framework Regulation. As for BfR XXXVI, it is worth noting that many of the approvals on this list pre-date the current approval process and so could still be open to question in the same way that we described for the BfR approvals.

3.2.4 Recycled Fibre Requirements

The Warenwet permits a wide range of plant based fibre including wood dust and paper and paperboard.

- *Natural cellulose fibres.*
- *Wood pulp*
- *Paper and Paperboard fibres*
- *Plastics subject to them complying with the relevant regulation for that plastic described elsewhere in the Warenwet (Chapters I and X).*
- *Regenerated cellulose in compliance with chapter VIII*
- *Textile fibres in compliance with Chapter VII*

There are no restrictions set out within the Warenwet on the recovered paper groups which are permitted in food contact papers or for the purity or control of recycled fibre in food contact paper. However, finished papers must clearly comply with the wider requirements of Chapter II of the Warenwet, as would be the case for any other papers. On this basis, it is difficult to make a case that use of the Warenwet, without the back up of a suitable code of practice, provides a suitable Framework to establish the safety of recycled fibre under either the Framework Regulation or GMP regulation.

3.2.5 Declaration of Compliance

The Warenwet does not currently contain any detailed guidance on the contents of a Declaration of Compliance.

3.2.6 Code for Good Manufacturing Practice

There is no current Guidance on GMP either within the Warenwet or incorporated by reference.

3.2.7 Rules for Multilayer Materials

The use of a wide range of plastic coatings is permitted under Chapter X of the Warenwet. However, Chapter 2 (Paper and Cardboard) of the Warenwet also makes it clear that where a plastic coating has been applied, the overall migration limit and any specific migration limits that might apply to the plastic in its own right also apply to the multilayer structure. The testing regime applied to the finished article is incorporated into Chapter 2 by reference to the section relating to plastics. In this respect, the testing is therefore aligned

to the testing protocols for plastics in contact with foods, despite some of the known problems of carrying out overall migration tests on multilayer materials based on paper.

The position of the Warenwet for multilayer materials containing paper can therefore be summarised as follows; (a) any paper layers should comply with the requirements of Chapter 2 and (b) plastics layers should also comply with the composition rules and migration limits which apply to them under Chapter I (which itself is increasingly aligned with EC Directive 2002/72/EC and its amendments). In this respect, it is apparent that Warenwet is currently consistent with the proposed approach contained in the current draft of the plastics implementing measure and at the moment probably exceeds these requirements.

3.2.8 Testing Requirements under Warenwet Chapter II

In addition to the requirements relating to coated papers, there are also some testing requirements detailed in the Warenwet Chapter 2 for uncoated papers. These include measurements of overall migration into aqueous and fatty foods which should be carried out according to conventional migration testing protocols for plastics or equivalent (or more severe methods of test). In practice, given the well-documented difficulties in carrying out overall migration tests on paper, the following two sets of extraction tests have been used as 'more severe' methods to give upper estimates of the level of overall migration into aqueous and fatty foods;

- Water extractable material with the water extract prepared according to EN 647 (hot water) or EN 645 (cold water) and the extractable material determined according to EN 920, and
- Measurement of overall migration into iso-octane using method EN 1186-15.

Additionally, under the Warenwet, a short list of substances used in paper chemicals are subject to specific migration limits and in general, these are substances which are approved for use in paper and cardboard and the SMLs are harmonized with the limits in the Plastics legislation.

3.3 French Legislation

The French Legislative Framework for papers in contact with foodstuffs has been developed over many years and started in 1912 with measures which were put in place to control arsenic based compounds which were being used in colourants in food contact papers[26]. This legislation also had the effect of banning the use of print in direct contact with foods, which is a position which remains in place today. In later years, the legislation was developed through a series of circulars, instructions and circular letters which had the effect of approving a number of paper chemicals and setting standards for finished food contact papers in a relatively ad-hoc manner and these were incorporated in legislative documents which contained details of a number of different food contact materials. These approvals are drawn together in a single volume in Brochure 1227 which details all the French legislation relating to food contact materials[27]. However, the information contained is structured according to the original legislative texts with the provisions relating to paper mingled with those for other food contact materials and hence this is not the most convenient manner of accessing the French legislation on food contact paper and board.

A more convenient description of the French legislation is given in *'DGCCRF Information Note 2004/64'* which draws together all of the provisions of the French legislation and compiles them into a single document with the provisions segregated according to food contact material type[28]. This document is also supported by *'DGCCRF Information Note* 2006-156', which provides an explanation of the rules in relation to coated papers and cardboards[29]. Also referenced from within these documents and thereby forming part of the French legislative framework is a guide to good manufacturing practice the *'Guide de bonnes practiques de fabrication des papiers et carton',* which is most commonly known as the GDBP[30].

3.3.1 Rules for Selection of Paper Chemicals

There is currently no comprehensive or binding French positive list for substances which can be used in food contact papers (although amongst the list of substances approved there is a list of approved optical brighteners). For the greater part, NI 2004/64 instead refers manufacturers to the GDBP for further details of selection criteria. The *'guide de bonne practiques'* acknowledges the suitability of chemicals for use in food contact papers

provided that they are approved under BfR XXXVI or the Regulations contained in USA FDA 21CFR §176.170 and §176.180[31]. For this reason, auditing of the formulations against French legislation is generally confined to checking the status of optical brighteners under French legislation with all other chemicals generally being assessed under Recommendation BfR XXXVI, or when the substance is not listed there by reference to FDA regulations. This de-facto recognition of the value of the FDA regulations has the effect that it removes some of the grey areas left by the BfR distinction between paper and process chemicals and provides some clearer rules to justify the use of process chemicals based on FDA regulations. However, these FDA approvals have not necessarily been granted on the basis of petitions which would conform with the EFSA approval process, and hence there is the possibility that they would not always be accepted universally across the EU as some member states with more prescriptive and binding positive lists would be at liberty to adopt their own position on such chemicals.

In our opinion, this means that despite the absence of a comprehensive positive list, the French legislation meets the requirements of the GMP regulation with regard to having clear guidelines for selection of paper chemicals. Its adoption of the FDA list of approved paper chemicals could, however, lead to conflict with member states with more binding positive list requirements such as the Dutch Warenwet.

3.3.2 Restrictions on Paper Chemicals

The same restrictions that are under place in the FDA regulations or BfR recommendations (maximum use levels or residual levels) are also implemented under the French legislation.

On this basis, and given the foregoing discussion about the BfR recommendations, we can conclude that, under the French legislation, where the chemicals are selected according to the BfR list and its limits, the migration of substances into foods will be in line with the requirements of Article 3 of the Framework regulation.

3.3.3 Approval Process for Inclusion on Positive List

Since there is no comprehensive or actively maintained French positive list and the French approval system relies largely on the BfR lists (and therefore its underlying approval process), the French system is subject to the same strengths and weaknesses as those described for the BfR Recommendation above.

3.3.4 Recycled Fibre Requirements

The requirements for fibres are described in the GDBP, which permits the use of virgin fibres (bleached or unbleached) obtained by mechanical, thermochemical, semi-chemical or chemical processes. It also permits the used of fibres manufactured from regenerated cellulose or from high polymers where they meet the requirements of relevant EU legislation. The GDBP also permits the use of recycled fibres apart from the following classifications of recycled papers defined according to EN 643.

'A 0 Mixed waste paper (unsorted), thus designated "mixed waste paper (unsorted) including unsorted consolidated materials from households, no guarantee of absence of unusable materials.

A 12 "Shredded office waste paper (unsorted)"
B 11 "White carbonless copy paper"
B12 " Coloured carbonless copy papers"
Thermocopy papers are also to be excluded.'

In general, the GDBP permits without further authorisation, a wide range of fibres reclaimed from the manufacturing process, converting process and from public services, industries and retailers. Additionally, there is an approval process for fibres which do not meet this definition and a requirement for the submission of dossiers to the DGCCRF.

Additionally, and of relevance to recycled fibre in particular, the GDBP specifies a limit of 2 mg per kg for the level of PCBs in food contact paper and cardboard. This limit was clearly harmonised with the limit specified in BfR Recommendation XXXVI. The BfR removed this restriction in 2001. The reason for this withdrawal of the limit arose from the phase out of PCBs in carbonless copy papers and a number of other applications. Following a

series of studies in the late 1990s, it was concluded by the BfR that the level of PCBs in recycled fibres had fallen to such an extent that they were no longer of concern, and the BfR felt able to remove this restriction. The limit in the French legislation can therefore be seen as a throwback to this earlier version of the BfR recommendations, but it should nonetheless be respected as it clearly forms part of the French legislation.

In common with the BfR recommendation, because there is no detailed set of instructions about how to demonstrate the safety of recycled fibre in general and printed recycled fibre in particular, the French guidelines do leave operators open to being caught out when printing chemicals are found in their papers. Because the French framework does not include DIPN or DIBP within the list of contaminants to be controlled, it could be argued that it offers a slightly lesser degree of control, although these would merely be two potential contaminants. In our opinion, the French guidelines would definitely be improved by the incorporation of a longer list of contaminants subject to restrictions and possibly some form of broad band test with the goal of establishing that the recycling process is functioning properly.

In summary, the French legislative texts do offer some guidance on the use of recycled fibres in food contact applications, but in our opinion, this guidance stops some way short of providing sufficient information to fully satisfy the requirements of the Framework and GMP Regulations.

3.3.5 Declaration of Compliance

The French legislative documents do not currently contain any detailed guidance on the contents of a Declaration of Compliance.

3.3.6 Code for Good Manufacturing Practice

A clear advantage of the French legislative framework by comparison to the BfR Recommendation or the Warenwet is the Code for GMP described in the GDBP. In essence, this provides a set of guidelines for;

- Selection of raw materials including fibres and paper chemicals
- Description of acceptable manufacturing and converting technologies
- A description of likely risks and hazards associated with these processes and their likely impact on food contact issues including means of protection, inspection and follow up/documentation.
- Restrictions on the level of certain chemicals and contaminants present in papers.

The GDBP clearly predated the GMP regulation and therefore its wording is not perfectly-aligned. However, in our opinion, it is a strength of the GDBP that it recognises that the paper industry is highly-dependent on a wide range of raw materials and defines a framework for control of these materials. This was quite far-sighted and came some considerable time before similar requirements were put in place by the EU through the GMP regulation. However, the wording of the document has now been superseded to some extent by the GMP regulation and there is potential for confusion between these two documents. Additionally, the requirements of the GDBP can be viewed as top line quality objectives rather than a detailed road map showing how to implement a suitable quality system. Industry and those carrying out audits would benefit greatly from a more focussed set of requirements.

In our opinion therefore the French legislative Framework clearly offers a partial set of guidance along the lines of the GMP regulation, but would benefit from being updated to bring it in line with the GMP regulation and to provide more industry-focussed guidance.

3.3.7 Rules for Multilayer Materials

Rules for coated papers in contact with foods are laid out in Information Note 2006/156 which deals with paper and cardboard coated with *'wax, wax with additives, paraffins, paraffins with additives, silicones and polymeric emulsions that in the finished product state are designed to come into contact*

with foodstuffs.' Other types of multilayer structures based on plastic coated or laminated papers are legislated under the 'Composites' section of Information Note 2004/64.

For the types of products covered by Information Note 2006/156, there is a general requirement that the underlying paper meets the requirements of the French Legislation. Means of demonstrating compliance with the compositional requirements of the legislation for the coating include compliance with a number of items of French legislation and the Framework regulation. There is an additional reference to compliance with the legislation of other regulators including the BfR, the FDA and also the council of Europe Resolution on coatings in contact with foods[32]. There are additional requirements for the migration testing of finished products.

