FoodContact

Industry Guideline

for the Compliance of

Paper & Board Materials and Articles for Food Contact

Questions and Answers

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1. What is the Industry Guideline?

It is a manual for the manufacture of safe paper and board for food packaging as required by Regulation (EC) No 1935/2004.

2. Is it a legal requirement?

No.

3. Is there not already regulation in this area?

Yes. All operators in the food packaging chain must comply with Regulation 1935/2004 which applies to all materials, including glass, metals, paper and board, and plastics.

4. So what does the Guideline add?

It offers advice, which is specific to paper and board, about achieving compliance with the requirements of Regulation 1935/2004.

5. Is such advice available anywhere else?

Regulation 1935/2004 calls for the EU to write "specific measures" to cover individual materials. These measures offer a route to compliance. There are such measures for plastics and regenerated cellulose film but not for paper and board. It is not on the Commission's current development programme.

Certain countries such as Germany, France, Italy and The Netherlands have national legislation on paper and board. Also, there is a Resolution on paper and board written by the Council of Europe but this is not recognised by the EU or any member state and is, anyway, partially out-of-date and no mechanism is in place to update it.

6. Why is the Guideline needed?

Customers increasingly demand evidence of compliance with EU law. Paper and board appears to them to be "unregulated"; there is no recognised method of demonstrating its compliance with EU law and they prefer to turn to something like plastics which can be certified as "safe" according to its EU specific measure.

Also, there are concerns about food scares, "molecule of the month" and the safety of recycled packaging. The Guideline goes a long way towards offering assurances in those areas.

7. Are all manufacturers required to use the Guideline?

No. The Guideline is a voluntary measure and operators can use existing, internal procedures if they believe these facilitate compliance with Regulation 1935/2004.

8. Is the Guideline aimed at all European countries?

No. Operators in countries already having a national specific paper and board measure should continue to use that national legislation as it has, by law, precedence over other, non-EU measures. However, the Guideline can be seen as an additional source of information on elements which may not be present in some of those national rules. Also, if the Guideline becomes recognised by a particular national authority, the principle of mutual recognition would benefit operators which import material to that country.

9. Who has written the Guideline?

A working group composed of members representing the whole paper packaging chain from chemical suppliers through to paper and plastic converters.

10. Why should my company spend extra resources to follow the requirements of the Guideline?

All food contact operators must meet the requirements of Regulation 1935/2004. Responsible companies will already be operating a best practice system to meet these requirements and it is believed that the Guideline would add no significant burden to those companies. Conversely, it would help those companies as it provides a standardised statement of compliance which will strengthen the claim they need to make to customers and authorities.

Additionally, the Guideline may reduce the testing burden as it contains rules which allow the reduction of testing frequency to one single occasion or even to zero in certain cases.

See also the answer to Q7.

11. Why does the Guideline mention biological tests as a possible future development?

Currently, CEPI is looking at completing the battery of biological tests which was developed in a joint industry/EU R&D project known as Biosafepaper. It is considered that these tests may possibly have a role to play in the future risk management process for food contact paper and board. At this time, the test battery is not sufficiently developed for use as a regulatory tool and, consequently, no biological tests are specified within the Guideline.

12. Why does the Guideline mention correction factors as a possible future development?

Paper and board is different to most other food contact materials in that the level of exposure to food is generally lower. Mainly dry foodstuffs or those which are going be washed or peeled are packed. Also in direct applications, the contact is often with less than 100% of the food surface. Indirect contact is covered by Regulation 1935/2004 even though the influence of the packaging on the food is regarded as low. To recognise and regulate these varying end-uses, experts in the industry are currently studying the possible use of correction factors, an extension of an idea already in use elsewhere in EU legislation. Their use would make the rules for limits on migration and contaminants more representative of the actual packaging application and not of an artificial, worst case, as embodied in mainstream plastics legislation. (See also the answer to Q18.) At this time, the correction factor concept is not sufficiently developed for use as a regulatory tool and, consequently, it is not used within the Guideline except for the special case of multilayers containing other materials such as plastics.

