Energy Curable Acrylates for Indirect Food Packaging Applications

Radtech Chicago April 30th, 2012 Dr. M. Heylen





- Role of food packaging
- Safety of food packaging
- Overview of food contact regulations in US, European Union and Switzerland
- Cytec developments for UV/EB food packaging

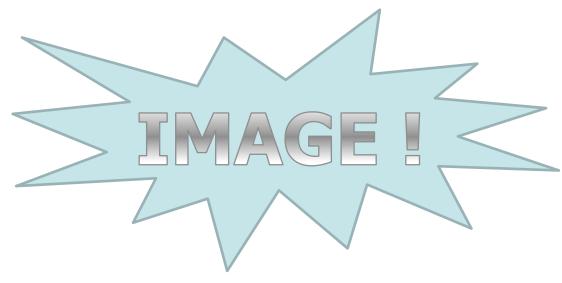


Role of food packaging

protection - increase of shelf life

Brand Recognition

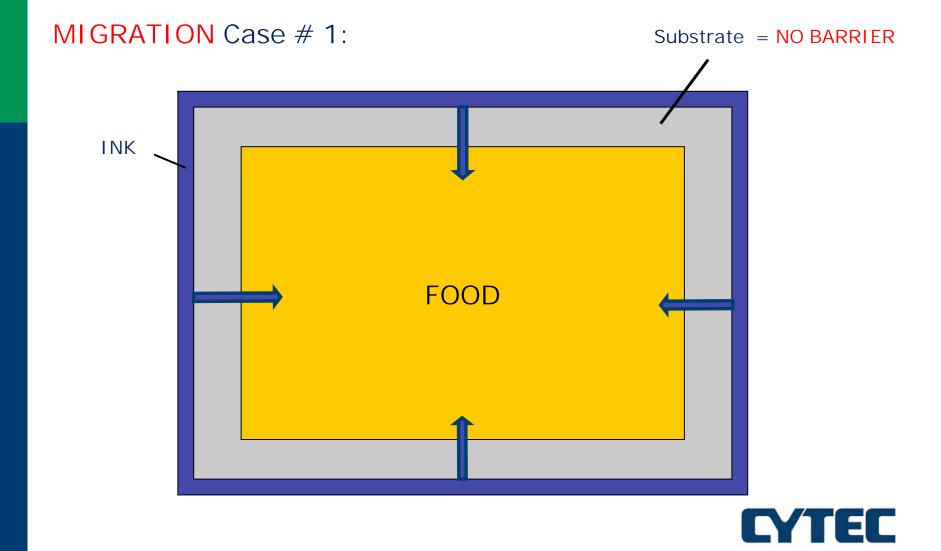
Eye Catching Packaging





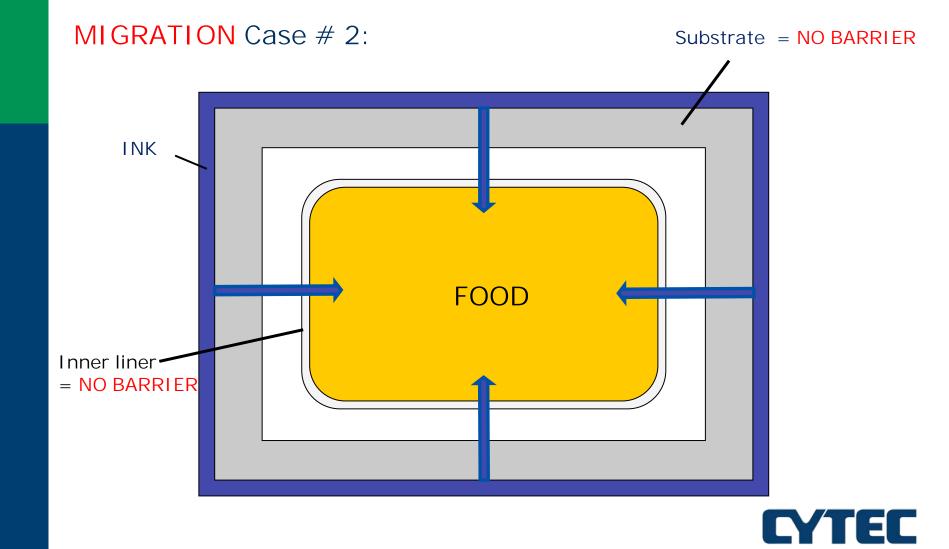


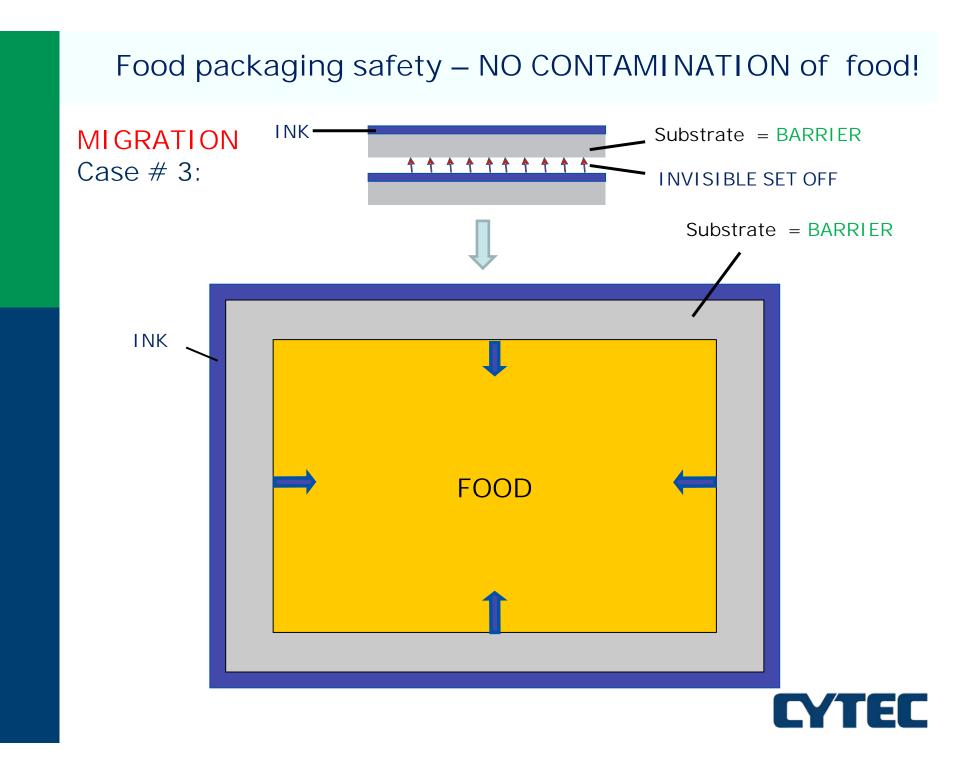
NO DIRECT CONTACT with the food!



Food packaging safety – NO CONTAMINATION of food!

NO DIRECT CONTACT with the food!

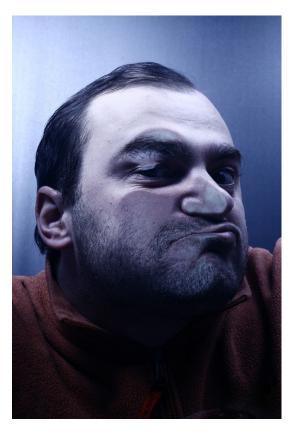




Food packaging safety – functional barrier principle!

BARRIER?

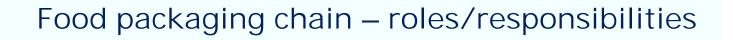
YES





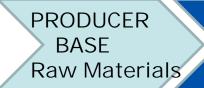
NO





PRINTER

CONVERTER







RESIN

"LEO" Resins

LEO = Low Extractables-Low Odor



BRAND

OWNER

- Printing inks are subject to laws of FDA
- FDA requires that:
 - Inks are manufactured and used under GMP
 - They need to be safe and suitable for the intended use
 - Requirements for food additive are applicable
- FDA defines a food additive as:
 - Substance that is "reasonably expected to become a component of food under the intended conditions of use"
 - Printing inks components are generally considered to be food additives ... unless the contrary can be demonstrated
- Use of printing inks must be covered by:
 - A suitable clearance in the food additive regulation or
 - An effective Food Contact Notification (FCN) or
 - A Threshold of Regulation exemption letter