For laminates and plastic coated papers, there is a requirement that the paper layers shall comply with the requirements of the French legislation and that the plastic layer shall meet the compositional requirements of the plastics in contact with foodstuffs legislation. Additionally, there is a requirement that the finished product shall meet the Overall and Specific migration limits that would have applied if it had been a plastic monolayer

The position of the French legislation for multilayer materials containing paper can therefore be summarised as follows; (a) any paper layers should comply with the requirements that apply to paper, (b) wax coatings should comply with French legislation and/or the Framework Regulation and the Council of Europe Resolution on coatings and (c) plastics layers should also comply with the composition rules and migration limits which apply to them under EC Directive 2002/72/EC and its amendments). In this respect, it is apparent that the French Legislation is currently consistent with the proposed approach contained in the current draft of the plastics implementing measure and at the moment probably exceeds these requirements.

3.3.8 Testing Requirements under Information Note 2004/64

One of the key strengths of Information Note 2004/64 is that it offers a very clear summary of the testing requirements for papers in contact with foods which is not offered in either BfR Recommendation XXVI or the Warenwet, where to some extent the testing requirements are scattered throughout what

is essentially a positive list. This gives a great advantage in readability to the French legislation. These tests are primarily based on the same schedule as BfR Recommendation XXXVI and include;

- No visible migration of antimicrobials constituents when tested by EN 1104
- Organoleptic Inertness EN 1230 parts 1 and 2
- Pentachlorophenol (PCP) content
- Heavy Metals Pb, Cd, Hg, Cr(VI) by ENV 12497 and ENV12498.
- Formaldehyde in a cold water extract by EN 1541
- Glyoxal in a cold water extract (BfR Method)
- Migration of Fluorescent Whitening Agents when measured by EN 648
- Colour Migration by EN 646 (only be needed for coloured papers)

Additionally, there are some further tests required under the French legislation which are not already covered by BfR XXXVI are including;

- Measurement of PCBs by EN ISO 15318
- Water extractable material with the water extract prepared according to EN 647 (hot) and the extractable material determined according to EN 920
- Fluorine content

In contrast to BfR recommendation XXXVI, the French Information Note specifies different tests to be carried out according to the end use of the paper (i.e. dry foods, wet or fatty foods, cooking and hot filtration). In essence, these different tests focus effort on applications where the contact with the food is most intimate and the temperature is highest and it is in these circumstances where the migration of substances into foods would be expected to be highest.

3.4 Italian Legislation

The Italian legislation on paper and contact with foods was first put forward in 1973[33] within a general document on food contact materials (DM 21.3.1973) and this legislation has been amended on a number of subsequent occasions[34]. The most significant of these amendments dates from 2001[35] in which the legislation was altered to permit the use of fluorescent whitening agents and to bring the testing requirements partly in line with the requirements other EU member states for the non migration of these substances.

3.4.1 Rules for Selection of Paper Chemicals

The legislation as originally published in 1973 consisted primarily of a relatively short binding positive list of substances. In a number of amendments, this list has been expanded, but at present date , we do not believe that this list covers the full range of substances that are commonly used in the manufacture of food contact paper and board (the list is certainly shorter than the approved lists in either BfR Recommendation XXXVI or the Warenwet).

The positive list authorises the use of a number of fluorescent whitening agents (FWAs) in food contact paper and cardboard at levels up to 0.3%, subject to a requirement that they do not migrate into foods. The contents of this list and the upper use are all consistent with the requirements of BfR Recommendation XXXVI, although it should be mentioned that the Italian list specifies a greater range of FWAs than are currently listed in the Warenwet.

In our opinion, the Italian legislation meets the requirements of the GMP regulation with regard to having clear guidelines for selection of paper chemicals, but the list as it is currently structured is somewhat shorter than the positive lists in place in either Germany or the Netherlands and may not offer a sufficient range of substances to meet industry's requirements. There is also scope for conflict between the positive lists given in the Italian legislation and that of other member states, particularly with respect to FWAs. This is not an ideal situation given that one of the principal aims of the Framework Regulation was to harmonise national measures.

3.4.2 Restrictions on Paper Chemicals

Where a food contact substance is listed in the Italian positive list it is often listed with a maximum use limitation and/or a specific migration limit, and this may need to be tested in food simulants under conditions which replicate the end use of the paper. In principle this is in line with the requirements of Article 3 of the Framework regulation, but given that the positive list is not actively maintained to the same extent as the German or Dutch positive lists, in our view this could be viewed as an unnecessary complication as it brings no significant advantage over the approach adopted under BfR XXXVI whilst only going part of the way to offer the consumer the same degree of protection.

In our opinion therefore, the limits that are in place under the Italian legislation only partly meet the requirements of Article 3 of the Framework Regulation.

3.4.3 Approval Process for Inclusion on Positive List

Additional substances can be added to the Italian positive list by application to the Minister of Health using a procedure which is briefly referred to in Article 4 of the DM 21.3.1973. In practice, the process relies on previous assessments made for submissions under the plastics legislation and in principle should therefore be aligned with the EFSA. However, the legislation itself does not clearly set out the required information which should be submitted to the Minister of Health. It is, therefore, hard to argue that the current system as operated fully meets the requirements of Articles 8 to 12 of the Framework Regulation with regard to having clear rules for the approval process.

3.4.4 Recycled Fibre Requirements

The Italian legislation contains no comprehensive set of requirements for the levels of contaminants in recycled fibres when compared to virgin fibres, apart from the imposition of a limit of 2 mg per kg for the level of PCBs in the finished paper. This limit is also present in the French legislation, but was deleted from BfR Recommendation XXXVI following research which showed that PCBs were no longer present in fibres following a reduction in the use of these chemicals.

It is, however, worth noting that a 1993 amendment to the legislation contains a requirement that articles manufactured from recycled fibres should not be used in contact with foods for which migration testing would normally be required. The interpretation of this clause is that recycled fibre should not be used in contact with moist or fatty foods. This requirement clearly aimed to minimise the exposure of consumers to contaminating chemicals by restricting the use of recycled papers and boards to foods with low extracting power. However, from surveillance work carried out in the UK[36], it is known that chemicals such as diisopropylnaphthalenes (DIPNs) can migrate at significant levels from recycled board into dried foods (such as breakfast cereals), even when there is an intermediate layer of plastic between the card and the food. In the light of these findings, which came after the Italian legislators adopted their position on dried foods, it is hard to argue that the Italian legislation as it is currently framed is capable of controlling the migration of contaminating chemicals from recycled paper and cardboard and it would certainly benefit from monitoring a wider range of potential contaminants.

In our opinion therefore, the Italian legislation does not currently offer sufficient guidance to fully satisfy the requirements of the Framework and GMP Regulations with regard to the use of recycled fibres.

3.4.5 Declaration of Compliance

DM 21.3.1973 contains a requirement for a Declaration of Compliance, but the document does not currently contain any detailed guidance on the contents of such a Declaration of Compliance and this seems to be a gap compared to current EU practice in relation to other food contact materials.

3.4.6 Code for Good Manufacturing Practice

There is a general requirement under Article 27 of DM 21.3.1973 that GMP should be exercised to ensure to the presence of technological adjuvants is only at trace levels. However, in our opinion, this does not constitute detailed Guidance on GMP as would now be desirable to meet the requirements of the Framework and GMP regulations.

3.4.7 Rules for Multilayer Materials

The Italian legislation offers no specific or comprehensive guidance on multilayer /multimaterial structures based on paper/board in combination with plastics and/or metal layers. In our opinion, it therefore does little to clarify the requirements of Article 3 of the Framework Regulation in this area. There is, however some guidance on the use of cardboard multilayer materials and additional requirements on adhesives, colourants and waxed papers.

3.4.8 Testing Requirements under Italian Legislation

In addition to the specific migration restrictions described in an earlier section which apply when certain paper chemicals have been used, the Italian legislation also contains a requirement for 2 generic tests on food contact papers and cardboards.

- FWAs by EN 648
- PCBs by EN ISO 15318

The first of these is required under both BfR Recommendation XXXVI and the French Legislation, so in general, no additional work is required to establish compliance with the Italian legislation, if the paper/board already complies with German and French requirements. Experience tells us that the local enforcement agencies in Italy are particularly diligent in examining the transfer of FWAs into simulated foodstuffs.

3.5 Summary of National Legislation on Food Contact Paper and Board

In summary, we have seen that each of the pieces of National legislation reviewed has gone at least some way to satisfying key requirements of the Framework and GMP regulations. Each set of legislation has strengths and weaknesses and none fully meet the success criteria we identified for legislation to meet the requirements of the Framework and GMP regulations and the principal strengths and weaknesses.

German BfR Recommendation XXXVI

Key Strengths

- Clear practical positive list backed up by rigorous approval process that is now in line with EFSA protocols.
- Limits contained in the legislation at least reflect the level of chemicals to which consumers would be exposed.

Key Weaknesses

- No definition of requirements of a Declaration of Compliance
- No description of GMP requirements

Possible areas for improvement or partial gaps

- Positive list depends in part on historical approvals of chemicals carried out under protocols which are not well-aligned with current EFSA practice.
- Approach for recycled fibres is fragmentary and could be improved.
- Positive list is non-binding and hence there is a lack of clarity about whether some process chemicals should be listed.
- Multilayer structure rules do not allow for paper chemicals with SMLs under plastic legislation.

Dutch Warenwet

Key Strengths

- Clear practical positive list backed up by rigorous approval process that is now in line with EFSA protocols.

- Limits contained in the legislation reflect the level of chemicals to which consumers would be exposed and are to some extent harmonised with limits in the plastics legislation.

Key Weaknesses

- No definition of requirements of a Declaration of Compliance
- No description of GMP requirements
- No clear guidance on recycled fibre content.

Possible areas for improvement or partial gaps

- Positive list depends in part on historical approvals of chemicals carried out under protocols which are not well-aligned with current EFSA practice.
- Multilayer structure rules do not allow for paper chemicals with SMLs under plastic legislation.

French Legislation and the GDBP

Key Strengths

- No full positive list, but recognises the BfR and FDA positive lists.
- Limits contained in the BfR lists reflect the level of chemicals to which consumers would be exposed.
- Useful summary of GMP detailed under the GDBP.

Key Weaknesses

- No definition of requirements of a Declaration of Compliance
- Very little guidance on recycled fibre content.

Possible areas for improvement or partial gaps

- Positive lists incorporated by cross-reference depend in part on historical approvals of chemicals carried out under protocols which were not well-aligned with current EFSA practice.

Italian Legislation

Key Strengths

- Clear positive list for fluorescent whitening agents.

Key Weaknesses

- No clear definition of requirements of a Declaration of Compliance.
- No clear code for GMP
- No specific rules for multilayer/multimaterial structures.

Possible areas for improvement or partial gaps

- The positive list of approved substances is a little short and would benefit from updating and extension, to cover a greater number of the substances cleared under BfR XXXVI and the Warenwet.
- Clearer explanation of the rules for approval of new substances would be beneficial.
- There is only partial guidance on the contaminants in recycled fibres.

Clearly, within each of these four member states, these items of legislation must be respected, but the different positive lists and differing restrictions mean that ensuring compliance in all four states is very far from being a straightforward exercise. For instance, if one used a fluorescent whitening agent in a food contact paper/board, one would have to ensure that it was included on each of the four positive lists, each of which are framed in slightly different ways. Furthermore, even when one set of legislation acknowledges the positive list of a separate member state (as is the case in the French recognition of the BfR XXXVI list), the testing requirements of the legislation can be different. We have summarised the key testing requirements of the different member states in table 3.5.1, but it is clear that there are a number of differences between the approaches of the different states and this creates many anomalies one of which is the persistence of restrictions on PCBs in the French and Italian test matrices, long after this test was deemed not to be necessary under the BfR system.

In conclusion, although each of the sets of national legislation reviewed here do at least aim to ensure compliance with the GMP and Framework regulation, none of them are perfect and differences in approach mean that compliance across Europe can be fraught with difficulty. In this light, industry would clearly benefit from harmonised legislation or standards provided that the approach taken was practical and proportionate to the risks involved. It was with these aims in mind that the CoE resolution and the Industry Guidelines were developed and we will now discuss each of those documents in more detail.