13. Why are rules needed for food contact material destined for dry food contact?

Regulation 1935/2004 requires that packaging materials do not transmit their constituents to food. There is no distinction between dry food and any other sort. The Guideline gives information in Table 1 and elsewhere about the circumstances in which testing might not be required. However, it is essential to note that responsibility rests with the operator to obey Article 3 of the above Regulation and decide if this advice is to be followed after considering the details of the envisaged food use and the likelihood of migration taking place.

14. Recently some discussion has been raised about residues in recycled packaging materials originating from printing inks or adhesives. Would the Guideline have solved such issues?

The Guideline sets safety limits for chemical purity. These cover, amongst others, substances which are known, from past experience, to arise in recovered paper. However, increases in the sensitivity of analytical test methods sometimes result in the discovery of new substances. This leads to the expression of new concerns, many of which prove subsequently not to be founded on toxicological principles, the so-called "molecule of the month" phenomenon. So, the short answer to the question is no, the Guideline would not help as, like all food contact legislation, it deals only with known substances and existing testing methods. This makes the development of biological testing (see also Q11) more urgent as it is believed such tests will accurately detect potential toxicological problems in materials which contain currently undetectable traces of substances.

There are two other initiatives relevant to this issue. First is the current EU "FACET" R&D programme which will have capability to rapidly predict consumer exposure to "new" substances in all packaging materials. Second is work within the whole value chain from ink manufacturers to packaging converters to develop and apply principles of eco-design to ensure that substances applied to paper are safe during manufacture and use, through to the end-of-life phase.

15. Has the Guideline received comprehensive industry input and approval?

Yes. There have been two full, internal industry consultations within the complete paper packaging chain followed by approvals from the CEPI Associations' Directors Group and the Boards of CEPI and CITPA.

16. Has the Guideline received any independent approval?

Yes. Pira International, an institute with a high reputation for knowledge of both paper and board and food contact matters, performed a Peer Review early in 2009. The results were very positive with Pira concluding that the Guideline drew together the best parts of existing national legislation and was more complete and efficient than any of them in offering a route to compliance with Regulation 1935/2004. PIRA performed a follow-up review following amendments to the Guideline in 2009 and confirmed their earlier findings and expressed the view that the Guideline had been improved by the amendments. Both reviews can be found at http://www.cepi.org/content/default.asp?PageID=558&DocID=27381

17. Did the Peer Review say anything about possible development in the areas of biological testing and correction factors?

Yes. Biological tests were ruled out for routine quality assurance testing of paper rolls. However, Pira believed the tests might eventually be introduced into the guideline as a method of validating the recycling process, for those mills using recovered paper, in order to avoid the possibility of expensive process challenge tests, as required under plastics legislation. They might also be used as a method of determining, in a single test, the safety of raw materials and substances not already subject to approved safety assessments.

Encouragement to continue the development and inclusion of correction factors was given. (As noted in the answer to Q12, the EU already has the door open on this matter.)

18. Would it not be easier and less demanding on the paper industry to not have this Guideline?

As stated in the answer to Q10, companies operating best practice probably already use a system equivalent to the requirements of the Guideline. So, the more relevant question is "What would happen if the Guideline did not exist?"

It is believed that the concerns of EU member states and the food industry, about recent food scares and the "unregulated use" of recovered paper, will shortly drive the Commission to start work on a specific measure for paper and board. This is likely to be along the lines of plastics' legislation with its emphasis on approved raw materials and the associated requirement on industry to produce expensive safety assessments for all of them. It will also probably follow the lead taken by the Council of Europe, in its Resolution ResAP (2002) 1, by requiring extensive controls on internal manufacturing procedures. (Unfortunately, it is known that such procedures are often a deterrent to process innovation.) In keeping with plastics legislation, it is likely that all recycling operations would have to be officially approved and inspected and a challenge test introduced, where contaminants are artificially introduced into the recovered paper system and then measured in the paper produced.

