

# CONSUMER COMPACT

THE CONSUMER PRODUCT PUBLICATION THAT KEEPS YOU INFORMED

FEBRUARY • 2012

## THE **CHEMISTRY** BETWEEN CONSUMERS AND YOUR PRODUCTS



**EU TOY DIRECTIVE COUNTS DOWN TO CHEMICAL COMPLIANCE  
CONTAMINATED MEAT HITS CHINA, MEXICO AND SPORTS  
NANOMATERIALS REGULATION ON THE HORIZON**

**SGS**

# DEAR READER,

Consumer products manufacturing will be heavily influenced in 2012 by worldwide implementation of a range of regulations on the use of chemicals in consumer products. Producers as well as importers and retailers will have to assume more responsibilities and perform more actions to ensure the chemicals used in their products are safe for consumers and the environment.

The first 2012 edition of CONSUMER COMPACT brings you the latest updates on various chemical regulations, their implementation schedules and compliance requirements. Read a detailed analysis on the chemical restrictions included in the new toy regulations in North America and Europe and find out how to cope with the increasing number of requirements under REACH. Also in this issue, details about EUs plans for a nanomaterials regulation and the latest on green chemicals.

See the range of SGS services designed for consumer products at: [www.sgs.com/cts](http://www.sgs.com/cts)  
SGS Consumer Goods and Retail Marketing Team

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# REACH - IS IT BECOMING BEYOND YOURS?

REACH is based on the principle that industry is best placed to ensure that chemicals placed on the market (whether as chemicals or included in products) do not adversely affect human health or the environment. To do this, the industry must have knowledge of the properties and risks associated with the substances it places on the market.

## COMPLIANCE REQUESTED FROM ALL MARKET PLAYERS

For retailers who are importers of products from outside the EU, and as such are considered legally responsible for compliance for the products they import, this places specific additional requirements upon them. While those who are sourcing products from EU based importers have few legal obligations under REACH, the requirements of The General Product Safety Directive (GPSD) still apply to them, of which the requirement to place on the market products which are chemically safe is of paramount importance.

## HOW TO STAY ON TOP OF REACH REQUIREMENTS?

One of the major elements of the REACH regulation is the requirement to communicate information on chemicals up and down the supply chain. This ensures that manufacturers, importers and also their customers are aware of information relating to health and safety of the products supplied. For many retailers the obligation to provide information about substances in their products within 45 days of receipt of a request from a consumer is particularly challenging. Having detailed information on the substances present in their products will allow retailers to work with the manufacturing base to substitute or remove potentially harmful substances from products. The list of harmful substances is continuously growing and requires organisations to constantly monitor any announcements and additions to the REACH scope. This can be done on the [European Chemicals Agency's website](#).

By ensuring all actors in the supply chain understand their REACH requirements

the use of harmful chemicals in the EU will begin to reduce. It is estimated that REACH compliance will lead to the removal of 2-8% of the chemicals currently on the market, with some businesses choosing to remove specific chemicals because of the cost and complexity of REACH registration.

## CHALLENGES IN COMMUNICATING REACH PROGRESS

A number of Non-Governmental Organisations (NGOs) are also increasing the pressure on large, multi-national enterprises (MNEs) to reduce the use of toxic chemicals, using name and shame tactics. This will inevitably have a knock-on effect on small and medium enterprises (SME) and manufactures supplying MNEs.

The requirement for communication and the need to obtain such detailed information on chemicals means that legal importers must ensure their supply base understands and is carrying out their REACH obligations. This is leading to ongoing demands for information which many suppliers outside the EU are finding difficult to address whether because of a lack of regulation knowledge further down the supply chain or because of a lack of understanding of what is required. As a result some importers are requiring an on-site audit of every supplier or testing of every product to ensure compliance.

Whilst effective, this would be both impractical and economically unviable and would require frequent repetition to avoid changes in components and raw materials. Training of suppliers is also proving problematic given the complexity of regulations and the geographic spread.

One alternative is to tailor compliance efforts using a risk based approach



which itself requires an understanding of the products and the supply base. This can, on itself, provide an audit trail that would form part of a due diligence process.

## SOLUTIONS AT HAND

Self-assessment and declaration forms can be the basis of any such approach – but information gathered this way can be misleading, often because the supplier does not understand what information needs to be in their possession and to be communicated.

So how can an importer be confident of the accuracy of the information being supplied? SGS has developed a web based REACH supplier assessment and training tool which not only requires the supplier to report on the information and controls they have in place, but also provides on-line training to ensure that they have implemented appropriate controls and are retaining required records to support their answers.

For more information on SGS REACH solutions visit: [www.sgs.com/reach](http://www.sgs.com/reach)

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# CLENBUTEROL - CONTAMINATED MEAT HITS CHINA, MEXICO AND SPORTS

Clenbuterol, a fat-burning drug that is used as a feed additive in pigs and other animals, returned to the spotlight in recent months with a new ban in China, an outbreak in Mexico, and possible contamination from meat purchased in Spain that caused the temporary suspension of a world champion cyclist.



Used to produce leaner or higher muscle-to-fat ratio in meat products, Clenbuterol has been banned in meat in the U.S. since 1991 and in the EU since 1996 because of health concerns including increased heart rate, muscular tremors, headache, nausea, fever and chills. In most cases these symptoms are reversible.<sup>1</sup>

## IN CHINA

The government banned the production, use and sale of Clenbuterol tablets on September 30, 2011, in order to improve food safety.<sup>2</sup> The ban was announced shortly after the arrest of 989 people in a crackdown triggered by incidents of Clenbuterol-tainted pork that sickened hundreds of people in March 2011.<sup>3</sup>

<sup>1</sup> USDA FSIS Backgrounders on Clenbuterol

<sup>2</sup> China bans production, sale of clenbuterol to improve food safety

<sup>3</sup> Amid Scandal, China Bans More Food Additives

<sup>4</sup> Meat quality improves after China's crackdown on illegal additive

<sup>5</sup> What Is Clenbuterol?

