



Chemicals safety in the value chain

How the European chemical industry manages safe use of chemicals

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Introduction



The chemical industry has a long and proven track record of ensuring the safe use and handling of its products, up and down the value chain. Thanks to these efforts, accidents in the production, distribution, use and disposal of chemicals are rare. And, since safety is of paramount importance to our industry, we are constantly looking to improve upon our achievements to date.

Intended for authorities, interested stakeholders and an informed public, this publication aims to describe what the industry has been doing, is doing and will continue to do to ensure its products are handled and used safely at every step.

We are fully aware of societal concerns about risks from certain new and existing chemical substances, sometimes calling for special precautionary measures. These are legitimate concerns the chemical industry needs to address. So we would also like in this publication to focus on the public debate surrounding substances of concern, nanomaterials, endocrine disruptors, combination effects or legacy chemicals. And to explain what industry is doing to ensure robust science is applied when uncertainties are identified.

Based on a life cycle approach, the development of products is subject to regulatory control at every stage. Additional voluntary initiatives from industry are also detailed. These include care for employee programmes and improvement in production processes to enhance safety, health and the environment. The value chain is also the subject of particular attention, starting with distributors and encompassing customers and end users as well as the disposal and recycling of products.

The European chemical industry is well regulated, with the EU legal framework for chemicals recognised as one of the most advanced worldwide, encompassing safety of workers, information sharing with classification and labelling, registration and evaluation of chemicals through REACH. In addition, product safety legislation focusing on the most critical products, like food or cosmetics, provides another level of protection where appropriate.

We believe continuous dialogue and transparency should drive our societal choices for improving chemicals safety.

How companies address chemicals safety



Integrated product safety starts at the research and development stage, and covers the sourcing of raw materials as well as their use in all subsequent processes. All chemicals produced must be transported, used and managed safely, including their end-of-life.

We carry out these activities with our industrial partners, such as distributors, and producers of consumer goods. Employees, trade unions and the relevant authorities also contribute to our efforts, helping raise awareness in preventing accidents and answering public concerns.

Risk assessment based on hazard and exposure data is at the core of safety management, whether in the research laboratory, on the production site or outside it. Results of risk assessments and risk management measures, ensuring that chemicals are safe for intended use, are communicated through safety data sheets and factsheets. Europe's REACH legislation – covering the Registration, Evaluation, Authorisation and Restriction of Chemicals – sets the highest standards worldwide in terms of chemicals safety.

Voluntary efforts complement and frequently go beyond regulation in search for safer and more sustainable products and processes. Industry's Responsible Care initiative, launched in Europe over 20 years ago, fostered the product-specific programme known as the Global Product Strategy (GPS). The Long-range Research Initiative (LRI) leads to increased knowledge and better testing, enhancing our understanding of complex issues like nanomaterials or endocrine disruptors. This approach facilitates the decision process about how to handle chemicals safely.

RESPONSIBLE CARE

helps companies to improve their safety, security, health and environmental performance, to be open and engage with stakeholders. It plays a significant role in industry's drive for sustainability and includes products as well as industrial processes.

In 2006 the United Nations Environment Programme (UNEP) adopted the Strategic Approach to International Chemicals Management (SAICM) to promote safe chemicals management around the world. Our industry launched the Responsible Care Global Charter and the Global Product Strategy (GPS) with the aim that by 2020, industry will have established and communicated hazard and exposure information adequate to conduct safety assessments for chemicals in commerce.

LONG-RANGE RESEARCH INITIATIVE (LRI)

Exposure science is one major research area. Industry's investment is leveraged through collaborations with publicly-funded projects that maximise project value. The results are published and shared freely with stakeholders. Since 2005, the LRI has sponsored annual workshops on current issues in risk sciences and chemicals management.

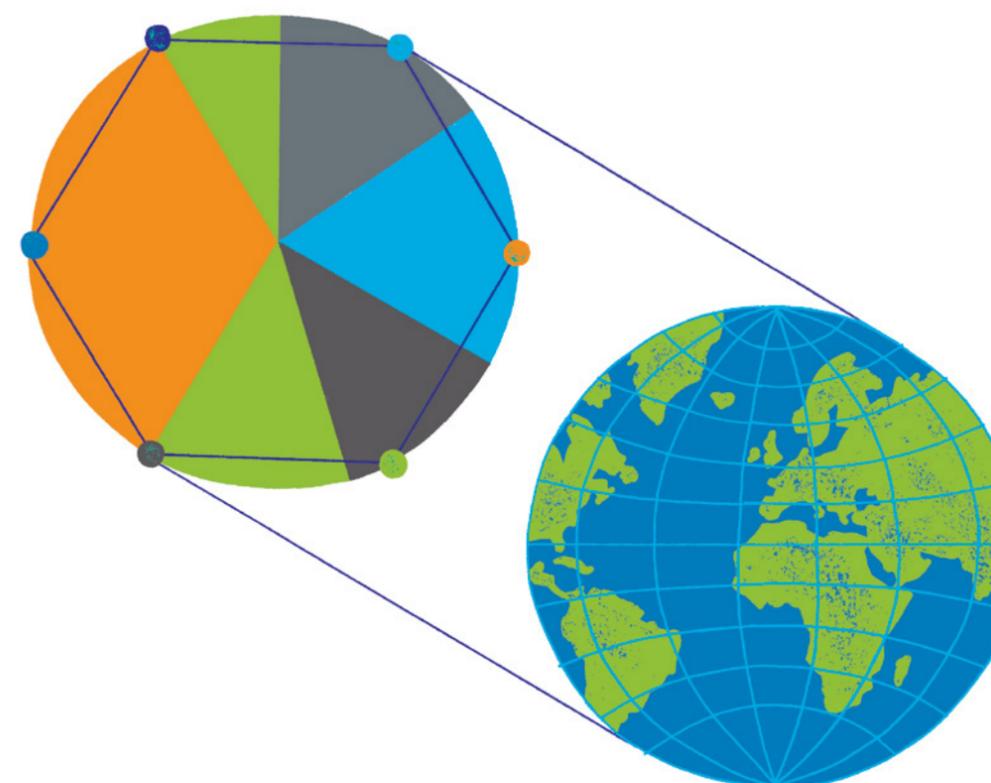
We are conscious of the need to improve Responsible Care harmonisation and uptake throughout Europe. This is particularly the case with the small and medium enterprises (SME) community but encompasses the total value chain. Cefic's network of companies, associations and partners has an ongoing programme of activities to pursue these goals. Likewise, we focus efforts on improving GPS visibility and ensuring that activities complement those undertaken by other obligations.