Also, there exists the possibility that the food industry will develop advice on paper and board for its own members. (An experimental initiative, already seen in this area, was very negative towards the paper industry.)

The Guideline offers the much more preferable alternative of voluntary industry self-regulation. If successful, in the longer term it would have a serious influence on Commission thinking when it eventually writes its specific measure. It might even persuade the legislators that such a measure was not needed anyway.

19. Have any other industries tried a similar initiative?

Yes. A voluntary "Code of Practice" has been developed by the metal coatings industry.

20. Is the view of the Commission and food industry known?

Informal discussions with both have taken place. The Commission cannot give a formal opinion for procedural reasons but unofficial encouragement for the Guideline has been given. The Commission's ultimate focus is on Regulation 1935/2004 and they will expect operators to use systems which facilitate maximum levels of compliance. The food industry, at European association level, has seen early drafts of the Guideline and no major criticisms were made. After the Guideline has been launched within the paper industry, both will be invited to take more formal positions.

21. Why is the Guideline not called a GMP (Good Manufacturing Practice)?

Basically, food contact legislation requires two elements. The first is a set of rules laying down how the risks to human safety of packaging materials can be managed. The Industry Guideline, in conjunction with Regulation 1935/2004, is that set of rules. The second is a description of the management systems which have to exist at the premises of an operator in order for those rules to be obeyed. That is a GMP.

22. Is a GMP required in addition to the Guideline?

Yes. Regulation 1935/2004 requires that all food contact materials must be made in accordance with GMP. The Commission has produced Regulation (EC) No 2023/2006 which describes the elements which should be included in a GMP. There is a papermaking GMP included in the Council of Europe Resolution ResAP (2002) 1 and CEPI is in the process of revising it to comply with Regulation 2023/2006. A draft copy is available on CEPI Member's Only website: http://www.cepi.org/content/default.asp?PageID=558&DocID=27287

23. Can the REACH Regulation not be used instead of the Guideline?

Not currently. REACH is about workplace and environmental safety. Safety assessments of substances which are likely to be ingested through the diet are not covered. REACH is a complementary measure that in time will improve safety of chemical compounds used in manufacturing and converting of food contact materials.

24. What are the main advantages of the Guideline?

- It is a moving document capable of being quickly modified in the light of scientific advances;
- its emphasis is on final product testing and good manufacturing practice;
- it is voluntary and can be used for self certification;
- for the first time, it includes in one place, all components needed to facilitate compliance with EU law and thus makes the industry prepared when the Commission decides to legislate for paper and board;
- it is tailored specially to the specific requirements of the paper industry, enhances the responsible nature of the industry and has been given a very positive peer review by an independent, specialist institute.

25. I am an operator in the paper and board food packaging chain. What do I need to do with the Guideline?

- Study EU Regulation 1935/2004 and review the mechanism your company uses to ensure compliance with its requirements;
- if you have national legislation for paper and board for food contact then it has legal precedence over the Guideline and you should use that national legislation as your compliance tool rather than the Guideline. However, you may find that the Guideline contains compliance elements not contained in your national legislation and you may find those elements of additional use;
- if your internal or corporate systems offer already a complete route to compliance with 1935/2004 then you have no need for the Guideline;
- all remaining operators should consider using the Guideline. This will involve performing the risk assessments for using recovered paper and manufacturing secondary packaging, if relevant, and then proceeding to implementation of the clauses of the Guideline, accompanied by dialogue with customers, as appropriate.

26. Where can I see a copy of the Guideline and the Peer Review?

Guideline: http://www.cepi.org/content/default.asp?PageID=558&DocID=27427

Peer Review: http://www.cepi.org/content/default.asp?PageID=558&DocID=27381

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