<sup>6</sup> Soccer Players Blame Beef for Drug Positives

<sup>7</sup> Mexico Targets use of Clenbuterol in Livestock

<sup>8</sup> Contador must wait six to eight weeks for Cas doping verdict

<sup>9</sup> German lab shows inadvertent doping

<sup>10</sup> Basque officials insist their beef is clenbuterol-free

<sup>11</sup> Sheep feed tainted with clenbuterol

During the crackdown, 2.5 metric tons of Clenbuterol and 5.9 metric tons of meat containing Clenbuterol were confiscated. China's Ministry of Agriculture (MOA) subsequently reported that 99.3 percent of the meat products analyzed during the second quarter were free of the drug, indicating the success of the effort.<sup>4</sup>

## IN MEXICO

Here Clenbuterol has been banned in meat products for a number of years, the drug was found in the urine of 109 soccer players from multiple countries who were participating in the under-17 world soccer championship in June/July 2011. Clenbuterol is banned by the World Anti-Doping Agency, the International Olympic Committee and other sporting organizations because of its muscle-building properties,<sup>5</sup> but the athletes in the June incident as well as an earlier suspension of five Mexican players blamed Clenbuterol-tainted beef for the findings.<sup>6</sup>

Over the next several months, government inspectors in Mexico shut down 14 livestock markets where 99% of 6,421 meat samples tested positive for the drug. Previous enforcement of the ban had reduced the frequency of Clenbuterol contamination from 555 incidents in 2005 to 89 in 2010.<sup>7</sup>

## IN FRANCE

Clenbuterol hit the headlines in September 2010 when Spain's cycling hero Alberto Contador tested positive for the drug as he biked toward his third victory in the prestigious Tour de France race and was suspended from cycling pending investigation. He blamed the problem on a steak that his chef purchased from Spain. He was subsequently cleared by the Spanish cycling federation but the case was appealed to the Court of Arbitration for Sport with a decision expected in the first few weeks of 2012.<sup>8</sup>

Contador's defense was buttressed by a study by the German Sports University Lab in Cologne finding that humans can inadvertently ingest Clenbuterol from meat.<sup>9</sup> However, no traces of the drug were found in more than 19,000 animal samples tested in Spain between 2008 and 2009, and only one positive was found among 83,000 samples tested in the EU during the same period.<sup>10</sup>

## BACK IN CHINA

Concerns are now being raised that Clenbuterol contamination may not be limited to beef and pork. In October 2011, the government found that sheep feed in one province was found tainted with Clenbuterol.<sup>11</sup>

SGS laboratories can perform testing for Clenbuterol by various methods GC/MS, LC-MS/MS and ELISA methods at a level <1 part per billion (ppb) or lower.

For more details on SGS Food services visit: [www.sgs.com/foodsafety](http://www.sgs.com/foodsafety).

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# DEADLY LISTERIA OUTBREAK LINKED TO CONTAMINATED CANTALOUPE

In early September 2011, the US Food and Drug Administration and US Centers for Disease Control began investigating a multiple state outbreak of listeriosis in which cantaloupe was the suspected infection vehicle. Four outbreak strains of *Listeria monocytogenes* were found in 26 U.S. states, leading to 29 deaths and 33 additional illnesses. Settlements to the families may cost \$150 million.<sup>1</sup>

## SYMPTOMS DEVELOPMENT

The bacteria that causes *Listeria monocytogenes* produces varying symptoms depending on a person's risk factors. Generally listeriosis starts with diarrhea followed by fever and muscle aches similar to flu-like symptoms. Pregnant women will develop flu-like symptoms as well as endure side effects including miscarriage, stillbirth, premature delivery or a fatal infection of the newborn infant. Elderly people with compromised immune systems and young children may develop headache, stiff neck, mental confusion, loss of balance and convulsions that sometimes result in fatal meningitis or encephalitis. Most people do not remember the source of the infection because symptoms can occur between three days to two months after the infection occurs.<sup>2</sup>

## THE OUTBREAK TIME LINE

The Colorado Department of Public Health and Environment reported it had nine cases of listeriosis including two deaths on September 2, 2011 prompting the US Food and Drug Administration (FDA) and US Centers for Disease Control (CDC) to commence an urgent investigation of the multiple state outbreak in which cantaloupe was the suspected infection vehicle.<sup>3</sup>

On 10 September 2011 the US FDA and Colorado state officials visited Jensen Farms and collected multiple

samples. Of the 30 environmental swabs taken, 13 were confirmed positive for *Listeria monocytogenes* with pulsed-field electrophoresis (PFGE) pattern combinations that matched three of the four outbreak strains. Twelve of these swabs were from the processing line and one was from the packing area. Additionally cantaloupes from the firm's cold storage area were confirmed positive for *Listeria monocytogenes* with PFGE pattern combinations that matched two of the four outbreak strains.

Rocky Ford cantaloupes from Jensen Farms were recalled on September 14, while cut product from Carol's Cuts and Fruit Fresh Up (both of which purchased whole cantaloupes from Jensen Farms) were recalled on September 23 and October 6, respectively.

## HOW CONTAMINATION OCCURS

Evaluating the Jensen Farms operation, the US FDA identified factors that most likely caused the introduction, spread and growth of *Listeria monocytogenes* in the facility. The problem may have been introduced by low levels of *Listeria monocytogenes* in the field where the cantaloupe were grown or through contamination of the packing facility by a truck that hauled culled cantaloupes to a cattle operation. The bacteria may have been spread by water collecting near the machinery and employee walkways, hard-to-clean floors and/or machinery in the packing facility, or equipment previously used for other agricultural products. Bacteria growth may have been caused by condensation stemming from the lack of a pre-cooling step to remove field heat from the cantaloupe before cold storage.<sup>4</sup>



If the facility had followed non-binding recommendations for minimizing microbial food safety hazards in melons that were published by the US FDA in July 2009,<sup>5</sup> these problems might have been averted. Mandatory produce safety standards are scheduled to be promulgated under the Food Safety Modernization Act of 2010, providing new enforcement authorities for the US FDA.

SGS has testing labs throughout the world that can test for *Listeria monocytogenes*.

For more details on SGS Food Safety solutions visit: [www.sgs.com/foodsafety](http://www.sgs.com/foodsafety).