3.5.1 Summary of tests required against the requirements of individual EU member States

	Tests Required in member States			
Test	**Germany‡**	**France**	**Netherlands‡**	**Italy**
OBAs EN 648	Yes	Yes	§	Yes
Colour Migration EN 646 or equivalent method for Warenwet	Yes	Yes	-	-
Formaldehyde EN 1541	Yes	Yes	§	Yes
Glyoxal BfR Method	Yes	Yes	§	-
PCP CEN Method	Yes	Yes	§	-
3MCPD/DCP BfR Method	Yes		§	-
Antimicrobials EN 1104	Yes	Yes	-	-
Heavy Metals Pb, Cd, Hg, Cr(VI)	Yes	Yes	☼	-
Organoleptic Inertness EN 1230	Yes	Yes	♠	♠
PCBs EN ISO 15318	-	Yes	-	Yes
Water extractables EN 645 or EN 647 and EN 920	-	Yes	♦	-
Heptane or iso-octane extractables			♦	-

‡ Please note that the legislation applying in Germany and the Netherlands contains additional provisions related to the migration of certain additional substances (expressed as SMLs or extraction limits or residual limits).

§ SMLs are given for these substances in Warenwet Chapter II.

☼ SMLs are given for Hg, Cd and Cr under Warenwet Chapter II.

♦ Tests carried out as worst case extractions to demonstrate compliance with overall migration requirements of Warenwet Chapter II.

♠ Requirement of Framework Regulation, hence no strict need to replicate this requirement in National Legislation.

NB The above table is for comparative purposes only and is not designed to be a comprehensive description of all testing requirements. The original legislative documents should always be consulted when devising test programmes.

4 Council of Europe Resolution on Paper and Board in Contact with Foods; Resolution RESAP 2002(1) Version 3

The Council of Europe started work on the Paper and Board Resolution in 1987 with two main aims;

- Protection the health of the consumer
- Harmonisation of the approach taken towards paper and board food contact packaging materials.

The Council of Europe Resolution on paper and board was formally approved by the Committee of Ministers of the Council of Europe [CoE] on 18th September 2002 and has been subject to two subsequent revisions. The current text of the Policy Statement on *'paper and board materials and articles intended to come into contact with food'* (Version 3 - 11 December 2007[37]) is based around six documents. The first document contains the resolution itself with the remaining five being technical documents which are referenced from the main resolution and provide guidance on compliance with the resolution:

- Resolution ResAP (2002) 1 on *'paper and board materials and articles intended to come into contact with foodstuffs'*
- Technical document No. 1 – *'List of substances to be used in the manufacture of paper and board materials and articles intended to come into contact with foodstuffs'* (Version 2)
- Technical document No. 2 – *'Guidelines on test conditions and methods of analysis for paper and board materials and articles intended to come into contact with foodstuffs'* (Version 3)
- Technical document No. 3 – *'Guidelines on paper and board materials and articles, made from recycled fibres, intended to come into contact with foodstuffs'* (Version 2)
- Technical document No. 4 – *'CEPI Guide for good manufacturing practice for paper and board for food contact'* (prepared by CEPI)
- Technical document No. 5 – *'Practical Guide for users of Resolution ResAP (2002) 1 on paper and board materials intended to come into contact with foodstuffs'* (Version 2)

The resolution applies to all food-contact paper, including coated board and multilayer materials. Paper that is used in food-contact articles, but that is separated from the food by a functional barrier, non-woven materials, kitchen towels, napkins, and certain filter materials do not fall within the scope of the Resolution.

4.1 and 4.2 Rules for Selection of Paper Chemicals and Restrictions on Paper Chemicals

The part of the resolution where criteria for selection of raw materials are laid out is the inventory list given in Technical Document 1. This contains lists of Food Contact Substances (FCSs) permitted for use in food contact applications. Additives are divided between List 1 and List 2 substances.

- List 1 includes Additives evaluated by either (a) the SCF, (b) an EU Member State, or (c) by the US Food and Drug Administration, and (d) substances authorized as direct food additives. Inclusion in this part of the list requires the presence of a dossier which meets EFSA requirements and which allows the FCS to be classified in SCF Lists 0-4. List 1 therefore consists primarily of substances which have been assessed by EFSA in preparation of the plastics in contact with foodstuffs legislation.

- List 2 includes FCSs that do not meet the criteria laid down for List 1 substances. List 1 is further subdivided into Categories A and B;
    - Category A contains the list of authorized additives with the established restrictions
    - Category B contains a temporary list of additives authorized in Member States or approved by the US Food and Drug Administration, with restrictions to be fixed.

Monomers for use in the manufacture of polymeric additives are divided into three Appendices.

- Appendix A lists approved monomers approved at the European level with established restrictions
- Appendix B lists monomers authorized only in Member States or approved by US Food and Drug Administration, with restrictions to be fixed

- Appendix C lists monomers not yet assessed.
  In principle, because the approach adopted in compiling the inventory list was that adopted by EFSA, it is easy to argue that the list and its associated limits meet the requirements of Article 3 of the Framework regulation. However, the usability of the list as a tool for safety assessment of food contact chemicals, as required by the GMP regulation, is severely restricted by the large number of widely-used paper chemicals which are included on List 2 and therefore have not been through the EFSA approval process. For instance List 2 contains all the fluorescent whitening agents approved under National regulations and also glyoxal. Since none of these have previously been assessed by EFSA for use in plastics, the only comment next to their entry is that a restriction is yet to be fixed. It is therefore hard to argue that this element of the CoE Resolution will offer clear guidance on selection of materials without significant expenditure on the registration of these substances through EFSA or a national authority.

  Where restrictions are given in the lists, they are generally in the form of SMLs and these are based on the same assumptions as would be the case for plastics (i.e. consumers eating 1kg of food every day packed in the same material and in contact with 6 dm^2 of packaging material). It is questionable whether these assumptions are correct for most plastics in contact with foodstuffs. However, given the different usage ratio of paper/board in food contact and also the generally lower exposure of consumers to food packed in paper/board or coated paper/board, it is our opinion that these assumptions represent a significant overstatement of actual exposure risks to paper chemicals.

  One other point of confusion may arise from the common use of polymeric additives as paper chemicals. For instance, the kymene-type wet strength agents which are based on polyamine-epichlorohydrin type chemistry. These are listed according to the SMLs assigned to individual monomers and therefore have the potential to attract several SMLs for each wet strength agent rather than the relatively short list of extraction tests currently specified under BfR Recommendation XXXVI.

  Additionally, it is worth noting that under the Resolution, a None Detected SML (DL < 0.01 mg/kg) is assigned to epichlorohydrin, whereas under BfR

recommendation XXXVI a limit is instead placed on the level of DCP and 3MCPD (the hydrolysis products of epichlorohydrin) in a cold water extract (DCP < 0.002 mg/kg and 3 MCPD < 0.012 mg/kg). The BfR tests are carried out using an extract of 40 g of paper in 1 litre, hence for a 100 gsm paper, this is equivalent to 0.0003 mg of DCP per dm^2 of paper, which is equivalent to an SML of 0.0018 mg per kg using the conventional EFSA assumptions. It is therefore quite likely that BfR recommendation XXXVI is already controlling this risk to a greater extent than would be the case under the Resolution.

In summary, whilst the approach adopted in Technical Document 1 of the Resolution is clearly aligned to Article 3 of the Framework Resolution, its reliance on the existence of an EFSA assessment of the substance before any interpretation can be made of the suitability of the formulation means that it is quite likely that manufacturers would remain dependent on National Regulations to demonstrate suitability for many years until a large backlog of paper chemicals had been assessed. It is therefore hard to argue that it offers any clear rules that could be applied in the near future for the selection of raw materials to satisfy the requirements of the GMP regulation.

Additionally, in our opinion, given the lower exposure of foods to paper when compared with plastics, without incorporation of more sophisticated exposure modelling this is not likely to be a proportionate approach to controlling the risks. We therefore do not believe that the added level of complexity of the proposed system compared with that offered by the existing national lists would be justified.

4.3 Approval Process for Inclusion on Positive List

The proposed approval process for the incorporation of a substance on List 1 of the CoE resolution depends on the existence of a suitable dossier which has been assessed by EFSA. This approach is clearly aligned with the requirements of Articles 8 to 12 of the Framework Regulation. However, the EU do not currently have a harmonised regulation for paper in contact with foods, and so EFSA are not currently open to such applications.

If a decision were taken by the European Commission to adopt this approach, it would take a considerable amount of effort and expenditure to work through the EFSA approval process on those chemicals which have only been

assessed by the member states. This process could easily take 5 to 10 years based on the time that was required to develop the plastics legislation. There would almost certainly be a requirement for some clarification in the notes for guidance document to accommodate the different practical approaches which might be required to carry out migration studies on papers (e.g. agreed worst case extraction conditions etc).

4.4 Recycled Fibre Requirements

In our opinion, the Resolution offers a significantly enhanced Framework to demonstrate the safety of recycled fibres in contact with foodstuffs, when compared with the National Legislation described earlier in this report. The approach is based on three principles;

- The source of recovered paper and board
- The processing technologies used in the recovery/decontamination and
- The food types with which the recycled fibres may be used.

The general principle of the Resolution is that the cleaner the source of fibre, the less rigorous the cleaning process would need to be and the greater the range of foods with which the end product could be used (i.e. intimate contact with moist and fatty foods rather than just contact with foods to be peeled and/or washed).

Technical Document 3 also refers to the need for the use of GMP in the manufacture of paper and board in contact with foods. The requirements are laid out in more detail under Sections 3, 5 and 6 of Technical Document 3.

In the current version of the Technical Document, recovered paper/board is categorised into four Groups;

- Group 1 - Paper manufactured from food contact approved substances as defined in Technical Document 1. Unprinted, cuttings shavings etc from food contact paper.
- Group 2 - Paper with non-approved or unknown additives, unprinted, lightly printed or lightly coloured.

- Group 3 - Printed paper and board, corrugated board from supermarkets, paper and board from households and industry
- Prohibited waste paper; Hospital waste, paper/board that has been sorted from mixed household refuse, batches consisting mainly of carbonless copy paper, old archival papers etc.

Since these definitions are somewhat general, the Technical Document also clarifies Groups 2 and 3 using a number of standard paper types according to EN 643 which is widely used in the recycling industry.

Food types are defined as;

- Food type I; Aqueous and/or fatty foodstuffs
- Food type II; Dry, non-fatty foodstuffs
- Food type III; Foodstuffs which are shelled, peeled or washed before consumption.

A number of restrictions are then placed on certain contaminants known to be of concern in printed/recycled fibres;

[1] Di-isopropylnaphthalenes (DIPN); 'as low as reasonably achievable'.
[2] Partially hydrogenated terphenyls (HTTP); 'as low as reasonably achievable'
[3] Phthalates; see EC Directive 2002/72/EC and amendments for restrictions
[4] Solvents; 'as low as possible'
[5] Polycyclic aromatic hydrocarbons (PAHs); (SML = Not Detectable, Detection Limit 0.01 mg/kg in Food)
[6] Benzophenone; SML = 0.1 mg per dm^2 of paper
[7] Michler's Ketone (SML = Not Detectable, Detection Limit 0.01 mg/kg in Food)
[8] 4,4'-bis(diethylamino) benzophenone (DEAB), (SML = Not Detectable, Detection Limit 0.01 mg/kg in Food)
[9] Azo-colours; No detectable primary aromatic amines in the paper using a method with a detection limit of 0.1 mg/kg
[10] Primary aromatic amines suspected as carcinogens; same limit as given for Azo-colours
[11] Fluorescent whitening agents, no visible migration when tested by EN 648.

These test requirements do not apply when the source of the paper is purely from the collection of approved food contact papers (i.e. Group 1 Fibre), or when the finished article is intended for use only in contact with Food Type III. Items [1] to [6] apply to use of Group 2 and 3 papers in contact with all other food types. Items [7] to [11] only apply to the use of Group 2 paper in contact with aqueous and fatty foods. Group 3 Fibre is not permitted in contact with aqueous or fatty foods.

The above approach certainly goes beyond that adopted in any of the sets of member state legislation in identifying more compounds of risk which are likely to be present in and also in providing a framework which links the source of the fibre to the degree of care that is required both in the decontamination of the fibres and also in the extent of testing that is required. There is after all little practical benefit in testing unprinted fibre for residues which are most likely to be present in printed fibres.

