Stericycle® ExpertSOLUTIONS™

Q2 2015
European Recall & Notification Index

RESPONSIBILITY ROLE CALL

Responsibility Role Call: Are You Doing Your Part to Keep Consumers Safe?

In the complicated global supply chain all stakeholders — manufacturers, suppliers, distributors, regulators, and even consumers — must take ownership of ensuring product safety.

In the complicated global supply chain all stakeholders — manufacturers, suppliers, distributors, regulators, and even consumers — must take ownership of ensuring product safety. Recent industry events have shown that discrepancies in product classification requirements can put both a manufacturer's brand and consumers' health at risk, making it critical that all parties work together. This collaboration is especially critical given the significant product safety issues that are prevalent throughout the European Union. According to RAPEX data, the number of safety notifications and recalls has been on an overall upward trend since 2003. These events were divided into three categories based upon risk level, with a surprising 88 per cent of recalls and notifications classified in the most serious threat category.

The Stericycle European Recall and Notification Index examines the product safety ecosystem in greater detail, and helps identify the roles stakeholders play in promoting better safety practices. Ultimately, every party bears some responsibility for product safety. In our ever-changing environment with emerging technologies, new regulations, and country-specific requirements, the question becomes: Are you doing your part to keep consumers safe?

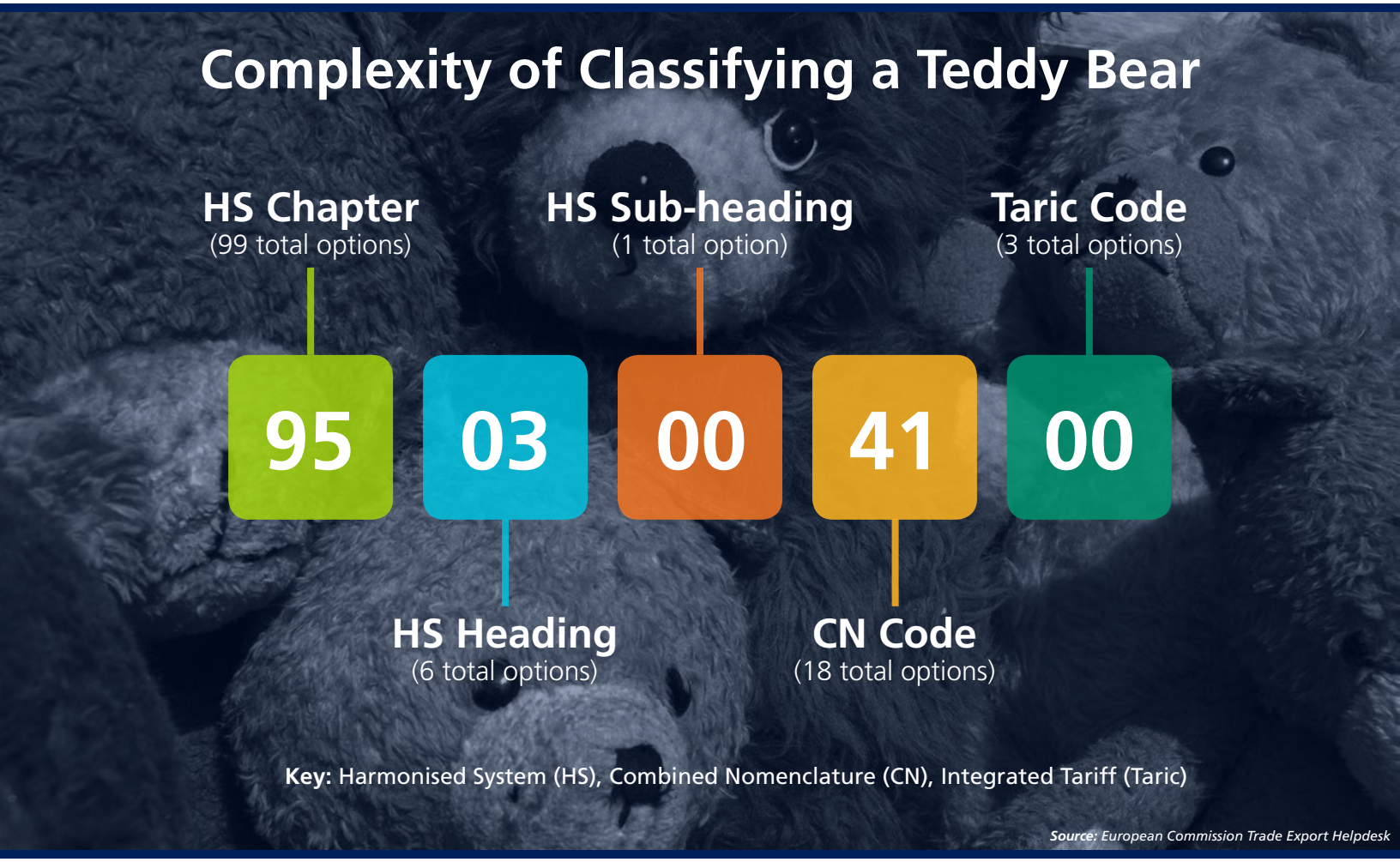
88% *of recalls and notifications since 2003 have been classified at the highest level threat, according to RAPEX data*