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<sup>1</sup> Listeria Cantaloupe Outbreak Could Cost \$150 million

<sup>2</sup> 2 More Deaths in Listeria/Cantaloupe Outbreak

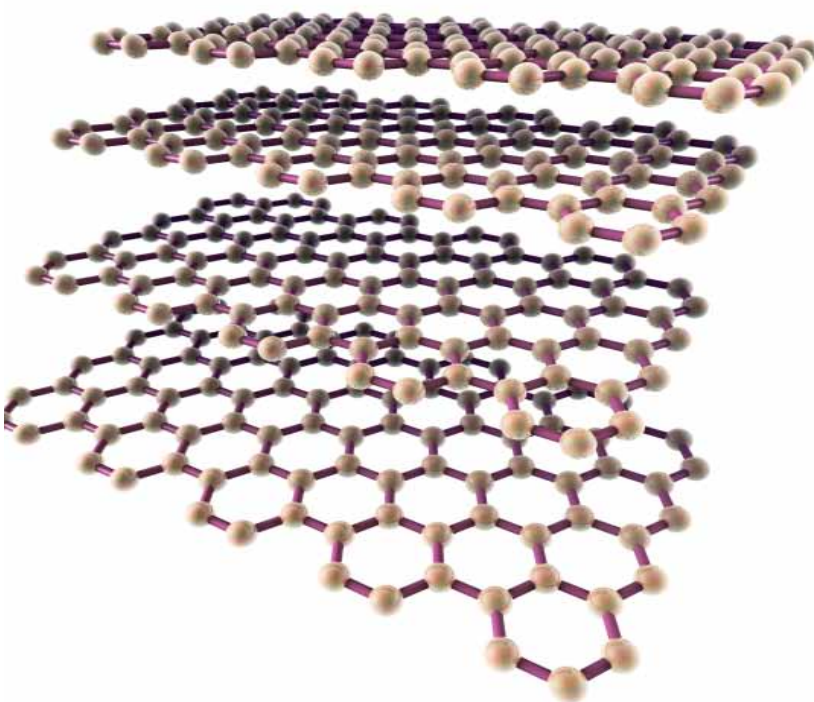
<sup>3</sup> Colorado Department of Health warns of Listeria outbreak

<sup>4</sup> US FDA Information on the Recalled Jensen Farms Whole Cantaloupes

<sup>5</sup> US FDA Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons:

# EU NANOMATERIALS REGULATION ON HORIZON

Consumer product regulations are set to change as EU publishes definition of nanomaterials, 2011/696/EU. On October 18, 2011 the European Commission (EC) adopted recommendation 2011/696/EU, providing for the first time a clear definition of nanomaterials, applicable to future legislation that may describe regulations for product labelling, testing and controls. It is anticipated that this definition will provide a basis for consistency across different areas of legislation that may be produced by the European Commission.



## HOW ARE NANOMATERIALS USED IN ELECTRICAL AND ELECTRONIC INDUSTRIES?

Nanomaterials are a key part of the emerging field of nanotechnology, which has a range of current and potential applications in both consumer electronics and a range of other industries. Nanomaterials, usually regarded as those with structural features around 1 - 100 nanometres in scale, have potential due to the unique physical, chemical and electrical qualities exhibited at the nanoscale. Within the electrical and

electronics (E&E) industry, nanomaterials and other nanotechnologies have shown application and promise in approving the efficiency of batteries, flash memory, processors, photovoltaics, lighting, displays for computers and mobile devices and in unique applications in medical sensors and interfaces. The value of the nanotechnology sector has continued to grow as a result of these developments.

## WHAT ARE THE RISKS RELATED TO NANOMATERIALS?

While the benefits of nanomaterials continue to be explored, relatively little is known about their risks. At present, there is no international

regulation of nanomaterials. What is known is that some of the properties that give nanotechnologies potential benefit also pose potential risks. Health effects include possible implications of easy absorption into tissues, organs, bloodstream, and possible permeation of blood-brain barrier.

Environmental concerns include permeation of NMs into soils, water cycle and airways. Some observers such as food industry body ELC have pointed out that nanoparticles are already abundant in nature and produced in inadvertently through a range of simple

## NANOMATERIALS DEFINITION

The EC Recommendation defines nanomaterials as follows:

"A natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm.

In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %. By derogation from the above, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials."

<sup>1</sup> ELC statement regarding the Commission Recommendation (2011/696/EU) on the definition of nanomaterial

and apparently benign mechanical processes, such as coffee grinding or wheat milling.<sup>1</sup> As such it might seem reasonable to expect that many nanomaterials will turn out to be of low risk.

Even with such reassurances, and while nanomaterials embedded in E&E products may be less likely to come into direct contact with consumers than in textiles or cosmetics, potential risk factors related to E&E use of nanomaterials are still demanding attention. For example, work is already underway from within the Environment Directorate of the OECD to determine means of dealing with nano-risk in battery disposal.<sup>2</sup>

While carbon nanotubes show promise in batteries, they have also been shown to cause low level DNA damage in some contexts. Furthermore, nanomaterials show promise in medical electronics, where more direct exposure to living tissue may be expected. Toy

manufacturers will likely also be among those needing to consider risk factors related to contact with or ingestion of nanomaterials that they may wish to employ in batteries, displays, coatings and other parts of their products.

#### **WHAT ARE THE REGULATORY IMPLICATIONS FOR E&E BUSINESSES?**

The actual regulatory implications of the EU's definition of nanomaterials remain to be seen. The EU definition is seen for now as being a tool for future legislation that may need to make reference to nanomaterials.<sup>3</sup>

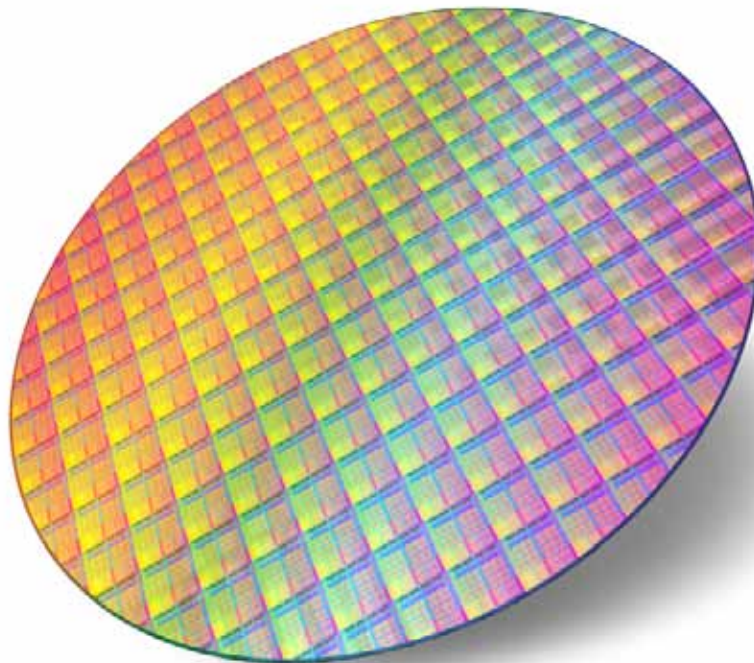
However, it is expected that Risk assessment and REACH implications will exist for all materials classified as nanomaterials. REACH guidelines will be presumably updated, referencing the EU definition of nanomaterials, and providing unique means of risk assessment for nanomaterials based on their unique properties. For now, E&E manufacturers

may need to wait to see what regulatory changes emerge.

