

INTRODUCTION

Also this edition of the Monitor will reach you through the electronic highway. It is like all previous editions an update on the developments of environmental legislation effecting the flexible packaging industry. We are very pleased that the opening address is prepared by Gerard Blatrix, Vice-Chairman of FPE. His address deals with the topic sustainability and includes an important message for saving food stuff through the use of flexible packaging. This Monitor furthermore contains several bullet point informations on a variety of topics, easy to read and all relevant for our industry.

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Flexible packaging stands for resource efficiency

A real contributor to food waste prevention

'Waste not, want not' well describes the real work packaging does in providing food safety and most importantly in preventing food waste - and that's without mentioning the important marketing and brand messages it provides.

Most consumers are completely unaware of the amount of food they throw away (identified as over 30% by WRAP, UK). Instead, consumers often focus on what they see as "wasteful" packaging. However, consumers will surely have a better understanding, and at the same time stop berating packaging, if they appreciate its role both in the prevention of waste and ensuring product safety.

The World Health Organisation estimates that 30% of the food in developing countries perishes due to the lack of packaging.

In fact packaging saves ten times more waste than it creates.

As an example of the positive contribution packaging can make, research by INCPEN (the Industry Council for Packaging and the Environment) estimates that in developed countries, where food packaging is widespread, less than 3% of food is wasted in the supply chain between food production and retailer level.

Nonetheless the pressure on the packaging sector to examine its environmental impact has never been greater. Thanks to a series of Life Cycle Assessments (LCAs) for food products conducted on behalf of Flexible Packaging Europe (FPE), it has been demonstrated that packaging is a net saver of resources.



Gérard Blatrix, FPE Vice-Chairman

In the past many packaging studies have concentrated on material comparisons and consequently have not created a real picture of packaging's part in any "eco-balance" across a products complete life cycle. However, an LCA for FPE showed that for flexible packaging applications the impact of packaging is negligible when compared with food production, processing and consumer behaviour.

Among the many benefits of flexible packaging is that it offers savings in transportation energy generated across the supply chain. For example juice in flexible pouches utilises 94% of a lorry load during transportation, while juice in glass bottles has an occupancy of a lowly 48%. At the same time the space occupied by the packaging is just 6% for stand-up pouches and a hefty 52% in the case of glass bottles (based on a Capri Sun LCA).

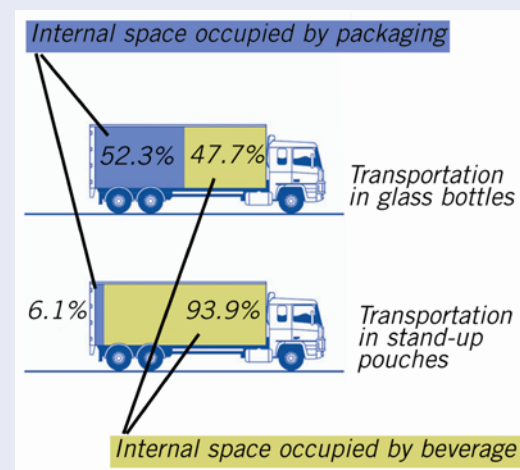


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It doesn't end there; the light weight of flexible packaging provides real savings in terms of materials and energy which in turn minimises the generation of greenhouse gases and other pollutants.

Moreover, improvements in material performance and product design have led to significant packaging weight reduction of flexible packs, thus minimising material and energy use.

It is not necessarily efficient to recycle flexible packaging but there are a number of other recovery opportunities including energy recovery through which the recovered thermal content provides energy from waste incineration to provide an alternative

source of energy. This valuable resource can be re-used in the form of heat and steam to power electricity generators.

The ultimate message is that flexible packaging is a net saver of resources and plays an important role in helping to achieve more sustainable food distribution and consumption.

The aim of FPE is to ensure this message gets through to customers and the final consumer.

G rard Blatrix
Vice-Chairman
Flexible Packaging Europe

REACH and Solvent Recovery

Under REACH, recovered substances do not have to be registered again, if a few simple requirements are met. The recovered substance must be the same as the original, it must have been registered by a manufacturer or importer and the necessary information (i.e. a good Safety data Sheet) must be available.

