

# The EU Product Safety and Market Surveillance Package: What US exporters need to know



Washington, D.C., 10 June 2013

# Introduction

- On 13 February 2013, the European Commission adopted a Product Safety and Market Surveillance Package
- Objective: providing more uniform safety rules for non-food products, many of which are regulated under different and overlapping legal frameworks
- Main elements of the Package:
  - A proposal for a new Regulation on Consumer Product Safety, repealing and replacing the GPSD
  - A proposal for a new Regulation on Market Surveillance of Products, deleting and replacing the provisions on market surveillance in Chapter III of Regulation 765/2008
- Both are set to apply from 1 January 2015
- What does this entail for US exporters?

# Speakers



- Jean-Philippe Montfort, Partner, Mayer Brown Brussels



- Erika Jones, Partner, Mayer Brown Washington, D.C.



- Miles Robinson, Partner, Mayer Brown London



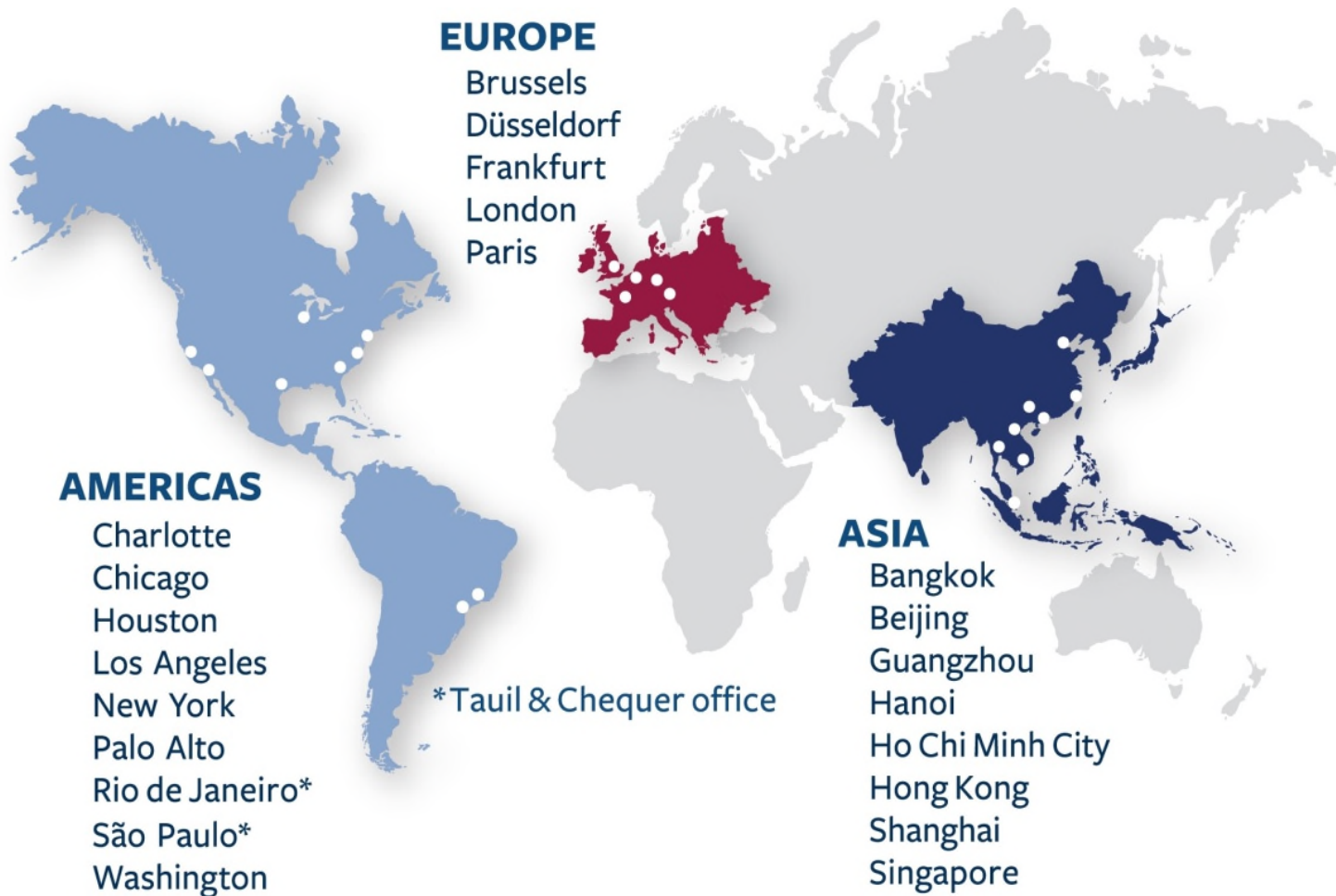
- Sébastien Louvion, Counsel, Brussels

# Agenda

- 3:00-3:20**      **Background – Rationale and Prospective for the Proposed Reform**
- 3:20-3:45      The draft Consumer Product Safety Regulation (CPSR)
- 3:45-4:10      The draft Market Surveillance Regulation (MSR)
- 4:10-4:30      Key Issues and Impact on US Manufacturers
- 4:30- 5:00      Q&A and Conclusions

