

Can recycling material fulfil the requirements of the GMP regulation?

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Content

- EC-Regulation 2023/2006 GMP
- Recycling of fibres
- Production control
- Hygiene management

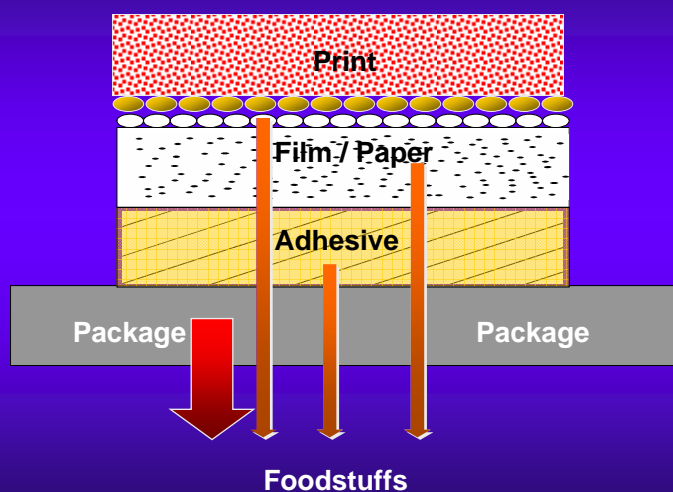


Food Contact

- Up to 2006, the European legislation mostly referred to direct food contact material.
- EC-regulation 1935/2004 has restricted the migration of substances which
 - endanger human health
 - bring about an unacceptable change in the composition of the food
 - influence organoleptic characteristics
- The indirect food contact is only mentioned, without further information. **Reality?**



Food Contact



Specific Measures

Single directives or specific measures may be adopted

Annex I of 1935/2004:

- Plastics
- Varnishes and coatings
- Regenerated cellulose
- Elastomers and rubbers
- Paper and board
- Ceramics and glass
- Metals and alloys
- Cork and wood
- Textiles
- Waxes
- Active and intelligent materials
- Adhesives
- Ion-exchange resins
- Printing inks

National measures can be maintained



Packaging of Food

- In 2004 and 2005, there were several grave damages with packed foodstuffs.
- The most expensive and well-known incident was the ITX-issue.
- In every case, the food contact material itself would have been in conformity with the 1935/2004.
- Only the combination with other products caused the problems.



GMP Regulation

- 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

Into force from 1. August 2008



GMP

- After the ITX issue, there was an urgent need for action in order to avoid the impression of passivity.
- Uniform Regulation instead of all existing GMP Systems
- Obligation for all greater business operators
- As an horizontal law, the GMP regulation is valid for all materials listed in Annex I of the 1935/2004.



GMP

- The Annex of GMP regulation itself focuses on the use of printing inks.

Article 5 Chapter 2:

Starting materials shall be selected and comply with preestablished specifications that shall ensure compliance of the material or article with the rules applicable to it.

- All business operators need to have a quality control system and have to ensure the conformity of the base materials.



GMP

- The GMP regulation consists of several single demands
- The GMP regulation was written for manufacturers who are supposed to know the composition of their products exactly
- Defined chemicals can be specified with a stipulated composition
- With regard to the formulation, this is difficult concerning the composition of natural products (cork taste of wine)



GMP possible?

- Waste paper as raw material can be classified in standard grades.
- The paper producer is dependent on a careful prior sorting of the waste paper.
- Baled waste paper can only be tested qualitatively and sensorially.
- Specification of risk cannot be evaluated at this point.

GMP is not possible for the choice of waste paper alone



Control System for Risk Assessment



Additives

- Additives for the manufacture of paper and board can be determined beforehand.
- The conformity with the German Recommendation XXXVI or a possible European additive list is equivalent to the conformity with the 1935/2004.
- Pre-established specifications can be fulfilled.



Limits for Additives

Parameter	Sample matrix	Approximate figure or demand
Formaldehyde	WE	1.0 mg/dm ² paper
Glyoxal	WE	1.5 mg/dm ² paper
MCPD	WE	< 12 µg/l
Dichloropropanol	WE	not detectable < 2 µg/l
Antimicrobial constituents	paper	not detectable
Colourants	paper	must not bleed
Optical brighteners	paper	must not bleed
SML values	WE	have to be kept



Demands for Impurities

Parameter	Sample matrix	Approximate figure or demand
Lead	WE	3.0 mg/kg paper
Cadmium	WE	0.5 mg/kg paper
Chromium (VI)	WE	not detectable
Mercury	WE	0.3 mg/kg paper
Pentachlorophenol (PCP)	WE	0.15 mg/kg paper
Primary aromatic amines	WE	not detectable
SML values	WE	have to be kept



GMP for Additives

- Maximum additive concentrations in the manufacture of paper and board can be regulated by certain measures.
- The finished product can be analysed to ensure that all limit values are observed.