Logic would have it that where registration is not necessary, pre-registration is useless and therefore not necessary. Not so! Recovered substances will have to be re-registered, otherwise they are illegal. It may sound unbelievable, but that is the official opinion of the European Commission.

The European Commission's legal services point out that the legal text speaks only of 'registration' and not of 'pre-registration'. And since DG Environment never ever contradicts the legal services, the Commission's message is clear: recovered substances must be pre-registered! The Commission opinion must still be discussed by the Member States, but there are no indications that Member States will disagree with

the Commission. As a result, it is recommended to pre-register recovered substances, even if there is no intention at all to ever register them.

The consequences for the Flexible Packaging are not enormous. Under REACH there must first have been a waste before you can have recovery. There are not many cases of real 'REACH recovery' in the industry. Simple in-house distillation and filtering of a cleaning solvent is not a recovery operation since the cleaning solvent was never a waste. The same goes for plastic trimmings that are reused immediately in a film blowing process.

Solvent recovery from waste gasses seems to be the most important case of real REACH recovery. Here the solvent is a waste (it is in the waste gasses after all...) and the recovered solvent is really 'recovered'. The recovered solvents that are reused or sold should be pre-registered. (The heavier solvents that are disposed of as waste remain exactly that: waste).

Paul W. Verspoor

Nanomaterials in Food packaging

Nanomaterials have very much acquired the attention of the authorities. All existing legislation regarding chemical substances is of course written with their 'normal' form in mind. And many otherwise harmless substances are feared to be dangerous, or at least potentially dangerous, to human health when they are nano-form. Some nanomaterials are for example known to easily penetrate the human skin and others may settle in the lungs and in the long term possibly cause harm over there.

It is therefore not surprising that DG Sanco is interested in the use of nanomaterials in food and in packaging for food. In June a questionnaire was

sent out to packaging producers. It inquired after nanomaterials already in use in food packaging, as well as after those still under development.

Also in June the European Commission published a Communication on the regulatory aspects of nanomaterials, which was titled "Towards a European Strategy for Nanotechnology". In this communication, the Commission states that R&D and technological progress into nanotechnology must be accompanied by a scientific investigation and assessment of possible health or environmental risks that may be associated with it. An 'Integrated, safe and responsible approach' is the core of EU



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policy for nanotechnology. All applications and all use of nanosciences and nanotechnologies should also comply with a high level of protection of public health, safety, consumers and workers, and environment. The Commission also announced a review of all the EU legislation that seems relevant and applicable to nanotechnologies and nanomaterials.

With specific regard to food and feed, the EFSA Scientific Committee published a draft for its scientific opinion on 'The potential risks arising from nanoscience and nanotechnologies on food and feed safety'. Not surprisingly, the Committee stresses the numerous uncertainties and the small amount of available information. There are for instance difficulties in detecting and measuring

nanomaterials. There is also but little information on the toxicokinetics, the toxicology and the possible exposure. But in spite of these uncertainties, the Committee concludes that today's methods for risk-assessment are a good starting point for work on nanomaterials. It warns however that there may be additional toxic effects that are not readily detectable by the current standard protocols. Also the Committee warns that the toxicity of nanomaterials cannot be fully be inferred by extrapolation from data on their non-nanoforms. An important question is for instance whether after ingestion the materials actually remain in nanoform. If so, special repeated-dose toxicity studies will be necessary.

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Under Construction

Active and intelligent packaging

The Framework Regulation (EC) No 1935/2004 on food contact materials sets the general principles for all materials and articles intended to come into contact with food. This framework regulation also covers 'active and intelligent materials and articles'. 'Active materials' are understood to be intended to extend the shelf-life or to maintain or improve the condition of packaged food. They are designed to deliberately release or absorb substances into or from the packaged food or the environment surrounding the food. 'Intelligent materials' monitor the condition of packaged food itself or they monitor the environment surrounding the food.