The following chapters offer readers insights into the many elements involved in integrated product safety: a combination of company level and sector-specific programmes, embedded in national and European regulation.

Our intended audiences – interested stakeholders and the informed public – seek more detail on what the European chemical industry does to keep people and the environment safe. We hope you find this publication informative and would appreciate receiving your feedback.

KEY PRINCIPLES OF REACH

- Ensures a high level of protection of human health and the environment
- Enables free movement of substances in the internal market
- Makes industry responsible for managing chemical risk and providing information to users
- Promotes alternative test methods to animal testing
- Enhances competitiveness and innovation



The basics of chemicals safety



Central to all our chemicals management programmes are the understanding and communication of one key topic: the relationship between hazard, exposure and risk. It is a topic which has developed into a wider societal debate, sometimes involving confusing jargon and misleading information.

Companies need to know the hazard properties of raw materials and the chemicals they produce or handle in order to manage them safely at all stages of the value chain. Once hazard data are available, companies address exposure based on the uses of a product. Knowing about the hazards and exposure enables a risk assessment to determine how the chemical can be safely used.

Key points include:

- In discussions about chemicals, the words 'risk' and 'hazard' are often used incorrectly, as if interchangeable.
- A **HAZARD** describes the way in which an object or a situation may cause harm. A **RISK** defines the chance that the hazardous effect will actually occur.
- For a risk to materialise there must be both the hazard and **EXPOSURE** leading to an adverse effect. Without both at the same time, there is no risk.
- The degree of risk is defined by the extent to which the recipient is exposed to the hazard.
- Risk can be high or negligible, depending on the likelihood that harm will occur. Risks are all around us in our daily lives: we make judgments, consciously or not, about the hazards involved and assess the risks before taking action whether at home, crossing the road, taking a plane or driving.
- Even if a chemical has hazardous properties, the risk to human health or the environment will be negligible, provided *the chemical is handled safely under controlled conditions*.
- Risk assessment is an important management tool to determine how and in what circumstances a chemical can be used safely.

What about the Precautionary Principle?

Cefic strongly supports the European Commission's Communication on the precautionary principle of February 2000, which sets out some requirements that are essential to the application of that principle.

"According to the Commission, the precautionary principle may be invoked when a phenomenon, product or process may have a dangerous effect, identified by a scientific and objective evaluation, if this evaluation does not allow the risk to be determined with sufficient certainty."

The Commission stresses that the precautionary principle may only be invoked in the event of a potential risk and that it can never justify arbitrary decisions.

PRELIMINARY CONDITIONS FOR APPLYING PRECAUTION

- Identification of potentially adverse effects
- Evaluation of the scientific data available
- The extent of scientific uncertainty

FIVE PRINCIPLES TO BE TAKEN INTO ACCOUNT

- Proportionality
- Non-discrimination
- Consistency
- Cost/benefit of action or inaction
- Review measure

Safety at every stage



Products are designed, developed or modified both to meet customer needs and to ensure they are safe during production and intended use. When developing new products, companies identify potential issues at different stages of the production, use, and disposal of substances or formulations. Products on the market are constantly tested, not only by manufacturers but also, for example, by independent scientists, authorities and consumer associations. When significant new information on hazard or risk becomes available, companies assess it, adapting safety recommendations accordingly or substituting the product.

CARING FOR OUR EMPLOYEES

Sourcing and Research & Development

Raw materials – the substances used in a chemical production process for modification or transformation – come from fossil-based materials, renewable raw materials and inorganic minerals.

In line with our drive towards sustainability, companies use a life cycle assessment (LCA) to determine the optimal sourcing strategy in relation to raw materials. Additionally, as LCAs do not assess safety, we assess risk separately.

Research and development contribute to increased knowledge and adaptation of testing requirements, with safety starting at a very early stage of the R&D process and continuing throughout the whole life cycle. High standards for safe working practices in the laboratory help set the bar for all stages of the product lifecycle. As noted by one leading chemical company, 'analysing the hazards and mitigating the risks are part of designing an experiment. Safety is part of the scientific method.'

Whether sourced in Europe or imported, all companies must ensure that relevant data on a substance are available with details of properties, including hazard information. Suppliers usually provide supplementary data that will be useful to customers, in addition to the information required by law.

«TOGETHER FOR SUSTAINABILITY»

In order to enhance sustainability within their global supply chains, six multinational chemical companies joined forces in the Together for Sustainability (TfS) initiative. Open in the future to other firms and organizations all over the world, the TfS initiative successfully concluded its first year of piloting supplier sustainability assessments and audits in 2013. TfS aims at developing and implementing a global supplier engagement programme that assesses and improves sustainability sourcing practices, including ecological and social aspects. Based on good practices, the initiative builds on established principles – such as the United Nations Global Compact, the Responsible Care Global Charter and others. During its pilot phase over 12 months, TfS members have initiated in total close to 2,000 supplier assessments and audits.