Where the proposed guideline leaves something of a gap is in the establishing the efficacy of decontamination methods for recycled fibres. There is certainly potential for a wide range of contaminants to be present apart from those covered by the tests [1] to [11] and this clearly leaves the finished products open to the periodic discovery of new contaminants and consequent scare stories (for example, ITX and 4 methyl benzophenone). This is not an entirely dissimilar situation to that which presented itself to the plastic recycling industry, where plastics can clearly pick up contaminants in use. The solution evolved to support the use of recycled plastics in food contact is described in the recent EU Regulation on recycling of plastics EC Regulation 282/2008[38]. Regulation 282/2008 is essentially set up as an amendment to the GMP regulation and a key requirement is that the holders of a process should be able to demonstrate that it is capable of removing contaminants to an extent that they are considered not to pose a risk to health. The mechanism for this proof is through what is known as a challenge test[39] whereby known amounts of specified contaminants are fed into the recycling process and then the output of the process analysed to demonstrate safe removal. The challenge testing process was clearly designed with plastics recycling in mind and is almost certainly not appropriate for the paper and cardboard industry where paper mills operate on a much larger scale, but

it does demonstrate that an approach where there is imperfect knowledge about the precise content of the raw materials (and hence finished products) can be acceptable under Article 3 of the Framework Regulation and the GMP Regulation. The key issues that would need to be demonstrated for this to be accepted would be (a) the existence of an adequate GMP system with control points properly identified and (b) some means of demonstrating removal of contaminants.

Additionally, it should be noted that some of the clarity of this approach is compromised by the text in the consolidated testing matrix which contains a number of provisos which state that there is a requirement for specified clean up processes unless they are 'not necessary'. There is no explanation of when the processes might not be necessary and this leaves significant room for misinterpretation of the Resolution.

In our opinion, the Resolution clearly offers an improved approach towards the demonstration of the safety of recycled fibre than is present in any of the member state legislation and in our opinion goes a significant way towards satisfying the requirements of Article 3 of the Framework Regulation and the GMP Regulation. However, one area which might require further thought is what steps could be taken to demonstrate the safe removal of contaminants which are not included in the test schedule of the Resolution.

4.5 Declaration of Compliance

The Council of Europe Resolution does not currently contain any detailed guidance on the contents of a Declaration of Compliance and in our opinion, due to the complex interaction of fibre source, process technologies and tests that we have described in Section 4.4 above, it would be particularly important to communicate clearly which types of food could be used in contact with the finished recycled papers.

4.6 Code for Good Manufacturing Practice

A relatively brief description of the requirements of a GMP system Technical Document No. 4 which was prepared by CEPI in 1999. In essence, this provides a set of guidelines for;

- Selection of raw materials including fibres and paper chemicals (by reference to Technical Documents 1 and 3)
- Description of acceptable manufacturing and converting technologies
- A description of likely risks and hazards associated with these processes and their likely impact on food contact issues including means of protection, inspection and follow up/documentation. The is similar in structure to the French GDBP.
- Restrictions on the level of certain chemicals and contaminants present in papers contained in the other Technical Documents are incorporated by cross-reference.

Technical Document No 4 clearly predated the GMP regulation and therefore its wording is not aligned perfectly, but it does put in place a partial framework for Good Manufacturing Practice in the paper industry. However, since the wording of the document has now been superseded to some extent by the GMP regulation and there is clearly potential for confusion between these two documents.

In our opinion therefore Technical Document 4 offers a partial set of guidance along the lines of the GMP regulation, but would benefit from being updated to bring it in line with the GMP regulation and to provide more industry-focussed guidance. We understand that a revised GMP document is being prepared in support of the Industry Guidelines described later in this review.

4.7 Rules for Multilayer Materials

In principle, the Resolution specifies that paper layers should comply with the resolution itself and also states that when a plastic coating is present, it should be formulated in accordance with the plastics in contact with foodstuffs legislation. If any substances are present in the structure which are subject to restrictions (either QM, QMA or SML), regardless of which layer they are present in, they would be subject to that restriction in the finished product as a whole. This would mean that where a melamine-formaldehyde wet strength agent is used in a paper layer, the finished structure would be subject to the SMLs for formaldehyde (15 mg/kg) and melamine (30 mg/kg), regardless of whether the paper actually comes into contact with the food or not.

Where a functional barrier can be demonstrated, it would be possible to argue that you do not require to demonstrate compliance with the SMLs, but demonstration of the efficacy of functional barriers is not a simple matter in itself.

In our opinion, therefore, the CoE Resolution clearly deals with the issue of paper in multilayer products and in our opinion is already aligned at least to the requirements of the proposed Plastics Implementing Measure and already allows application of SMLs for non food contact layers which may be brought forward in future amendments of the Plastics Implementing Measure. It can therefore be viewed as satisfying the requirements of Article 3 of the Framework Regulation for this important category of materials.

4.8 Testing Requirements under Council of Europe Resolution

Due to the requirements associated with the use of recycled fibres, it is clear that there is potential for a significant volume of testing to demonstrate compliance with the Resolution. On the following page, we have detailed the tests which must be carried out on all paper materials and also where recycled fibres might be present. Additionally, there are a good number of common paper chemicals which might have SMLs. Testing of finished paper and board would therefore be relatively complex under the Resolution.

To mitigate this, the resolution offers clear guidelines on how to convert from SMLs to QMA type limits. However, these use the conventional ratio of 6 dm^2 of packaging material to each kg of food which is applied to plastics and may not be appropriate to papers. Additionally, the resolution permits the use of worst case extraction conditions in the demonstration of compliance. However, these steps cannot completely dilute the complexity of the compliance framework.

Limits Applying to All Food Contact Paper and Board

Substance	Limit	Method
Cadmium	0.02 mg/dm^2 paper & board	In an aqueous extract according to EN 12498
Lead	0.03 mg/dm^2 paper & board	In an aqueous extract according to EN 12498
Mercury	0.03 mg/dm^2 paper & board	In an aqueous extract according to EN 12497
Pentachlorophenol	0.15 mg/kg paper& board	In an aqueous extract according to EN 15320
Antimicrobial Substances	Paper and Board shall not release substances in quantities which have an antimicrobial effect	EN 1104
Dyes and colorants (where used)	no bleeding	EN 646

Limits Applying only When Recycled Fibre is Present		
Michler's ketone	Not detectable in foodstuffs (detection limit 0.01 mg/kg)	
4, 4'-bis (diethylamine) benzophenone	Not detectable in foodstuffs (detection limit 0.01 mg/kg)	
DIPN	As low as reasonably achievable	
HTTP	As low as reasonably achievable	
Phthalates	Limits taken from EC Directive 90/128/EC with guidance on conversion between SMLs and residual limits.	
Solvents	As low as possible	
Primary aromatic amines (PAAs)	Not detectable in foodstuffs (detection limit 0.01 mg/kg) Testing required for Food Type 1 only.	
Azo colourants (which may cleave to form PAAs)	Primary aromatic amines not detectable in foodstuffs (detection limit 0.01 mg/kg) Testing required for Food Type 1 only.	
Polycyclic Aromatic Hydrocarbons (PAH)	Not detectable in foodstuffs (detection limit 0.01 mg/kg)	
Benzophenone	Specific migration limit of 0.1 mg/dm^2 of paper	

4.9 Summary of Council of Europe Resolution

In summary, we have seen that the council of Europe Resolution set out to address some of the key weaknesses in the pre-existing member state legislation, but still it has distinct areas of strength and weakness.

Key Strengths

- Rigorous approval process for chemicals which sets out to be harmonised with EFSA protocols, and therefore limits are based on specific migration levels and are consistent with the approach previously taken for plastics.
- A top level GMP code is contained within the Resolution.
- A significantly more rigorous framework for the approval of recycled fibres when compared to national legislation including fibre source, clean up processes and testing protocols, but this comes at the price of complexity.
- Clear rules on multilayer materials.

Key Weaknesses

- The positive list contains a large number of substances which have not been fully assessed by an EFSA protocol and therefore the list does not currently offer sufficient guidance to determine whether their use is safe. Significant additional work would be required to assess the remaining substances.
- Specific migration limits where they are specified are based on consumption and exposure factors that are not realistic for paper/board.
- No definition of requirements of a Declaration of Compliance

Possible areas for improvement or partial gaps

- GMP Guidance would need to be brought into line with the requirements of the GMP regulation.

In our opinion, the key issues which detract from the usability of the Council of Europe Resolution are related to (a) the lack of clarity in the positive list, (b) the overestimation of consumer exposure and (c) the complex system of approval for recycled fibres based on the consolidated matrix. These would be key points that should be addressed in the preparation of any future legislation or Industry Guideline.

5 Industry Guideline for the Compliance of Paper & Board Materials and Articles for Food Contact

The Industry Guideline for the Compliance of Paper & Board Materials and Articles for Food Contact has been prepared by a working group formed of members from CEFIC, CEPI, CITPA and FPE with the aim of producing a more practical and consistent framework to ensure the safety of food contact paper and board than is currently offered by national legislation or in the CoE Resolution. In doing this it picks up on many strands from these other documents and develops them. In discussing the Industry Guideline, we have therefore adopted the same strategy as our review of these other documents and most of the details of the Guideline are discussed in sections 5.1 to 5.8.

There are, however, two important new concepts contained in the Industry Guideline which we would like to introduce before starting this review; correction factors and biological testing.

We would also acknowledge at this point the statement in section 1b of the Industry Guideline which reminds users that even if they comply with this document, they are still bound by the requirements of national legislation in the member states until such a point that the EU brings forward harmonised legislation. This has a number of consequences that should be considered carefully including the differences between positive lists for fluorescent whitening agents and some different tests which are required between countries.

5.0.1 Correction Factors

Annex 5 of the Industry Guideline introduces the concept of correction factors when assessing compliance with any restrictions for paper chemicals. These aim to provide a method to take into account the less intimate manner in which food often comes into contact with paper when compared to plastics and also to fulfil the role taken in the Council of Europe Resolution by the consolidated matrix.

The correction factors apply to;

- The limits given in Annex 1 (i.e. the substances approved under BfR recommendation XXXVI and therefore including substances such as formaldehyde etc), and
- Table 1 (i.e. the contaminants potentially originating from recovered fibres) with the exceptions of PCP which must comply with the uncorrected limit and any contaminants with a non-detectable limit.

The way in which this correction factor is intended to work is to multiply 2 factors; (a) a food type factor (1 for dry and fatty foods, 1.5 for dry non-fatty foods and 10 for washed and peeled foods) and (b) a temperature factor (1 for T>10ºC, 2 for 0ºC<T<10ºC and 5 for T<0ºC. The two factors would then be multiplied together to give a total correction factor which would be used to adjust the restriction for substances in papers.

It is worth pointing out that the document in its current version states that there is not sufficient data available to fully justify this approach, so the correction factor will be set to 1 until this data has been provided. The derivation of these factors has been very well described in the final report of the Biosafepaper project[40], where for benzophenone they compare the results of food surveillance data[41] on the level of this substance in foods and compare this with the level of the substance in the packaging. This has demonstrated that for benzophenone, this approach is feasible.

In our opinion, if it could be shown that this approach also works for a wider range of chemical substances (covered by restrictions under the Industry Guideline) and a wider range of exposure temperatures (to reflect for instance fast food storage), there would be a very good case to support the argument that the correction factors are consistent with Article 3 of the Framework regulation. When more data is available it is quite possible that the correction factors will be different to those given above. Until the data is available, we think the approach of setting the factor to 1 by default is a prudent one.

It is worth noting that in the current draft of the Industry Guideline, there are a number of references to the ratio of packaging material to food and the conventional assumption of 6 dm^2 per kg of food. Since the factors proposed

in Annex 5 and Table 2 do not correct for the exposed surface area of packaging, we would suggest that Annex 5 should be edited to just focus on the issue of correction factors without mention of the surface area, so as to prevent confusion with clause 7 which does include some references to correction for exposed surface area.