Unless "no migration" is demonstrated



Overview Food Contact Regulations in US

- Food additive regulations
 - No single regulation lists all components of a printing ink
 - Each component may be cleared under various regulations
- Food Contact Notification (FCN)
 - For substances that have been demonstrated to be safe for their intended use
 - Assessment based on the exposure (consumption factors)
 - Proprietary to the notifying company(ies)

• FCN 772

- TMPTA, TMP(EO)TA, BADGEDA, TRPGDA
- Mutagenicity & migration data
- Migration limit of 1 ppm thanks to low consumption factor (5%)

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Overview Food Contact Regulations In European Union

- No Specific European harmonized legislation for inks but several legislative instruments which impacts materials and articles for food
- Some examples
 - Regulation EC 1935/2004:
 - Art 3: use of Good Manufacturing Practice (GMP) in order to avoid transfer into the food
 - Art 16: Declaration of Compliance (conformity)
 - Art 17: Proof of Traceability at all stages
 - Regulation EC 2023/2006: rules on GMP
 - Directive 10/2011 (Plastic Regulation)
 - Relating to plastic materials and articles intended to come in contact with food
 - Overall migration limit (OML): 60 mg/kg food
 - Specific migration limit (SML) for individual substances
 - Contains a positive list of monomers and other starting materials

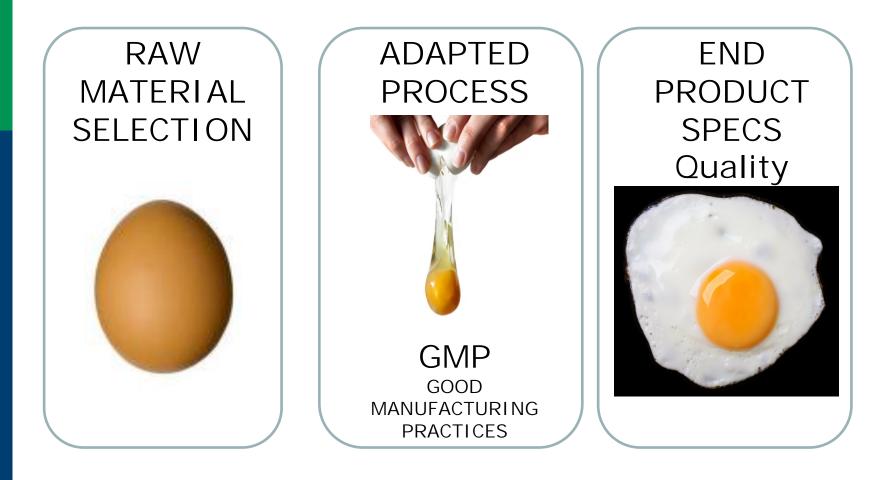


Overview Food Contact Regulations In Switzerland

- Swiss ordinance is the first specific and complete legislation on printing inks
- It became market requirement in EU and beyond
- Consists of positive lists: A lists and B lists
- A lists consist of evaluated substances (with their migration limits)
- B lists consist of non-evaluated substances which can only be used if their migration is < 10 ppb