Classification Conundrum

In today's complex regulatory environment, product classification is an important component of product safety. Varying regulations govern different product categories, so even if a product passes all safety standards in one industry, it might not be considered safe in another.

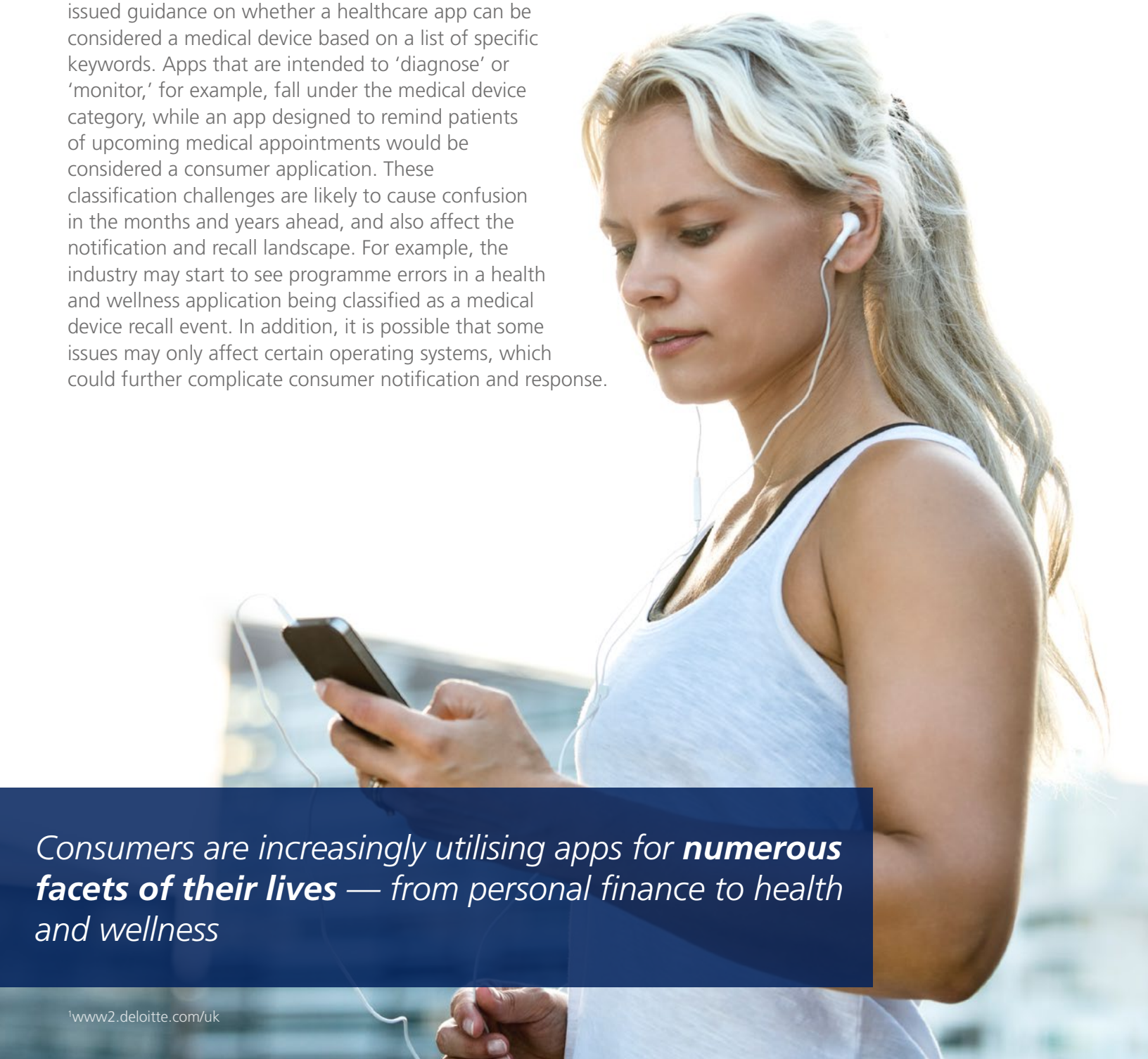
An unfortunate example of this phenomenon occurred in England last year when a child's Halloween costume caught fire and seriously injured an eight-year-old girl. The costume, classified as a toy, passed all the necessary safety standards for the product category and was legal for sale in the UK and Europe. However, by classifying the costume as a toy rather than clothing, the product did not require the same level of flammability testing. In the months following the incident, many safety advocacy groups expressed outrage at this legal loophole, putting increased pressure on manufacturers to reconsider their product classifications.