# About Mayer Brown

*Significant Presence in Europe, Asia and the Americas*



# EU Legal Framework on Product Safety

Current Legal Framework	Proposed Legal Framework
<ul style="list-style-type: none"><li>• General Product Safety Directive 2001/95/EC (GPSD)</li><li>• Directive 85/374/EEC on Liability for Defective Products</li><li>• The « Goods Package »:<ul style="list-style-type: none"><li>• Regulation 765/2008 on accreditation and market surveillance for harmonized products</li><li>• Decision 768/2008 on a common framework for the marketing of products</li><li>• (Regulation 764/2008 on mutual recognition)</li></ul></li></ul>	<ul style="list-style-type: none"><li>• New Regulation on Consumer Product Safety (replacing GPSD)</li><li>• Directive 85/374/EEC on Liability for Defective Products</li><li>• New Regulation on Market Surveillance of Products (replacing Reg 765/2008)</li><li>• (Decision 768/2008 on a common framework for the marketing of products - Will it still be used?)</li><li>• (Regulation 764/2008 on mutual recognition)</li></ul>

# The General Product Safety Directive

- Adopted in 2001, replacing Directive 92/59/EC
- Applies to non-food consumer products
- Acts as 'safety net' where sector specific legislation does not include more specific requirements
- Applies to the aspects and risks or categories of risks not covered by specific EU provisions on the products involved
- Includes provisions on the circulation of information on unsafe products between the Member States and the Commission, notably through RAPEX

# GPSD: The Safety Obligation

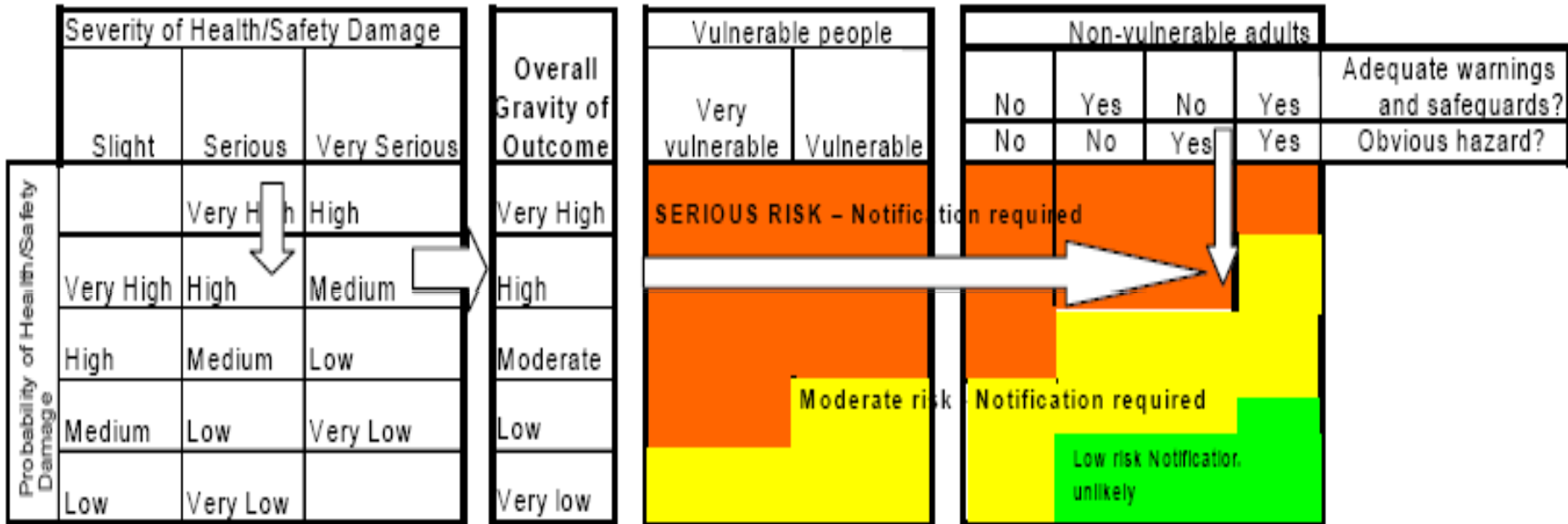
- Places onus on producers and distributors
  - Producers must only place “safe products” on the market.
  - Distributors must “act in due care” to help ensure compliance with the safety requirements.
- What is a “safe product”? A product that, under normal and reasonably foreseeable conditions of use does not present any risk or only the *minimum risks* compatible with the product’s use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the characteristics, effects, presentation and categories of users of the product, in particular children and the elderly