Chemicals sourcing and purchasing involves far more than negotiating the lowest price. As with every activity within chemical manufacturing, the staff responsible for purchasing has a key role to play in terms of safety management. The chemical industry's own initiatives – and increasingly regulation – require a commitment from companies to:

- evaluate all aspects of materials in contracts between supplier and user
- ensure suppliers are fully aware of product specifications
- understand the implications of a product hazard profile in terms of both process safety and worker safety
- promote industry best practices through assessment of suppliers (for their safety performance)
- use the same criteria, such as LCA, to evaluate all sourcing materials (e.g. fossil fuels and renewables).



Process and production

Not only must our products be safe to use, they must be made under safe worker conditions. The European chemical industry's safety record is about twice as good as manufacturing as a whole, because we pay great attention to the safety of our employees and installations. That is our licence to operate. Industry would not succeed without the constant innovation improving technologies and ways of working. Specialist training, conferences, workshops and award schemes enable industry to share best practices and new developments, thus ensuring ongoing safety improvement at the workplace.

Operating permits and regulations require companies to carry out a risk assessment of their work processes to ensure that employees, the local population and the environment are protected at all stages. These risk assessments must be regular and rigorous. They must take into account the latest information on a substance.

To carry out this process effectively, companies need to have effective management systems in place. Cefic developed the Responsible Care Management Systems Framework guidance nearly a decade ago to support smaller chemical firms with implementation of the programme, including the identification of hazards and risk assessment.

Ambitious targets

Many of Cefic's member companies set ambitious internal goals to improve their health, safety and environmental performance, reviewing progress against these goals on a regular basis.

Ensuring that our production sites are safe to operate is closely linked to product safety, especially when dealing with hazardous products. Employees must know the correct procedures for storage, handling, intended use and disposal management of products to keep themselves and their colleagues safe. The chemical industry invests major resources – human and financial – in the training and education of its employees and contractors to ensure sites are safe.

When incidents do happen, or nearly happen (near misses), thorough investigations help companies put in place systems and procedures to avoid a repetition (e.g. root cause analysis). Experience tells us that most accidents involve slips, trips, falls, lifting and carrying which can be due to human behaviour. They also show that contractors' workers suffer more accidents than regular employees. Therefore, a number of chemical manufacturers have schemes specifically targeting contractor safety.

IMPROVING SAFETY BY DESIGN

AkzoNobel and its Spanish partner GRIT developed a sustainable technology offering major advances on existing approaches, and addressing occupational health issues surrounding the treatment and preservation methods used by the leather industry. This closed-loop extraction process using liquid dimethyl ether (DME) solvent offers very low toxicity, easy recovery, limited emissions, significant reduction in the use of water and chemicals, low energy consumption, low waste water generation, and valorisation of extracted fat normally considered as waste. DMEs use as an extraction agent in the production of food additives has been approved at EU level. This innovation won the partners Cefic's 2012 Responsible Care Award.

Everyone involved in the process, from senior managers to plant operators, has an important role to play to ensure safe and efficient production. Behavioural-based safety training, widely used throughout the industry, can make a major difference up and down value chains.

Chemical industry accidents are infrequent, but when they do happen their impact can be severe, involving serious injuries or even fatalities, damage to the environment and property. Some high-impact and highly publicised failures in recent years have again turned the spotlight on process safety. Industry played a major part in the development of the OECD Guidance on Corporate Governance for Process Safety, aimed at senior leaders in high hazard industries and launched in June 2012.

Occupational health is also important to help ensure workers' safety. Companies and industry associations develop guidance and best practices for specific chemicals; these can cover handling practices, health protection recommendations, checks and audits, recommendations in case of accidents, and treatments in case of injury.

The chemical industry's **VECAP (Voluntary Emission Control Action Programme)** has evolved from its original concept of a tool to control emissions during handling and use of flame retardants into a system for more efficient management of chemicals, which can be applied to a much wider range of processes and raw materials. The origins of the VECAP programme lie with the UK Textile Finishers Association (TFA), who in 2004 initiated a Code of Good Practice that called on the UK textiles industry to audit their processes, and take action to reduce emissions of one specific flame retardant from their processes. Actions ranged from simple adjustments in working practices to the installation of an effluent treatment plant, while the companies involved varied in size from 7 to 350 employees. Today, uncontrolled emissions of substances included in the programme have been massively reduced. The programme has been adapted to meet the wider needs of the European textile and plastics industries, and has been introduced in North America and Japan with notable successes. Discussions are also going on with the Chinese authorities. VECAP principles have been recognised as materials management system applicable to other chemicals in other industries.

CARING THROUGH THE VALUE CHAIN

Transport & distribution

The chemical industry fosters close links at company and association level with its partners in the value chain to help make the transport of goods to and from manufacturing sites and storage locations safe. We have developed successful partnerships at European and national level under Responsible Care with non-manufacturing sectors, such as transport and distribution. These involve cooperation on the organisation of joint events and development of guidance materials related to safety, which are regularly reviewed and updated.

At a company level, many manufacturers cooperate with third-party distributors to give value-added services to customers. This requires a strong relationship built on a proven track record, trust and reliability, particularly when dealing with hazardous products. Under the distribution sector's participation in Responsible Care, companies undergo independent third party assessment of their quality, safety and environmental performance; alternatively, manufacturers can carry out assessments. Also, suppliers typically provide technical training to their distributors' staff to ensure they can provide the same high level of customer support.

SQAS

Industry makes widespread use of a third party assessment programme for storage, logistics, tank cleaning and transport providers, Safety and Quality Assessment Systems (SQAS). SQAS assessments are carried out by a European network of accredited independent third-party assessors using a standard questionnaire to ensure consistency. It helps logistics and other service providers to increase their HSE performance by identifying potential areas for improvement. Developed by Cefic, SQAS has been adopted as far afield as China and Brazil. The scheme has been developed for chemical distributors, in cooperation with the European Association of Chemical Distributors and for shippers in co-operation with the Chemical Distribution Institute.