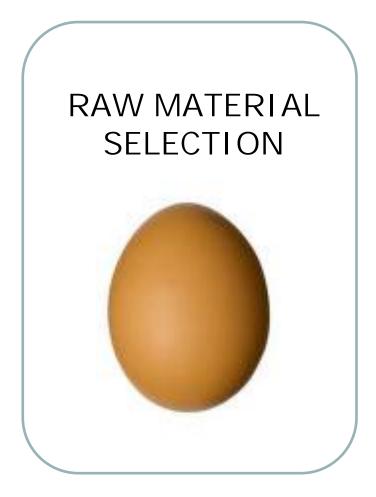


Development at different levels



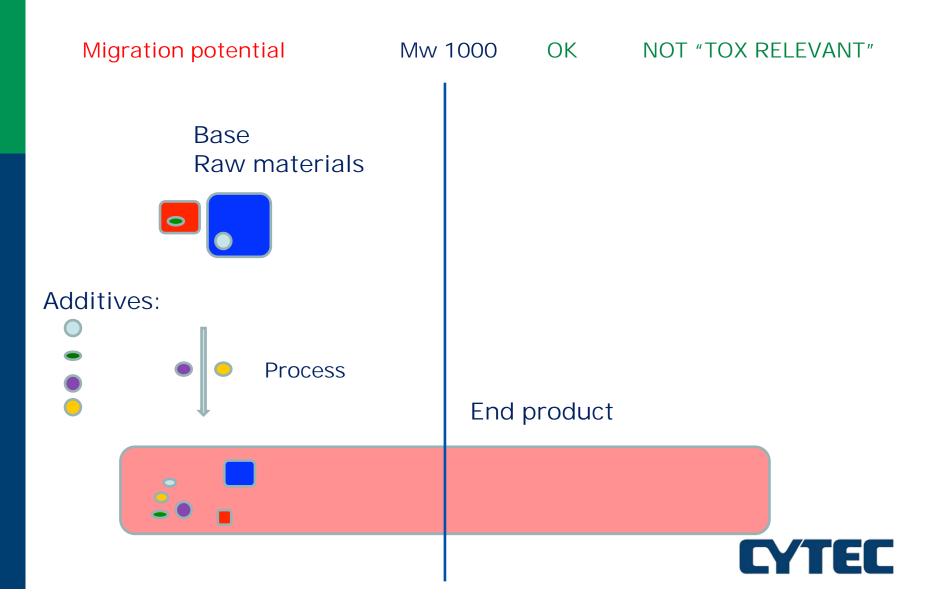


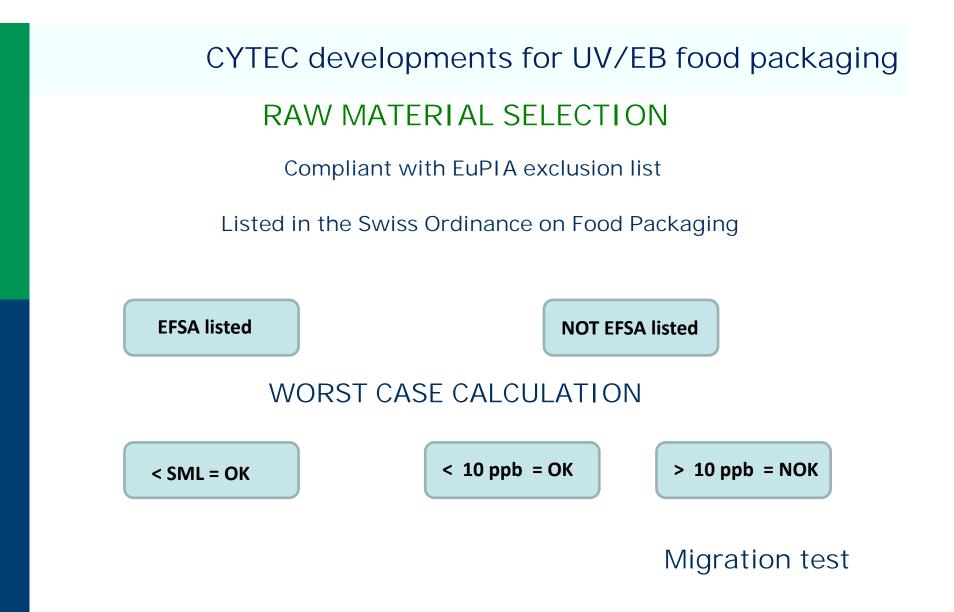
Development at different levels





RAW MATERIAL SELECTION: What are potential migrants?





EFSA = European Food Safety Authority

SML = Specific Migration Limit

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RAW MATERIAL SELECTION: Worst Case Calculation

- Calculation:
 - "Formulation" is 100% of acrylate concerned
 - Y g/m² print thickness
 - 6 dm² packaging in contact with 1 I food
 - 100% migration:

Migration (ppb) = 0.06 x Y x Component content in acrylate (ppm)

Ex: 0.06 x 3 g/m² x 50 ppm = 9 ppb

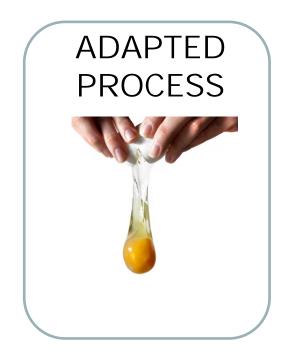


RAW MATERIAL SELECTION: RAW MATERIAL SUPPLIER

- Higher molecular weight
- Higher purity (specs on residuals defined)
- Additives used



