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**Impact of FCN772 for Future Food
Packaging Applications with
UV/EB Technology
&
The Real-Life Converting Practice**

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Common Concerns from Converters

- Odor (1st generation RM, by-products)/ Taste
- Migration (un-reacted RM, fragment-PI)
- Lack of simple & secure cure monitoring mechanism
- Lack of understanding regarding FDA status /regulations of UV/EB chemistry
- Lack of proper testing protocols

Regulations from US Food & Drug Administration

Food Contact Substance:

“any substance intended for use as a component of materials used in manufacturing, packaging, packing, transportation, or holding food if such use is *not intended to have a technical effect in food*”.

Statutory Exemption Evaluation:

Evaluation options by which food contact substances can be determined to be exempt from or compliant with FDA regulations.

- Threshold of Regulation Letter
- GRAS Substances.
- Prior-Sanctioned Substances.
- *“No Migration”/ “No Food Additive” Determination. (50 ppb)*
- *Functional Barrier Doctrine. (50 ppb)*
- Basic Polymer Doctrine.
- Mixture Doctrine.
- Houseware Exemption.

Examples under FDA Statutory Exemption Evaluation:

* Well-known Industry Example:

Epoxy Can Coatings for foods & beverages.
(No Migration/no food additive Exemption).

* Radtech industry Efforts: (few examples)

- Ciba-Geigy – Indirect FDA compliant initiator.
- Goldschmidt Chemicals – Cationic Release Coating.
- Sun Chemicals --- FDA UV/EB compliant inks.
- Henkel – Advanced Testing Protocol & Products for FDA compliance UV/EB coatings & adhesives. #
- Northwest Coating (now Ashland) – UV/EB laminating adhesives

, ... etc.

Reference papers in “TAPPI 2002 PLACE; Radtech Europe Conference 2003; 2005 TAPPI-Europe-PLACE; Radtech 2004 e/5 Conference; 2005 PIRA Conference (London).”

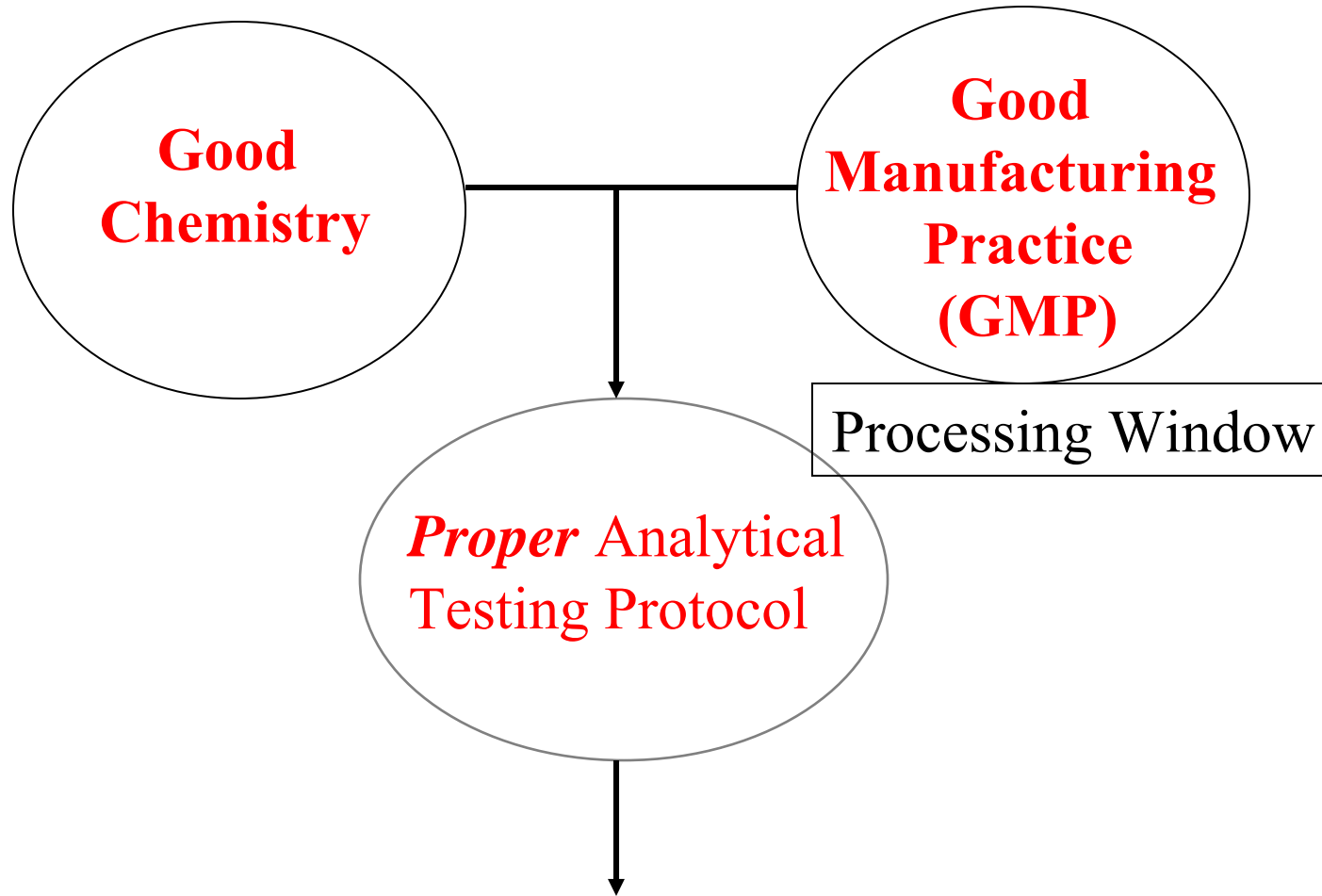
What are the impacts of FCN772 ?