One key strength of this approach, assuming it is supported by further data, is that it would be possible to quote a minimum correction factor for a paper/board to ensure compliance and then users could determine very easily whether their application meets these requirements.

5.0.2 Biological Testing

Under clause 5 of the Industry Guideline, there is provision to use the methodology developed under the Biosafepaper project to demonstrate safety of food contact papers. This methodology is discussed very fully in the final report of this project, and a brief summary is given in Figure 4 of the Industry Guideline, so we do not intend to discuss this in detail here. However, in essence the methodology involves carrying out extraction tests (akin to migration tests or BfR extraction tests) on finished papers and then subjecting the extracts to a number of biological assays (Ames test, Acute Cytotoxicity, Comet assay and RNA synthesis inhibition). The method can therefore be viewed as being an abbreviated version of the toxicity tests which are carried out by EFSA with the tests carried out on extracts of the finished paper and therefore taking into account a wide range of substances including paper chemicals and contaminants from the recycling process which may have been present in the paper.

Currently, although there is some ongoing work in relation to provision of additional biological end-points (e.g. endocrine disruption), there does seem to be agreement between research institutes, legislators and industry that the approach could be used as part of the battery of tests for studying the food contact safety of paper/board and hence it has been included in the Industry Guideline. What is not currently included in the Industry Guideline, however, is an indication of the circumstances under which the Biosafepaper methodology should be used.

In our opinion, although the Biosafepaper methodology is extremely powerful, it is not well-suited to replace the routine type of testing that is today carried out against BfR recommendations. Principally, this is because the methodology is quite involved and hence expensive. The methodology also relies heavily on biological assays which can give ambiguous results and therefore would not be suited to routine compliance testing of the type usually required by end customers such as McDonald's and where simpler tests may be more appropriate. In later sections (5.1. and 5.4) we have identified two key areas where we think the methodology could help resolve problems faced by the paper industry, with regard to the use of recycled fibres and paper chemicals which have not been fully assessed. When and how this test methodology should be employed is clearly a key issue to be addressed within a later edition of the Guideline and in our opinion, Industry should seek to reach a clear consensus of what it is hoping to achieve from the method, so that it can get the best value from this novel approach.

5.1 Rules for Selection of Paper Chemicals

By contrast to the CoE Resolution, the Industry Guideline proposes to rely primarily on BfR Recommendation XXXVI in the selection of appropriate paper chemicals for food contact paper/board. A separate approach is suggested for the selection of fibres. Furthermore, the Industry Guideline states that any restrictions applying to substances under BfR Recommendation XXXVI should be applied (e.g. the restrictions on DCP/3MCPD, formaldehyde, glyoxal etc and also maximum use limits specified in the BfR Recommendation XXXVI). The Industry Guideline also mentions that other substances which are subject to other approvals may be acceptable provided that their use can be shown to be in line with the requirements of Article 3 of the Framework Resolution. Specifically, the Industry Guideline mentions USA FDA Regulations 176.170 and 176.180 relating to paper in contact with aqueous and fatty or dry foods respectively[31].

Although the Dutch Warenwet list is a binding list of approved substances and forms National legislation within the EU, it is not mentioned specifically in the Industry Guideline, even though by inference it can be taken to meet the general requirements of the Guideline. Given that the underlying processes behind the Warenwet are similar to those used by the BfR, one could make an argument that the Warenwet should be included in the Guideline on at

least an equal footing with the FDA legislation. Given the fragmentary and sometimes incomplete nature of the French and Italian National lists, in our opinion there would be little benefit if they were included specifically.

The approach described in the Industry Guideline clearly has an advantage of usability over the CoE Resolution in that it provides clearer guidelines for the selection of paper chemicals and that most commonly used paper chemicals are on one of these lists and have at some point been assessed. For a great number of such chemicals, the CoE Resolution just states that a restriction is yet to be fixed and hence does not form a useful guideline for the selection of raw materials or in identifying suitable tests on finished products. However, because the Guideline adopts the lists from National legislation, it also reflects all the problems and inconsistencies of these National lists. Specifically;

- Where a substance has been approved under the BfR system, there is an issue of whether that assessment has been carried out recently under processes which are well-aligned to EFSA protocols, or historically in which case the linkage will not be so strong. In the first case, it is easy to argue that the use of the chemical is supported by the Framework Regulation in the second case it could be more difficult.

- There is a clear potential for conflicts between restrictions for individual substances given in (a) BfR XXXVI, (b) The Warenwet and (c) FDA Regulations. For instance take the case of glyoxal which is approved under BfR XXXVI for use as a wet-strength agent subject to an extraction limit of 1.5 mg per dm^2. Under the Warenwet, it is approved for use as *'an insolubilising agent in glucose-based layer. Level not to exceed 1 % by weight of the glucose content. Only for non alcoholic foods and beverages'*. To confuse matters further, the same substance is approved under FDA regulations *'for use only as an insolubilizing agent in starch- and protein based coatings that contact nonalcoholic foods, and limited to use at a level not to exceed 6 percent by weight of the starch or protein fraction of the coating solids.'* Having a clear set of rules for resolving these conflicts within the guideline would be helpful (e.g. by identifying which limit is most restrictive), but in this case the approval of the substance would still be restricted to different applications under the different sets of legislation. In our opinion, for glyoxal

the BfR approach makes the most sense. After all, the human metabolism doesn't know which type of additive has transferred the glyoxal into its food. There is logically either a safe limit, or it is not safe. However, clearly the Warenwet will remain in force in the Netherlands and therefore its use restriction must be respected.

- When the FDA regulations have been used to support the selection of a chemical, there is a clear potential that the assessment will have been carried out using a protocol that is significantly different from that used by EFSA. This will especially be the case where the approval is historical, bearing in mind that FDA approvals in some cases stretch back 50 years. In the case of substances which have been approved more recently under the Food Contact Notification Programme (since 2000), or under the Food Additive Petition process (from 1993 when it was partially harmonised with the EFSA procedure) there is a better argument that the approval can be used to support selection of the chemical.

  Clearly, by relying on BfR Recommendation XXVI as the primary list, it can be argued that the Industry Guideline offers at least the same degree of assurance that is currently in place throughout Europe where this approach is widely accepted. However, one clear question that comes out of the above discussion is how to cope with the criticism that the approvals have been granted over a long period of years and were not always well-aligned to current EFSA protocols. This criticism applies equally to some of the historical approvals under BfR or FDA regulations and leaves at least some question mark over the use of some of the substances on these lists as it is not possible to argue unequivocally that their use has been shown to be in line with Article 3 of the Framework regulation.

  One possible solution would be to adopt the line of the CoE Resolution and to re-evaluate a great number of individual substances using the standard EFSA protocols. This would be consistent with the Framework Regulation, but would have the disadvantage of cost and the length of time taken to work through this process which we have previously discussed. Additionally, given the known lower exposure to food contact paper and board compared to that for plastics, it is arguable that this would not be proportionate to the risks.

Another possible solution to this problem would be to make use of the methodology used in the Biosafepaper project and segregate paper chemicals approved under BfR XXXVI, Warenwet and USA FDA 21CFR into two categories;

1. Substances which have been assessed recently under protocols which are well-aligned to current EFSA practice.
2. Substances which were previously assessed and which were subject to less stringent assessment.

For the first group of substances, the National approval could be taken directly. For the second group of substances, a review could be carried out of the original dossier and if any significant gaps in information are identified (i.e. if there are any doubts that the substance would be approved by the BfR today without any further supporting data), further supporting evidence could be produced by using the Biosafepaper methodology to establish that no harmful levels of substances are migrating into foods from finished samples of paper containing the substances. Only if the materials did not clear this battery of biological tests would there be a need to go further down the EFSA approval process. In our opinion, this would make it significantly easier to argue that the Industry Guideline was aligned to the requirements of the Framework and GMP Regulations for the selection of paper chemicals.

In our opinion, this means that The Industry Guideline partly meets the requirements of the GMP regulation with regard to having clear guidelines for selection of paper chemicals, at least to the same extent as BfR Recommendation XXVI. It would be a significant improvement to the clarity of the Recommendation if it were to contain some clear guidance on priorities when BfR XXXVI, The Warenwet and FDA conflict in the restrictions they assign to individual chemicals.

5.2 Restrictions on Paper Chemicals

For the greater part, under the Industry Guideline, it is expected that restrictions on the use of chemicals would be taken from BfR Recommendation XXXVI and hence could be viewed in the same manner and it is likely that they would be subject to (a) a maximum use level and/or (b) an extraction restriction.

As explained in the section relating to BfR Recommendation XXXVI, these restrictions on paper chemicals can be viewed in one of two ways. Whilst at first glance, many of these limits are expressed as extraction limits into water they can also be viewed as residual limits on the substance in food contact papers and can therefore also be seen as compositional limits which are easier for industry to comply with than specific migration limits. The restrictions can also be converted between QM, QMA and SML figures using simple arithmetic and conventional assumptions about the weights of paper, the amount of paper in contact with each kg of food and complete transfer of substances. The transfer of chemicals from paper to foods is, after all, not likely to be diffusion-limited (as is often the case in plastics) and there therefore seems little merit in becoming mired in the differences between QMA and SML limits, which should be equivalent.

However, since the restrictions set for recently approved substances are based on migration studies and known toxicology for the substance and have been set using reasonable assumptions to relate migration levels to the level in paper, it can be viewed that they are in effect controlling the level of migration of paper chemicals (and/or their constituents and contaminants) into foods in line with the requirements of Article 3 of the Framework Regulation.

It should also be noted that the Industry Guideline aims to apply the correction factors described in section 5.0.1 to the assessment of compliance with the limits specified for individual chemicals. Pending further experimental data, the correction factor has been set at as 1, but it is envisaged that this would be a central feature of the final edition of the guideline and in our opinion (subject to further supporting data), the approach would be consistent with the requirements of Article 3 of the Framework Regulation.

On this basis, we can conclude that, where specified, the limits within the Industry Guideline (largely by incorporation from BfR Recommendation XXXVI) are based on an assessment of the migration of substances into foods, and are at least partly capable of controlling that migration in line with the requirements of Article 3 of the Framework regulation.

5.3 Approval Process for Inclusion on Positive List

Under the current version of the Industry Guideline it is not proposed to develop an approval process outside of the BfR process. The Guideline can therefore be considered to meet this requirement to the same extent as the BfR Recommendation or the Warenwet.

5.4 Recycled Fibre Requirements

The issue of how to demonstrate the safety of paper/board manufactured from recovered fibre is essentially a matter of how one chooses to manage the risks associated with a variable feedstock of recovered fibre which may be contaminated with inks, adhesives, residues of substances picked up in use and bacteria or moulds picked up in handling during the time which the paper/board spends in a domestic environment and is out of control of the manufacturer or converter. The approach adopted within the Industry Guideline to ensure the safety of paper/board produced from recovered fibre is based on several key elements;

- Selection of recovered paper of an appropriate quality
- Selection of appropriate processing technologies
- Operation of Good Manufacturing Practice
- Testing of finished products to ensure that a number of known potential contaminants are absent from the recycled paper/board.

The problem can be viewed to some extent as a similar challenge to that faced by the recyclers of food grade plastics and covered by the recent regulation on the recycling of plastics for food contact applications[38]. The plastics recycling regulation is structured as an amendment to the GMP regulation and deals with a very similar problem to paper recycling (i.e. variable and contaminated feedstock) and seeks to ensure that appropriate systems are put in place to select raw materials, demonstrate process efficacy and identify critical control points which can be used in the quality control systems of those companies operating recycling plants. The approach taken within the plastics industry to demonstrate efficacy and identify critical control parameters is through what is known as a challenge test. Under this methodology, known amounts of contaminants spanning a range of physicochemical properties are introduced to the waste stream

entering the recycling process and the output is analysed to assess the removal efficiency. This approach was developed within the plastic industry and hence is tailored to the recycling processes used for plastics. Given the relatively large scale of paper mills compared to individual plastics recycling lines and also the nature of the relative technologies, it is unlikely that such an approach would be practicable in the recycled paper industry. However, it does demonstrate the point that by using good manufacturing processes which are aligned to the requirements of the GMP regulation and by defining some measure to demonstrate that the clean up has been effective, the European Commission have felt comfortable enough to put in place an approval process for recycled plastics despite the fact that no-one can be 100% certain of the precise composition of the recycled material. Given the differing technologies involved in recycling paper/board when compared to plastics and lower exposure of consumers to food contact paper/board, it is very likely that the practical means to demonstrate clean up would be different to those in the plastics industry.