However, costume manufacturers are not the only companies affected by differing safety criteria. Companies across all industry sectors are faced with this same challenge and are grappling with how to handle it. The Halloween costume incident had a significant impact and remains an important reminder of the need for cohesive safety standards across product categories.



Challenges from product classification complexities can also be found in the mobile applications sector. Consumers are increasingly utilising apps for numerous facets of their lives — from personal finance to health and wellness. The health and wellness category in particular illustrates responsibilities app developers must bear to ensure the safe use of their product. According to a recent report from the Deloitte Centre for Health Solutions, there are currently more than 100,000 medical apps available in the UK app store and 70 per cent of the population owns a smartphone[1].

With technologies that remind consumers to take critical medications or monitor life-threatening conditions, health-related mobile apps have the potential to revolutionise how people approach health and wellness. As consumers become more reliant upon these technologies, it is incumbent upon developers and manufacturers to educate themselves on the regulations governing them. The Medicines and Healthcare Products Regulatory Agency (MHRA), the body responsible for governing medical devices in the UK, and the European Commission have both issued guidance on whether a healthcare app can be considered a medical device based on a list of specific keywords. Apps that are intended to 'diagnose' or 'monitor,' for example, fall under the medical device category, while an app designed to remind patients of upcoming medical appointments would be considered a consumer application. These classification challenges are likely to cause confusion in the months and years ahead, and also affect the notification and recall landscape. For example, the industry may start to see programme errors in a health and wellness application being classified as a medical device recall event. In addition, it is possible that some issues may only affect certain operating systems, which could further complicate consumer notification and response.



*Consumers are increasingly utilising apps for **numerous facets of their lives** — from personal finance to health and wellness*

[1]www2.deloitte.com/uk

The Manufacturing Scramble

While all stakeholders play a critical role in ensuring product safety, none is arguably more important than that of the manufacturer.

The global economy complicates this even further for manufacturers in the EU. For example, current regulations require that the letters 'CE' — an abbreviation of the French phrase 'Conformité Européene' — appear on many products as an indicator of compliance with safety legislation. It falls to the manufacturer to ensure that the CE marking is placed on all required products, however, there is no single EU enforcement agency overseeing compliance with the CE legislation. Rather, it is the responsibility of member countries to interpret and enforce the regulations in accordance with national laws and procedures.

