



Global Product Strategy

Gaining public trust in chemicals through wider communication of the results obtained under REACH





Better safety and trust through communication

With growing globalisation, the concern for the safe use of a chemical down the value chain is not limited to the country of its origin.

A weakness or worst an accident in one country has an impact on the acceptance of the chemical industry in many regions and markets. Our world is drawing closer together, not just economically but also on political and environmental issues. International agreements are building more and more bridges that connect all the continents with one another. The activities of the United Nations, the World Trade Organisation (WTO), the OECD and other international organisations influence the practices of businesses in our industry in Europe and the rest of the world. Examples are the Rotterdam Convention for handling dangerous chemicals, the Globally Harmonized System of Classifying and Labelling Chemical Substances (GHS), and also the Strategic Approach to International Chemicals Management (SAICM) to ensure the safe use of chemicals worldwide and throughout the value chain.

ICCA's "Global Product Strategy" (GPS) is the right answer to the objectives of the United Nations' SAICM. Cefic was a major collaborator in the structure and content of this strategy. For chemical companies based in the EU, the implementation of REACH, GHS, and GPS go hand in hand. GPS will allow wider communication of results obtained under REACH.

Thereby, the GPS will strengthen public trust in the safety of our products all around the globe. This initiative will also improve public acceptance – the "de facto licence to operate" of our industry here in Europe.

I call on all Cefic member federations and companies to support the implementation of GPS in Europe. It is to the benefit of us all.

Director General Cefic,
Alain Perroy

GPS IS A VOLUNTARY INDUSTRY PROJECT RUNNING SINCE 2006

- All chemical companies around the globe are expected to contribute
- Result in 2018: product safety information open to the public for all marketed substances
- Substance information compiled for REACH compliance is sufficient for GPS purposes



Chemicals management: expectations of the public

The international community expects the chemical industry to take measures for the safe and appropriate management of chemicals globally. Relevant resolutions were made by over 100 environment and health ministers from all over the world at the International Conference on Chemicals Management (ICCM-1) in February 2006 in Dubai, where the Strategic Approach to International Chemicals Management (SAICM) was adopted. SAICM is not binding under international law and is thus a voluntary initiative. All the same, this strategy has much political weight, as it was adopted at ministerial level.

SAICM: Combining global measures and closing gaps

A total of about 650 delegates from 145 countries attended ICCM-1. With the Dubai Declaration, they fulfilled a pledge which had already been given at the second World Summit on Sustainable Development (WSSD) in Johannesburg in 2002, where the international community decided to develop SAICM. At that time, the adopted Johannesburg Plan of Implementation stated the following goal: "...until 2020 chemicals are used and produced in ways that lead to the minimization of significant adverse effects to human health and the environment ..."

The subsequent Dubai Declaration reflects the commitment of governments, civil society and industry to enhance global chemicals safety. This declaration also highlights the positive role of voluntary initiatives such as Responsible Care® Global Charter (RCGC) and the Global Product Strategy, both of which were launched at ICCM-1 to fulfil the global industry's commitment to SAICM.

The Responsible Care® Global Charter (RCGC) extends the Responsible Care initiative to product stewardship.

Product stewardship is the chemical industry's responsibility to ensure the safe use of chemicals throughout the value chain, i.e. in their manufacturing, use, recycling and disposal. The GPS is the response to the product stewardship part of the RCGC and addresses product stewardship world-wide, including the value chain, promising a new level of information sharing and transparency. Today, product stewardship and its implementation through GPS have become central pillars of the Responsible Care initiative. The SAICM process has been guided and continued with a number of UN follow-up conferences, for example, ICCM-2 in May 2009 in Geneva, and further conferences are scheduled for the years 2012, 2015 and 2020.

Cefic Position

Cefic formally endorses the Dubai Declaration and ICCA's initiatives because they will help safer handling of chemicals. The regional, national and international actions and numerous agreements in chemicals management will be coordinated and verified with SAICM and Cefic is working with its member federations and companies to effectively implement the RCGC and GPS initiatives using REACH data.





What does GPS mean for European chemical companies?

WHAT STRATEGIC KEY ELEMENTS ARE ENCOMPASSED BY GPS?

- 1 Develop global guidelines for Product Stewardship
- 2 Develop a management system approach
- 3 Define a tiered process for completing risk characterizations and risk management recommendations for chemicals in commerce
- 4 Improve product stewardship cooperation with industry groups and companies and address product challenges throughout the chemicals value chain
- 5 Develop partnerships with inter-governmental organizations and other interested stakeholders
- 6 Make relevant product stewardship information available to the public
- 7 Participate in scientific inquiry to address new and emerging health and environmental concerns
- 8 Develop a process to communicate internally and externally
- 9 Develop global advocacy principles

With the implementation of REACH recently started most companies have pre-registered their substances. Now companies are gathering data and information that must be submitted by 2018 at the latest for each substance that is manufactured or imported in volumes of over one ton per year. The necessary risk assessments must cover all uses of the substance along the product chain. Furthermore, the “Globally Harmonized System for Classification and Labelling” (GHS) is being introduced simultaneously in Europe. This requires a new classification and labelling of substances and preparations - intended to lead to a standardised system worldwide.