GMP for additives is possible.



Purity of Fibres

- Recycling Paper is not made of waste paper but of recycled fibres.
- The technical document no. 3 of the CoE Resolution describes a lot of possibilities for the preparation and cleaning of recycled fibres.
- The manufacturer is responsible for determining which method is most suitable.
- The manufacturer's decision can be evaluated on the finished product once again product has to be examined.



Purity of Fibres

- With a number of recycling material manufacturers a production supervision system was built up in the last 25 years and implemented successfully.
- It is based on the supervision of a mixed sample of 10 production days each.
- It comprises a testing scheme to analyse for all relevant contaminants alternately.



Testing scheme

Spectroscopic and chromatographic checks of extracts for evaluation of migration

The migration from paper (transfer of contaminants) is not comparable to the migration from plastics

- Water extracts, hot or cold
 - EN 645 and EN 647
- Solvent extracts, transfer into fat
 - EN 15519
- Migration into tenax Dry food
 - EN 14338



Contaminants

Today we have a great experience regarding:

- Typical contaminants or NIAS
 - **DIPN, Phthalates, Bisphenol A, Aliphatic Hydrocarbons**
- Elimination of contaminants
 - **Watersoluble, polar and unpolar organic Chemicals**
- Success of the fibre treatment during production
 - **Level and possible migration of contaminants**
- Possibility of early intervention in the process



Evaluation

If the contaminants in the product are known, the waste paper received can be evaluated.

- Supplier quality
- Effectiveness of the supervision of the goods received
- Productivity of the technical equipment

**Firm requirements for quality
and safety are possible**



Hygiene Management



Hygiene Management

- Purity control alone does not suffice.
- Experience has to influence future action.
- Possible dangers have to be considered beforehand.
- This can be easily achieved by implementing a Hygiene managements system.



Hygiene Management

- Standards for hygiene management systems for packaging
 - EN 15593
 - BRC/IOP
 - INREKA
- They were all similar for the control of critical points within the production
- The conformity with a standard facilitates the control of
 - Use of additives
 - Technology for the recycling of fibres



Hygiene Management

- **With an implemented hygiene management concept a manufacturer knows from the start**
 - the employed raw materials
 - the qualification of the suppliers
 - the quality of the fibre preparation
 - the relevant analytical data
- **Training of staff is part of the system**



Hygiene Management

- The user of recycled fibres can establish any requirements to his raw materials on the basis of his experience.
- The purity and conformity with the legal provisions can be ensured.
- The number and kind of possible chemical contaminants (NIAS) which have to be supervised are limited.
- Single impurities can always occur. These so-called “hot spots” do not endanger the consumer according to experience.



Achievements

- With the combination of regular production supervision and hygiene management, considerable success was achieved in the last years.
- The content of contaminants was greatly reduced:
 - DIPN > 40 % PCP > 60 % Heavy metals > 80 %
- Problems with new contaminants could be controlled rapidly:
 - Di-isobutylphthalate from adhesives after its re-classification in 2006
- Queries regarding to harmful substances could be resolved quickly.



Conclusions

- The execution of the GMP regulation is not clear up to now
- Most materials have been subject to general demands up to now
- The ITX problem would not have been prevented by the GMP regulation
- The “contaminants of the month” in recent times do not originate in recycling

DiBP, Diethylhexylmaleate, Benzophenone, o-Phenylphenole



Summary

- Contrary to the opinion of official German delegates, single demands should not be evaluated alone, but under consideration of the whole system.
- With the Recommendation XXXVI, the requirements of the 1935/2004 have been taken into consideration up to now.
- The production can be controlled by hygiene management or similar measures
- Given an intelligent combination of the measures, the pre-sorting, even of recycled raw materials, can be supervised.

GMP is also possible when using recycled fibres.



**Thank you
for your kind attention!**

Dr. Ralph Derra