Allowed Products & Ingredients Comparison

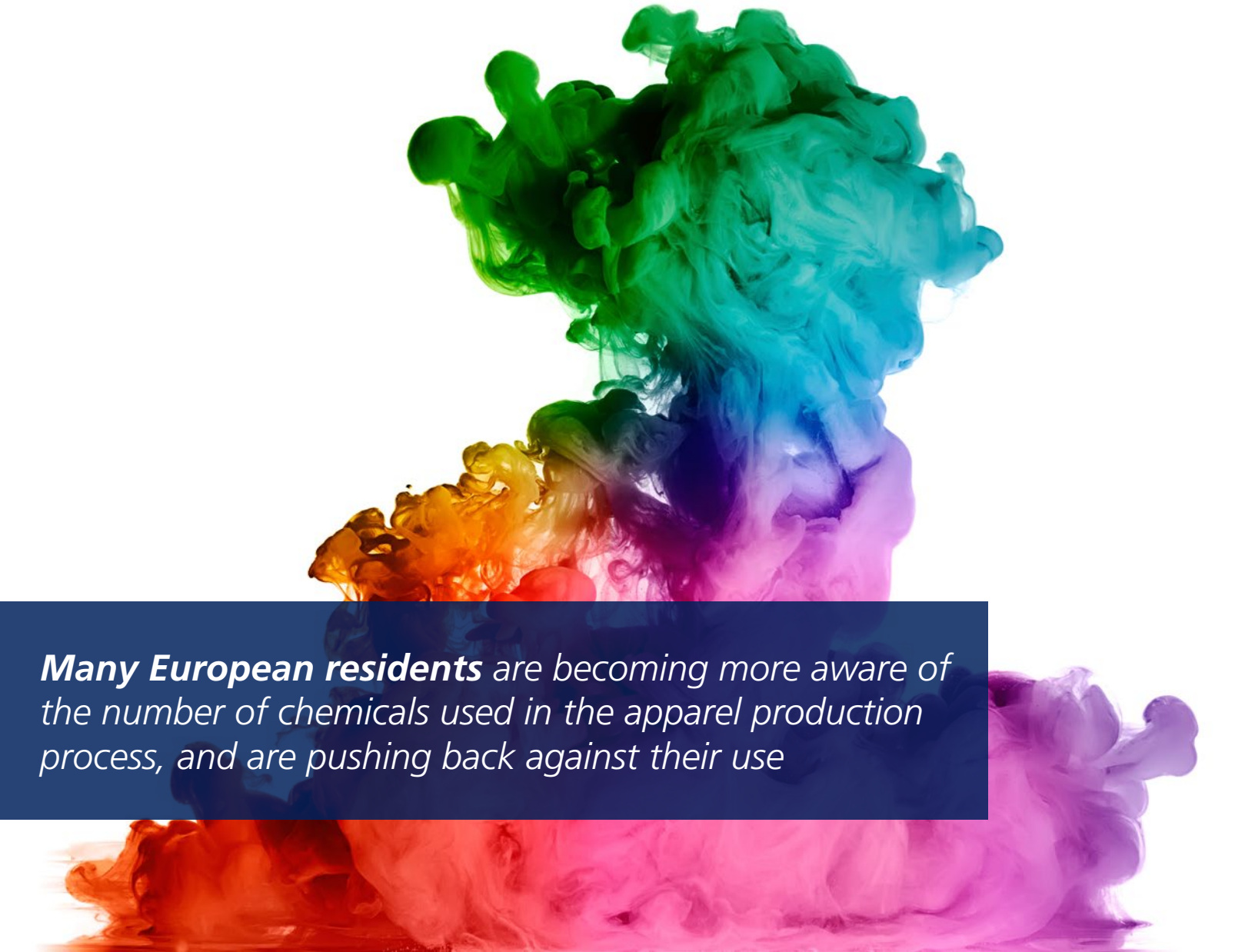
Product / Ingredients	UK	US	Rest of World
Arsenic	No	Yes	No
Atrazine	No	Yes	No
Azodicarbonamide	No	Yes	No
Butylated Hydroxyanisole (Bha)	No	Yes	No
Formaldehyde	Limited	Yes	Limited
Methyl Cellosolve	No	Yes	No
Neonicotinoid	Limited	Yes	Limited
Parabens	Limited	Yes	Limited
Petroleum Distillates	No	Yes	No
Potassium Bromate	No	Yes	No
Red Dye No. 40	No	Yes	Yes
Yellow Dye No. 5	No	Yes	Yes
Yellow Dye No. 6	No	Yes	Yes

Large disparity in allowed ingredients across countries and continents

Source: *Newsmax & Ensia*

This and other differing regulations can cause challenges for manufacturers, a prime example of which can be found in the clothing industry. The EU restricts a large number of chemicals in production, as outlined in the REACH regulations, which were established to protect consumers and the environment from the risks associated with chemical substances. However, many dye restrictions vary between countries. This area is likely to become even more complicated as consumer awareness and preference for environmentally safe products increases. Many European residents are becoming more aware of the number of chemicals used in the apparel production process, including fertilisers and pesticides, dyes and other toxic chemicals, and are pushing back against their use. As a result, some manufacturers are reassessing their supply chain and production processes and are starting to use more organic fibers and natural/low-impact dyes.