# GPSD: Duties of Producers and Authorities


- **Producers** must take appropriate actions to:
  - Be informed of the risks of their products
  - Take appropriate action including, if necessary to avoid these risks, market withdrawals and recalls
  - Notify authorities of marketed products presenting a risk
- **Authorities** can take the following measures:
  - Market surveillance activities (e.g. take samples)
  - Consumer warnings, temporary marketing bans
  - Order market withdrawals, alerts and product recalls
  - Notification of products presenting a serious risk to the Commission for placing on RAPEX
- **Commission Guidelines on risk assessment**

# Risk Assessment Matrix for Industry



# Risk Assessment Matrix for Authorities

Risk level from the combination of the severity of injury and probability

Probability of damage during the foreseeable lifetime of the product		Severity of injury			
		1	2	3	4
<p>High</p>  <p>Low</p>	> 50 %	H	S	S	S
	> 1/10	M	S	S	S
	> 1/100	M	S	S	S
	> 1/1 000	L	H	S	S
	> 1/10 000	L	M	H	S
	> 1/100 000	L	L	M	H
	> 1/1 000 000	L	L	L	M
	< 1/1 000 000	L	L	L	L

S — Serious Risk
H — High risk
M — Medium risk
L — Low risk

# The New Legal Framework

- In 2008, the EU adopted 3 measures applicable to products (also known as the «Goods Package»):
  - A regulation on the application of national technical rules to products lawfully marketed in another Member State («mutual recognition») (Regulation 764/2008)
  - A regulation on requirements for accreditation and market surveillance for the marketing of harmonized products (Regulation 765/2008)
  - A Decision on a common framework for the marketing of products (Decision 768/2008)
- They are applicable since 1 January 2010

# Reg. 765/2008 on Marketing of Products

- Applies to ALL products covered by Community harmonized legislation, including professional products
- Covers any “product” defined as “a substance, preparation or good ... other than food, feed...”
- Covers not only consumer safety but also the protection of workers and the environment
- Requires authorities to withdraw, prohibit or restrict the marketing of products which are not safe or which are not in compliance with Community harmonized legislation
- Products presenting a “serious risk” to be notified under RAPEX
- Call for development of information support system for non-serious risks (ICSMS)

# RAPEX: Input from Regulation 765

- 2011: 25 notifications concerning professional products/other risks, incl. 17 notifications on products presenting a serious risk
  - 5 (29%) professional products posing health & safety risk and 12 (71%) on consumer products posing environmental risks
- 17 notifications concerned explosive atmosphere equipments and pyrotechnics articles (6 notifications, 35%), machinery (5, 29%), clothing & textile (2, 12%) and plastic packages (4, 24%).
- Examples:
  - Germany: compressors (professional products) posing a serious risk of injuries as they can explode
  - Finland: plastic bag of toys containing cadmium exceeding limits that poses an environmental pollution risk
  - Finland: gas fridge poses a chemical risk by releasing excessive amounts of carbon monoxide (CO) into the environment

# Common Framework Decision 768/2008

- Decision 768 is addressed to the legislator and contains specific language that must be used in new or recasted EU harmonized measures
- Contains definitions and specifies the obligations on economic operators (manufacturers, importers, distributors) with respect to ensuring conformity with EU harmonized rules, traceability markings, CE markings and others, that must be taken on board by the legislator, depending upon the type of conformity assessment, procedures that are applicable to a given sector
- It has already been used as part of e.g. the new Directives/Regulations on toys, cosmetics and for new approach Directives

# Current Legal Framework: Gaps and Overlaps

Products	Consumer Products	Professional Products
Subject to EU harmonized rules	Specific EU harmonized rules + GPSD + Regulation 765	Specific EU harmonized rules + Regulation 765
Not subject to EU harmonized rules	GPSD	No horizontal Community rules on market surveillance



# GPSD Review

- In the summer of 2010, the Commission launched a stakeholder consultation on the revision of the GPSD
- Main issues for the revision:
  - Better and faster use of standardisation
  - Facilitate the resolution of conflicts in case of diverging safety evaluations by Member States
  - Better coordination of national market surveillance activities
  - Alignment to free movement of products package
  - New rules to ensure the traceability of products
- Dec 2010: Stakeholder meeting
- Spring 2011: Commission focused stakeholder meetings
- February 2013: Two Commission proposed Regulations

# The Future Legal Framework

Products	Consumer Products	Professional Products
<b>EU harmonized rules:</b>		
<ul style="list-style-type: none"> <li>Obligations on Economic operators</li> </ul>	Sector specific EU harmonized rules + <b>Consumer Product Safety Regulation +</b> <b>Regulation on Market Surveillance</b>	Sector specific EU harmonized rules + <b>Regulation on Market Surveillance</b>
<ul style="list-style-type: none"> <li>Market surveillance /RAPEX</li> </ul>	<b>Regulation on Market Surveillance</b>	<b>Regulation on Market Surveillance</b>
<b>No EU harmonized rules:</b>		
<ul style="list-style-type: none"> <li>Obligations on Economic operators</li> </ul>	<b>Consumer Product Safety Regulation</b>	None
<ul style="list-style-type: none"> <li>Market surveillance /RAPEX</li> </ul>	<b>Regulation on Market Surveillance</b>	<b>Regulation on Market Surveillance</b>

