Impact of new requirements for suppliers

How do suppliers become aware of and implement new requirements

Excample: Amcor Flexibles Singen GmbH

Iris Lovric
Peter Claessens
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Content

- Amcor – some background information
- Process overview regarding product safety data
- Amcor organizational chart – product safety and product development
- Collecting Information
- Processing Data and updating documentation
- Assuring availability of up to date documents
- Conclusion

We are a global leader, with a proud history

US $9 billion
annual sales

35,000+ **Co-workers** globally

200+
manufacturing sites worldwide

Operations across
43
countries

Began operations in the
1860s

75,000+
shareholders

Our global footprint brings our customers a world of experience as we share our knowledge across markets and products

Corporate Headquarters
2 offices
2 countries

Capsules Operations
6 manufacturing plants
6 countries

Flexibles Europe, Middle East & Africa
53 manufacturing plants
18 countries

Flexibles Asia Pacific
37 manufacturing plants
8 countries

Rigid Plastics
69 manufacturing plants
12 countries
** Includes one Rigid Plastics Plant operated by Flexibles Asia Pacific*

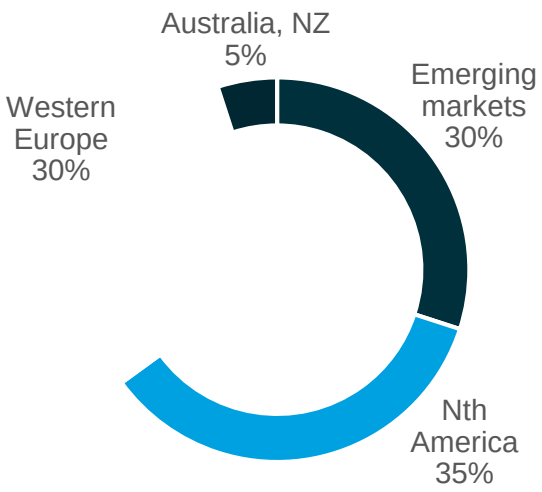
Tobacco Packaging
21 manufacturing plants
18 countries

Flexibles Americas
16 manufacturing plants
6 countries

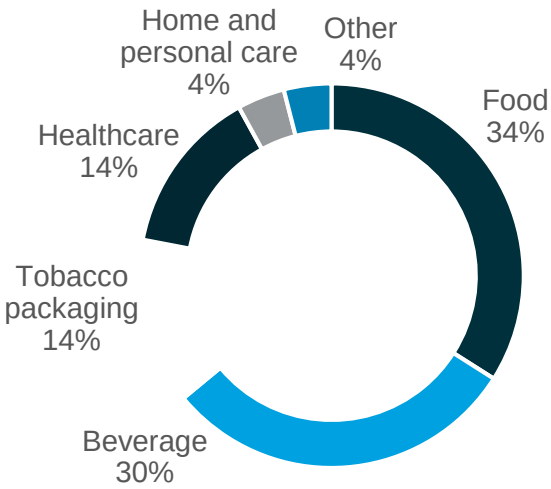
Centres of Excellence

Highly specialised portfolio, with a global footprint and strong exposure to emerging markets