Manufacturers in the food and beverage industry also are struggling with recall challenges and regulatory variances. Late in 2014, an alcoholic drink was recalled in some European markets for containing what regulators deemed an unsafe level of Propylene glycol — a chemical found in antifreeze. In the U.S., where the drink is made, the Food and Drug Administration (FDA) considers Propylene glycol to be a GRAS substance, which stands for "generally recognised as safe." However, stricter EU guidelines on Propylene glycol have forced state-owned retailers to pull the drink from shelves in Sweden and Finland.



***Many European residents** are becoming more aware of the number of chemicals used in the apparel production process, and are pushing back against their use*

Regulatory Reaction

The regulatory environment for product safety is in a continual state of flux as regulators and lawmakers look to simplify the process and develop a more streamlined set of rules.

Currently, the European Parliament and the Council of the EU are reviewing a new package of legislative and non-legislative measures proposed by the European Commission to improve product safety and strengthen market surveillance. The goal is to make it easier to remove dangerous products, align surveillance and consumer safety rules, define clear responsibilities for each stakeholder, and foster an environment of greater collaboration.

Goals of New Legislation

More Safety for Consumers

Less Burden for Businesses

More Collaboration Among Authorities

While this package is under review, the Commission has the power to force member states to ban and/or recall products posing a serious safety risk from the market in the form of emergency measures. This temporary enforcement, generally for a period of up to one year, is an attempt to impose a uniform safety standard throughout the EU in situations where regulations lag behind the reality of how consumers are using products. Often emergency measures are used in situations where children are at high risk and, in some cases, these measures are extended further into more permanent legislation. This was the situation in 2008 with a ban of novelty lighters that resembled toys. Emergency measures were also used to set standard safety requirements for blind cords/corded window coverings following concerns about strangulation and internal asphyxiation to children.

Emergency measures are an effective means for fostering an environment of better safety practices. However, given their temporary nature, it's critical that all regulators come together and enact permanent policies in order to provide clarity to the marketplace.

Consumer Watchdog

The role that consumers play in product safety cannot be overlooked. RAPEX, the Rapid Alert System established by the European Commission, was created to be a public platform to disseminate product risk alerts to consumers.

Consumers can use this information to stay informed of the latest product safety notifications and recalls. It is also important that manufacturers encourage consumers to engage in on-going dialogue and notify them of any issues they are experiencing with products. In some cases, this vigilance might be the impetus for a recall. This was the situation in May 2015 when complaints stemming from the EU about mold in a bottle led to a pharmaceutical drug recall. The recall affected 77,000 units and spread to the UK and ten additional EU countries.

In the past, recall communication was restricted to traditional methods including phone calls, mailings, and in person notifications. Today, social media offers an increasingly popular channel for consumers to communicate directly with companies. According to a study conducted by the Institute of Customer Service, the number of consumer complaints made via social channels in the UK has increased *eight times* since January 2014[2]. Additionally, one in four social media users complained about a brand in the first quarter of 2015 on Twitter, Facebook, or another social channel.

***39%** of consumers say they regularly provide feedback online to companies about their products*

The Institute of Customer Service

While consumer complaints certainly provide important information for companies to evaluate whether a recall is necessary, valuable intelligence can also be gleaned from social conversations containing less negative sentiment. Thirty-nine per cent of consumers in the Institute of Customer Service survey say they regularly provide feedback online to companies about their products. Engaging in open conversations with consumers enables organisations to better understand their customers, how they are using the product, and can help them identify potential product problems before they become large-scale issues.