The European Commission is now drafting an additional Regulation to set down specific requirements for active and intelligent packaging. The Commission states that many different types of active and intelligent materials and articles exist, that substances responsible for the active or intelligent function can be contained in a separate container for instance in a small paper sachet or that the substances can be directly incorporated in the packaging material for instance in the plastic of a plastic bottle. The active and intelligent materials and articles may be composed of one or more layers or parts of different types of materials, such as plastics, paper and board or coatings and varnishes.

This new regulation will cover the safety of substances that are used, the validity of the material specific requirements e.g. on plastic food contact materials, the labelling of parts that can be mistaken for food and the declaration of compliance. There will be a 'Community list' of substances, which will include the name, conditions, restrictions or specifications or conditions of use of the substances.

Recast Plastics Directive

The European Commission is preparing a 'recast' of the plastics directive. A 'recast' means that there will be a limited number of large changes and large number of small changes. The small changes are supposed to have no implications. They are only streamlining the legislation and they will not be discussed. Only the large changes will be discussed in the Council and Parliament.

The aim of EU Commission is to put all existing Directives on plastic food contact materials and articles into one consolidated document and to get rid of today's inconsistencies. A first draft is available. The recast is to be finished in 2009

The scope of the directive will be extended to all multimaterial multilayers of which the food contact layer is plastic. Monomers and additives will be included in one single positive list and there will be an internet accessible database with information on authorised substances and on substances under evaluation.

Some important changes are that a number of food simulants will be changed, that there will be clear rules on dual use additives (additives used in both food and food packaging), the functional barrier concept cannot be used for nanomaterials and that there will be a difference between testing suspected non-compliant products aimed at taking them from the market (verification) and the methods used to demonstrate compliance (screening approaches).

Recast IPPC and VOC Directive

The SED (Solvent Emissions Directive) requires emission control from any flexible packaging plant using more than 15 tons of solvent per year. The IPPC



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Elipso

Elipso is the name for a new French federation for the plastic packaging and flexible packaging trades. It is created by CSEMP (French plastic packaging federation) and UNITES (French flexible packaging federation). It comprises 370 companies that employ more than 42,370 people and had a €7.1 billion turnover in 2007.

Adhesives GMP

Feica, the trade association of adhesives producers has published GMP code especially for the manufacture and use of adhesives and sealants intended for food contact materials.

Recycled Paper & Board

The European Food Producers Association (CIAA) has published draft guidelines for the safe use of recycled paper and board for food contact. The guidelines are based on a paper of the British Food Industry Association (FDF). Publication of the final version will follow later this year.

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IPPC directive (IPPC: Integrated Pollution prevention and Control) is the basis for the environmental permits for any flexible packaging plant using more than 200 tons of solvent per year. The 'Solvent Coating Industries' BAT Reference Document is available with IPPC permitting requirement for flexible packaging plants.

Now, when the implementation date of both directives has only just been passed, the Commission has proposed a recast of the IPPC directive with an integration of several other environmental directives, including SED. The SED part of the proposal is almost equal to the original, except for a few details and the fact that the Emission Limit Values can now be changed by 'committology' and no longer require a complete law making process.

The Commission proposal for the IPPC directive however is fundamentally different from the original. The Commission very much wishes to restrict the Competent Authority's possibilities to take local conditions into account when establishing Emission

Limit Values. Strict rules with regard to prevention of soil pollution are incorporated and the thresholds for the applicability of the directive for large Combustion Installations will go down.

S always the European parliament does not think that all this is strict enough. The liberal rapporteur is trying to get a majority for his proposals by compromising with the greens. The Member States are more reluctant to accept the Commission proposal. They would for instance have to inspect plants at fixed intervals every year or two. Also of course industry is intensively lobbying the proposal. The outcome is uncertain, both in content and timing. Even though many changes are fundamental, it is not expected that they will very much affect the flexible packaging industry. This is especially the case since in the BAT levels as described in the BREF are attainable for most plants and the exceptions are also described in that document.