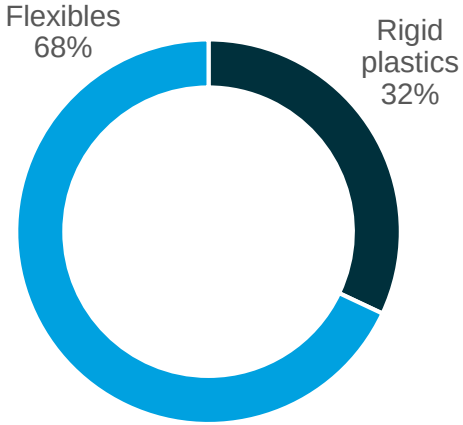
FY2017
Sales, global footprint



FY2017
Product segments



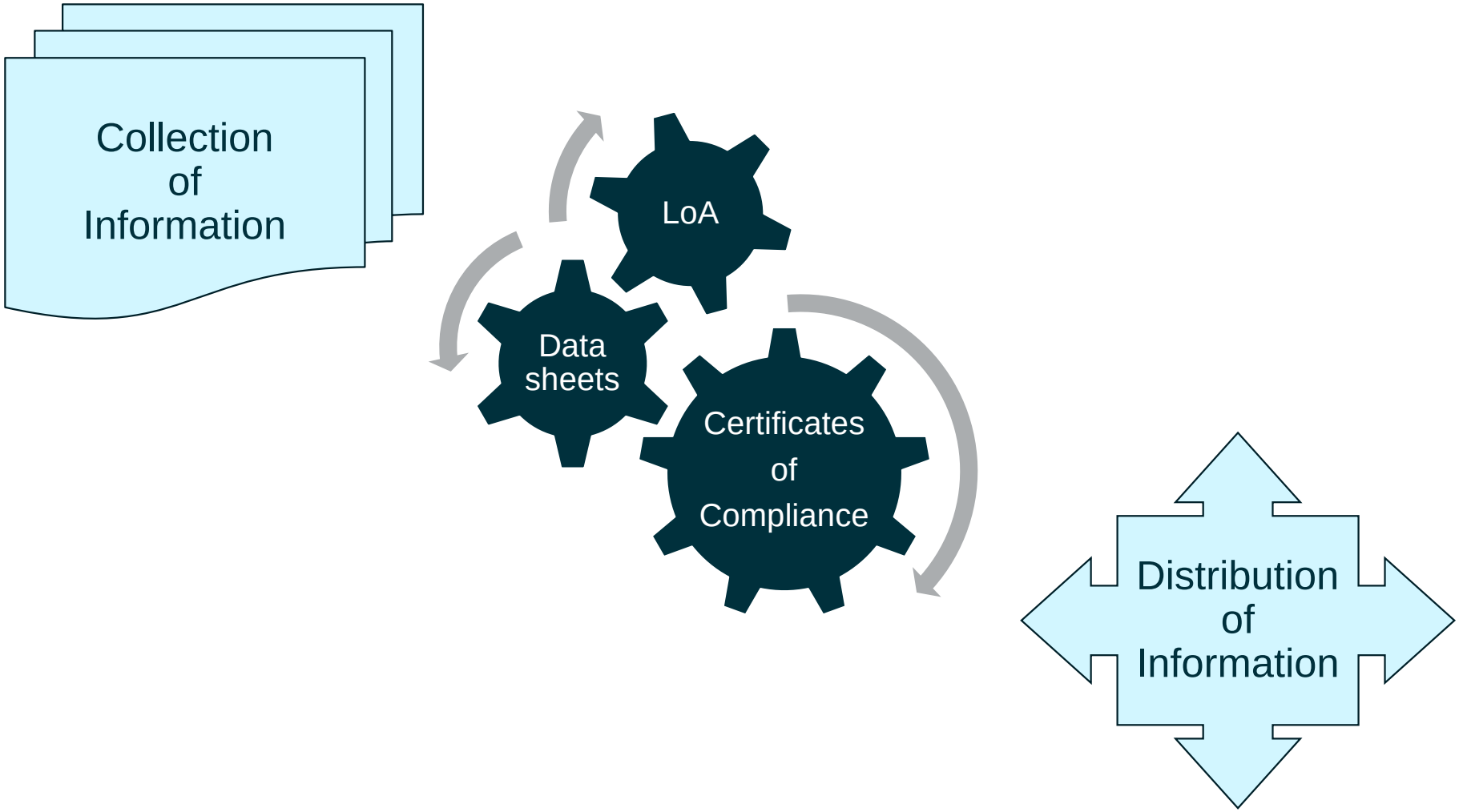
FY2017
Sales, focused portfolio



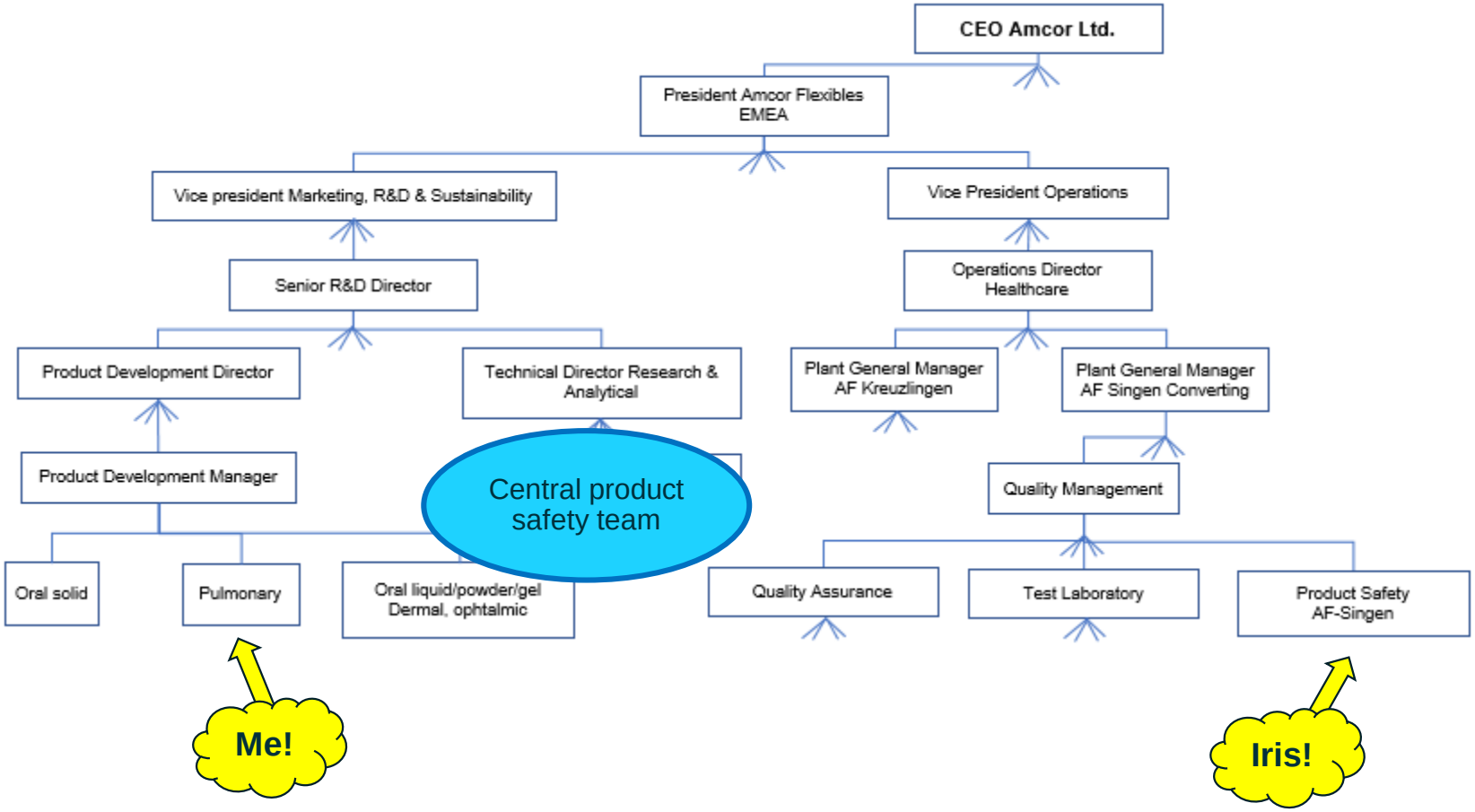
Amcor is today a US$9 billion global business with strong exposure to developed markets and the emerging markets of Asia, Latin America, Eastern Europe and Africa

Over 95% of annual sales are from consumer staples for which there is generally steady demand regardless of economic conditions including food, beverage, healthcare, home and personal care and tobacco products