Twenty years ago, national distributors associations developed Responsible Care for distributors. More recently Fecc, the European Association of Chemical Distributors, strengthened the scheme to support both national distributor associations throughout Europe and individual distributors in countries where there is no association. Fecc's revised Product Stewardship Guide updates the product management responsibilities of distributors and shares best practice.

Loading and unloading are important areas of safety focus; before contracting to supply highly hazardous substances, it is common practice for producer and distributor companies to audit customer off-loading facilities. An on-site assessment is carried out and training is provided to ensure that the receiving company is suitably equipped to handle the product safely, typically done by the supplier's own experts.

Industry and its partners provide guidance on Behaviour Based Safety (BBS) focused on Safe Loading & Unloading. The BBS management programme seeks to improve the safety of operations by positively influencing the behaviour of all those involved in loading or unloading of chemicals through a process of observation, coaching and communication.

Other European-level initiatives targeting safety in the value chain include:

- a Responsible Care partnership agreement between Fecc and the European Chemical Transport Association
- industry's emergency response support for national authorities under the ICE programme (Intervention in Chemical Transport Emergencies), covering most of Europe
- simple information sheets called ERICards, developed by Cefic, which give essential product information and are freely accessible online to the emergency services in most European and Asian languages.

SAFETY SUMMARIES

The results of risk assessments carried out by companies under the Global Product Strategy are documented in Safety Summaries prepared and published by companies on the Chemicals Portal, a public website at icca-chem.org. Currently it holds around 4,000 summaries. These Safety Summaries offer direct, easy-to-read and free access to information on chemical products as part of efforts to increase public confidence that industry fulfils its voluntary commitments and regulatory requirements. Safety Summaries are straightforward explanations of potential hazards and exposure possibilities during intended use, as well as suitable use, safe handling and risk management information directed at the authorities, downstream users and the public in general. They do not replace legally required documents such as safety data sheets.

CARING ABOUT CUSTOMERS AND END USERS

The chemical industry acknowledges the importance of communication on safety with downstream users. Regulatory requirements ensure hazard information gets to the user or handler. However the information, often too complex and lengthy, sometimes leaves them none the wiser.

Through voluntary efforts, chemical companies can take a more proactive role. Responsible Care's focus on dialogue and on product stewardship, latterly boosted by the Global Product Strategy, has led to significant improvements. These activities take place at association level via Europe-wide or national campaigns with their counterparts in downstream sectors, through interactions with the authorities and regulators – as well as at company level.

Producers partner with a range of stakeholders to share information, improve knowledge and heighten awareness to ensure the safety of those who come into contact with their products. They work with customers and service providers to identify needs and expectations, areas of concern, knowledge gaps, correct use and misuse, what and how to improve. Campaigns target specific downstream groups from dry cleaners to nail salons, and from insulation foam sprayers to farmers.

The services provided to customers to enhance the safety of product handling and use can include:

- Customer assistance and training
- Assessment/audit of customer site
- Provision of safety advice, possibly equipment and engineering support
- Provision of regulatory compliance advice and support
- Expert advice and training on product & packaging disposal
- Take-back services for specialist products.

Commercial staff play an important role in making sure that the products supplied to customers are fit for purpose. Selling chemicals is a specialist job requiring detailed knowledge and training. As the 'face' of the company, sales force and customer service staff need a good understanding of process safety, occupational health and safety, a product's physico-chemical and (eco)toxicological properties, correct use conditions and legislation relevant to the sectors they supply. This knowledge helps a company take important decisions, such as when not to supply products for certain applications and uses, effectively establishing additional restrictions on certain chemicals.

THE 'KNOW YOUR CUSTOMER' CAMPAIGN

In close co-operation with the Chemical Industries Association (CIA) and the Chemical Business Association (CBA), the UK National Counter Terrorism Security Office developed the 'Know Your Customer' (KYC) campaign. This voluntary scheme is designed to raise awareness within industry about the potential for misuse of chemicals and products used or supplied in the course of legitimate business. KYC complements industry's product stewardship activities. It encourages personnel to use their knowledge and expertise of the working environment and customer profile to identify actions, such as unusual enquiries or suspicious transactions, and to report them directly or through their line management to the Anti-terrorist Hotline. The CIA and CBA have endorsed and promoted the campaign as good practice. A joint industry code of conduct, which all members must comply with, includes KYC principles as good practice in all areas of product supply, including internet sales.

KEY SAFETY STEPS IN THE MANUFACTURING, MARKETING AND SUPPLY PROCESS

- Manufacturer establishes product parameters in order to meet quality requirements, for example different grades of the same chemical (concentration, purity, etc) depending on application
- Products are tested to ensure they meet requirements. Normally a certificate of analysis or conformity accompanies the delivery
- Traceability is achieved through a batch number on paperwork or label. Chemicals in pharmaceutical applications need to be manufactured to current good manufacturing practices (cGMP). Ingredients for cosmetics, pesticides and biocides, and chemicals used in food contact are subject to specific approvals. Other customers may require Kosher and Halal certificates confirming that no substances of specific animal origin were used on the site where the products were manufactured
- Documentation usually includes Safety Data Sheets and labelling, and/or product technical data sheets with production process-related information and clear indication for specific uses
- Some products may also include information on safe disposal and process safety procedures.

Reasons for such decisions vary – it can be to pre-empt legal requirements (e.g. the UK nonylphenol ethoxylates programme); the unsuitability of a product grade for certain applications (e.g. industrial versus pharmaceutical); insufficient data to assess the risk for a specific use (eg spray formulation versus liquid); availability of a better alternative; or a product being no longer economically viable. In a few cases, alternative business models such as chemical leasing may be viable, although only practical in limited applications.

