



artis

stretching the limits

IOM3 Afternoon Technical
Discussion Meeting.

Rubber and Food Contact.
02/07/10

Paul Marchant CSci MIMMM

Rubber and Food Contact.

- ARTIS - Polymer R&D laboratory part of Avon Rubber plc.
- Based in Semington Wiltshire.
- Specialise in Elastomers.
- Offer material R&D, testing, and analytical solutions.
- Have significant experience in the food contact area owing to involvement in Avon Rubber Dairy business / Avon Aerosol gasket business.



Rubber and Food Contact.

- Avon ~ £70 Million Sales.
- Manufacturer of respiratory protection products.
- Dairy Products – Worlds Leading supplier of Dairy Liners.



Rubber and Food Contact.

- Hope to give a brief overview of:
 - Legislation on the use of rubber in food contact.
 - Both US / European.
 - Implications of this.
 - Challenges for the future.

Rubber and Food Contact.

- Rubbery materials find use in a wide range of food contact applications.
- Main uses are probably seals and tubing.
- Need to protect the food from contamination.
 - Food safety aspect.
 - Taste / discolouration aspect.
- Some countries have food contact legislation covering the use of rubber in food contact applications.
 - USA – FDA legislation is in place.
 - EU – No legislation yet specifically for rubber, other than for baby teats / soothers. Regulation 1935/2004 covering regulation for food contact materials.
 - German – BfR Guidelines are in place for rubber - commonly used.
 - Other member states such as Italy / France / Holland do have legislation in place for rubber.

FDA Legislation.

- The USA Food and Drug Administration (FDA) consider three different food additive types
 - Direct food additives - components added to the food.
 - Secondary direct food additives - Components that are added as part of a treatment or process, such as an extraction process.
 - Indirect food additives - substances that may come into contact with food but not intended to be added directly to food (packaging / food process equipment etc)
- Code of Federal Legislation 21 CFR 177 – covers polymers as ‘indirect food additives’.
- Most specific FDA legislation for rubber is CFR 21 FDA 177.2600, ‘rubber articles intended for repeated use’.

FDA Legislation 21 CFR 177.2600.

- Recognises specific food types (fatty / aqueous)
- Contains a list of permitted materials with caveats on their use.
 - Essentially a list of permitted base 'elastomers', 'vulcanization materials', 'accelerators', 'retarders', 'activators', 'antioxidants', 'plasticizers', 'fillers' 'colourants', 'emulsifiers' and other 'miscellaneous' additives.
 - Main Caveats on use:
 - Accelerators < 1.5%
 - Activators < 5%
 - Retarders < 10%
 - Antioxidants < 5%
 - Plasticisers < 30%
 - Channel or Furnace Carbon Black < 50% (non-milk / edible oil contact)
 - Furnace black content to be <10% in edible oil / milk contact applications.
- Designing an edible oil / milk contact compound can be very difficult – owing to limits in place for furnace black content.
- Means other filler types such as silica have to be used – which can be problematic.

FDA Legislation 21 CFR 177.2600.

- Use of listed ingredients must comply with regulation under sections 174-178, &179.45.
- Ingredients / materials not listed in 177.2600 may also be used.
- Recognises that some materials are inherently safe, these are classed as 'GRAS', 'generally recognised as safe'.
- Sensible approach, which widens the realms of possibility from a rubber compounding perspective.
 - Examples of GRAS materials include..... Calcium stearate, rapeseed oil...
- Substances also listed under parts 170 – 189 of CFR 21 may also be used, subject to provisions of this regulation.

FDA Legislation 21 CFR 177.2600.

- Product extraction limits (per unit SA product) in place for each food type.
 - Fatty foods – n-hexane extract limit (mg/ square inch)
 - 20 milligrams / square inch – 1st 7 hours
 - 1 milligram / square inch – next 2 hours.
 - Aqueous foods – water extract
 - 175 milligrams / square inch – 1st 7 hours
 - 4 milligram / square inch – next 2 hours.
- It is possible to design a formulation around the compounding rules – which fails to meet product extraction requirements.
- 177.2600 also requires rubber products to be thoroughly cleansed prior to first use.



FDA Legislation 21 CFR 177.2600.

- Very sensible approach
- But list is in some need of up-dating !
- Some material 'nasties' populate the list !
- Asbestos, and β -naphthylamine included, so the compounder or importer of rubber-food contact products does have to take care !

FDA Legislation.

- Revised and updated editions of Code of Federal Regulations (CFR) 21 re-issued April in each year.
- Online access can be found at :

<http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=d36753bca57802e9889f3bc4f277c77e&rgn=div5&view=text&node=21:3.0.1.1.8&idno=21#21:3.0.1.1.8.3.1.21>

EU Legislation.