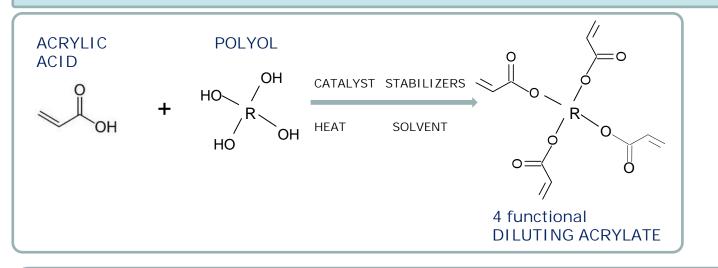
Development at different levels





Adapted Process

Example: Monomers ("diluting acrylates") process



• Longer stripping to minimize residuals (solvent and acrylic acid)

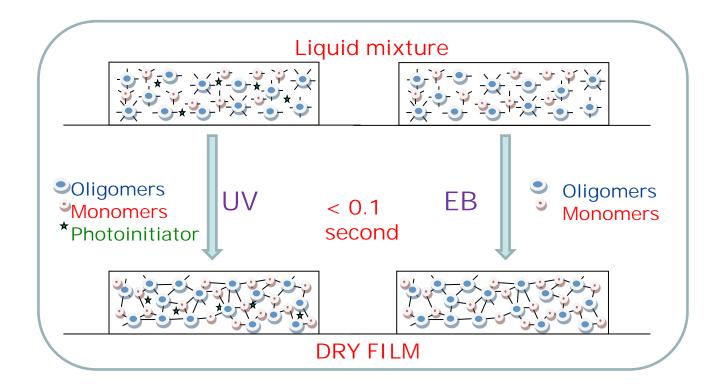
LOW ODOR

• Higher conversion degree to limit mono and di-acrylates

 \Rightarrow LOW MIGRATION



Adapted process: Why limit amount of lower functional acrylates?



REACTION of AT LEAST 1 ACRYLATE FUNCTION:

NO MIGRATION



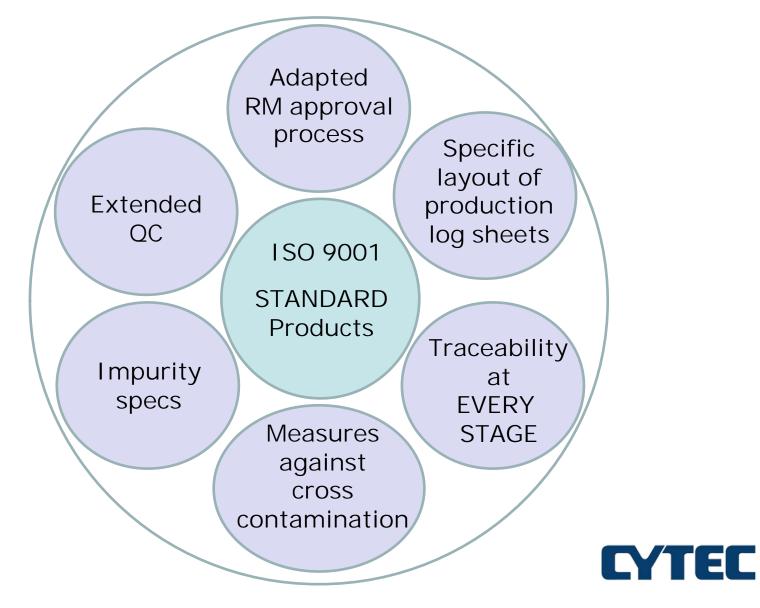
Development at different levels



GOOD MANUFACTURING PRACTICES (GMP)



Good Manufacturing Practices (GMP) at CYTEC:



IMPORTANCE OF Good Manufacuring Practices (GMP)

CONFORMITY with QUALITY STANDARDS

Frame Work Directive 1935/2004



Good Manufacturing Practices (GMP) OBLIGATION?