A key concern raised about the EU's definition is the question of its scope, which some have argued may result in a range of products that have existed for many years being now classified as nanomaterials. These include some mineral pigments and fillers. Among those who have raised this concern are the German Federation of the Chemical Industry (VCI) and Cefic, the European Chemical Industry Council.<sup>4</sup>

For more information on nanomaterials and how the new EC definition of nanomaterials might affect your business, contact:

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<sup>2</sup> OECD: Nanomaterial Approaches to Enhance Lithium Ion Batteries

<sup>3</sup> Asser Institut: Commission adopted Nanomaterial Recommendation

<sup>4</sup> Getting the measure of nanomaterials

# CALIFORNIA GREEN CHEMISTRY INITIATIVE WILL IMPACT US CONSUMER PRODUCTS

Green chemistry is an approach intended to bring about a whole new way of thinking about production processes. Such an approach represents a major change – why deal with toxic chemicals at the end of the lifecycle when you can try to reduce or exclude them from the start of the production process? This is the sort of change the California Green Chemistry initiative is trying to bring about.

## US GREEN CHEMICALS INITIATIVES

There is no lack of green initiatives in the United States, in fact, there are several states where green chemistry is not only being reported as a requirement but it is also implemented as legislation. In the state of California (CA), the Green Chemistry Initiative is intended to make all consumer products safer. Green chemistry is defined by the California Department of Toxic Substances Control (DTSC) as the “innovation, design and manufacture of chemical products and processes intended to reduce or eliminate the creation and use of materials hazardous to human health and the environment.”

This applies for all products sold in California, including electrical and electronic (E&E) equipment. In fact, there are more than 100,000 toxic chemicals used in production today<sup>1</sup> and most of the electronic gadgets that we use contain these chemicals. The production of a laptop, for example, uses approximately 3200 litres of water and 160 litres of fossil fuels<sup>2</sup>, but the main toxic culprit is the complex chemical process that is used in the production of a silicon microcircuit.

## WHAT DOES THE INITIATIVE MEAN FOR MANUFACTURERS?

There is a big difference between managing chemicals at the end of a product's lifecycle and managing chemicals from the start of the product design phase. Green chemistry experts will explore several stages of the product's life: the manufacturing process, the consumption/usage process



and the disposal process, thus trying to eliminate dangerous chemicals from the start or replace them with benign chemicals. The challenge brought by the CA Green Chemistry initiative to manufacturers will be trying to find the right kind of substitutes that are less harmful than their predecessors.

Manufacturers will also need to provide a report to retailers, certifying that their products are free of Chemicals of Concern (CoC). If not, they need to prove that a research program is being undertaken to find safer alternatives for the CoCs used. If the use of the CoCs contained in the products is authorized by the relevant agencies, the manufacturers also need to present a waste management program to avoid any negative effects from the disposal of CoCs in the environment.

The initiative will translate into additional tasks for manufacturers, but if environmental and public health protection are not enough of an incentive to implement green chemistry measures, maybe the 'green' in green

chemistry will be. Green chemistry can amount to significant cost savings in the production and disposal process. By not using large amounts of hazardous chemicals in the production process there will be savings on the disposal and recycling end. In addition, sales will rise due to the increasing popularity of green products among the average consumer base.

SGS can support companies in achieving compliance with the California Green Chemistry initiative and with other green chemistry regulations through testing articles for CoCs, using a risk-based approach.

For more information on the complete range of SGS Restricted Substances Services visit: [www.sgs.com/rohs](http://www.sgs.com/rohs).

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<sup>1</sup> California Green Chemicals Initiative

<sup>2</sup> Based on calculations by Arizona State University



# FROM RECALL TO PREVENTION

Technical progress and more demanding customer requirements lead to higher complex solutions in the automotive industry. In combination with time, cost and market pressure greater risks for technical failures arise. In some cases, especially where safety-relevant components are affected, recall campaigns have to be triggered leading to extremely high costs and in many cases an accompanying loss of image.

## WARRANTY SITUATION IN THE AUTOMOTIVE INDUSTRY

With the exception of a short era during the economical crisis in 2009/2010, the number of recalls in the automotive industry is continuously increasing. As reported by Warranty Week magazine the 2010 warranty costs of the US-based automotive industry reached nearly USD 12 billion. The worldwide automotive warranties can be estimated as USD 40 billion per year which correlates to a loss in sales of 3 – 5 % in the OEM business.

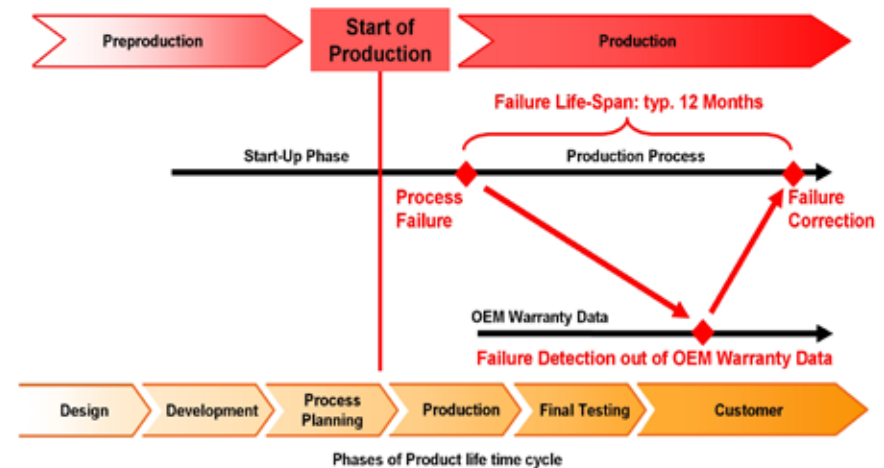
## POSSIBLE REASONS FOR RECALLS

The lack of technical interface definition as well as insufficient communication between OEMs and subcontractors are two of the major reasons for failures. This results in the usage of incompatible materials and chemicals as well as hard- and software problems.