Cooperation with downstream users

Depending on the hazard profile of the substance supplied, risk management can range from providing hazard and safe handling information, to requiring customers to demonstrate the ability to safely receive, store and use a product prior to sale. If there are gaps in this ability, a supplier can take steps to help customers improve their practices. Cooperation, mutual support and knowledge sharing are essential elements in the supplier-customer relationship.



Cooperation between organisations representing suppliers and customers is also important when downstream user groups develop guidance or other support tools for their members, such as the CosmeticsEurope website on safe hair colouring. A recent initiative of the detergent association AISE, focuses mainly on young children and covers the safe and appropriate use and storage of liquid laundry detergent capsules to reduce accidental exposure. It is based on a commitment by individual companies to implement safety measures which reduce the visibility and access to these capsules.

The International Fragrance Industry Association (IFRA) requires members to adhere to a Code of Practice. The IFRA Standards form the basis for the globally accepted and recognised risk management system for the safe use of fragrance ingredients. This voluntary initiative is based on risk assessments carried out by an independent expert panel.

In the plastics sector, a multi-pronged Europe-wide effort involves CEPE (Paint, Printing Ink and Artists' Colours Association), PlasticsEurope and 11 other upstream and downstream industry associations. They are cooperating in an EU research project called FACET, a food chemical exposure surveillance system, which estimates exposure to flavours, additives and other materials coming in contact with food (e.g. from packaging). This study will contribute to achieve ever higher levels of consumer protection. It demonstrates how industry continuously works with its value chains to improve its materials and engages in research projects to understand the safety of the substances it uses, beyond what is legally required.

More broad-based actions are also worth noting. For example, ongoing safety and product stewardship activities led by the European solvents sector group include publication of a third Safety DVD on the safe handling of bulk containers, with a follow-up on the safe use of gloves being planned. Recent actions include the update of Best Practice Guidelines, including one on static electricity issued mid-2013. Cooperation with stakeholders can significantly improve the effectiveness of communication efforts, as demonstrated in the successful exchange between members and EU-OSHA (European Agency for Safety and Health at Work) on the sharing of materials and best practices under the 2012-13 campaign "Healthy Workplaces".

In the case of hazardous substances such as ethylene oxide, acrylonitrile, acrylic acid, and propylene oxide, detailed Safe Handling Guidelines help to make sure that everyone in the value chain is properly informed and handles the substances in a responsible way.

WIN-WIN SOLUTIONS

Solvay has developed and implemented recycling technology for the six rare earths contained in the fluorescent powders of used low-energy light bulbs. Rare earths – strategic metals used in around 50% of new energy saving technologies – are mainly sourced from China. Current end of life practices mean these rare earths are mainly landfilled, but Solvay aims to achieve a 99% recycling rate for these light bulbs to secure the supply of Terbium in France by 2015. With lighting consuming an estimated 19% of global electricity production, the project has an excellent social and environmental impact: benefits include the introduction of a closed loop process that reduces the large quantities of hazardous waste sent to landfill, the creation of new jobs in Europe, and the security of supply and elimination of a huge amount of mining. This project earned Solvay the 2013 Cefic Responsible Care Award.

Disposal and recycling

As part of the learnings from life-cycle analysis, industry is focusing greater attention on the end-of-life of materials. Chemicals can be recovered if unused at production level or re-used if a closed loop for a mixture is in place. In both cases a safety evaluation is made to ensure that unintended risks are avoided and controlled. Where recovery of a substance is more complex, suppliers work with downstream users to analyse the processes involved.

Innovation is enabling more and more final products to find new life at the end of their first use. Examples of such recovery, re-use or recycling are often driven by environmental or economic considerations as well as safety issues (see panel). Industry seeks a balanced approach to sustainable development and aims to approach these in an open and transparent way without compromising product safety.



To avoid dangerous chemicals ending up in landfill or incineration, ESPA, the European Stabiliser Producers Association (www.stabilisers.eu) is participating in an ambitious programme to develop recycling of PVC articles. ESPA is an active contributor to the PVC's sustainability programme VinylPlus (www.vinylplus.eu) which involves the development of studies to support the benefits of recycling lead-containing PVC waste.

In 2000, the ESPA members committed to replace lead-based stabilisers by the end of 2015 in the EU and by the end of 2013, 81% had already been replaced. Concerning long-lived PVC articles (e.g. sewage water pipes, profiles for window frames and electrical cables), the lead remains embedded in the plastic matrix. Hence, its bioavailability is very low and its presence poses no particular problem. Instead of landfilling or incineration, recycling of PVC to make new articles is the best way to minimise risks to human health and the environment, while saving raw materials and energy.

Europe's legal framework



In addition to the voluntary initiatives mentioned in the previous chapter, the European Union also has a long history of chemicals legislation which ensures consistency, harmonisation and transparency and puts all companies on a level playing field.

Since 2007 REACH has been the regulation under which the industry operates. Considered to be the most stringent chemicals regulation worldwide, it has shifted the responsibility on industry, including the downstream industry, to provide information on chemicals to the EU competent authority ECHA (European Chemicals Agency).

REACH is underpinned by the precautionary principle and risk assessment. It was created to ensure better use of available knowledge of chemicals for a higher level of protection of human health and the environment, to improve the quality of the data, to increase transparency of the communication of publicly available data and to enhance competitiveness and innovation.

Industry has worked hard to make the implementation understandable for customers. However, harmonisation and translation into national languages continue to be challenging for all involved stakeholders. Cefic and its members are closely engaged in efforts to help companies at all levels of the value chain tackle REACH implementation.

That support is outlined in a roadmap published by ECHA in July 2013 where action items reflect industry's objectives to improve the safe and appropriate use of its products – in this instance by improving the content and use of exposure scenarios. The hazardous properties of chemicals are embedded in the Registration Dossiers, which users can access via the ECHA website. They hold essential information on the safe use of chemical substances and mixtures for downstream users, authorities and REACH registrants alike.