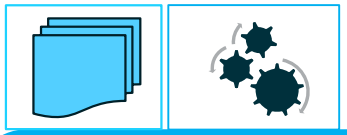
General Process overview of the product safety data



Product Development and Safety – organigram extract

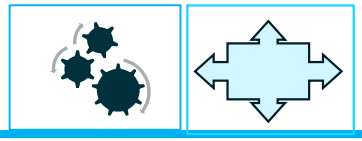


Product Development and Safety cooperation



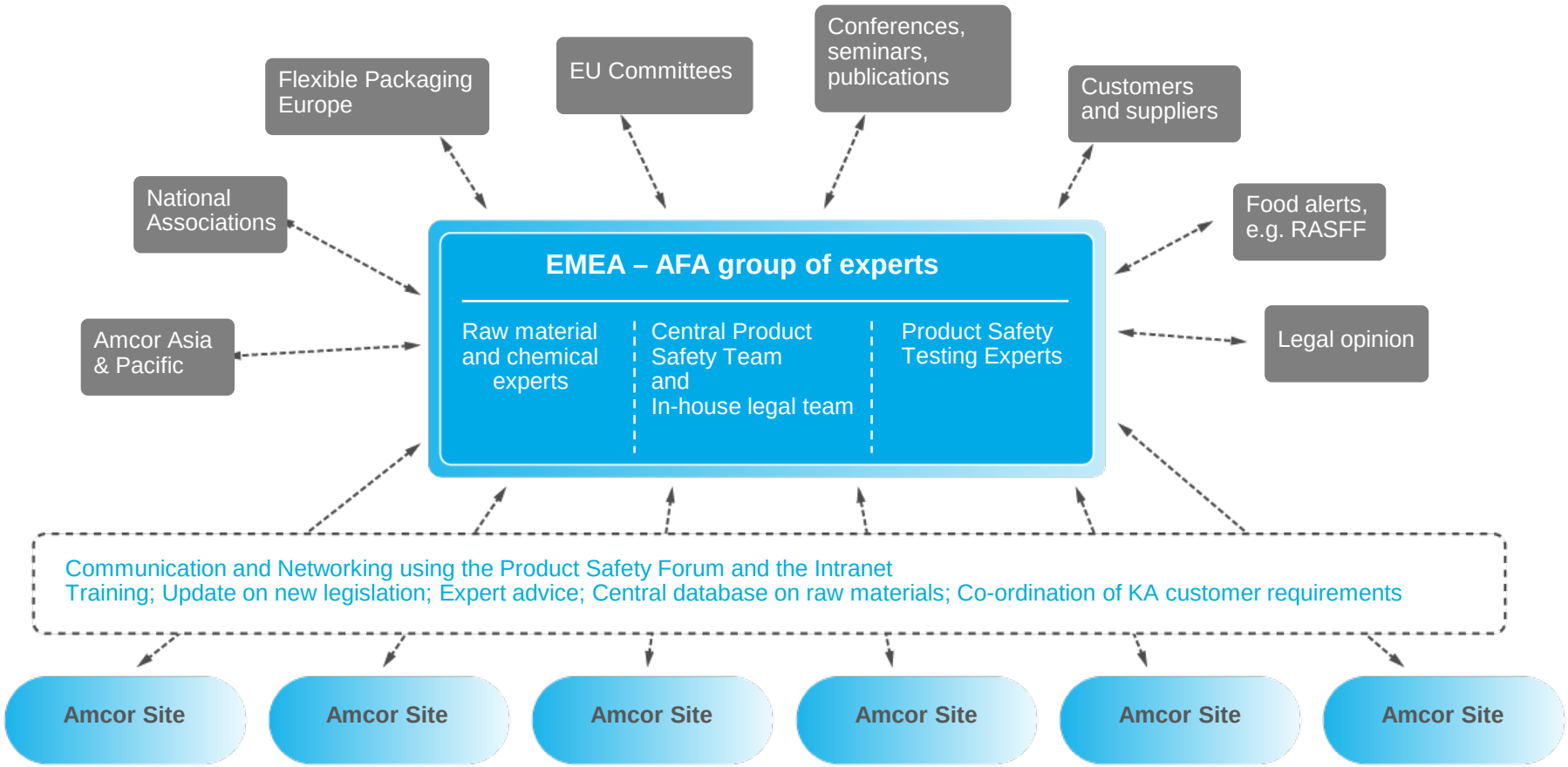
Central Product Safety Team
- Guidance and expert advice
- Updating legal requirements
- Updating key account customer requirements
- Maintenance of product safety intranet website