# Agenda

- 3:00-3:20 Background – Rationale and Prospective for the Proposed Reform
- 3:20-3:45 The draft Consumer Product Safety Regulation (CPSR)**
- 3:45-4:10 The draft Market Surveillance Regulation (MSR)
- 4:10-4:30 Key Issues and Impact on US Manufacturers
- 4:30- 5:00 Q&A and Conclusions

# Proposed Regulation on Consumer Product Safety

- Scope: Similar to the GPSD, the Regulation applies to all non-food consumer products, with a number of new key exclusions
- New Regulation would repeal GPSD
- General safety requirements: not fundamentally changed
- Clarification of relationship with sector-specific legislation and standards
- Expanded obligations for economic operators (manufacturers, importers and distributors) in line with Decision 768/2008
- New authority for Commission to request the drafting of European standards
- Market surveillance/RAPEX provisions moved to Market Surveillance Regulation
- New provisions on penalties (still at national level)

# CPSR: Scope (1)

## Definition of Consumer Products:

- Products obtained through a manufacturing process placed or made available on the market, whether new, used or reconditioned, and which any of the following criteria:
  - (a) which are intended for consumers;
  - (b) which are likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them;
  - (c) to which consumers are exposed in the context of a service provided to them.
- Distinction “placing on the market” and “made available on the market”. Impact on products in stock and second hand products

# CPSR: Scope (2)

## Exclusions from Scope:

- Medicinal products for human or veterinary use
- Food and feed
- Food contact materials to extent risks already covered by EU law
- Living plants (including GMOs) and animals, and products thereof relating directly to their reproduction
- Animal by-products and derived products
- Plant protection products (but not biocides)
- Equipment on which consumers ride or travel operated by service provider in the context of service provided to consumers
- Antiques
- Products to be repaired or reconditioned prior to being used where those products are made available on the market as such

# CPSR: Scope (3)

## Partial Exemption from Scope:

- Products already subject to requirements designed to protect human health and safety under EU harmonized legislation are only subject to Chapter I of Regulation including general safety requirement and country of origin labeling (excluded from the main part of the Regulation -- Chapters II to IV)
- Preamble § 8 explains more specific obligations of economic operators under the Regulation should not apply where EU harmonized legislation already includes equivalent obligations, such as legislation on toys, cosmetics, electrical appliances and construction products
- Exemption requires clarification
- Also question about whether EU will continue applying Decision 765 to sector specific legislation

# CPSR Chapter I: General Safety Requirement (1)

- **Definition of “safe product” very close to GPSD:**

Any product which, under normal or reasonably foreseeable conditions of use of the product concerned, including the duration of use and, where applicable, its putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered acceptable and consistent with a high level of protection of health and safety of persons;

- **Presumption of Safety** for products complying with the following by order of priority:

- EU harmonized requirements protecting from risks to human health and safety
- Published European standards covering the relevant risks
- National laws of countries establishing health and safety requirements covering the relevant risks



# CPSR Chapter I: General Safety Requirement (2)

- In the absence of EU laws, EU standards or national laws covering the relevant risks, safety to be assessed based on, e.g. :
  - Characteristics of the product (composition, packaging, instructions)
  - Presentation of the product, labeling, warning and instructions
  - Categories of consumers at risk, especially vulnerable consumers
  - Appearance of the product
- Feasibility of obtaining higher level of safety or availability of other products presenting a lesser degree of risk not grounds to consider a product not safe
- Other aspects to be taken into account, when available, e.g. :
  - State of the art and technology
  - Other standards, including International and national standards
  - Commission recommendations or guidelines on product safety assessment
  - Product safety codes of good practice
  - Reasonable consumer expectations concerning safety

# CPSR Chapter I: Indication of Origin

- Products must bear indication of country of origin based on Community Customs Code non-preferential origin rules
  - *When more than one country involved, country of origin determined by last, substantial, economically justified processing or working in an undertaking equipped for that purpose and resulting in the manufacture of a new product or representing an important stage of manufacture.*
- Indication must appear on product itself if possible, otherwise on packaging or accompanying document
- For EU products, indication of origin can “EU” or specify MS
- Applies to all consumer products subject to the CPSR.
- Applies to manufacturers and importers
- Preamble § 21: Objective = traceability
- Very divergent views of stakeholders on country of origin

# CPSR Ch.II: Obligations of Manufacturers

- **GMP requirements:**

- Design & manufacture in accordance with general safety requirement
- Ensure series production remains in conformity
- Sample testing of products, investigate and keep register of complaints, non-conforming products and product recalls, and keep distributors informed \*
- Draw up technical documentation\*, to include, as appropriate:
  - general description & essential properties relevant to safety,
  - analysis of possible risks and solutions to reduce risks
  - List of applicable EU standards, national laws or standards
- Maintain records for 10 years and make available to market surveillance authorities upon request.