As one of the stakeholders involved in developing the five-year roadmap, Cefic is also a signatory to a charter issued by ECHA, which calls for more stakeholders to take part. As a signatory, Cefic demonstrates industry's commitment to continuous improvement in the field of exposure assessment and downstream communication.

Production and worker safety regulations

Sites that make, use and store chemicals are subject to stringent regulatory requirements to control emissions to soil, air and water, and waste management. Safety standards for plant design include filters to reduce emissions, separate sewage systems to isolate site water run-offs, and secondary containment around large capacity storage tanks and reactors to ensure that any accidental release of products is totally contained.

MUTUAL SUPPORT

In Belgium, national chemical association essenscia created a unique concept with support from the regional governments to help industry, especially SMEs, with the implementation of REACH and CLP. For several years, mentors from large companies have helped guide smaller ones and downstream users through their REACH and CLP obligations under regional implementation projects (VLARIP for Flanders and WALRIP for Wallonia).

The exchange of information and experience between groups of participants at monthly meetings is reinforced by 'learning by doing', and has proven an effective approach to the successful implementation of the EU legislation.

The EU Industrial Emissions Directive, for example, covers industrial activities, including the production of chemicals. Plant operators need to demonstrate the use of Best Available Techniques (BAT) before permits can be granted to allow production at industrial installations.

A key piece of legislation for handling chemicals is the Chemical Agents Directive (CAD). This requires employers to evaluate the hazard and exposure to chemicals and to ensure risk elimination or reduction. The protection of workers includes training on emergency arrangements, access to risk assessment results and safety data sheets, precaution, personal or collective protection measures and medical surveillance.

Other legislation covers specific groups of workers (e.g. pregnant women, young workers) or specific effects (e.g. carcinogen, mutagen) and exposure limits. Lack of harmonisation of legislation and variable implementation in the different member states are a source of concern. Industry focuses additional efforts such as capacity building on those countries where it has identified the greatest needs.

The level of planning required to deal with emergencies is dictated by the amount and the type of chemicals held on a site (Seveso III Directive). Sites with larger amounts of high hazard substances are subject to the most stringent requirements. Some sites, not subject to such stringent requirements, also actively engage with local emergency services; voluntary efforts at national and local level reinforce these activities.

Classification and labelling – standardisation of hazard communication

The UN Globally Harmonised System of Classification and Labelling of Chemicals (GHS) provides a harmonised set of rules to define, classify and communicate hazards. Labels and safety data sheets (SDS) are used to communicate hazards and thus support the protection of human health and the environment during the handling and transport of substances. The chemical industry, through GHS, supports requirements to provide a basis for harmonisation of rules and regulations at the global level. This is particularly important for the safe chemicals management during the course of international trade.

In Europe, progressive adaptation of the legislation on classification, labelling and packaging (CLP) of substances and mixtures to integrate the GHS is underway. The CLP Regulation was implemented for substances on December 1, 2010; the deadline for mixtures is June 1, 2015.

The EU continues its work to harmonise classification and labelling for some specific endpoints (e.g. CMRs and respiratory sensitisers). The inventory of notified substances gives the self-classification of all hazardous substances on the European market (<http://echa.europa.eu/information-on-chemicals/cl-inventory>).

Product safety

The General Product Safety Directive requires producers and distributors to place only safe consumer products on the market and to take all the necessary measures to prevent risks for consumers. Among such measures, the directive introduces the obligation that producers and distributors notify the competent authorities appointed by the member states when a product available on the market proves to be unsafe for its intended use.

RAPEX is the EU rapid alert system for the exchange of information between member states and the Commission on measures taken to prevent or restrict the marketing or use of products that pose a serious risk to the health and safety of consumers. Note that food, pharmaceutical and medical devices are covered by other mechanisms. Chemicals are involved in around 18% of the cases identified by RAPEX, with around half of these related to imports, mainly on consumer products non-compliant with REACH restrictions. This highlights the need for enforcement and control from the authorities.

Labelling products and providing safety data sheets for chemicals presenting hazardous properties are a legal requirement in most countries around the world. Depending on a product's properties, companies often provide additional information such as best practice guidelines to ensure they are used and handled safely.

The safe transport of chemicals is governed by the dangerous goods transport legislation. Specific requirements apply to all modes of transport, under conditions that are primarily defined and agreed at UN level. These are, then, cascaded down through the various transport modes and regional or national legislation. The regulatory framework defines what substance can be transported by what means, in what type of containers and in what quantities.



Chemicals in the public debate



Interview with Peter Smith, Cefic Executive Director in charge of Product Stewardship

Q: The public are eager to know more about new and highly innovative areas of the chemical industry, but feel kept in the dark as to their benefits and risks. What is the chemical industry doing to develop and disseminate its knowledge in these areas?

As you know, industry is constantly building on its product knowledge. The combination of voluntary and regulatory programmes has helped us continue to improve the way we share this knowledge through the supply chain to the end user or the general public. Our Responsible Care and Global Product Strategy (GPS) initiatives are contributing to a better dissemination of information.

Q: Consumers are naturally concerned about the risks to human health and the environmental behaviour of products they hear about in the media. They see scare stories about certain substances heightening their concerns. How can the scientific community allay consumer fears and bring clarity to the debate?

As I see it, the scientific community has the duty to distinguish between the latest research results and the latest scientific knowledge. They are different. Speaking as a member of the public, I want to know about the latest scientific knowledge. I do not want to know about new hypotheses that will not stand up to subsequent scrutiny or more extensive studies. This is also true for the media. The latest research results might make for a good story, but it's unlikely to guide my everyday behaviour.