Product Safety AF Singen
- Performing compliance work
- Managing local supplier DoC's
- Arranging migration testing on representative samples
- Preparation of DMF, CoC's, LoA's, etc.
- Maintenance of database "babtec"

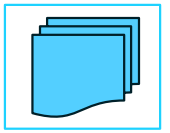


(Pulmonary) PDE's
- Contact with customers
- Definition of materials
- Preparation of technical data sheets
- Link between customer and product safety during development

Central product safety team: input / output



Central product safety team: updating requirements



EU Regulations

- EU Framework 1935/2004
- GMP Regulation
- Plastics Regulation
- REACH
- Packaging Waste
- Biocides
- Cosmetics

ISO/National Standards

- Swiss Ordinance
- US FDA CFR
- EU Member State legislation
- China YBB standards
- MERCOSUR
- ISO/EN Medical Pkg. Standards

Amcor tracks developments at all levels of the regulatory environment and takes necessary actions to ensure full compliance. We also ensure customer-specific guidelines are followed.

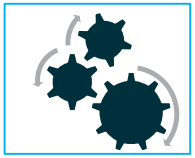
Customer Requirements

- Guidance note on packaging inks.
- Corporate Packaging Food Safety Visa

Relevant Guidelines

- FPE GMP Guideline
- CoE Resolutions
- EuPIA Exclusion list & guideline on printing inks
- CEPI industry Guideline for paper & board
- USP Guidelines

Product Safety AF Singen



- **Compliance Work**

  - Checking supplier DoCs for the needed requirements.
    If there aren‘t sufficient information's available requests will be send out to the supplier (i.e. absent by design substances, amendments of regulations, etc.).

  - Reasonableness check of supplier DoCs.

  - If necessary, initiating migration tests with regard of legislation requirements and customer demands at a certified lab.

  - Reasonableness check of test reports.

  - Maintainig DMF, issue DoC’s and LoA’s

Assuring availability of up to date documents

Quality Management Software “babtec”

Quality Management Software

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Certificate of Compliance

Amcor Flexibles Singen GmbH (AFS) & Amcor Flexibles Kreuzlingen AG (AFK)

Material description	Specification number
FP001 (3104665; AFK) FPA010 (3204725; AFS)	COCP0170-E Version 6

Substitute for COCP0170-E dated 14.12.2016

Created by Stojkovic, Olivera | Verified by Beltramo, Tanja 01.08.2018 | Approved by Schulz, Sigrid 16.08.2018

1. Product

FORMPACK® Coldform Laminate

2. Application

Blister Pack Bottom
powders)

3. Conditions of us

Kind of fillings:
Filling temperature:
Storage conditions

4. Compliance with

4.1 General

- EU Framework Regulation (EC) No 1935/2004
- Regulation on Good Manufacturing Practice (EC) No 2023/2006
- US Code of Federal Regulations 21 CFR, applicable paragraphs.
- EC Directive 94/62/EC Art. 11 including amendments
  (Overall content of Pb, Cd, Hg; Cr(VI) < 100 ppm)
- American CONEG (Overall content of Pb, Cd, Hg; Cr(VI) < 100 ppm)
- ICH Topic Q3C (current version), Guideline for Residual Solvents, Class 3

4.2 Compliance of the components of the contact layer

The components of the contact layer comply with the following legal provisions:

Component	Country	Legal Provisions (recommendations, codes, decrees) for plastics, aluminium, paper/ board, coatings and other components.
PVC film	EU	Regulation (EU) No. 10/2011 (*)
	EU	European Pharmacopoeia, monograph 3.1.11, 3.2.2
	USA/FDA	21 CFR 175-199, relevant paragraphs
Adhesive	EU	All monomers and additives are listed in annex 1 of Regulation (EU) No. 10/2011 (*)
	USA/FDA	21 CFR 175.105

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4.3 Compliance of the components of the non contact layer

The components of the non contact layer comply with the following legal provisions:

Component	Country	Legal Provisions (recommendations, codes, decrees) for plastics, aluminium, paper/ board, coatings and other components.
Aluminium foil	EU	EN 602
	USA/FDA	21 CFR 178.3910
Primer	EU	"Exclusion list for printing inks and related products" of the European Council of Paint, Printing Ink and Artists Colours Industry (CEPE). Our primer suppliers are following the EuPIA "Guideline on Printing Inks applied to the non-food contact surface of food packaging".
Adhesive	USA/FDA	21 CFR 175.105
oPA film	EU	Regulation (EU) No. 10/2011 (*)
	USA/FDA	21 CFR 177.1500 (a)(6), (b 6.1-6.2)

(*) Regulation (EU) No 10/2011 replaces Directive 2002/72/EC since 1 May 2011. It was amended by Regulations 321/2011, 1282/2011, 1183/2012, 202/2014, 2015/174, 2016/1416, 2017/752, 2018/79, 2018/213 and 2018/831. Reference to Regulation 10/2011 in this document includes these amendments unless noted otherwise.

Raw materials derived from animal origin used for the manufacture of this product are produced in compliance with EMEA/410/01 rev.3 "Note for Guidance on minimising the risk of transmitting animal spongiform agents via human and veterinary medicinal products" and therefore do not present a risk of BSE/TSE.

7. Drug Master File

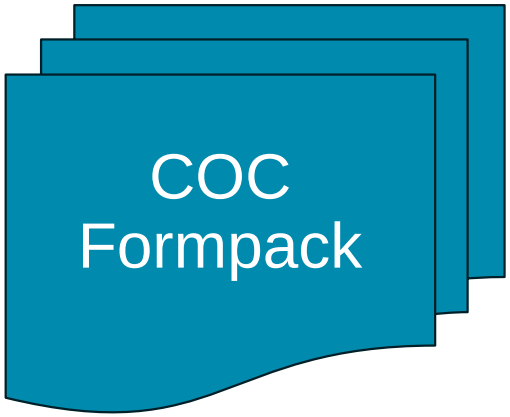
Amcor Flexibles Singen and Amcor Flexibles Kreuzlingen own DMF files at the US FDA and Health Canada. Letters of authorisation could be issued for this material on request.

8. Disclaimer

This certificate is given in good faith and to the best of our current knowledge. It is the responsibility of our clients to decide whether the contents of this confirmation are sufficient to allow packaging, manufactured from the above described material, to be put into circulation for the designated purpose in the designated countries. Compliance to migration limits is investigated applying the rules and using the simulants as laid down in the relevant European legislative provisions. The evaluations refer to the above described material which may be combined with others to a package. It is therefore the client's responsibility to ensure that the finished package complies with applicable migration limits in the specific food or filling good itself under the actual conditions of use. Our confirmation is only valid when our packaging material is properly further processed, and is not altered by other processes than the intended and communicated ones.
The technological suitability of the above described material (e.g. compatibility of the filling, process ability) is not confirmed by the above information and must be checked by means of appropriate filling and storage tests. Possible interactions of the packaging material and its components with

Accessible by R&D, Sales, Customer Service …

„Extended“ compliance statement



Conclusion

- The regulatory environment is complex and multiple legislative prescriptions, requirements and guidelines have to be considered.
- This environment is steadily changing as new findings lead to new or modified requirements.
- A closer cooperation or even alignment between regulatory organisations like FDA, EMA, CFDA, ANVISA could simplify this never ending task.
- Keeping all documents up to date is a challenging task to which there is no alterative.

Thank You!
Questions?