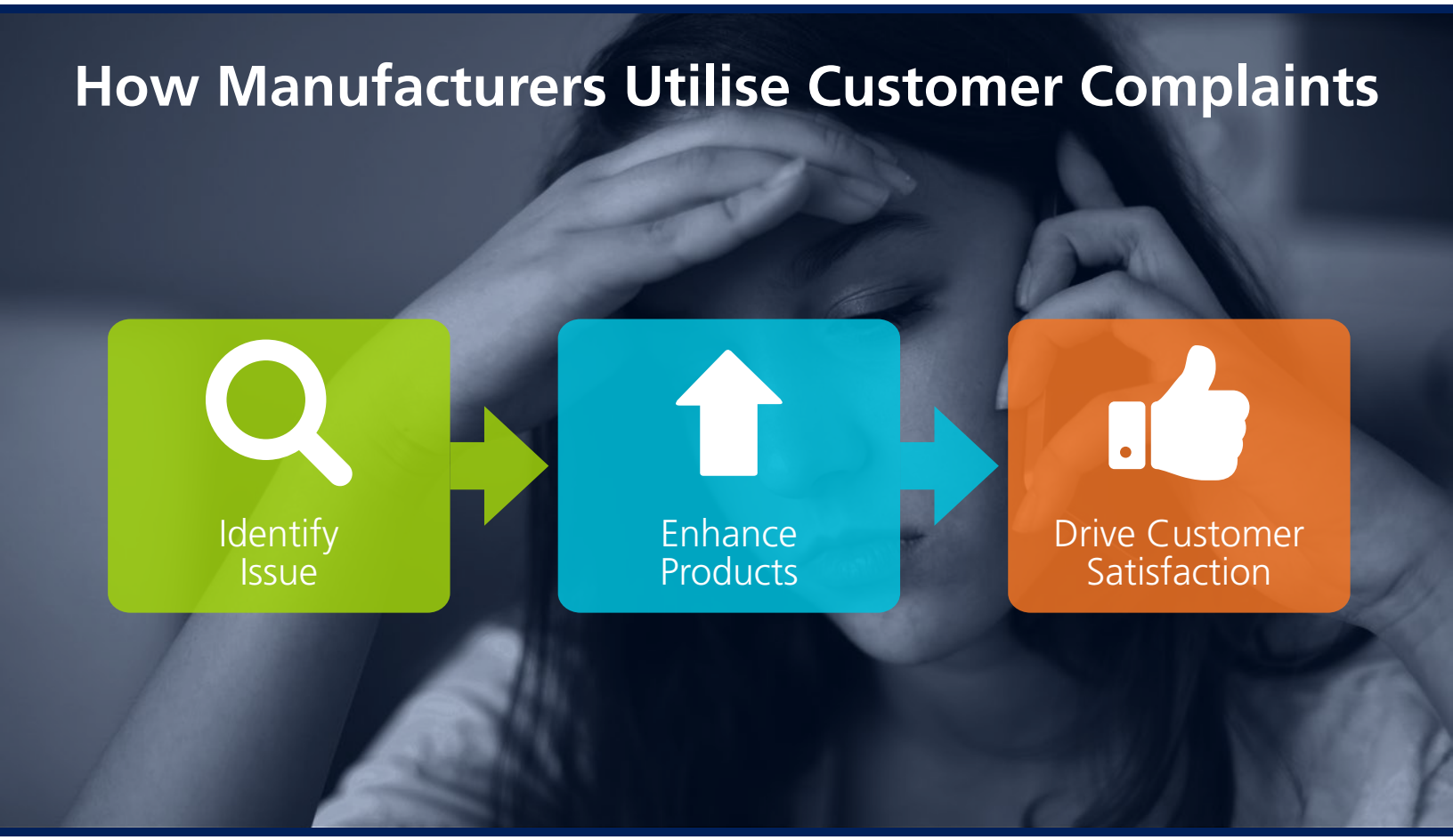
[2]www.theguardian.com

The Social Domain

While it used to be enough to release a statement and notify the media to make consumers aware of a recall, companies are now being driven by the public to leverage social media as a complimentary method for keeping consumers up-to-date.

Several studies have found that companies who use social media to communicate with customers about recalls can decrease negative sentiment. On the other hand, the viral nature of social channels can quickly create headaches for manufacturers if they are caught unprepared when a recall occurs. Negative reviews can be shared in real-time on social media, elevating a single consumers' experience or perception into a national, or, in some cases, global stage. Fortunately, several studies have found that companies who use social media to communicate with customers can actually decrease negative sentiments throughout the customer experience[3][4].