One should always put these results in the right context – something which is achieved, for instance, by the UK Science Media Centre (<http://www.sciencemediacentre.org/>).

Q: Some substances, like cadmium, a carcinogen and teratogen, are particularly dangerous, their harmful effects on both health and the environment undisputed. What is being done to protect consumers from these very hazardous substances?

Much is being done. The production and use of Substances of Very High Concern (SVHC) is today subject to demanding safety standards. Europe's REACH legislation, being implemented since 2007, sets out criteria under which these substances must be identified and prioritised for risk management, including authorisation and restriction. They are the procedures by which uses of substances can be greatly reduced or eliminated altogether.

It works like this: substances are identified as SVHCs if they are carcinogenic, mutagenic or toxic for reproduction; if they are persistent and bioaccumulative and toxic; or where there is scientific evidence of probable serious effects to health and the environment.

REACH states that these substances should be “progressively replaced by less dangerous substances or technologies where suitable economically and technically viable alternatives are available”.

The European Commission has already identified some chemicals which need to be “authorised”, meaning that producers or users must obtain their authorisation if they aim to carry on using them. A review period is then set, allowing industry time to look for safer alternatives

Q: So in Europe we have REACH, hence tight regulation ensuring safety. But what about all the products imported into the EU whose components are manufactured in countries with lower safety standards?

There are two issues to consider here. The first deals with the safety of EU citizens. REACH and other legislative measures also apply to imported products. So, provided enforcement controls are effective at EU borders, there should be no risks from imports.

The second relates to people living and working in the industry outside the EU. Whilst these countries do not have REACH, they have other regulations in place. Additionally, systems such as the globally harmonised classification of hazardous substances (GHS) help to ensure standardisation. Other programmes such as the UN's Strategic Approach to International Chemicals Management (SAICM) are also helping to revise the standards of chemical management throughout the world. Cefic is actively involved in SAICM.

Q: Hardly a day goes by without a media scare about an endocrine-disrupting chemical. How would you define such a substance? And is any substance that acts upon the endocrine glands automatically classed as an endocrine disruptor?

Perhaps the best place to start is the internationally agreed WHO definition. It states that endocrine-disrupting chemicals act on the endocrine system in a damaging way. When this happens, health issues ranging from low fertility, abnormal growth, to cancer can arise. And when this is the case, the use of such materials needs to be carefully controlled.

Against this background, you need to consider that the endocrine system is a complex set of glands that regulate hormone levels and receptors in the body. These glands and hormones control or influence functions such as metabolism, blood pressure, growth and reproduction. Well-known hormones include adrenaline, insulin, oestrogens and androgens.

Some everyday products such as coffee and soy milk contain natural endocrine-active chemicals which interact with the endocrine system but do no harm. However some chemical substances, natural or man-made, known as endocrine disruptors, can seriously harm health, causing lower fertility, foetal abnormalities and cancer.

Q: And what will be done to assess EDCs?

Scientific and regulatory debates are underway to determine how best to identify endocrine-disrupting substances. In the EU, the Commission is developing criteria for this purpose. Once identified, endocrine disruptors will be assessed for their potential to cause harm under realistic conditions. Industry is very much engaged in the discussion and has provided expertise to the debate.

Over the last 20 years, the chemical industry has made significant contributions to the basic and applied research on endocrine mechanisms and specific testing. We are keen to establish safeguards for chemicals identified as endocrine disruptors and ensure that the existing regulatory framework manages their safe use.

Q: Some NGOs are saying the European Commission is dragging its heels over publishing its own strategy on EDCs, as a result of heavy industry lobbying. Is this a fair criticism?

These criticisms are quite unfounded. The European Commission does have a strategy. But since its publication in 1999, it is in need of being updated. The European Commission has not yet published a revision to the strategy, not because of industry lobbying, but because of the complexity of the issue and the difficulty in defining the right criteria.

Q: We hear more and more about nanomaterials these days. Which materials are people talking about and where might I find them?

Naturally occurring nanomaterials include smoke, soot, dust and sand. Manufactured nanomaterials are chemicals at the nano-scale (1-100 nm). They include, for example, ultrafine titanium dioxide (TiO₂) - used as a protective ingredient in sunscreens, carbon black used in rubber and plastic products (to improve resistance) and new materials such as fullerenes - used in medicine for molecular therapies.

Nanomaterials have valuable properties, which are proving helpful in tackling issues from climate change to health. This is why the EU has recognised nanotechnology as a key enabling technology to address major societal problems. But there are safety concerns over, for example, whether they can easily penetrate the skin or cells to harm health.

Q: Most people acknowledge the benefits they bring. Yet some nano substances, like nanosilver, are nonetheless perceived as dangerous. What is being done to ensure the safety of these products, and are they subject to a different approach from that applied to other substances?

Again, much is being done. After six years of work with industry support, the OECD and its member countries concluded: "approaches for the testing and assessment of traditional chemicals are in general appropriate for assessing the safety of nanomaterials, but may have to be adapted to the specificities of nanomaterials." This is important because it concludes that there are no unique safety issues associated with nanomaterials. They just need to be assessed in the same way as other materials.

Industry assesses the risk of nanomaterials case-by-case, complying with REACH and CLP (classification, labelling and packaging) obligations. Several of our national federations and member companies have codes of conduct for responsible management of nanomaterials. To help ensure that industry's nano-based materials, products and technologies are researched, designed, manufactured and used safely and responsibly throughout their entire life cycle, Cefic has published guidance: Responsible Production and Use of Nanomaterials.

Cefic's Long-range Research Initiative has completed three projects on testing and assessment of reproductive toxicity and safety to human health of nanomaterials, and has launched a fourth one to develop evaluation process best practice.

Q: Some member states and non-governmental organisations have called for national or European inventories of nanomaterials. Why is the industry opposed to such national or European registers?