5.4.1 Control of Feedstock

This is clearly a key issue and the Industry Guideline firstly adopts the same policy as that taken under the Council of Europe Resolution by excluding mixed waste from refuse sorting stations or from multi-material recycling systems. Additionally, a number of other categories of fibre are excluded from use in food contact paper and board including hospital waste, batches consisting mainly of carbonless copy paper, old archival papers etc.

The Industry Guideline refers to a system whereby recovered paper and manufacturing industries would use a system to identify batches of paper supplied to paper mills based on the supplier reference and the EN 643 classification of each batch of paper. In our opinion, this would be aligned to the requirements of the Framework Regulation for backwards traceability (at least by one step).

Backing this system up is the CEPI Guideline on responsible sourcing of fibre [42] and guidance on the selection/rejection of unusable fibre sources. These documents all provide useful controls in the manufacture of recycled papers, but when viewed alongside the GMP Code of practice which we have reviewed in Section 5.6 , they form a slightly confusing set of documents

which would benefit from being compiled into a single document rather than the current position where they are cross-referenced.

In common with the national legislation previously described and the CoE Resolution, the above approach does have two blind spots which leave open the possibility of criticism;

- It is not possible to guarantee that all paper/board taken into the recycling process was manufactured only using substances approved for food contact. There will inevitably be some intermingling of non-food contact paper/board in the collection process.

- In use, the paper/board may have been printed and or used in conjunction with adhesives. These classes of materials are not subject to specific EU legislation and this means that the feedstock for the recycling process will have potentially been exposed to a wide range of poorly-regulated and unknown contaminants which will probably have been removed to some extent by the recycling process. However, it is also highly likely that some residues remain in the recycled paper/board and these leave the manufacturers open to periodic scare stories arising from analyses of food packed in recycled paper/board either by enforcement agencies or non-governmental organisations campaigning against the packaging industry.

  One possible solution to the above two problems would be to use the Biosafepaper methodology to demonstrate that the finished product of the recycling process is safe and that the process is being operated with correct controls in place to ensure that the finished paper/board meets the safety requirements of Article 3 of the Framework Regulation. This may still take a little further development work to the Biosafepaper methodology using additional endpoints until the majority of regulators accept the approach. However, in our opinion, the Biosafepaper project clearly has the potential to offer an extremely powerful means to demonstrate the efficacy of the recycling systems in place at recycled paper manufacturers and could therefore be used as part of an authorisation procedure for paper recycling processes.

5.4.2 Selection of appropriate processing technologies and Operation of Good Manufacturing Practice

From communications with CEPI, we understand that a revised GMP Guide for Paper is currently being prepared and have been provided with a draft copy of the document. In our opinion, it appears to be aligned well with the wording of the Framework and GMP regulations and has clearly been structured to reflect best practice in the paper industry. For simplicity and the prevention of conflict between different documents, consideration should be given to incorporating the CEPI guideline on responsible sourcing within this document (or as an appendix).

In our opinion, therefore the approach taken within the Industry Guideline towards selection of process technologies and GMP is therefore aligned with the GMP regulation, subject to the drafting process being completed.

5.4.3 Testing of finished products

We will discuss the testing requirements of the Industry Guidelines more fully in Section 5.8 below, but it is worth noting that the list of contaminants tested for under the Industry Guideline takes as a starting point the list of substances under the full testing set of the CoE resolution. The list is based on known contaminants (from inks adhesives etc) in recycled fibres. There are a few differences between the lists in the CoE Resolution and the Industry Guideline. For instance, there is no requirement for testing of solvent residues or HTTP under the Industry Guideline whereas these were listed in the CoE Resolution. Care should be taken to ensure that there is a rational argument for leaving these substances out of the list.

It is also worth noting that under the Industry Guideline, many of the limits which applied only to recycled paper under the CoE Resolution have been extended to cover virgin paper too although we know that the contaminants are likely only to be present in recycled fibres. We will comment on this later in section 5.8 on testing requirements, but it is clear that it reduces complexity in the approach compared to the CoE Resolution at the expense of additional testing for virgin paper/board.

It is also worth noting that the limits given in the Industry Guideline have mostly been expressed in the form of QMA limits rather than SMLs as was the case in the CoE resolution. The two sets of limits are essentially equivalent and in our opinion, for practical reasons, it makes more sense to measure the residues of these substances than to control them by measuring migration into food simulants. In reality, the CoE resolution also provided this option, but by explicitly stating that the limit is a QMA, the Industry Guideline points its users in the most practical direction.

In our opinion, the approach taken offers a more rigorous approach to the control of contaminants in recycled paper than is the case under National Regulations and therefore goes a very long way towards meeting the requirements of Article 3 of the Framework Regulation in controlling these contaminants.

5.4.4 Summary of Recycled Fibre Requirements

From the forgoing discussion, we can conclude that the approach which has been put in place goes a very long way towards meeting the requirements of the Framework and GMP regulations with regard to the selection of recycled fibres, recycling process and ensuring that the finished fibre is of an appropriate quality. The two key issues we would suggest that are developed further would be;

- Use of the Biosafepaper methodology in validation of recycling processes
- Further work on a more specific GMP Guidance Document

In summary, it is our opinion that the Guideline puts in place the beginnings of an approach which is both practical and aligned with the requirements of the Framework and GMP Regulations. In doing so, it is very easy to argue that it provides a more useful set of Guidelines for the safe use of recycled fibres than is currently in place under any of the National Regulations.

5.5 Declaration of Compliance

Unlike any of the pieces of National legislation or the CoE Resolution reviewed in earlier sections, the Industry Guidelines contain some very clear guidance about the contents of a Declaration of Compliance. The contents described in the suggested format include most of the points required under

Article 16 of the framework regulation and would, in our opinion form a very useful set of guidance in informing an end user of the paper/board what the product can safely be used for. This is ultimately the point of a Declaration of Compliance.

The format of the Declaration is additionally well-aligned with the general methodology adopted under the Industry Guideline, particularly in item 4.5 where 2 options are given for communicating the acceptable end uses for the products (a) quoting suitable food types and temperatures or (b) quoting a minimum Correction Factor (see discussion in section 5.0.1). In our opinion, the two approaches are broadly equivalent with the correction factor approach being slightly more elegant, but if it is used in a statement, such a Declaration would benefit from a short table giving a partial list of the most common food types/temperatures and the correction factors associated with them.

One absence from the Declaration of Compliance is a statement on *'dual use'* or *'multiple function'* additives. These are additives which would have a use in paper and also have a use as direct food additives. Under EC Directive 2002/72/EC and its amendments, manufacturers of plastics have an obligation to declare when they have such an additive present, so that end users can ensure that they do not accidentally contravene any separate restrictions under general food law. We would strongly suggest the inclusion of a statement about 'dual use' additives in the standard Declaration. This could be backed up with an agreed list of what the industry regards as dual use additives.

Additionally, we would like to highlight point 4.6 in the Guideline which deals with substances in paper which are subject to separate SMLs under EC Directive 2002/72/EC and its amendments. The aim of making such a statement is undoubtedly to inform users of the paper in multilayer laminates that they should test their finished products in line with any SMLs under either the Industry Guideline or the Plastics Implementing Measure when this is brought forward. This would apply to a relatively short list of substances which have uses in paper **and** plastics. There is already a working list of these within the Warenwet. For reasons of clarity and openness, we would generally tend to recommend the approach of making a straight declaration of these substances and their associated restrictions without requiring users to

enter into a confidentiality agreement. After all, there is little intellectual property in knowing that paper often contains additives containing formaldehyde which is subject to an SML of 15 mg/kg in foods. We would suggest that confidentiality is only invoked relatively infrequently when there is a genuine need to protect an innovative product.

If by calculation from the residual level of such a substance, it can be shown that the finished paper will not exceed this limit under any circumstances, an additional comment should be included in the statement, so that the producer of the multilayer product knows that they need not carry out any further work.

One additional point we would like to highlight is that of validity period for the Declaration. For many years, it has been common practice to incorporate a validity period of two years on statements of compliance with BfR Recommendation XXXVI. There is no mention of this validity period within the Recommendation itself, so this has been added externally. There are a number of questions associated with including a validity period;

- What should happen if the legislation is amended at some point after the issue of the statement and prior to renewal?

- Given that the results of tests against extraction limits are dependent on the variability of the product and statements are generally supported by only a single set of data without any long run of data to support the assumption that they are representative of the production as a whole, the best they can represent is a snapshot of production on a single day. To extrapolate a validity period on this basis is therefore not easy to justify. In reality it would never be possible to know whether the period selected is too long or indeed too short without repeated testing.

  For these reasons, we would not favour setting a validity period within the industry Guidelines. If individual operators have sufficient robust statistical information to feel confident in setting validity periods, this should not preclude them from doing so, but it would be difficult to generalise and we would tend to exclude it from the Guideline.

In our opinion, the format for the Declaration of Compliance offered in the Industry Guidelines is generally a good one and (with a few minor amendments) it is possible to make a very strong case that it meets the requirements of Article 16 of the Framework Regulation.

5.6 Code for Good Manufacturing Practice

As previously discussed in Section 5.4.2, a new version of the CEPI guideline for GMP is currently under preparation to supersede the version published in the CoE resolution and to bring its requirements into line with the GMP regulation. We have seen a draft copy of this document and it appears to deal with all of the requirements of the GMP regulation and the traceability requirements of the Framework regulation as well as having been written from a practical perspective providing guidelines for quality managers and auditors. We can therefore conclude that the Industry Guideline through this document (when it is published) will provide clear guidance on GMP.

Prior to its publication, we would suggest a careful reading of the CEPI GMP Guideline alongside the GMP regulation itself to ensure that all requirements of the GMP regulation have been dealt with clearly and in a manner which is well-aligned with operating practices in the paper/board industry.

5.7 Rules for Multilayer Materials

As previously discussed, the rules relating to multilayer materials under existing EU legislation are far from clear and hence form an important area which requires clarification. In our opinion, this could therefore be a very useful role for the Industry Guideline. We note, however, that the position of paper multilayer materials may well be affected by the expected plastics implementing measure and hence, this part of the guideline might be superseded or may need to be brought into line with EU legislation and should therefore be thought of as a draft for development. The following discussion is based on the current draft of the document and offers our opinion on the suitability of the approach and suggestions for further improvements.

The rules provided under Clause 7 relate to all multilayer structures manufactured using a paper/board layer and are split into 3 categories;

- **Category 1:** Multilayers with no plastic or aluminium layer between the paper/board and food; in which case the paper, in the same way as would be the case for a single layer material, and the other layer/s in the construction would have to comply with EU or national legislation.

- **Category 2:** Multilayers with at least one layer of plastic between paper/board and the food, but no aluminium foil; these pose a significantly more complex problem and are dealt with by a combination of migration tests and extraction tests with the results corrected by exposure factors and also the use of the correction factors described in section 5.0.1 as well as the conventional fatty food reduction factors taken from the plastics legislation.

- **Category 3:** Multilayers with aluminium foil between the paper/board and food (with or without additional layer(s) of plastic); in which case paper shall comply with the Guideline, but the highest correction factors shall be applied irrespective of end use. Other layers shall comply with applicable EU or National Standards.

Clearly, the area which has been most open to debate under existing legislation is how to ensure safety in use for Category 2 laminates, particularly since these products currently lie outside the scope of EC Directive 2002/72/EC and its amendments. The proposal within the Industry Guideline is that all layers shall comply with the compositional requirements that apply to them under National or EU legislation. This means that the plastic would need to be formulated solely from monomers and additives which are listed in EC Directive 2002/72/EC as amended. For the paper layer, the Industry Guideline is also quite clear in stating that this should comply with the requirements of the Guideline. However, the Industry Guideline also proposes a scheme for the assessment of the finished multilayer product to ensure that they comply with overall and specific migration limits.