The intention is that GPS uses results and information obtained for REACH, to the greatest extent practicable, to support GPS. The aim is to avoid any duplication of work.

Strengthening trust in the Chemical Industry and its products

GPS establishes global standards and procedures for a focus on product stewardship in order to enhance the safe handling and use of chemical products worldwide. This is designed to strengthen trust in the chemical industry and its products.

GPS essentially consists of the following elements: Initially, a base set of information is gathered for any product placed on the market. This basic information includes physical-chemical parameters, toxicological and eco-toxicological data, and information on use and exposure. For substances with an increased hazard potential or higher exposure of humans or the environment, more information is needed as part of an incremental approach. A risk assessment is conducted based on the substance-specific information.

The information needed for this risk assessment is to be made available and jointly used by the companies. For this purpose, an internet portal will be set up to support the exchange of information.

Results regarding the safe use of substances and necessary risk management measures derived from the risk assessments are to be communicated along the product chain. This requires transparency and a mutual exchange of information along the entire value chain.

Furthermore, to promote greater transparency, companies will provide the general public with information about marketed substances, in an easily understandable format and made accessible via the internet. National associations will promote the process.

The measures described above will be implemented by 2018 for all marketed substances. This means that necessary safety-relevant basic information and risk assessments will be available by that date world-wide along with the communication of suitable risk management measures.

Preparatory work done by large companies

Several large companies are leading the way by preparing the implementation of GPS and providing examples of “best practice”. Over time, increasing amounts of substance-specific information will become available under REACH and GHS – e.g. in the database of the European Chemicals Agency (ECHA) or through publication of product-related information on company websites. Under GPS, information will be made available globally to all companies via a central web portal, which will enable companies to use such information for risk assessments to promote safe use of products. This is a major contribution toward better product safety in all regions of the world (“capacity building”).

Under GPS, companies can publish relevant substance information on their own websites – e.g. under a heading “product stewardship”. Within this framework they can demonstrate to their customers that they fulfil relevant legal requirements and that they have pre-registered or registered their substances under REACH.

Due to their close interrelation, GPS and REACH will be implemented in a synchronized manner. GPS is a way to communicate the tremendous work done under REACH more widely.



Risk assessment and information exchange

BASE SET OF INFORMATION ICCA GLOBAL PRODUCT STRATEGY		
Toxicological data requirements	Standard parameters	Ecological data requirements
LEVEL 1 (e.g. minimal exposure, no toxicity) Irritation (eye/skin) in the event of exposure	1 Identity	LEVEL 1 (e.g. minimal exposure, no toxicity) Relevant eco-toxicological data in the event of exposure
LEVEL 2 (e.g. low exposure, low toxicity) Irritation (eye/skin), mutagenicity (Ames test), sensitisation (structure)	2 Physical/Chemical properties	LEVEL 2 (e.g. low exposure, low toxicity) Acute toxicity (sensitive species)
LEVEL 3 (e.g. medium exposure, medium toxicity) Irritation (eye/skin), mutagenicity (Ames test), sensitisation, 28-days subacute	3 Toxicity/Ecotoxicity (exposure to product)	LEVEL 3 (e.g. medium exposure, medium toxicity) Acute toxicity (daphnia), acute toxicity (fish), acute toxicity (algae)
LEVEL 4 (e.g. high exposure, high toxicity) Irritation (eye / skin), mutagenicity (Ames test, etc), sensitization, 28-days subacute, reproductive and developmental implications	4 Biodegradability	LEVEL 4 (e.g. high exposure, high toxicity) Acute toxicity (daphnia), acute toxicity (fish), acute toxicity (algae), chronic toxicity

For European companies, all safety-relevant sets of information and risk assessments for all marketed substances will hopefully be compiled by 2018.

Like REACH, GPS applies to all marketed substances exceeding the REACH annual production volume of one ton per year per company. Furthermore, GPS applies also to those substances below that volume threshold which have a particularly high hazard potential for humans and the environment. As with REACH, GPS will not apply to chemicals which are already covered by special legislation (e.g. food additives, medicinal products, plant protection products, biocide products).

Substance Specific Assessment - Information requirements under GPS

The information requirements for a risk assessment under GPS are defined in base sets of information in four levels. The foundation is provided by a set of standard parameters, which must be stated for all substances (e.g. physical-chemical properties, biodegradability, acute toxicity etc). Building on this "standard package", there is an additional level assigned depending on toxicological and eco-toxicological data requirements that increase with the hazard potential of the substance: see table above.