Furthermore, the increasing amount of electronic components in modern high class vehicles leads to more complex environments especially when used in the engine compartment with high temperature as well as mechanical and chemical loads.

Higher cost and market pressure, shorter time to market, as well as low priced production leads to decreased product quality. The usage of identical components in several applications, trading of with having lower costs for development, carries the risk of having the same failure in different products. Outsourcing of qualified employees comes out with a lack of technical expertise and also a loss of knowledge concerning processes and techniques.

Stringent legal demands abet faster recalls as new product laws come into force. Not to be neglected is also the presence of world wide web, bringing



together car owners and lawyers from all over the world. Therefore, the reasons for recalls are various and their number is increasing more and more.

## THE TRADITIONAL FAILURE FORMATION IN AUTOMOTIVE INDUSTRY

The image above illustrates the traditional way of failure formation in the automotive industry.

With regard to the different phases of product life time most failures are introduced in the production phase. Within afterwards failure detection and its correction, usually a life span of 12 months can be expected, where products having the same failure are delivered to customer resulting in high recall costs, as weak points are identified late in the whole process. To prevent such a scenario it is important to have early failure analysis by means of R&D support in the start-up phase.

## GET THE BEST SUPPORT AVAILABLE

SGS has introduced a three-step model to support automotive customers in recall prevention. Based on our 20 years experience in failure analysis, in a first

step a technological failure mode and effects analysis (FMEA) of processes, materials and products is carried out to discuss potential weak points in a component from a theoretical point of view.

Against the background of the FMEA risk prioritisation the qualification procedure of the automotive part is discussed together with the customer in the next step. As an alternative to the traditional QA approach, new innovative aspects such as robust validation can be incorporated to identify the real operational limits.

As the last step, a detailed evaluation of the component and its essentials is carried out using various modern analytical techniques in failure analysis. This is done on pre-qualified parts as well as on new samples.

For more info on how SGS can support, take a look at our [Failure and Damage Analysis portfolio](#).

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# TOY SAFETY'S CHANGING CALENDAR

Ever since the Consumer Product Safety Improvement Act of 2008 (CPSIA) was signed into law, toy manufacturers have struggled to keep track of a complex timetable that has been complicated by stays of enforcement on specific provisions of the legislation. Deadlines continue to shift as the Consumer Product Safety Commission (CPSC) grapples with industry concerns, technical challenges and practical considerations such as a lack of adequate lab capacity for certain kinds of testing. Here is a partial checklist of recent enforcement activity, arranged by effective date, as a guide to U.S. compliance efforts.



## **100 PPM LEAD CONTENT IN SUBSTRATES: AUGUST 14, 2011**

On August 12, 2011, two days before the ceiling on lead content in substrates in children's products was due to be lowered to 100 ppm, President Obama signed a bill amending the law. One provision of the bill, H.R. 2715, stipulated that the 100 ppm limit would be applied only to goods manufactured on or after August 14, 2011 – not to finished products already made, in the supply chain and on store shelves as required under the CPSIA.

Products already manufactured, in transit, in warehouses and distribution centers, and in retail stores as of August 14, 2011 were allowed to sell through as long as they complied with the previous lead content limit of 300 ppm. This eliminated the need to remove older products from the supply chain, easing the burden on smaller manufacturers and retailers.

## **COMPONENT TESTING OPTION: DECEMBER 8, 2011**

To help spread testing costs across the supply chain, new CPSC guidelines that took effect on December 8, 2011, allow component parts such as zippers, buttons and blocks to be tested and certified by the component manufacturers themselves. This option – which is voluntary for component manufacturers - reduces expense for finished product manufacturers by eliminating the need to retest certified components under most circumstances. It also eliminates duplicate testing for components used in multiple products.

## **300 PPM LEAD CEILING FOR BICYCLES: DECEMBER 31, 2011**

Again under H.R. 2715, the stay of enforcement on lead content in bicycle parts expired on December 31, 2011. As of that date, any metal bicycle component must comply with a limit of 300 ppm total lead content. This is an

exception to the 100 ppm lead substrate limit on other products, providing some leniency for bicycle manufacturers. In addition, third-party testing is NOT required for metal bicycle components.

## **THIRD-PARTY TESTING FOR PHTHALATES: JANUARY 1, 2012**

On July 27, 2011, the CPSC voted to enforce third-party testing for the phthalates DBP, BBP, DEHP, DIDP, DINP and DNOP for toys and childcare products manufactured or imported after December 31, 2011. The decision lifted a stay of enforcement that had been in effect since January 2009.

Here again, however, H.R. 2715 softened the blow by specifying that testing can be limited to plasticized components that are reachable in normal use and abuse. Inaccessible plasticized components are exempt, as are non-plastic parts. The six affected chemicals – used primarily as plastic softeners – have been banned since February 2009.

**COMPREHENSIVE THIRD-PARTY TESTING:  
FEBRUARY 8, 2013**

On October 19, 2011, following the same nearly three-year stay of enforcement that had affected phthalate testing, the CPSC adopted final rules on CPSIA-mandated third-party testing and certification requirements not already covered by previous decisions addressing small parts, pacifiers, and lead in surface coatings and children's metal jewelry. These final rules will take effect on February 8, 2013.

The new rules include specifications for required third-party testing intervals (once a year or every two or three years depending on the manufacturer's own testing regimen); require continued periodic testing of children's products whenever a product's design or manufacturing process undergoes a "material change"; and provide other guidelines for complying with the CPSIA's independent testing requirement.

**REASONABLE TESTING PROGRAM: ON  
HOLD**

For non-children's products, the CPSIA mandated a "reasonable testing program" to ensure that products not being tested by independent third-party labs comply with all applicable safety rules. The CPSC issued proposed rules for this self-certification program in May 2010, but effectively tabled enforcement of those rules until further notice in its October 2011 vote on third-party testing requirements for children's products.