- A giant step to initiate the creation of a comprehensive list of acrylated materials under FCN (Food Contact Notification).
- Industry-wide understanding and awareness of UV/EB chemistry in food packaging applications.
- More food packaging applications utilizing UV/EB chemistry as green alternative.
- Broader design latitude & more economic products.
- EB curing system may no longer hold dominating position in food packaging applications.



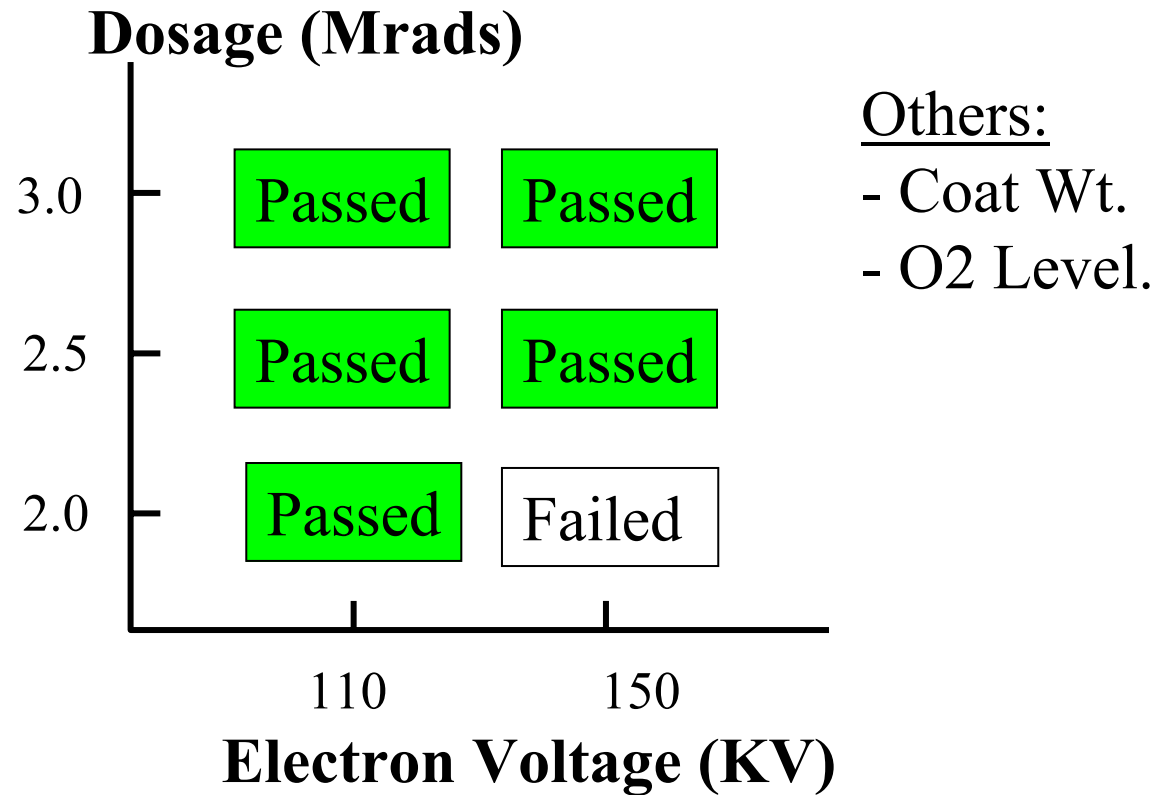
The Real-Life Converting Practice

FDA Certification Guide for EB Converters



FDA Compliant EB/UV curable Packages

Proper formulation + Good manufacturing Practice



Processing Window determination for Formula #3

Coated and cured on 50 Gauge OPP film based on 95% ethanol cell extraction results for direct food contact. (Coating weight range :1.5-1.9 lb/ream, condition of use "E")

Important Overriding Factors

- *Odor & Taste Test.*
- *Improper Cure.*
 - (Outside recommended processing window)
 - (UV lamp aging, loss or inertness for EB)
- *Un-intended Contamination.*
 - (e.g. slinging to backside of the substrate & no UV light or EB penetration)
- *Porous Stocks*
 - (especially crucial for UV curing).
- *Production line vs. pilot/lab*
 - (initial certification & systematic QC check extractables)



Potential & Emerging UV/EB Applications In Food Packaging

Flexible Packaging



Real life Commercial Products

EB Coatings Replacing Paper & Film Laminates

Old Structure
(Laminated)



New Structure
(Mono-Web)

- *Elimination of Lacquering Step, One film Layer & Laminating Adhesive*
- *On-Demand Manufacturing/Inventory Reduction*
- *Applied the New Testing Protocol for FDA Certification*
- *FDA Compliant for Direct or In-direct Applications.*