GMP regulation (EC 2023/2006)

1st August, 2008

Keller and Heckman LLP quote:

« Up to but excluding the production of STARTING SUBSTANCES»



Development at different levels





END PRODUCTS SPECIFICATIONS

Standard resins:

• Physical Properties

• Chemical Properties

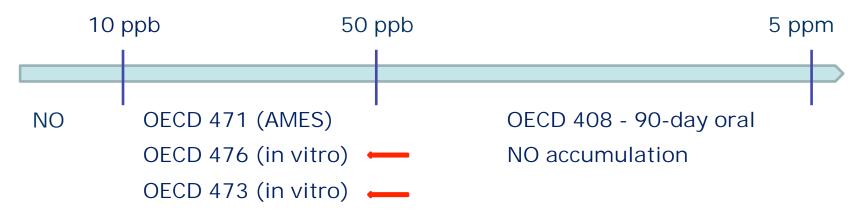
"LEO" resins:

- Physical Properties
- Chemical Properties
- Residuals (process) A
 - В
 - С
- Impurities (RM) A
 - В
- Potential contaminants (process)

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MUTAGENICITY assessment

MIGRATION limit



TOX DATA

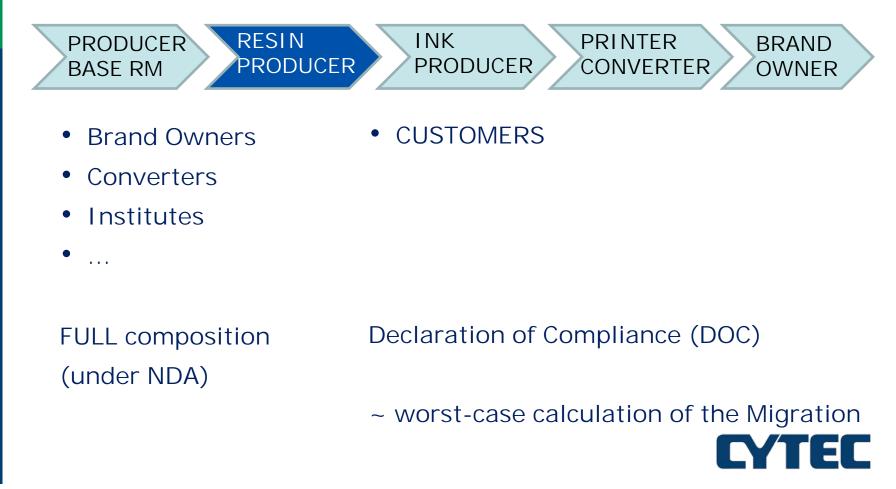
ACRYLATES: FALSE POSITIVES for OECD 476 or the OECD 473

"LEO" resins

- AMES
- Mouse Micronucleus test OECD 474 (in vivo) (in vivo test results supersedes in vitro test results)

END PRODUCTS SPECIFICATIONS

Transfer of Compositional Information on "LEO" resins



ACTUAL PRODUCT RANGE

PRODUCT	Туре	Viscosity at 25°C (mPa.s)	Offset	Flexo	OPV
EBECRYL LEO [®] 10501	3-functional diluting acrylate	80	\checkmark	\checkmark	\checkmark
EBECRYL LEO [®] 10551	amine modified polyether acrylate	75		\checkmark	\checkmark
EBECRYL LEO [®] 10552	amine modified polyether acrylate	450		\checkmark	\checkmark
EBECRYL LEO [®] 10502	4-functional polyether acrylate	170	\checkmark	\checkmark	\checkmark
EBECRYL LEO [®] 10553	amine modified 4-functional polyether acrylate	220		\checkmark	\checkmark
EBECRYL LEO [®] 10601	modified epoxy acrylate	200000	\checkmark	\checkmark	\checkmark
EBECRYL LEO [®] 10620	standard epoxy acrylate	200000	\checkmark	\checkmark	\checkmark
EBECRYL LEO [®] 10801	6-functional polyester acrylate	50000	\checkmark	\checkmark	



Conclusion

UV (EB) technology

DIVERSIFICATION INNOVATION in packaging design NEGATIVE IMAGE due to photoinitiator migration issues

CYTEC: EBECRYL LEO ®

REDUCED RISK for migration

UV/EB more ACCEPTABLE for Food packaging

To make UV/ EB successful in food packaging

ACCOUNTABILITY at EACH stage of the value chain (GMP) IMPROVE INFORMATION STREAM



THANK YOU FOR YOUR ATTENTION!

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