**SMALL BATCH MANUFACTURER TESTING:  
PENDING**

Relief may be in sight for small batch manufacturers for whom the CPSIA's third-party testing and certification requirements would be a major financial burden. H.R. 2715, the August 2011 bill amending the CPSIA, included a provision authorizing the CPSC to approve alternative testing requirements

or testing exemptions for manufacturers and importers with no more than \$1 million in annual gross revenue. Any alternative test mode or exemption would apply to products manufactured or imported in volumes of less than 7,500 units annually.

Since the bill was signed, the CPSC has held a public hearing and solicited public comments concerning the availability and economic feasibility of alternative testing options. As of this writing, the CPSC had not yet issued a ruling on the matter.

To find out more about how SGS can support toys manufacturers achieve compliance with global toys regulations visit: [www.sgs.com/toys](http://www.sgs.com/toys).

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# REACH GUIDANCE FOR TOYS

Toys manufactured, imported or sold within the EU are subject to complex chemical testing requirements. Consumer protection is paramount. As a manufacturer, importer or retailer it is your responsibility to make sure that the goods in your supply chain are compliant.



REACH – the European Union regulation concerning the Registration, Evaluation, Authorization and Restriction of Chemicals. It places responsibility on industry to manage the risks that chemicals may pose to public health and to the environment. It applies to all chemicals - not only those used in industrial processes but also those found in products which we use in our daily lives, including toys.

Setting up a REACH compliance programme will help guide you through the process.

## UNDERSTAND HOW REACH APPLIES TO TOYS

Toys can be classified as:

- Substance on its own e.g. chemistry sets
- Substance in a mixture e.g. slime, toy cosmetics, bubble solutions and inks in felt-tip pens

- Substance in an article e.g. teddy bears, toy bags, wooden blocks, bath toy sets, ride-on toys, inflatable toys and toy houses

It is essential to understand how REACH impacts your products. To achieve compliance you must first know the chemical composition of a toy and the quantities of each substance present. This will enable you to:

- Restrict the use of dangerous substances (REACH Annex XVII)
- Reduce the use of SVHC (Substances of Very High Concern)
- Communicate SVHC information through the supply chain

## WHEN THE QUANTITY OF A SVHC ON THE CANDIDATE LIST IS > 0.1% IN THE ARTICLE

If requested, EU companies are required to provide information on SVHC in

their articles to consumers within 45 days (free of charge). To obtain this information you should first check data from your suppliers. If the chemical composition data is not available you can obtain this information by conducting SVHC testing.

For each SVHC identified in a quantity greater than 0.1% you can also prepare a technical data sheet for your communications with consumers. This should include:

- Identification of the manufacturer/importer
- Identification of the substance (e.g. name, trade name)
- Manufacture and use of substance
- Classification and labelling
- Exposure and safe use information

## WHEN THE QUANTITY OF A SVHC ON THE CANDIDATE LIST IS > 0.1% AND > 1 TONNE PER YEAR

EU companies must notify a SVHC present on the Candidate List when the following conditions are met:

- The SVHC constitutes > 0.1% in the article AND
- The total quantity of the SVHC in the articles is > 1 tonne per year per manufacturer or importer

IMPORTANT: Notification is not required if the SVHC has already been registered for that use, or the risk of exposure to humans and the environment can be excluded.

In the event that you need to notify the SVHC you need to prepare an SVHC Notification Dossier. This should include:

- Identification of the producer/importer
- Registration number(s) if available
- Substance identification
- Substance classification

- A description of the substance's use in the article
- Tonnage range of the substance (e.g. 1-10 tonnes)

You should also arrange an assessment of the effect of exposure of each substance on human health and the environment.

#### IS SVHC AUTHORISATION REQUIRED?

EU producers who manufacture products containing an SVHC on the Authorisation List (REACH Annex XIV) must apply for the usage. Articles imported into the EU are not affected. Products containing SVHC on the Authorisation List can be placed on the market or used after the 'Sunset Date' only if authorisation has been granted for a specific use OR if the use is under exemption.

IMPORTANT: if authorisation is granted you must:

- Update the Safety Data Sheets (SDSs)
- Include the authorisation number on labels before placing substance or a mixture containing the substance on the market

SVHC testing can identify the presence and quantity of SVHC in your product. You should devise a substitution plan to identify safer alternatives to SVHC and check whether you can use substances that are non hazardous/more environmentally friendly while providing similar functions.

#### ASSESS COMPLIANCE WITH REACH ANNEX XVII (RESTRICTED SUBSTANCES)

Restricted substances testing can check REACH's Annex XVII requirements for toys and perform relevant tests for restricted substances. These may include:

- Phthalates
- Azo dyes
- Cadmium content and many more

#### ACHIEVE ONGOING COMPLIANCE

Whether you are a manufacturer, importer or retailer, it is essential to have a strategy in place that allows you to feel confident in achieving REACH SVHC compliance. SGS offers a comprehensive suite of services to help customers comply with their obligations under REACH, from initial REACH registration to consulting, testing, auditing and verification services to support ongoing compliance.

For further information, please contact [reach@sgs.com](mailto:reach@sgs.com) or your local SGS sales representative.

The substances in toys also come under the scope of the EU Toy Directive. To know more about new chemical requirements that will apply from 21st July 2013, see our article "[EU Toy Directive Counts Down to Chemicals Compliance](#)" p.14.

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# EU TOY DIRECTIVE COUNTS DOWN TO CHEMICALS COMPLIANCE

The clock has started ticking. Following implementation of the new EU Toy Safety Directive 2009/48/EC in July 2011, toy manufacturers and their supply chain must comply with the chemical requirements from July 2013. It is time to prepare your toys' substance data and conduct the requisite chemical assessment.

The EU Toy Safety Directive's chemical regulations will tighten regulation of any toy's chemical composition to protect against exposing consumers, especially children, to potential chemical hazards.

## WHAT IS A CHEMICAL HAZARD?

A chemical hazard is regarded as the adverse effect on human health due to exposure to chemical substances or mixtures of which the toys are composed or which they contain, during foreseeable use.

## WHAT ARE NEW CHEMICAL REQUIREMENTS UNDER NEW TOY DIRECTIVE?

- Substances classified as CMR (carcinogenic, mutagenic or toxic for reproduction) are banned from the accessible parts of a toy
- 19 restricted elements are subject to tighter migration limits and particularly toxic heavy metals like lead or mercury are not allowed
- 55 listed allergenic fragrances may not be used in toys. Technically unavoidable traces are allowed up to 100ppm. Another 11 allergenic fragrances must be declared if present in concentrations higher than 0.01% by weight
- Nitrosamines/Nitrosable substances may not be used in toys for children under 36 months or in toys intended to be placed in the mouth
- Toys shall comply with EU REACH (see "REACH Guidance for Toys" p.12)

Don't wait until 20 July 2013 – act now. 2012 is the time to set the ball rolling and ensure that your products are ready in good time. The assessment process starts in the supply chain with data gathering.