Alternative sources of information can also be used for assessment purposes instead of results from animal testing. These alternatives include Quantitative Structure-Activity Relationships (QSAR), conclusions by analogy of similar substances (read across), category approach, waiving, in-vitro methods, expert judgement of in-vitro methods, historical human data (e.g. biomonitoring at the workplace), available literature and data bases. Additionally, existing data from other programmes (e.g. REACH, High Production Volumes – HPV, Long Range Initiative – LRI) will be included and used for base sets of information.

Under GPS, it is the responsibility of companies to assign the substances to levels 1-4, depending on the respective hazard and/or exposure and also to decide which substances to report upon, allowing them to be guided by deadlines under REACH. Relevant guidance to help companies and associations in this process is currently being developed by Cefic.

Concept for the exchange of information and data under the global product strategy

Base sets of information do not need to be compiled separately by each company; they can be collected via a central information portal (web portal) and made available to all member companies for risk assessments.

All information necessary for the risk assessment of a substance will be made available free-of-charge to other companies. This includes:

- Information published by ECHA,
- All dossiers prepared under the High Production Volume of OECD,
- Safety data sheets,
- Training materials for performing risk assessments,
- Training materials for risk management,
- Exchange and standardization of usage and exposure information,
- Further information made available by the companies.

The gathered information will be made available on a website in two parts:

- 1. Public forum with free access for all and weblinks to the source documents**
 - Safety summary of products
 - OECD dossiers
 - EU risk assessment
- 2. A separate part accessible only to Industry**
 - Study Summaries available from ECHA
 - Safety data sheets
 - Guidelines for risk assessment
 - Exposure scenarios
 - Risk management
 - Contact person

Why is the Responsible Care® Global Charter (RCGC) so important?

Our Commitment to Sustainability is included in this Charter

The Global Product Strategy and the Responsible Care Global Charter are complementary. They both became public at the same time within the framework of the International Conference on Chemicals Management of 2006 in Dubai. And they have the same origins in the responsibility and competence of businesses in the chemical industry worldwide.

The Global Charter extends the scope of Responsible Care in three dimensions:

1 Geographical extension

Through the Global Charter, Responsible Care has become the ethical basis of the global chemical industry. It enables signatory companies to demonstrate Responsible Care in countries where no national RC association exists.

2 Extension through the value chain

The Global Charter aims to go beyond the chemical industry by establishing Responsible Care in partner sectors such as the distribution, transport and logistics sectors.

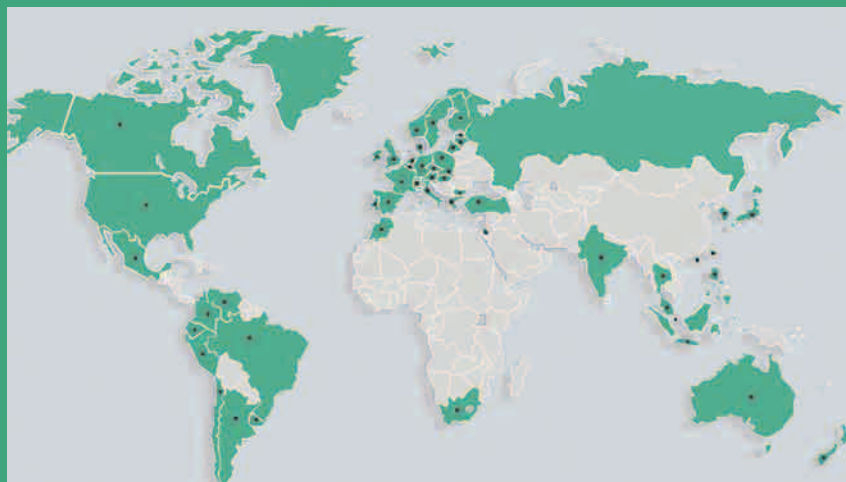
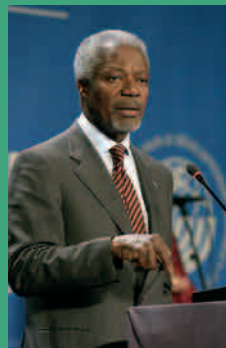
3 Extension of scope

Finally, the Global Charter aims to go beyond good on-site management of environment, health and safety by including product stewardship and sustainable development into the Responsible Care approach.



The nine key elements of the Responsible Care Global Charter

- Adopt global Responsible Care core principles
- Implement fundamental features of national Responsible Care programmes
- Commit to advancing sustainable development
- Continuously improve and report performance
- Enhance the management of chemical products worldwide - product stewardship
- Champion and facilitate the extension of Responsible Care along the chemical industry's value chain
- Actively support national and local Responsible Care governance processes
- Address stakeholder expectations about chemical industry activities and products
- Provide appropriate resources to effectively implement Responsible Care



GPS is the product stewardship part of the Global Charter. Facilitating Responsible Care in the value chain corresponds exactly to the approach of the Global Product Strategy.

The Responsible Care Global Charter is available to the public on the Cefic website (www.cefic.org).

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