In this environment, social media is a valuable platform that fosters open and transparent communication between stakeholders. Additionally, social channels allow companies to respond immediately to consumer comments and reach a broader audience. Leveraging social media to respond to potential product safety concerns can help to mitigate unsubstantiated claims and protect the company's brand.



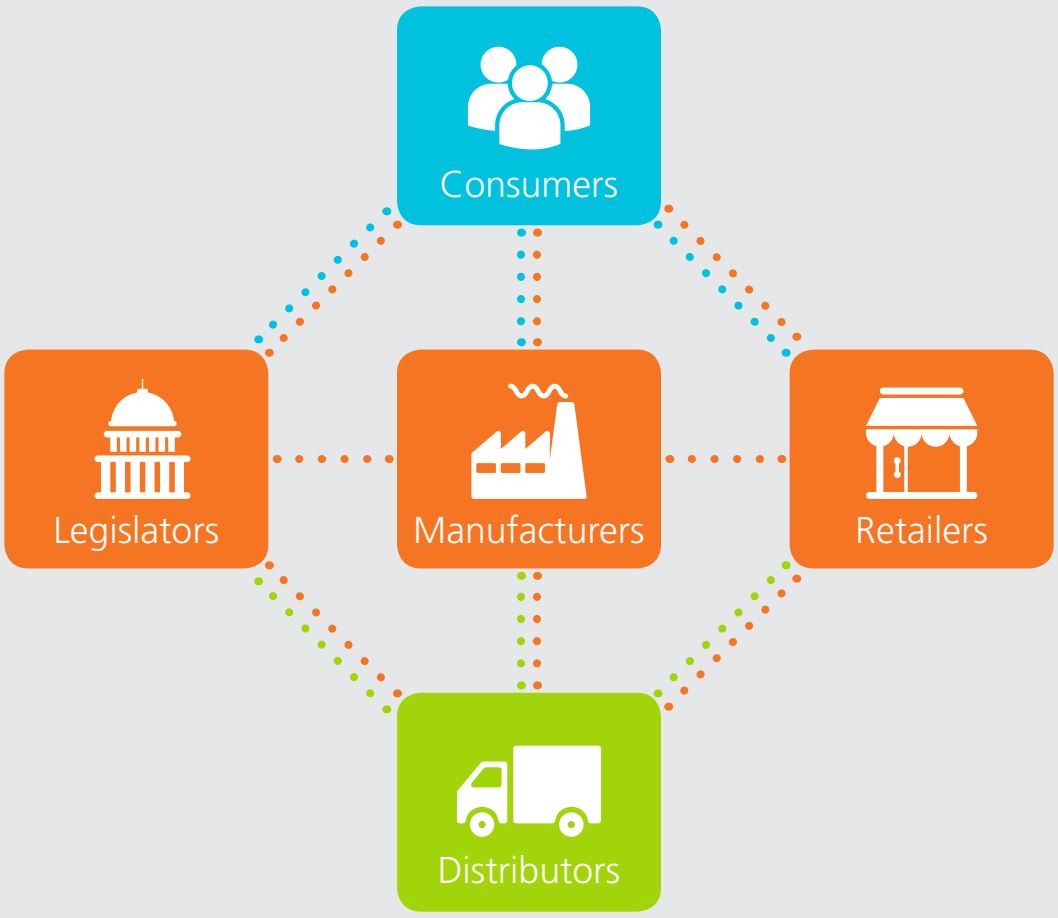
[3]www.chicagobooth.com
[4]www.prsa.org

Team Work

The product safety ecosystem in the EU is a complex patchwork of rules and regulations. With complicated global supply chains, confusing product classification rules across regions, and increasing consumer demand for product transparency, manufacturers are being challenged to meet a host of requirements before bringing their product to market.

To do this effectively and ensure product safety, manufacturers must work more closely than ever with suppliers, distributors, regulators, and customers. Given the temporary enforcement period of up to one year, emergency measures present a unique opportunity for stakeholders. Those who choose to utilise this time effectively can gain alignment on the best approach for protecting consumers and the future of their brand. Additionally, when a product safety issue leads to a recall situation, stakeholders can leverage outside consultants to foster collaboration amongst all parties and help ensure safe, effective, and compliant recall execution.