## BOM, BOS & SDS

The EU Toy Directive requires you to produce a Bill of Materials (BOM), Bill of Substance (BOS) for each product and Safety Data Sheet (SDS) for each chemical so far as relevant for assessment. The first step for manufacturers is to acquire chemical composition data from suppliers. Alternatively chemical testing can identify the presence and quantity of chemicals in products.

All substances in the BOS must be evaluated and found:

- Not to exceed concentration and/or migration limits in applicable legislation/standards
- Not to present an inherent hazard (if the defined user can be exposed to them)

No change can be made to the BOM or BOS unless the new material/substance has been assessed and approved.

## CHEMICAL SAFETY ASSESSMENT: SCOPE

Products manufactured for sale within the EU, from 20 July 2011, have required a chemical safety assessment to meet the EU Toy Safety Directive but that assessment must meet a wider remit.

The assessment must cover not only prohibited or restricted substances, but also other chemical hazards. These may be hazards posed by substances not presently prohibited/restricted but commonly known as undesirable in toys because of their inherent risks to human health.

## UPDATING YOUR ASSESSMENT

A successful chemical safety assessment is valid for as long as the toy remains unaltered. Changes to its

design, raw materials, additives, or paints may affect its safety and present new hazards. In these circumstances the safety assessment must be renewed.

Equally, the following events may also impact on a toy's suitability and safety, therefore requiring an updated chemical safety assessment:

- Changes in legislation or standards
- New scientific information on a specific substance becomes available
- Consumer complaints suggest that a toy presents a risk
- Recalls are made of similar toys after a risk assessment

If these factors do not change there is no need to renew the safety assessment. Instead, focus your energies on production control.

Stay ahead of regulatory changes and be sure that your toys comply with the new requirements. As the world's leading inspection, verification, testing and certification company our toy laboratories are internationally recognized by major industry associations and accreditation bodies. In addition our toy labs are strategically located in key manufacturing zones and transit points worldwide. Take advantage of our technical expertise and global experience in toy safety regulations and ensure that your products meet the new requirements of the new toy directive.

For help with any questions, you can visit [www.sgs.com/toys](http://www.sgs.com/toys) and email us at [consumer.products@sgs.com](mailto:consumer.products@sgs.com).

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# WHEN WEST MEETS WEST - CHEMICAL SAFETY AWARENESS GROWS FOR APPAREL AND FOOTWEAR

Starting with the 60s, European governments began establishing new regulations and directives to control or restrict the use of certain dangerous chemicals in textiles and clothing. From the first azo dye rules to the present day REACH regulation, there is now a long list of harmful chemicals that have been regulated and controlled for textile products in the EU. Many European companies have had their own Restricted Substance Lists (RSL) for years, to help control chemicals in their supply chain. In the last decades in North America, on the other hand, there haven't been many mandatory regulations controlling harmful chemicals used in textile products. With more global brands and increasing awareness of consumer product safety, the topic is now getting hotter here as well.

## USA IS GETTING ALERTED

Proposition 65, a California law, known as the Safe Drinking Water and Toxic Enforcement Act, was enacted in 1986. Currently over 850 chemicals listed that are considered causing cancer, birth defects, etc. are now taken as the reference to identify dangerous chemicals that are to be prohibited.

The Consumer Product Safety Improvement Act (CPSIA) of 2008 was implemented on 14 August 2009. The Act reauthorized the Consumer Product Safety Commission (CPSC) for 2010-2014 and expands the Commission's role in ensuring the safety of consumer products. Joining the party are California's Green Chemistry law, the Washington State Law on Chemicals in Children's products and the proposed laws in Maine and Minnesota.

## U.S., CANADA AND MEXICO TO STRENGTHEN CONSUMER PRODUCT SAFETY ACROSS NORTH AMERICA

Following the US CPSIA, the Canadian government announced a new regulation (Canada Consumer Product Safety Act) restricting the use of lead and phthalates in children's products. This regulation became effective in June 2011.

On September 26th and 27th, the First North America Consumer Product Safety Summit was held at the CPSC Headquarters in Bethesda, MD. Representatives from the consumer

product safety agencies of NAFTA members, the United States, Canada, and Mexico met to discuss how to promote and strengthen cooperation and engagement in ensuring the safety of products made and sold across the region.

The US Consumer Product Safety Commission (US CPSC), the Mexican Federal Consumer Protection Agency (Profeco), and Health Canada have reached an understanding on actions needed to strengthen their trilateral cooperation, in a spirit of cooperation, respect for sovereignty and the limits of domestic laws, and concern for the safety of consumers.

According to the summit's joint statement the Consumer Product Safety Commission, Health Canada and the Consumer Protection Federal Agency of Mexico (Profeco) agreed on a cooperative engagement framework that will allow technical staff to engage bilaterally or trilaterally during the next two years in six areas:

- Consultation on proposed regulations and voluntary standards
- Co-operation on risk assessment
- Co-operation on import and market surveillance
- Co-operation on training and outreach within and outside North America
- Co-ordinate consumer awareness campaigns



- Consultation on potential joint recalls or other corrective actions

Mexico and Canada share major land borders with the United States and products made in North America, or imported from outside NAFTA territories, may easily find their way into each other's jurisdictions. We can easily trace a trend for the all of North America to get together for harmonization of consumer products safety regulation.

For more information on SGS market access services for footwear and apparel visit: [www.sgs.com/softlines](http://www.sgs.com/softlines).