\* « Proportionate to possible risks »

# CPSR Ch.II: Obligations of Manufacturers (2)

- **Consumer information, traceability and labelling requirements:**
  - Products to bear type, batch, serial no or other identification
  - Products to indicate name, registered tradename/trademark and single point of contact address (*except low risk products*)
  - Information must be provided on product itself or, if not possible on packaging or accompanying document
  - Products must be accompanied by instructions and safety information (except obvious products)
- **Post-marketing obligations:**
  - When reason to believe product on market is not safe or non-compliant, Immediately take corrective action necessary to make product compliant or withdraw/recall
  - When product is not safe, immediately inform market surveillance authorities of MS

# CPSR Ch.II: Obligations of Importers

- **Pre-market compliance check:**

- Verify product complies with general safety requirement
- Verify manufacturer has drawn technical documentation
- Verify manufacturer has identified and labeled product as required
- If importer has reason to believe product is not compliant, cannot place it on market until product is brought in conformity
- If importer has reason to believe product is also not safe, must inform manufacturer and market surveillance authorities of MS where importer is established

- **Additional labelling requirements:**

- Name, registered tradename/mark and address of Importer
- Accompanied by instructions and safety information

# CPSR Ch.II: Obligations of Importers (2)

- **General requirements:**

- Ensure storage and transport conditions do not jeopardise compliance with general safety requirement or traceability
- Conduct sample testing of marketed products, investigate and keep register of complaints, non-conforming products and product recalls, and keep manufacturer distributors informed
- Keep technical documentation and traceability records for 10 years

- **Post-marketing obligations:**

- When reason to believe product on market is not safe or non-compliant, Immediately take corrective action necessary to make product compliant or withdraw/recall
- When product is not safe, immediately inform market surveillance authorities of MS

# CPSR Ch.II: Obligations of Distributors

- **Pre-market compliance check:**

- Verify manufacturer and if applicable importer have identified and labeled product as required
- If reasons to believe product is not compliant or not safe, same obligation as importers

- **General requirements:**

- Act with due care in relation to requirements of the Regulation
- Meet general traceability requirement (*see later slide*)
- Ensure storage and transport conditions do not jeopardise compliance with general safety requirement nor traceability or labelling requirements

- **Post-marketing obligations:**

- When reason to believe product on market is not safe or non-compliant with traceability/labeling requirements, Immediately take corrective action
- When product is not safe, immediately inform manufacturer or importer and market surveillance authorities of MS

# CPSR Ch.II: General Traceability Requirements

- General obligation for all economic operators to be able to identify suppliers and customers (one step up, one step down)
- 10 year recordkeeping requirement
- Commission can adopt delegated act to require additional traceability requirements for products susceptible to bear serious risk to health and safety of persons:
  - Electronic data collection and storage identifying product and economic operator in supply chain
  - Placement of data carrier enabling access to data on product itself, packaging or accompanying documents
- Commission to take account of:
  - Cost-effectiveness and impact on businesses, particularly SME
  - Compatibility with international traceability systems



# CPSR Ch.II: Exemption from Notification

- Manufacturers, importers and distributors exempted from requirement to notify market surveillance authorities when the following conditions are fulfilled:
  - Only a limited number of well-identified products are not safe
  - The economic operator can demonstrate that the risk has been fully controlled and can no longer endanger health and safety of persons
  - The cause of the risk is such that knowledge does not represent useful information for the authorities or the public
- Commission has authority to adopt implementing acts to develop on situations meeting such (presumably cumulative) conditions
- Exemption not new, based on 2004 Commission guidelines for the notification of dangerous products

# CPSR : Other Provisions

## Chapter III: European Standards

- New Commission powers to request drafting of European standard from one or more European standardisation organisations, determine requirements and deadline for adoption
- Validity of standards based on publication in EU Official Journal

## Chapter IV: Final Provisions

- Penalties to be adopted by MS, must be effective, proportionate and dissuasive and take account of business size; can be increased for repeat offenders and include criminal sanctions for serious infringements
- Exhaustion of stocks: products covered by and compliant with GPSD already on market on day of application can continue to be made available

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# Proposed Market Surveillance Regulation

- Scope: Covers all products subject to harmonized legislation (including consumer products), with key exclusions
- Extended authority for Commission to supervise market surveillance operations
- Extended powers for market surveillance authorities
- Strengthening of rights for economic operators
- Provides framework for extended information exchange between MS and Commission, including RAPEX rules moved from GPSD
- Deletes Market Surveillance chapter from Regulation 765/2008 (Chapter III), which would now be dedicated solely to accreditation of conformity assessment bodies
- Increased emphasis on penalties

# Market Surveillance Regulation: Scope

- Covers all products subject to **harmonized legislation** (consumer and professional products), **if no specific provision with same objective**
- **Very broad framework** to verify compliance with requirements on health and safety (consumer, workplace) but also environment
- **Full exemption from scope:** EU legislation on official controls for e.g.:
  - Food and feed safety; GMOs in to the environment, Food contact materials
  - Plant reproductive material, plant protection products and pesticides
  - Organic production and labelling of organic products
  - Use and labelling of protected designations of origin, protected geographical indications and traditional specialities guaranteed
- **Partial exemptions** from more limited provisions for other products