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The continuing story of Bisphenol A (BPA)

Early April the European Commission invited several hundred REACH specialists to a workshop. Only those with a large network were allowed to participate. The workshop was the kick-off for the 'Awareness Campaign'; telling the industry in Europe and the rest of the world that REACH is there and that the pre-registration period was close. The Commission has good reason to start such a Campaign. Till that point in time, the Agency's web site had had only 13,000 unique visitors. 'Only' you may ask? Yes; Subtract a few thousand for all the consultants, competent authorities, NGO's and trade federations and you will be left with less than 10,000 different 'real' companies, where it is expected that there will be more than 30,000 companies who will have to register substances. Less than a third of the potential registrants had till the beginning of April taken the trouble to have a look at the official guidance documents or any other of the useful information on that site. And this just three months before the beginning of the pre-registration period.

My own company has started an 'Only Representative Service' and we can confirm the Commission's worry. We get a steady stream of inquiries from non-European companies. But most of these are of a very general nature. Does REACH apply to my company at all? Are you sure that we have to register anything if we make only polymers? We don't manufacture chemicals; we just make inks etc. There are a large number of companies out there that don't

understand, don't want to understand or simply still need waking up! We know for instance that thousands of Chinese chemical companies have only just started thinking about REACH.

So the question whether industry will be in time is a legitimate one. It will be a small miracle if all manufacturers and importers will actually pre-register before December 1st. As a consequence there is still plenty of reason for flexible packaging plants to prepare themselves for REACH. The main purpose of the preparation still is to assure that your suppliers pre-register their substances in time.

What will the Commission do when far less than 30,000 companies will have pre-registered by December 1st? In their April workshop they firmly announced that there would be no postponement! And past experience shows that the European Commission doesn't easily swallow its words.

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Waste directive

A revised Waste Framework Directive has been adopted. It aims to streamline existing waste legislation, by incorporating the old directives on waste oils and hazardous waste. In June the European Parliament agreed to the new directive. This happened in spite of the fact that the directive lacks binding goals for Member States on waste prevention. The directive does however include targets for re-use and recycling. NGOs and green groups criticize the directive for not going far enough.

The directive requires that by 2020, 50% of the European household waste and 70% of the construction waste will be recycled. But rather than impose strictly binding obligations for each different material, the Directive calls on Member States to "the necessary measures". This may not look very

strict, but the European Commission has already announced that if the targets are not met, it will take Member States to court for non-compliance.

Part of the compromise between Parliament and Council was a comprehensive waste hierarchy. The order of preference for waste processing will be: prevention, re-use, recycling and recovery. Environmental disposal will be the last option.

Parliament had argued for the incineration of waste to be classed as 'disposal', rather than as 'recovery' as favoured by the Council. But in the final compromise the Council position survived. Waste incineration so retains its better position in the waste hierarchy.

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Melamine

The Melamine crisis in China invited a strong reaction from the European Commission. Imports of milk and milk products from China were already not allowed into the Community. But some 'composite products' (products which contain at the same time a processed product of animal origin and a product of non-animal origin) that were containing processed milk components, were thought to have reached the European Union's markets.

The limit for melamine in these imported composite products was put at 2.5 mg/kg. The commission decision covers products containing over 15% milk. All the products have to be consistently tested, and any containing more than 2,5 mg/kg must be destroyed.

There is a strange discrepancy between the 2,5 mg/kg limit and the migration limit of melamine from food contact materials, which is 30 mg/kg. The Commission is aware of this discrepancy, but does not plan to change the migration limit. The Commission has however asked converters for information about the use of Melamine in packaging into food and its migration. All the available data however showed that this migration was negligible and well below the 2,5 mg/kg limit.

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REACH: Progress Report

Pre-registrations well under way

By mid November over 10.000 companies had done some 1.200.000 pre-registrations in total. This includes a UK based firm and a German firm who both surprisingly pre-registered all the 100.000 existing substances in one go. It may safely be assumed that a lot of other pre-registrations are also made without any real intention for registration. ECHA has limited now the number of pre-registrations per company to 10.000 and will not take up the two super-pre-registrants in the SIEFs. In total some 50.000 different chemicals have indeed been pre-registered, where the estimation of substances marketed in quantities over 1 t/a was no more than 30.000.

Also there were 180 inquiries to determine if substances without the proper Einesc number are allowed the 'phase in' status, 230 notifications of new substances used for R&D (PPORD) and 5 registration dossier were submitted.