For determination of overall migration, there are issues surrounding the selection of food simulants and test conditions, given that for practical

reasons; olive oil can not generally be used as a food simulant with these types of materials. There are additionally a number of issues which cause the testing of these laminates with aqueous and volatile migration to be less than straightforward, particularly when the plastic layer is thin[43]. The guidance within this document of how to cope with the problems of overall migration testing is not completely developed. In our opinion, therefore, there is some need for additional guidance (either within this document of an additional technical guideline) on how to carry out overall migration testing on these materials.

The approach described in the Industry Guideline of how to approach checking compliance with SMLs essentially allows for two approaches; (a) measurement of migration at the food contact surface or (b) calculation of migration based on the known level of substances in the paper and in the plastic.

Where specific migration is measured at the plastic surface, the result may be corrected by the conventional reduction factor PLRF (referred to in the plastics legislation as DRF and only applying to migration into fatty foods) and then to multiply this by an additional exposure correction factor (EXCF) to reflect the low amount of food which comes into direct contact with paper/plastic laminates.

In general, the EC have stated that they are not averse to the use of exposure data when it is scientifically justified and this is the background to the recently launched FACET programme which is supported by the EU and industry, so in our opinion this approach could be useful, provided it is supported by rigorous scientific data.

EXCF is a correction factor predicated on the basis that when conventional SMLs were set under the plastics legislation, this was on the assumption of 6 dm^2 of packaging material being in contact with 1 kg of food and the consumer eating 1 kg of this food (packed in the same packaging every day of their life). This is clearly a cautious method of estimating exposure even for plastics. Data within the Industry Guideline suggests that a consumer's exposure to plastic coated paper/board is even lower at only 0.8 dm^2 per day and therefore EXCF = 6/0.8 = 7.8 (i.e. the directly measured migration of a

substances can exceed the SML by a factor of 7.8 before it is actually considered to be a problem). The acceptability of this approach will therefore depend crucially on the robustness of this assumption.

Within the guideline, it is not entirely clear whether the daily exposure of 0.8 dm^2 of plastic coated paper represents a mean, median or cautious estimate of exposure[44]. In our opinion, the derivation of this figure should be expanded upon to help support the approach. In compiling this review, we have carried out some rough calculations to assess the validity of the assumed 0.8 dm^2 per day exposure estimate. Consider for example a 1 litre carton of fresh fruit juice constructed from a paperboard/PE laminate (no aluminium layer) with an internal surface area of approximately 6.6 dm^2. Such packs are widely available from major retailers in the UK. Take into account a consumer who might drink 250 ml of fruit juice each morning (usually from a very similar pack) and through this means alone (and without considering the rest of their diet) will receive an exposure to 1.65 dm^2 to these laminates every day. Whilst these assumptions might represent an above average exposure to these materials, it is hard to argue that they represent an extreme consumer. It is also easy to envisage circumstances where consumers might get even more exposure to these materials through fruit juice alone, since consumption of more than 250 ml of fruit juice per day is not that uncommon. It is therefore quite likely that this daily exposure figure would be viewed with some scepticism by regulators or member states and may need to be set with slightly more caution.

This above argument poses the important question of what level of exposure to laminate materials does one need to take into account in setting EXCF. Clearly by considering a very extreme consumer, one would be overestimating exposure for most consumers, but by basing EXCF on the average consumer, there would still be a large number of consumers exposed to significantly higher amounts of these materials.

By means of illustration of what legislators might find acceptable, consumption data has already been used within the plastics legislation where a daily fat consumption of 200 g was one of the key assumptions behind the introduction of fat reduction factors to the plastics legislation under EC Directive 2007/19/EC. Before fat reduction factors were adopted, an

extensive study was carried out using consumption data gathered across the EU and a figure of 200 g per day was agreed on, based on the 90th percentile of fat consumption of consumers across the EU (as an explanation, roughly only 10% of the population consume more fat than this). This would clearly seem to offer some guidance of what the EC consider to offer a reasonable worst case scenario in assessing exposure risk.

The acceptance of this argument for plastics was a significant advance, because until then the legislators had felt constrained to think about very extreme consumers and this position clearly shifted. For an exposure approach to be an acceptable means to provide a correction for the area of paper/plastics laminates, in our opinion more work would have to be carried out to establish a reasonable worst case exposure figure (probably based on the 90th or 95th percentile) and this could be used to revise the estimate of EXCF. This will probably move the factor down, but it still would offer a useful relief from the full application of the uncorrected SMLs.

Where specific migration is determined on the basis of calculation from the paper and board layer only, the correction factor PBRF (conventionally set to 1, pending further information) is to be multiplied by EXCF to give a combined correction factor which can then be applied to the measured migration level.

As a general summary, in our opinion this part of the guideline has certainly been drafted bearing in mind the important principle of Article 3 of the Framework Regulation that substances should not enter foods from multilayer materials at a level likely to pose a risk to the health of the consumer. In this respect, it is entirely within the spirit of the legislation. However, there are clearly two factors used within this section to provide some relief from specific migration limits and which in our opinion would almost certainly require further data to support them before they are accepted fully by legislators; PBCF and EXCF.

As an additional general comment, this particular section of the Industry Guideline would benefit from the inclusion of a number of worked examples of how to use the guidelines to demonstrate compliance with SMLs for a paper/plastics laminate. This would greatly improve the readability of the document and clarify the concepts in the mind of the users. As previously

mentioned, care should also be taken to ensure that this section of the Industry Guideline remains harmonised with the plastics implementing measure as this develops.

5.8 Testing Requirements under Industry Guideline

The testing requirements for paper/board under the Industry Guideline break down into two broad categories; (a) those associated with paper chemicals (i.e. the limits applied under national regulations such as BfR XXXVI) and (b) those applying to fibres (even though the measurements are largely carried out on finished paper/board).

The first thing to notice about the testing requirements relating to fibres under the Industry Guideline is that the list of contaminants which are to be tested is very similar to the list within the Council of Europe resolution. However, it is worth noting that within the CoE Resolution, certain tests for residues of inks, adhesives etc apply only when recycled fibre is used. Under the Industry Guidelines, these limits have been applied to all fibre types regardless of whether any recycled fibre is actually present. This was a conscious decision on the part of those drafting the Guideline and was partly founded on the assumption that (a) only a minority of paper/board contains 100% virgin fibre, (b) a desire to show that the approach was rigorous, and (c) an aim to reduce some of the complexity associated with the Council of Europe Resolution where testing requirements vary with fibre source. The aim of this is an entirely laudable one and is certainly consistent with the requirements of Article 3 of the Framework Regulation, although it could be argued to place an unfair burden on virgin paper/board manufacturers.

From discussions with CEPI members, it is apparent that frequent testing against these limits was not intended for virgin fibre products and that they only envisaged this being carried out once . This is backed up within the text of Clause 3 of the Guideline where it is stated that *'if for instance it can be shown from calculations, from a knowledge of the constituents, or from other information giving conclusive evidence, that a particular substance could never exceed its restriction in the material or article, then the very lowest testing frequency (one single test) would be appropriate'*. However, this position does appear to conflict slightly with the comments on frequency of testing given elsewhere under Clause 3 of the Guideline, where there is a

statement that frequency of testing should be determined statistically. One reading of Clause 3 would be that virgin fibre operators would each have to determine their own frequency of testing based on repeated testing for these contaminants which we know are only likely to be present alongside recycled fibres. Additionally, this section could also be construed in different ways by end users and auditors who would possibly require this work to be carried out annually. In our opinion therefore, some consideration should either be given to exempting virgin paper/board manufacturers from these restrictions, or to clarify the wording of this section so that the responsibilities of virgin paper/board suppliers are more clearly defined with respect to frequency of testing.

It is also worth noticing that there are differences between the limits and chemicals listed in the CoE Resolution and the Industry Guideline. Some chemicals previously listed in the CoE Resolution are absent from the list in the Industry Guideline and have been replaced with others. Consideration should be given to how these differences can be rationalised and supporting information should be collated. This information should not necessarily be presented within the Industry Guideline itself, but should be available to support the approach should legislators request justification.

What were previously expressed as SMLs within the Council of Europe Resolution have been replaced by QM or QMA limits in the Industry Guideline. In our opinion, this is a perfectly reasonable approach and entirely consistent with the aims Article 3 of the Framework Regulation and the mechanism put in place to support the plastics legislation. It is therefore perfectly acceptable and offers a more practical means of control than direct measurement of SMLs. For comparison with the limits contained in the Council of Europe Resolution under Section 4.8, the restrictions specified in the Industry Guideline for all papers are given in the following table.

Limits Applying to All Food Contact Paper and Board

Substance	Limit	Method
Cadmium	0.5 mg/kg paper & board	In an aqueous extract according to EN 12498
Lead	3 mg/kg paper & board	In an aqueous extract according to EN 12498
Mercury	0.3 mg/kg paper & board	In an aqueous extract according to EN 12497
Pentachlorophenol	0.15 mg/kg paper& board	In an aqueous extract according to EN 15320
Antimicrobial Substances	Paper and Board shall not release substances in quantities which have an antimicrobial effect	EN 1104
Dyes and colorants (where used)	no bleeding	EN 646
Fluorescent Whitening Agents (where used and in case of recycled fibres)	no bleeding	EN 648
Michler's ketone	0.0016 mg/dm^2 in paper & board (non-detectable)	See test quoted in Annex 3
4, 4' bis (diethylamine) benzophenone (DEAB)	0.0016 mg/dm^2 paper & board (non-detectable)	See test quoted in Annex 3
Benzophenone	0.1 mg/dm2 paper & board	See test quoted in Annex 3
DIPN	1.3 mg/dm^2 paper & board	EN 14719
Phthalates	Dibutylphthalate: 0.05 mg/dm^2 Di(2-ethylhexyl)phthalate: 0.25 mg/dm^2 Benzylbutylphthalate: 5 mg/dm^2 Diisononylphthalate: 1.5 mg/dm^2 Diisodecylphthalate: 1.5 mg/dm^2 Diisobutylphthalate: 0.17 mg/dm^2	In aqueous extract according to prEN quoted in Annex 3
Primary aromatic amines and azo colourants (which by reductive cleavage will form primary aromatic amines)	as primary aromatic amine 0.1 mg/kg	In aqueous extract according to prEN quoted in Annex 3
Polycyclic Aromatic Hydrocarbons (PAH)	0.01 mg/kg paper & board (non-detectable)	According to prEN quoted in Annex 3

5.9 Summary of Conclusions relating to the Industry Guideline

In conclusion, it is our opinion that the current draft of Industry Guideline has built very successfully on a number of strengths drawn out from pre-existing member state legislation and the Council of Europe Resolution. On this basis, we have concluded that the Industry Guideline provides a useful structure to demonstrate compliance with the requirements of the Framework Regulation and the GMP Regulation. In our opinion, the Industry Guideline has more strengths and fewer weaknesses than any of these previous documents.

Key Strengths

- Clear practical positive list primarily derived from BfR Recommendation XXXVI backed up by BfR approval process for chemicals which is now harmonised with EFSA protocols, and therefore limits associated with the positive list are clearly related to toxicological assessments.
- A practical GMP code will be referenced from the Guideline with relevant provisions relating to the manufacture of virgin and recycled paper/board.
- A significantly more rigorous framework is offered for the approval of recycled fibres when compared to national legislation including fibre source, clean up processes and testing protocols, with the advantage over the Council of Europe Resolution that some of the associated complexity has been reduced.
- Clear rules on multilayer materials.
- Clearly defined format given for a Declaration of Compliance

Key Weaknesses

- Reliance on the pre-existing approvals defined primarily in BfR Recommendation XXXVI has two key problems;
  (a) the BfR list contains many approvals which were granted under approval processes prior to the BfR aligning their process with EFSA. Although these approvals were granted under state of the art assessment procedures at the time, here is a possible need for some of these approvals to be reviewed.
  (b) the BfR positive list is non-binding and there are many commonly used process chemicals which are not currently listed. Some clearer practical guidance on how to deal with these non-listed substances through the use of other listings (e.g. FDA, BfR, Warenwet etc), as permitted by the Industry Guideline would be beneficial.