Complex Stakeholder Network



The Recall & Notification Scorecard, Q2 2015

1,158
TOTAL RECALLS & NOTIFICATIONS

⬇ 7% from Q1 2015

of Recalls by Country of Origin

China	India	Turkey	France	Spain
324	76	63	46	46

Food Notifications

There were 773 food recalls and notifications in Q2 2015, including food, feed, and food contact material. This equates to an increase of two per cent from the prior quarter. The top three categories for food recalls were fruits and vegetables, nuts, nut products and seeds, and fish. These categories comprised over 50 per cent of the Q2 food recalls.

Italy was the leading notifying country with 100 events followed by the UK with 89 recalls. France (72 recalls), the Netherlands (71 recalls) and Belgium (45 recalls) rounded out the list of top notifying countries for Q2.

773
TOTAL FOOD RECALLS & NOTIFICATIONS
Including Food, Feed & Food Contact Material

⬆ 2% from Q1 2015

of Food Subcategory Recalls by Notifying Country

Italy	UK	France	Netherlands	Belgium
100	89	72	71	45

Does not include feed & food contact material recalls

Top 5 Food Recall & Notification Categories

20%	20%	11%	9%	6%
Fruits & Vegetables	Nuts, Nut Products & Seeds	Fish & Fish Products	Poultry Meat & Poultry Meat Products	Meat & Meat Products (Other Than Poultry)

Consumer Goods Notifications

The consumer goods industry experienced 329 recalls and notifications in Q2, a 22 per cent drop from Q1. This drop is largely attributed to a seasonal high in Q1 2015, which typically occurs after the holiday season. Once again the top consumer goods category was toys, which contributed to 27 per cent of the quarter's activity. However, the number of toy recalls for the quarter was the lowest since Q3 2012. Additionally, Spain led the list of notifying countries in Q2 with 53 recalls, followed by Hungary, Germany, France, and the UK.

329
TOTAL CONSUMER RECALLS & NOTIFICATIONS
22% from Q1 2015

of Consumer Recalls by Notifying Country

Spain	Hungary	Germany	France	UK
53	28	27	26	24

Top 5 Consumer Recall & Notification Categories

27% Toys

16% Clothing, Textiles & Fashion

11% Electrical Appliances & Equipment

6% Childcare Articles & Children's Equipment

5% Chemical Products

Automotive Notifications

There were 56 automotive recalls and notifications in Q2, a drop of 19 per cent from the first three months of the year. This was the first quarter with a decrease in motor vehicle recalls since Q1 2014. In keeping with prior quarters, cars were the leading recall type with 34 events. Motorbikes contributed to 12 recalls while vans, LCVs and buses were behind with 10 events. There were no recalls due to tyres or other items in Q2.

56
TOTAL AUTO RECALLS & NOTIFICATIONS
19% from Q1 2015

of Auto Recalls by Type

Cars	Motorbikes	Vans, LCVs, Buses, etc.	Other Items, Inc. Tyres
34	12	10	0

Stericycle ExpertSOLUTIONS & the European Recall & Notification Index Explained

Stericycle ExpertSOLUTIONS is a global leader in product recalls, retrievals, returns, audits and sustainability services. ExpertSOLUTIONS offers bespoke solutions for a wide range of industries that are designed to aid companies in protecting and enhancing their brands.

The Compilation of the European Recall & Notification Index

The European Recall and Notification Index gathers and tracks cumulative data from the primary European agencies that track recall notifications in the region. This data is segmented into multiple definitions of notifications and alerts, but collated into a central figure for the purpose of analysis. The data used for this report is current as of August 2015.

RAPEX

Rapid alert system for the exchange of information on measures taken to prevent or restrict the marketing of dangerous consumer products with the exception of food, pharmaceutical and medical devices, which are covered by other mechanisms.

RASFF

The RASFF provides food and feed control authorities with an effective tool to exchange information about measures taken responding to serious risks detected in relation to food or feed. The Rapid Alert System for Food and Feed tracks all food and drink recalls.

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