# Market Surveillance Regulation: Key Definitions

- **Product:** product obtained through a manufacturing process
- **Product presenting a risk:** product having the potential to affect adversely health and safety of persons in general, health and safety in the workplace, consumer protection, the environment and public security as well as other public interests to a degree which goes beyond that considered reasonable and acceptable under the normal or reasonably foreseeable conditions of use of the product concerned, including the duration of use and, where applicable, its putting into service, installation and maintenance requirements
- **Product presenting a serious risk:** product presenting a risk requiring rapid intervention and follow-up, including cases where the effects may not be immediate

# MSR Chapter II: Market Surveillance Framework

- **Obligation on MS** to organize, finance and carry out market surveillance through authorities with objective of blocking/removing risky products from market:
  - List of authorities must be published
  - Activities must be coordinated with EU external border controls
  - Activities must be reported to Commission, and summary and contact info made available to public
  - Market Surveillance Programs must be drawn and reviewed at least every 4 years, sector-specific programs every year, and be made available to Commission, MS, and public
- Exempted: medicinal products, medical devices, substances of human origin

# MSR Chap. II: Market Surveillance Framework (2)

- **Obligation on Authorities to:**
  - Perform checks and record them in Information and Communication System for Market Surveillance (ICSMS)
  - Cooperate with economic operators to prevent/reduce risks and encourage **voluntary actions** and **codes of good practice**
  - Exercise their powers independently and impartially, **in accordance with principle of proportionality**
  - **Safeguard confidentiality** of information collected
- **Market Surveillance Authorities Powers:**
  - Enter premises
  - Take necessary samples of products
  - Request any documentation or traceability information
- **Commission power to adopt implementing acts** for uniform control conditions on known or emerging risks



# MSR Chap. III: Control of products within EU (1)

- Extended powers for market surveillance authorities :
  - General authority to enter premises, request any necessary info
  - Consider a product subject to harmonized (sector-specific) legislation may present a risk simply due to lack of CE marking, incomplete documentation, labeling or instruction; economic operators to rectify
  - Take all necessary measures to deal with confirmed risks. Information to be published on dedicated website
  - Charge fees to economic operators to cover costs
  - Exemption for medicinal products, medical devices, human origin
- Strengthening of rights for economic operators:
  - Right to be heard within at least 10 days before measures are taken by authorities (except where product presents **serious risk**); and
  - Right to receive detailed grounds from authorities on measures taken and remedies under national law, see measures lifted without delay when required action was taken

# MSR Chap. III: Control of products within EU (2)

- **Commission power** to take appropriate measures by implementing acts for products presenting a **serious risk** if risk cannot be contained satisfactorily by MS or other procedures under EU law
- **Risk assessments:**
  - Obligation for market surveillance authorities to conduct risk assessment when suspect a product may present a risk
  - Risk assessment must take into account (by order of priority)
    - Relevant requirements under harmonized legislation, test reports and certificates issued by conformity assessment body
    - Specific health and safety rules under national laws
    - European standards published in the Official Journal of the EU
  - Compliance with the above establishes reversible presumption of safety for aspects covered
  - Availability of products presenting a lesser risk not a reason to consider that a product presents a risk

# MSR Chap. IV: Control of Imports (1)

- Applies to all products if no specific provisions on border controls and cooperation b/n authorities under EU law
- EU external border authorities to carry out appropriate documentary checks and physical/laboratory checks before products are released for free circulation
- Formal non-compliance with EU harmonization legislation gives presumption of risk, simply based on the lack of CE marking, required documentation etc.
- Border control authorities may suspend release of a product that may present a risk (allowing for preservation of perishables if possible); they must
  - inform national market surveillance authorities
  - transmit information to border control authorities of MS of final destination

# MSR Chapter IV: Control of Imports (2)

## Release:

- Border control authorities must automatically release products within **3 working days** of suspension if have not been ordered by then by market surveillance authorities to continue suspension
- Market surveillance authorities can require economic operator to rectify formal non-compliance before release even if no risk

## Refusal to Release:

- If market surveillance authorities conclude the product presents a risk, instruct external boarder controls authorities not to release
- Both market surveillance and border control authorities may destroy product at operator's expense
- Refusal to release is subject to legal remedies
- COM to communicate refusal to release for products subject to RAPEX notifications, to which a MS can object

# MSR Chapter V: Exchange of Information (1)

- **RAPEX:** Regulation integrates all the provisions on market surveillance and RAPEX:
  - COM to adopt modalities and procedures for the exchange of information by means of implementing acts
  - Participation in RAPEX open to applicant countries, third countries or international organizations
  - Notification of products presenting a risk through RAPEX
  - Information to be notified include corrective measures, refusal to release, all available details related to the risk
  - Process for MS to object to measures taken for products subject to harmonized legislation, ruled by Commission
  - RAPEX notification does NOT apply when the effects of the risk do not go beyond one MS
- Exempted: medicinal products, medical devices, human origin