The last two weeks before closure of the pre-registration window are expected to be hectic. The REACH IT system does not have enough capacity for the enormous numbers of pre-registrants during office hours. Many users access Helsinki in the evenings and nights. ECHA has already promised that they will have their full IT staff in the office during the last weekend before December 1st. Many non-EU companies seem slow in catching up with REACH. It is as if they are still investigating their options and are unwilling to come to the conclusion that there are not so many. The deadline of December 1st is approaching fast, and again and again the European Commission has made it clear that there will be no extension.

What will happen after December 1st?

The pre-registration deadline is November 30th at 24.00 hours. But it can safely be assumed that the pre-registration will by then not be complete. There will still be hundreds of companies who don't yet know about REACH, who misunderstand the regulation, who find themselves with substances that

cannot be found in the EC databases or who are simply late.

There are importers who were counting on their non-EU suppliers, but seeing no action now have to pre-register themselves. There are non EU producers of preparations (mixtures of chemicals) who still have no idea of their obligations and there are non EU producers who think that WTO will come to their help. Others think that there is bound to be an extension of the deadline.

Only recently has it become clear that recovered substances need to be pre-registered (See below). How many production plants in the EU recover solvents from their waste gasses? Several thousands surely! All these will have to pre-register the recovered solvents. And how about all sorts of other recovery processes employed in other industries.

One thing is sure: pre-registration will not be complete by December 1st. The question of course rises, what will happen then? Will the door simply be closed? No more access to REACH IT: "Sorry folks: no more pre-registrations. From today your chemicals are illegally on the market. Please send in a registration dossier before the end of the month...". Will perhaps all these late-comers have to lie and say that they are 'first time importers and manufacturers'? And will the European Commission believe all these thousands of 'first timers'?

Or will perhaps nothing happen at all? Will it simply be possible to still pre-register after December 1st? ECHA has no role whatsoever in policing REACH; that is completely up to the Member States. Of course a chemical marketed after December 1st without pre-registration is illegal. But surely companies that find themselves in an illegal situation should be allowed to rectify that situation? Who knows what ECHA and the Commission will decide. Perhaps they will remember that the decision not to take a decision is also a decision.

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REACH and 'Substances of Very High Concern'

Candidate list published

The Candidate list is published. It contains no more than 15 substances. This is much less than what was expected. From this Candidate list a 'priority list' will be chosen. Substances on the priority list will be the first to be evaluated for authorisation. There is however still a long way to go before any substances will reach the stage of appearing in the Annex XIV that will list these very special substances.

This first edition of candidate list can be downloaded from the [ECHA website](#). It may be a good idea to check with suppliers if any of the substances are used in the materials. If this is the case it is time to look at the possible consequences.

Consequences of the candidate list

Under REACH, substances on the candidate list are special. Information on their occurrence in articles and preparations must for instance always be given to 'recipients' and to consumers at their request. It is generally expected that the candidate list will work as a de-facto black list. It is very well possible that packer fillers will demand absolute absence of these substances in any products that they buy.

It is also expected that there will be a lot of unnecessary questions from the public wanting to know whether candidate list substances are present in products. NGO's have pre-printed postcards ready. As a consequence of course packer filler will ask the converters, and the converters will ask their suppliers.

Information on substances on the candidate list needs only to be provided if the article or preparation (blend of chemicals) contains more than 0,1% w/w.

REACH: Importers and their suppliers

Registration in non-EU supply lines

It has become possible that non EU manufacturers may (through an Only Representative) register substances under REACH, and that non EU formulators, who are their customers and who actually export the substances to the EU, do not have to register again. There will however be an obligation to show on batch level that the substances were indeed registered.

Although the non-EU based formulators do not need

Therefore the question is relevant: 'what is exactly is an article? Is it the whole car or is it every single nut and bolt?'

The European Commission has decided that the only legally correct answer is 'the whole car'. Several EU Member States however strongly disagree. Some have decided to accept the Commission's interpretation but to strive for a change in the law. Others, such as Denmark and Sweden, are intent on taking someone to court and hope to prove the Commission wrong.