Indeed, some authorities and non-governmental organisations have called for national or European inventories of commercial nanomaterials. We do not consider them to be necessary. We do however agree that transparency about nanomaterials' properties and uses is important, and believe the information is already available through regulatory and other sources, such as the chemicals legislation and the legislation governing cosmetics, or company websites. We support Commission plans for a European web platform on nanomaterials.

Q: EU chemicals policy mainly focuses on the safety of individual chemical substances. Yet recent findings, often appearing in the media, suggest that when substances that work in a similar way (natural and man-made) are combined they may cause adverse effects, even if the individual substances are present at harmless levels. Is the chemical industry taking these concerns seriously?

During our lives we are exposed to natural and man-made chemicals in food, medicines, clothing and the air we breathe. As you say, EU chemicals policy and risk management schemes mainly focus on the safety of individual chemical substances.

Although there is currently no evidence of 'combination effects' at levels typical in our environments, we need to ensure harm is avoided, so the chemical industry has begun targeted work to identify and assess potential risks. In 2012, the European Scientific Committees, in their Opinion on Toxicity and Assessment of Chemical Mixtures concluded that: "at low exposure levels, [combination effects] are either unlikely to occur or are toxicologically insignificant".

Evidence shows that when combined chemical exposures pose a risk it is usually driven by one substance within the mixture, so can be managed under current legislation. The committees said that a filter is needed to identify substances of potential concern, because the number of combinations to which humans, wildlife and plants are exposed is almost infinite.

Q: So, what is industry doing?

The chemical industry has developed screening criteria to prioritise combinations for assessment. Our newly-introduced Maximum Cumulative Ratio (MCR) helps identify potential combinations of concern in complex environments, such as water from river basins or indoor air.

The chemical industry has also created a decision tree to help evaluate human and ecological effects from exposure to multiple chemicals from a single or multiple sources, which has worked well in pilot studies. It is essential to agree on scientific methods and tools for use when specific risk assessment is needed. This will contribute to the policy debate triggered by EU institutions on how to safeguard citizens from environment-related pressures and risks to health and well-being.

Q: Some harmful substances are still found in the environment long after their dangers have been discovered and their production and use stopped. What is done to manage the risks from these 'lingering' substances?

The chemical industry supports efforts to further reduce the presence of what we term 'legacy chemicals' with voluntary action under our commitment to the UN's Strategic Approach to International Chemicals Management. Risk assessments, including the evaluation of Persistent, Bioaccumulative and Toxic (PBT) substances are designed to prevent new legacy issues in the future. Similarly, we support action on "legacy additives", which are substances used in PVC products. Their use has been discontinued, but they are contained in recycled PVC. Since the use of recyclable materials containing "legacy additives" may be restricted by recent legislation, the vinyl industry is committed to addressing the issue – in cooperation with the regulatory authorities – under its Programme Vinyl Plus.

Global conventions - as well as regional and national regulations - typically limit or prohibit the use of legacy chemicals, and provide guidelines on responsible management. For example the Stockholm Convention, which came into force in 2004, covers 12 persistent organic pollutants (POPs), many of which are harmful to human or animal health. Some, such as DDT, were widely used as pesticides during the 1940s and 1950s. Others, such as polychlorinated biphenyls (PCBs), were used as lubricants, or in applications such as paints, sealants and wallpaper.

Their use is now either banned or tightly restricted. POPs were used before rigorous testing was introduced and they were subsequently discovered to degrade in nature very slowly, turning up in unexpected places. They are especially problematic because they tend to accumulate so that organisms higher up the food chain have higher concentrations. They also tend to be easily transported by nature, spreading far from places where they were produced or used.

Chlorofluorocarbons (CFCs) and the use of mercury and lead are now subject to global regulation, as their properties have become clear and their presence in the environment recognised as a concern. CFCs are managed through the Montreal Protocol. Mercury emissions will be controlled through the Minamata Convention, whilst a partnership between the United Nations Environment Programme and the paint industry aims to reduce and ultimately eliminate the use of lead in paint.

AN OUTSIDE VIEW

The European Commission Flash Eurobarometer 361 survey on chemicals, published in February 2013 asking about the general public's perception and understanding of chemical substances, as well as attitudes towards their safety and awareness of regulations, touched on issues of product safety. Some of the key findings make it clear that we need to continue to address the gaps between perception and reality.

Consumer view on the safety of chemical substances in the EU

- Three in five Europeans say that the chemical substances on the EU market today are safer than they were 10 years ago.
- Half of Europeans think that EU manufactured products containing chemical substances are safer compared to those imported from outside the EU.
- Two thirds of Europeans agree that in the EU, products containing new chemical substances have been properly tested.

Look to the future



The chemical industry plays a major role in providing high quality of life through sophisticated products. Turning raw materials into chemical substances used in the production of basic consumer goods and selling advanced materials to virtually all manufacturing industries is our daily business.

Supplying products that are safe for their intended uses, combined with excellence in all aspects of chemicals management is our daily commitment. We want to extend this commitment to safety throughout the value chain, at all stages of a product's lifecycle.

We build on a comprehensive European and national regulation system as well as on voluntary initiatives, such as Responsible Care, the Global Product Strategy and the Long-range Research Initiative. We can rely on robust processes to address both new chemicals coming onto the market and existing chemicals, always integrating new knowledge delivered by scientific evidence.

We do not have all the answers, but in the spirit of transparency and dialogue, we will continue to work with our stakeholders and keep safety as our top priority.

We believe in the future of the chemical industry in Europe and its capacity to create wealth and provide high quality jobs, while managing chemicals safely. A thriving and sustainable chemical industry is an essential solution provider to the many challenges facing society today and tomorrow. We know this is not something we can achieve alone: it is fundamental that we continue to work, dialogue and partner with key actors throughout the value chain.



Chemistry – simply essential for a sustainable future

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