Recommendations for Possible Improvements in Future Drafts of the Industry Guideline

In reviewing the current draft of the Industry Guideline we have highlighted a number of areas where we think the document could be improved either to bring it more closely into line with the requirements of the Framework and GMP Regulations, or to improve its usability. Full details of these suggestions are given throughout Section 5 of this report, but we have summarised the key recommendations below

1. Further guidance should be given in the Guideline on how to apply the BfR and FDA positive lists particularly with regard to identifying when the approvals have or have not been granted on the basis of a process that is well-aligned to current EFSA approval process. Guidance should also be given on how to treat process chemicals which are not universally listed under BfR XXXVI.

2. Clarification should be given in the Guideline relating to when the Biosafepaper methodology should be used. We have highlighted two areas where it might provide solutions to contentious issues. Namely; (a) use of these tests to establish the efficacy of mill recycling operations in achieving food contact safety standards and (b) the use of these tests to validate pre-existing approvals for chemicals which were originally under approval systems which were not aligned to current EFSA practice.

3. Include in the Declaration of Compliance a comment on the presence (or absence of) of "dual use" or "multiple function" substances (i.e. substances present in the paper and board and also approved as food additives). This could be supported by a generally agreed list of multiple function substances which would be subject to this requirement.

4. It would be a useful addition to compile a generally-agreed list of papermaking substances which also have an SML under the plastics legislation so that these can be included on Declarations of Compliance issued to plastic laminators. If 100% migration of such substances will not result in the plastic SML being exceeded, a suitable statement should be made so that the laminator can make a robust decision of whether or not to test for migration of the substance.

5. We would not suggest the inclusion of a standard validity period in the Declaration of Compliance.

6. Include a requirement to use the “For Food Use” symbol or equivalent wording as required by the Framework Regulation.

7. Complete the work already started to develop a new GMP code of practice. Ideally, this should include appropriate elements of the CEPI Responsible Sourcing of recovered paper document, so that these can all be viewed in a single document. On completion, the new GMP code should be checked carefully to ensure it contains all the elements mentioned in Regulation 2032/2006.

8. For multilayer materials, more work is required to validate the PBCF factor. This work should focus on building up a larger data set to demonstrate the validity of the approach for a wider range of chemicals under different exposure conditions.

9. Care should be taken to ensure the wording of the section on multilayer materials remains in agreement with future drafts of the plastics implementing measure which is expected to include multilayer materials.

10. Further consideration should be given on how to develop the Exposure Correction Factor (EXCF) for coated paper/board with particular care taken to set the factor to be a cautious overestimate rather than basing it on mean consumption figures.

11. Consideration should be given to the inclusion of worked examples demonstrating how PBCF and EXCF are to be applied.

12. We would suggest some careful consideration of the position of virgin fibre producers with respect to the tests required to demonstrate compliance with Table 1 of the Guideline. The contaminants listed in Table 1 are primarily associated with recycled fibres and may not be appropriate to the virgin fibre sectors of the industry. The current version of the Guideline is open to misinterpretation in this area and could result in these producers being subject to requests from auditors for repeated testing of these contaminants, which in our opinion would be disproportionate. We would suggest that you possibly even consider exempting virgin paper manufacturers from testing against these requirements all together.

6 Final Conclusions

In our opinion, the current draft of the Industry Guidelines offers an extremely useful contribution towards the harmonisation of legislation on food contact paper/board and presents a more complete and practical package of measures to demonstrate compliance with the requirements of the Framework and GMP Regulations than has been the case under existing EU member state legislation or the Council of Europe Resolution. In particular, the Industry Guideline offers a significantly enhanced framework to demonstrate the safety of recycled fibres when compared to existing member state legislation and this is achieved without some of the complexity associated with the Council of Europe's suggested approach in this area.

Clearly until the Industry Guideline is either adopted by the EU as the basis of future legislation, or is otherwise adopted by individual member states, some care will be required to ensure compliance with the legislation in each of the member states as these are expected to remain in place for the foreseeable future. However, in our opinion, the Industry Guideline provides a useful model to form the basis of discussions with regulators about the future direction of harmonised legislation and it sets out a pragmatic approach to demonstrate compliance with the key requirements of the Framework and GMP regulations which is well-suited for paper and board in contact with foods.

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References

1 Cefic - European Chemical Industry Council

2 CEPI - Confederation of European Paper Industries

3 CITPA - Confederation of Paper and Board Converters in Europe

4 FPE - Flexible Packaging Europe

5 Regulation (EC) No. 1935/2004 of the European Parliament and of the Council, of 27 October, 2004 on materials and articles intended to come into contact with food and repealing Directive 80/590/EEC and 89/109/EEC).

6 *See* Article 1 of Regulation (EC) No. 1935/2004.

7 COMMISSION DIRECTIVE 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs (OJ L 220, 15.8.2002, p. 18) and its 5 amendments up to and including Commission Directive 2008/39/EC of 6 March 2008 (OJ L63, 7.3.2008, page 6)

8 Note for Guidance for Food Contact Materials, 30/07/2008, see http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902030817.htm

9 EC Directive 2007/19/EC gives the Declaration of Compliance Requirements for plastics food contact materials and similar requirements are in place for regenerated cellulose films (EC Directive 2007/42/EC), ceramics (EC Directive 2005/31/EC) and epoxy coatings (EC Regulation 1895/2005).

10 COMMISSION REGULATION (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food (OJ L 384, 29.12.2006, page 75)

11 COMMISSION SERVICES WORKING DOCUMENT IN PREPARATION OF A COMMISSION REGULATION relating to plastic materials and articles intended to come into contact with foodstuffs, EMB/1137, Brussels, 10.10.2008 SANCO/E/3/AS.

12 For details of BfR Recommendations XXXVI, XXXVI/1, XXXVI/2 and XXXVI/3, see the BfR web site at http://bfr.zadi.de/kse/faces/DBEmpfehlung_en.jsp.

13 Lebensmittel- und Futtermittelgesetzbuch in der Fassung der Bekanntmachung vom 26. April 2006 (BGBl. I S. 945).

14 Food Contact Legislation for EU Markets, 2nd Edition, Keller and Heckman LLP, Published by Pira International Ltd, 2008, Chapter 10 Page 61

15 BfR, Postfach 330013, D-14195 Berlin, Germany for the attention of Karla Pfaff karla.pfaff@bfr.bund.de

16 Note for Guidance updated 30/07/08 European Food Safety Authority.

17 Except where a barrier is present, migration is < 10 ppb from a non food contact layer and the substance is not authorised. The Council of Europe have proposed a threshold of regulation of 0.5 ppb in food but it is very difficult task to measure at this level.

18 Commission Directive 2007/19/EC

[19] Di-alkyl(C10-C22)diketenes, BfR XXXVI, B. I, 12 which was reviewed to expand its usabikity and Acrylic retention aids covered under B. III, 2 which was rewritten to include a broader definition. Private communication with Dr B Podd of Kimberly-Clark.

[20] Only rejects from manufacturing and processing, or recycled paper of equivalent quality, may be used. The sorts of paper that are suitable are listed in "Wiedergewinnung von Papierfasern; Beschreibung des Verfahrens" published by the German Pulp and Paper Association (Verband Deutscher Papierfabriken e. V. - VDP) in its loose-leaf collection, "Untersuchung von Papieren, Kartons und Pappen für den Lebensmittelkontakt", Erich Goltze Verlag, Göttingen.

[21] What must not be used are sort A 00 in the German Pulp and Paper Association's "Liste der Deutschen Standardsorten und ihre Qualitäten", and paper and paperboard from sorting plants for general or mixed component waste.

[22] For further details on the BfR position on DIBP, see; http://www.bfr.bund.de/cm/230/di_isobutyphthalate_in_food_contact_paper_and_board.pdf

[23] Bedarfsgegenständeverordnung vom 10. April 1992 (BGBl. I S. 866), which incorporates the Framework Regulation and the complete (amended) Series of Plastics in Contact with Foodstuffs Directives into German law.

[24] This is a non exclusive list focussing on the most common chemicals used in the paper industry and subject to restrictions under BfR Recommendation XXXVI. In drawing up a testing programme for food contact papers, the full text of the Recommendation should always be consulted.

[25] Food Contact Legislation for EU Markets, 2nd Edition, Keller and Heckman LLP, Published by Pira International Ltd, 2008, Chapter 10, Section D.

[26] Arrêté du 28/06/1912 (articles 7) relatif à la coloration, à la conservation et à l'emballage des denrées alimentaires et boissons J.O. du 29/06/1912.

[27] *Brochure nº 1227*, published by *Direction des Journaux Officiels*, 26 rue Desaix, 75727 Paris Cedex 15, tel: +33 (0)1 40 58 78 78, fax: +33 (0)1 45 79 17 84. http://www.journal-officiel.gouv.fr or http://www.legifrance.gouv.fr

[28] DGCCRF (General Directorate of Competition, Consumption and Fraud Repression) Information Notice No.2004-64, 'materials in contact with foodstuffs', see http://www.contactalimentaire.com/index.php?id=520&task=listarticles&category=58&target=4 for original copies and unofficial English translations.

[29] Available from http://www.contactalimentaire.com/fileadmin/ImageFichier_Archive/contact_alimentaire/Fichiers_Documents/Note_information/Coated_paper_and_cardboard.pdf

[30] Guide de bonnes pratiques de fabrication des papiers et cartons et des articles transformés en papier et carton destinés au contact des denrées alimentaires, approuvé le 09/09/97 par la section de l'Alimentation et de la Nutrition du CSHPF.

[31] 21CFR § 176.170 *'Components of paper and paperboard in contact with aqueous and fatty foods'* and §176.180 *'Components of paper and paperboard in contact with dry food.'* Available from **http://www.access.gpo.gov/nara/cfr/waisidx_08/21cfr176_08.html**

[32] Council of Europe Framework resolution on coatings intended to come into contact with foodstuffs, Version 2, 29 January 2008. See http://www.coe.int/t/e/social_cohesion/soc-sp/PS%20E%20COATINGS%20Version%202.pdf

[33] The Ministerial Decree of 21 March 1973 Disciplina igienica degli imballaggi, recipienti, utensili, destinati a venire in contatto con le sostanze alimentari o con sostanze d'uso personale. G.U. n. 104 del 20 aprile 1973

[34] See http://ec.europa.eu/food/food/chemicalsafety/foodcontact/docs/ReferencesEurNatLeg_20080625.pdf for more details.

[35] DMH No. 267 of 30 maggio 2001(modifications to paper and boards) Regolamento recante aggiornamento del decreto ministeriale 21 marzo 1973, concernente la disciplina igienica degli imballaggi, recipienti, utensili destinati a venire in contatto con le sostanze alimentari o con sostanze d'uso personale. G.U. n.155 del 6.7.2001 pag. 12

[36] United Kingdom Ministry of Agriculture, Fisheries and Food, Food Surveillance Sheet No 169, January 1999, 'Di-isopropylnaphthtahelenes in food packaging made from recycled paper and board.

[37] See http://www.coe.int/t/e/social_cohesion/soc-sp/public_health/food_contact/PS%20E%20PAPER%20AND%20BOARD%20Version%203.pdf

[38] COMMISSION REGULATION (EC) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006.

[39] See http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178717811412.htm

[40] Biosafepaper *'Application of bioassays for safety assessment of paper and board for food contact'*, Final Report, QLK1-CT-2001-00930, p 75 – 80.

[41] Food Additives and Contaminants, 2003, 20, 607-618.

[42] CEPI: "Guidelines for Responsible Sourcing and Supply of Recovered Paper". January 2006

[43] Unpublished work by PIRA on paper/plastics laminates.

[44] The figure actually represents a per capita average daily exposure.