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# SGS IN THE NEWS



## AUTOMOTIVE

- New SGS Lab in Chakan, Pune (India) Secures Daimler Approval and IEC ISO 17025 Accreditation - [read article](#)

## ELECTRICAL & ELECTRONICS

- SGS Launches Webinar on RoHS2 in November 2011 - [read article](#)
- SGS Hong Kong Becomes FCC DOC Conformity Assessment Body - [read article](#)

## FOOD

- SGS acquires Consolidated Laboratory (M) Sdn Bhd and Labservice (M) Sdn Bhd, Malaysia - [read article](#)
- SGS Acquires MSM, MRL, Özel Hatay and Sanilab in Turkey - [read article](#)

## HARDGOODS, TOYS & JUVENILE PRODUCTS

- CPSC Chairman Inez Tenenbaum Visits Fairfield Lab to Review New Juvenile Products Capabilities - [read article](#)
- Efficacy Testing of Skin Care Cosmetics / Claim Support at SGS Germany - [read article](#)
- Consolidation of Laboratories in Taunusstein (Germany): Increase Efficiency, Utilising Synergies - [read article](#)

## SOFTLINES

- Enhance Textile Testing Network - New SGS Laboratory in Jakarta, Indonesia - [read article](#)

## SUSTAINABILITY

- SGS Unveils Comprehensive Global Product Carbon Footprint Mark Program - [read article](#)



# SGS EVENTS JANUARY - MARCH 2012

For more events, please check the [online events calendar](#).

EVENT	COUNTRY	LOCATION	DATES	INDUSTRY	TRADE SHOW / CONFERENCE	BOOTH NO. IF ANY	CONTACT PERSON
HKTDC Hong Kong Toys & Games Fair 2012	Hong Kong	Hong Kong Convention and Exhibition Centre	Jan. 9 - Jan. 12	Toys and Juvenile Products	Trade Show	Hall 3 - Booth 3D - C38, C40	<a href="mailto:hk.hardlines.events@sgs.com">hk.hardlines.events@sgs.com</a>
Circuit Board Symposium Nuremberg 2012	Germany	Nuremberg, Maritim Hotel	Jan. 24	Electrical & Electronics (E&E)	Conference	N/A	<a href="mailto:ines.alte@sgs.com">ines.alte@sgs.com</a>
European Food Manufacturing and Safety Summit	Netherlands	Noordwijk, Grand Hotel Huis Ter Duin	Jan. 30 - Jan. 31	Food	Conference / Trade Show	Booth No. 15	<a href="mailto:jennifer.buckley@sgs.com">jennifer.buckley@sgs.com</a>
International Toy Fair Nuremberg	Germany	Nürnberg Exhibition Center	Feb. 1 - Feb. 6	Toys	Trade Show	Hall 11.1, Booth No.: G-04, F-03	<a href="mailto:stephanie.pionchon@sgs.com">stephanie.pionchon@sgs.com</a>
Car Symposium 2012	Germany	Bochum, Congress Center	Feb. 8 - Feb. 9	Electrical & Electronics (E&E)	Conference / Workshop	N/A	<a href="mailto:ines.alte@sgs.com">ines.alte@sgs.com</a>
New York Toy Fair	USA	New York Javits Center	Feb. 12 - Feb. 15	Toys	Trade Show	Booth No. 1320	<a href="mailto:richard.postman@sgs.com">richard.postman@sgs.com</a>
Global Food Safety Conference 2012	USA	Orlando (FL), Hyatt Regency Grand Cypress	Feb. 15 - Feb. 17	Food	Conference / Trade Show	Booth No. 24	<a href="mailto:jennifer.buckley@sgs.com">jennifer.buckley@sgs.com</a>
Automotive Testing Expo 2012	India	Chennai, Trade Centre	Mar. 6 - Mar. 8	Auto	Trade Show	Booth No. 5012	<a href="mailto:swati.tyagi@sgs.com">swati.tyagi@sgs.com</a>
Australian Toy, Hobby & Nursery Fair	Australia	Melbourne Convention and Exhibition Centre	Mar. 6 - Mar. 9	Toys	Trade Show	TBC	<a href="mailto:brent.crooks@sgs.com">brent.crooks@sgs.com</a>
International Boston Seafood Show	USA	Boston (MA), Convention & Exhibition Center	Mar. 11 - Mar. 13	Food	Trade Show	Booth No. 286	<a href="mailto:jennifer.buckley@sgs.com">jennifer.buckley@sgs.com</a>

## PRODUCT RECALLS

SGS compiles recall cases notified in the EU, US and Australia for consumer goods. They can help you minimize costly recalls by increasing your awareness of recall cases related to your business. SGS Product Recalls is now offered for no charge, and is included twice per month in the SGS SafeGuards publication.

Browse the Product Recalls library: [www.sgs.com/productrecalls](http://www.sgs.com/productrecalls)  
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# SAFEGUARDS

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## CONSUMER PRODUCTS

- ASTM Publishes Standard Method for Children's Jewelry - [read the bulletin](#)
- Canada Announces Plans to Assess Nine Groups of Substances - [read the bulletin](#)
- Revision of EN ISO 5912 Camping Tents - [read the bulletin](#)
- New ICC Rules on Combating Corruption - [read the bulletin](#)
- China Amended the Regulations on the Control over Safety of Hazardous Chemicals - [read the bulletin](#)

## AUTOMOTIVE

- Roll-Out for New Automotive Functional Safety Standard ISO 26262 - [read the bulletin](#)

## ELECTRICAL & ELECTRONICS

- EMC - New Emissions Standards for Residential, Commercial and Industrial Environments - [read the bulletin](#)
- Two New PAHs to Be Added to GS Mark Substance List - [read the bulletin](#)
- New RoHS Exemptions for Lead and Cadmium - [read the bulletin](#)

## FOOD

- European Commission approves Sweetener Stevia and improves Transparency for Additives - [read the bulletin](#)
- US FDA Steps Up Review of Fish Species Identification - [read the bulletin](#)
- EU Commission Updates Regulation of PAH in Food Stuffs - [read the bulletin](#)

## HARDGOODS, TOYS & JUVENILE PRODUCTS

- CPSC warns of Safety Risks Persist with High-Powered Magnets - [read the bulletin](#)
- EN71-8-2011 Now Harmonised under the New Toy Directive - [read the bulletin](#)
- EU Proposal to amend Food Contact Plastics Regulation (EU) 10/2011 - [read the bulletin](#)
- ASTM publishes F963:2011 revised U.S. Toy Safety Standard - [read the bulletin](#)

## SOFTLINES

- Denmark Raises Concern about Chromium VI Compounds in Leather Articles - [read the bulletin](#)
- AAFA Publishes Release 9 of the Restricted Substance List - [read the bulletin](#)
- Elimination of Nonylphenol Ethoxylates in the Textile Industry - [read the bulletin](#)



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