- Two types of legislation exist:
 - EU Directives – Implemented by the member state Government.
 - EU Regulations – Immediate European Law.
- Regulation 1935/2004 exists and applies to rubber. Sets up general requirements for **ALL** food contact materials.
- Main principle of this legislation is that food contact materials must not transfer constituents to food in a way which could endanger health, change the composition of the food, or cause a deterioration in organoleptic properties.

Note – organoleptic = sensory properties, smell, taste, colour, texture etc...

EU Legislation 1935/2004.



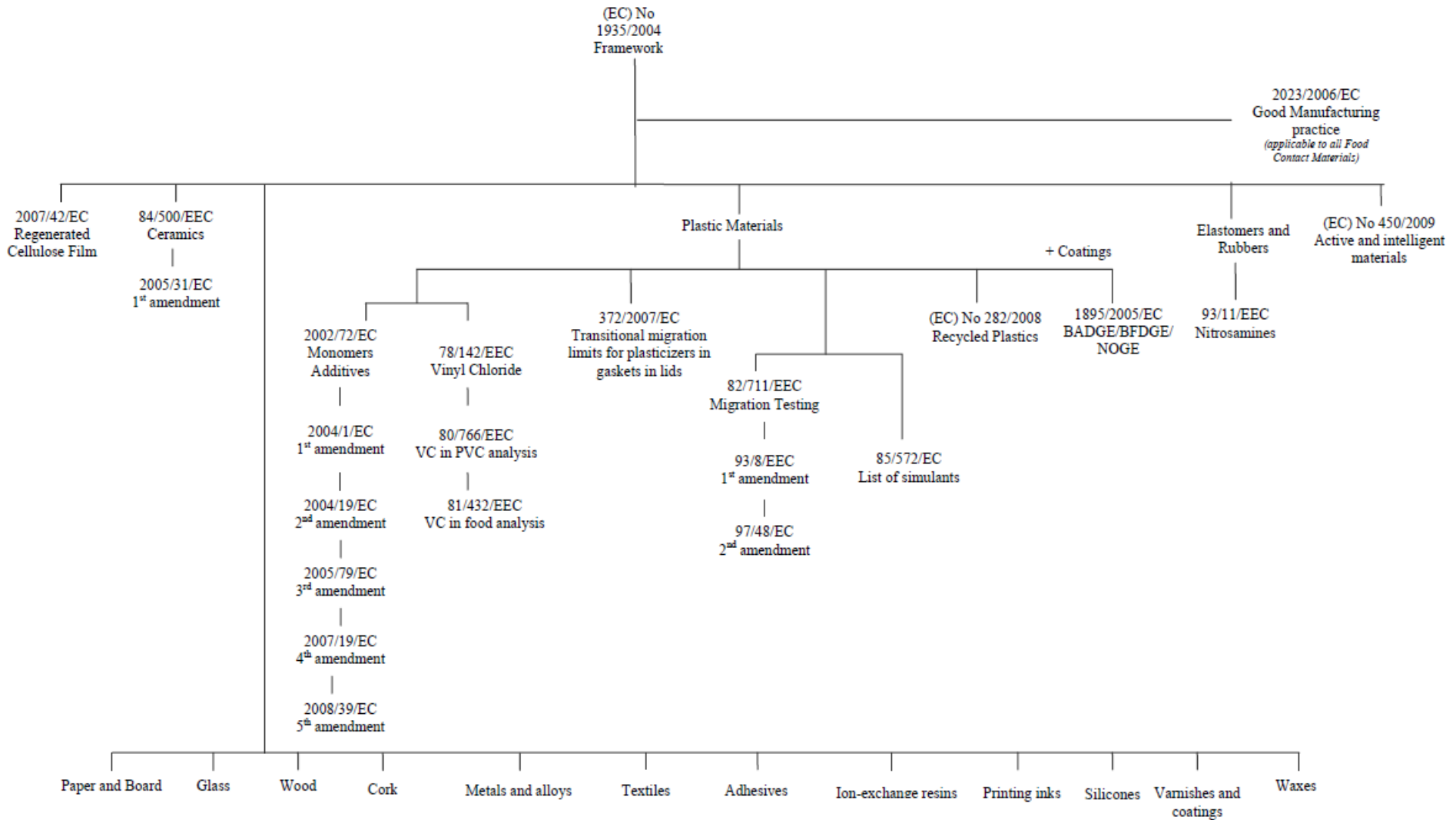
- Other Salient Points:
- Must comply with special requirements for specific material types listed in annex 1 (for eg Rubber, wood etc).
- Must comply with requirements for active materials – added to change the food in a positive manner.
- Outlines an authorization procedure for food contact materials / ingredients.
- Labelling requirements – instructions must be given on intended application / correct use, wine glass / fork symbol.
- Need for a ‘declaration of compliance’ (with the specific rules for each material type).
- Rules on traceability (critical due to potential recall situations).

EU Food Contact Legislation.