# MSR Chapter V: Exchange of Information (2)

- **ICSMS:** Officially establishes the Information and Communication System for Market Surveillance (ICSMS) to be maintained by the Commission
- Initially non-profit organization funded by MS, based in Germany, currently used by 11 MS and Switzerland
- Tool to collect information on:
  - Market surveillance authorities and their areas of competence
  - Market surveillance programs and activities
  - Complaints, reports about product risks, incl. test results
  - Measures based on non-compliance not notified under RAPEX
  - Objections raised by a MS to measures concerning a product subject to harmonized legislation (either under national operation or border control)

# MSR Chapter VI: Cooperation

- Principle of cooperation, mutual assistance and information exchange among different market surveillance authorities both at national and EU level, including possible cooperation with third countries
- Creation of European Market Surveillance Forum (EMSF), meeting of MS representatives at regular intervals, tool for consensus building and setting up of administrative cooperation groups for market surveillance, organization of joint market surveillance operations, or development on guidance on this Regulation
  - Organizations representing industry interests can be invited to participate as observers
- Commission authority to establish EU reference laboratories by way of implementing acts for categories of products or risks

# MSR : Other Provisions

- List of activities that can be financed by EU under MSR
- New provisions on enforcement:
  - MS to lay down penalties applicable to infringements of this Regulation and of any EU harmonization legislation if such legislation does not provide for penalties, take all measures necessary to ensure they are implemented
  - Penalties must be effective, proportionate and dissuasive, and take into account business size
  - Penalties can be increased for repeat offenders
  - Penalties can include criminal sanctions for serious infringements



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# Key Elements of the New Framework

- New provisions in directly applicable Regulations
- Remaining complexity of the legal framework, despite the intended simplification
- Need for each sector to review and assess applicability in light of status of EU harmonized legislation, intended use of products
- Consumer products:
  - New provisions (identification/traceability/GMP/Technical Documentation) applicable to all non-regulated consumer products
  - Country of origin requirement for all consumer products unless exempt from scope of Consumer Products Safety Regulation
- Market Surveillance:
  - Very large scope (work place, consumer protection, environment, etc.)
  - Specific provisions to control imports
  - Same market surveillance provisions for consumer and professional products

# Key Issues/Comments by Stakeholders

- Relationship CPSR/sector specific legislation
- Country of origin Labelling
- “Compliance” versus “safety”; Better definition of risk
- Third party testing and CE marking/certification
- Ensure practical level of enforcement by Member States; need for additional resources in addition to coordination
- Market surveillance to also cover ecodesign and energy labelling
- Additional information sharing: ICSMS data base; EU accidents and injury data base
- Stakeholders advisory board to the EMSF

# Timeline

- Publication of the package by the European Commission (13 February 2013)
- Lead Committee in the EP: IMCO Committee. Rapporteurs are:
  - Christel Schaldemose (S&D, DK) for the CPSR
  - Sirpa Pietikäinen (EPP, FI) for the MSR
- European Parliament hearing (29 May 2013)
- Rapporteurs draft reports: 11 June 2013
- INCO members amendments: 4 September 2013
- Vote INCO: October 2013
- Vote in Plenary expected in December 2013
- Adoption by April 2014
- Entry into force: 1 January 2015

# Product Safety: Advice to US Exporters

- Identify the rules applicable to your product with consideration of
  - consumer versus professional product
  - Subject to EU harmonized rules
  - Your role in the supply chain
- Monitor and possibly influence the ongoing revision
- Elaborate case studies for situations where things may go wrong (e.g. candidate list substance found above 0,1% threshold under REACH) and study possible consequences in terms of product safety and liabilities
- Elaborate crisis management manuals to prepare companies for situations where products on the EU market are found to present risk and/or are not in compliance

# New Legislative Framework: Scope per Product (1)

Products/ Activities	Consumer Product Safety	Market Surveillance
Food	Out of scope	Out of scope for all aspects covered by legislation on official controls on foodstuffs
Food Contact Materials	<b>Covered</b> for aspects other than chemical /biological risks	Out of scope for all aspects covered by legislation on official controls of foodstuffs
Medicinal products	Out of scope	Exempt from Chapters II, III, V, VI
Medical Devices	If consumer products; then subject to general safety requirement and indication of origin	Exempt from Chapters II, III, V, VI
Cosmetics	Subject to general safety requirement and indication of origin	Chapters I, II, III, V and VI (+IV if imports) apply to the extent not covered by sector specific legislation
Toys	Subject to general safety requirement and indication of origin	Chapters I, II, III, V and VI (+IV if imports) apply to the extent not covered by sector specific legislation