- *10-20% Cost Saving with Commercial Success.*

Folding Cartons



**Mainly EB systems currently
More UV systems
to participate**

Tags, Labels & Wrappers



**More can claim
FDA compliant.**



Due-Diligence Processes .

Common Concerns from Converters

- ✓ - Odor / Taste → { *Grounds for product rejection even with full FDA compliance.*
- ✓ - Migration → { *Qualify each product construction (different inks, substrates) & its production process windows*
- ✓
Somewhat - Lack of simple & secure cure monitoring mechanism → { *FCN status is not a blank check*
Good Manufacturing Process
Properly cured; Record keeping
Establish proper QC sampling
- ✓ - Lack of understanding regarding FDA status /regulations of UV/EB chemistry
- ✓ - Lack of proper testing protocols

Additional Considerations

- Product liability.
- Regional regulatory limits.
- Total package safety guaranteed by converters.
(coating, inks, substrates, food type & condition of use).
- Need to develop direct press side test method
(for complying with *migration limits*; only indirect
properties measurement).
- New medical studies /new toxicity data.

Summary

- FCN772 represents Radtech FCN member group effort to raise industry **awareness of the possibility** of using UV/EB technology in food packaging applications.
- FDA compliance for acrylates including FCN772 will still be **contingent** on proper curing, certification, GMP, frequent QC sampling. (Unlike GRAS or prior-sanctioned substance).
- There is still need to develop **direct press side test method** for complying with migration limits.
- UV/EB Chemistry has become one of the **choices of main stream chemistries** in food packaging applications.

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Thank You !