- Only specific legislation in Europe for rubber is for rubber feeding teats / soothers - Directive 93/11/EEC.
- However 1935/2004 states that where no European law exists for specific materials this regulation should not prevent existing member state 'National' provisions from being followed.
- German – Federal Institute for risk assessment (BfR) system is widely followed and well respected way of showing / proving rubber food contact credentials in EU.
- Regulation 2023/2006 also applicable to **ALL** food contact materials. Outlines good manufacturing practice requirements.
- Covers need for
 - a quality assurance / control system
 - documentation system
 - specific measures regarding printing processes.

EU Food Contact Legislation.

Overview of Community legislation (last update 02/06/2009)



BfR Recommendation 21.

- The main aim of the German BfR Institute is to work to make a major contribution to ensuring that food, substances and products become safer.
- BfR recommendation XXI covers natural / synthetic rubber.
- Separate recommendations are in place for other food contact materials, for example silicone rubber (XV), or polyethylene (III).
- These recommendations are not law.

BfR Recommendation 21.

- BfR recommendation 21 Contains a general list of permitted ingredients for four product categories
 - Category 1 is the most stringent (for long term contact)
 - Category 4 least stringent (short term contact).
- Category 1 list is limited, under each category an increasing number of ingredients are permitted.
- For example Storage containers for storage of foodstuffs for between 24hrs and several months come under category 1. Milk liners / tubes come under category 3 (shorter contact time).
- Formulation has to be designed to use each ingredient below any specified threshold levels.

BfR Recommendation 21.

- Stringent product migration / analysis limits are in place
- For category 3:
 - Limit on zinc content / lead content
 - N-nitrosamine extraction
 - Amine extract
 - Zinc-dibenzyl dithiocarbamate extract



- Approved laboratories undertake **product** tests to prove compliance of the formulation / product.
- Usually request a copy of the formulation – for checking / audit.
- RAL (German institute for quality assurance / certification) can then certify compliance.
- Display the German – knife / fork symbol on the product.



BfR Recommendation 21.

- Procedure is in place for introduction of other ingredients.
 - New ingredients can be proposed.
 - Must be very aware of any 'announcements' against any BfR recommendation.
 - For example one recent announcement against recommendation 21 changed the procedure for how a product extraction test is to be run.
 - These are published in the '**Bundesgesundheitsblatt**' (a German health sciences journal)
-
- Be careful – It is possible to develop a formulation which meets the BfR compound requirements, but fails to meet product extract requirements!

Future Challenges - REACH.

- Big challenge in Europe in the future is REACH (European regulation EC 1907/2006).
- 800+ Page document
- Deals with the Regulation, Evaluation, Authorization, and Restriction of chemical substances.
- Came into force on 1st June 2007.
- Main aims are to:
 - Improve the protection of human health and the environment from the risks that can be posed by chemicals
 - Enhance the competitiveness of the EU chemicals industry.
 - Promote alternative methods for the assessment of hazards of substances
 - Sharing of chemical safety information .

Future Challenges - REACH.

- All data for chemicals stored by the European Chemicals Agency (ECHA), who will also run the Evaluation process.
- All manufacturers or importers of chemicals have to register them.
- 30/11/10 First Registration Deadline
From this date onwards, it will be against the law to continue to manufacture or import any unregistered substances (covered by this deadline - depending on volume use / nature of substance).
- Some chemicals will not be registered – where current use level does not justify registration.
- Some chemicals will become / are becoming unavailable for use within Europe.

Future Challenges - REACH.

- Under REACH - Use of some chemicals is already restricted. For example phthalates not permitted for use in soft toys for children. (Annex 17 - Restrictions).
- List of substances of very high concern (SVHC) has been produced.
- SVHC list highlights materials where current restrictions may not be adequate.
- Number of phthalates are on that list, including DOP and DBP.
- Use of these will become more restricted / use may be subject to authorization.
- These materials are on both BfR / FDA listings as approved plasticisers !
- By 06/06/11 – Manufacturers will have to notify ECHA – if SVHC are present in products >0.1%.

Future Challenges.

- Volatile Raw materials market:
 - Means can be hard to source approved food contact materials.
 - Raw material manufacturing locations changing at short notice.
- Change process in food contact arena has to be managed in a professional and controlled manner.
- Some extract limits in place in BfR are into the realms of part per billion.
- Currently – close to analytical limit of detection, test repeatability issues.
- Developments in analytical technology.... And newer techniques mean extract limits in place may come down further.
- Food contact formulations with a long history of use could suddenly struggle or fail to meet extraction requirements or become obsolete or restricted due to REACH implications.
- Further EU legislation governing the use of rubber in food contact applications is to be expected. Specific Measures for Rubber

Any Questions?

Some Useful Websites.

www.artis.uk.com

ARTIS Homepage – Learn about how we can help you.

http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm

EU – Food contact website.

<http://www.bfr.bund.de>

BfR website

<http://www.foodcontactmaterials.com/>

Food Contact website, with useful information.

http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm

Information on REACH

http://www.echa.europa.eu/home_en.asp

European Chemicals Agency (ECHA) website.