# New Legislative Framework: Scope per Product (2)

Products/ Activities	Consumer Product Safety	Market Surveillance
Electrical Appliances	Subject only to general safety requirement and indication of origin	Chapters I, II, III, V and VI (+IV if imports) apply to the extent not covered by specific provisions in sector specific legislation
Chemicals substances and mixtures subject to REACH	Out of scope, unless qualifies as consumer products	<b>Covered</b> (with limited exemptions under Articles 11 and 18 related to controls)
Plant protection products	Out of scope	Out of scope for what is covered by official controls of PPP
Biocides	Out of scope, unless qualifies as a consumer product	<b>Covered</b>
Machinery	Out of scope (not consumer products)	<b>Covered</b> (with limited exemptions for pressure equipment and simple pressure vessels)

# Comparison with US Framework: Market Surveillance of Consumer Products in the USA

- Federal Government
- State Government
- Industry Competitors
- Citizen Suits
- Self-Regulation



# USA: Federal Government Market Surveillance

- Federal government agencies vary in their methods and authorities for market surveillance of compliance
- Some agencies (e.g. NHTSA, CPSC) spot-check in the market by purchasing products randomly and testing them for compliance
  - These agencies can also conduct audits of manufacturers, either by inspection or written documentation reviews
- Some agencies (e.g. FDA) have a more European-style pre-market type approval process
- Some agencies (e.g. NHTSA, FDA) have incident reporting requirements

# USA: Federal Government Market Surveillance (Cont.)

- Federal Trade Commission (FTC) monitors and enforces false advertising claims and unfair competition claims
- All agencies can assess severe penalties for noncompliance with regulations

# USA: State Government

- State Attorneys General
  - Most states have “little FTC Acts” that authorize investigations and litigation against product manufacturers for false advertising or “unfair” trade practices
- State Consumer Protection Agencies
  - Some States in the U.S. have separate Consumer Protection Bureaus or Agencies; others enshrine this function within in the Attorney General’s office
- Some Federal Statutes (e.g. Consumer Product Safety Act) confer shared authority for safety regulatory enforcement with the State agencies

# USA: Industry Competitors

- **Lanham Act**

- Federal law authorizing competitors to sue a company for false advertising
- Has been used to challenge unsupported advertising claims and other forms of false advertising that are alleged to have harmed the plaintiff
- Does not authorize consumer lawsuits against product manufacturers
- Often a “cease and desist” letter citing the Lanham Act results in market corrections

# USA: Citizen Suits

- Some U.S. regulatory statutes authorize individual consumers to sue to enforce the regulations
  - More common in environmental sector
- These laws are the exception, not the rule
- Ordinarily, individual consumers have no legal standing to sue to enforce federal safety regulations

# USA: Self-Regulation

- Some U.S. regulatory statutes provide for self-certification of compliance by product manufacturers
- A variation of this regulatory model is self-certification upon receipt of confirmatory testing from a government-approved third-party laboratory
  - Children's products regulated by the U.S. CPSC
- This regulatory model permits a product manufacturer to bring a consumer product to market without needing to await government type approval

# Impact on Product Liability in the EU

- Directive 85/374/EEC of 25 July 1985 on liability for defective products (PLD)
- The PLD establishes a system of strict liability so that producers are liable and must compensate an affected individual for the damage caused by their defective products irrespective of any notion of fault
- Applies to all products, not only consumer products
- Covers damages caused by death and personal injuries, as well as damage to property if above 500 EUR
- Applies to producers, including importers and, when no producer can be identified, to suppliers/distributors
- Legislation implemented at member state level (eg Consumer Protection Act 1987 in England)

# When is the producer liable?

- When is a product defective? « When it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including the presentation of the product, reasonably expected uses, time of marketing »
- What must the affected individual do?
  - Prove damage (death, injury or property damage), a defect and a causal link
  - Seek remedy in Courts within 3 years from awareness of all required elements and 10 years from date the actual product was placed on the market
- Defences are limited (e.g. the « development risk defence ») so argument tends to focus on whether a defect exists or causal link



# Impact on Product Liability in the EU

- The Package has no direct impact on the framework within which individuals can seek redress for damage caused by defective products
- However, likely to be some indirect impact, eg:
  - availability of technical/design data for claimants;
  - availability of traceability data; and
  - possible increase in enforcement actions.
- Risks may vary between Member States as a result of differing litigation systems (particularly in relation to disclosure)

# View from Member State Level - UK

- Limited amount of commentary on Package from government
- Existing enforcement regime: primarily at local level with limited national co-ordination – leads to inconsistent approach within UK
- Although Package envisages greater co-operation between authorities in Member States, difficult to see how this will happen without increased resources and/or overhaul of existing structure
- Existing resources focused on major issues and ‘rogue traders’: again, unlikely to see material change without increased resources, either from national government or EU

# Agenda

- 3:00-3:20 Background – Rationale and Prospective for the Proposed Reform
- 3:20-3:45 The draft Consumer Product Safety Regulation (CPSR)
- 3:45-4:10 The draft Market Surveillance Regulation (MSR)
- 4:10-4:30 Key Issues and Impact on US Manufacturers
- 4:30- 5:00 Q&A and Conclusions**

Thank you for your attention!