Substitute it Now! SIN list published

SIN stands for 'Substitute it Now!' The SIN list was made by environmental NGO's because they were dissatisfied with the shortness of the 'candidate list'. The SIN list contains some 300 substances. Some of these are obviously potential 'Substances of Very High Concern', many are already classified as Cat 1 or 2 CMR's (Carcinogens, Mutagens and Reprotoxic) and today already not permitted in articles in concentration > 0,1%. Other inclusions are debatable.

Some retailers, packer fillers and producers of consumer goods are seriously considering to ban both the SIN list substances and those on the Candidate list. It is may be wise to take note of this list. The SIN list can be downloaded [here](#).

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to register, they will need an Only Representative if they wish to relive their EU customers from the burden of pre-registration. There is no legal provision for using the pre-registration of a non-EU supplier. The situation is not clear and legally not settled. In order to prevent mishaps and long delays at customs, ECHA recommends that non-EU formulators pre-register all the substances in their products, even if their suppliers do the same. Only when the suppliers prove that they actually have registered the substances in question, is it wise to de-pre-register.



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Pre-registration and re-import

Re-imported chemicals (i.e. produced and registered in the EU, exported and then imported into the EU again) do not have to be registered again by the importer or the non-EU formulator.

However, just as for registration in a non-EU supply line, this does not go for pre-registration. ECHA

recommends that importers or non-EU formulators pre-register all re-imported chemicals. Only when the suppliers prove that they actually have registered the substances in question is it wise to de-pre-register.

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REACH and its many Technicalities

Technical Guidance Notes

Technical Guidance Notes keep being published. Of the TGD's intended for industry, only the TGD's on 'Classification and Labelling notification', 'Preparation of an application for authorisation' and 'How to comply with GHS' (the new C&L regulation) are still missing.

TGD's can be found [here](#)

Review Annexes IV and V (Exemptions)

Annexes IV and V with their important exemptions have been reviewed. They have been streamlined but not been altered fundamentally. For those dealing with substances occurring in nature it may be wise to check if these substances are not now exempted. Annex IV is a simple list some forty substances that are exempted, Annex V is more complicated, for this annex a Guidance Note will soon be published.

Tools

A number of tools have been developed to make life of the REACH affected easier. There is for instance 'REACH-link', a communication and record keeping tool for consortia. There is also a translation tool that makes excel sheets fit for pre-registration bulk uploads and at the same time checks if all the entries are correct. A tool for making exposure scenarios has recently been presented. Most of these tools can be found through the CEFIC web site

Registration numbers

Registration numbers will consist of two parts: one indicates the substance and another indicating the 'owner'. Registration number will have to appear on the Safety Data Sheets. Formulators and distributors are unhappy since this will tell their customers where they have bought their ingredients. Also it is unclear what to do when a distributor or formulators has more than one supplier for the same substance. Business Europe hopes to find and propose solutions.

GHS

GHS (Global Harmonised System) will replace the existing EU Classification and Labelling system. The two systems are very similar, but there are problems caused by differences in the details. The criteria for classification are often somewhat different. This results

in a change of classification for many substances. As a consequence the scope of all sorts of EU and national legislation also changes. German industry has for instance uncovered that the number of SOVESO II sites (Large storages of very dangerous substances, needing very strict and special permits) may dramatically increase. And in France the need to have an environmental permit sometimes depends on the classification of the substances used in a company. The storage of dangerous materials is also affected, since most of the national regulations refer to the classification and labelling of products, to determine whether their storage should be in different compartments.

Who is the importer?

It is utterly unclear who is an importer and who is not. (According to REACH: 'He who is responsible for the physical entry of the substance into the EU customs area'. This could be the crane driver of the truck driver, or almost anybody else). French industry has asked its government to take the lead for clarification already several months ago. But no guidance has been forthcoming.

Risk Management Measures in standard phrases With REACH the Safety Data Sheet becomes much more important. Users of chemicals are obliged to apply the 'Risk Management Measures' that the SDS mentions. The SDSes are no longer a list of good advice, but documents that must be followed when using a chemical.

Since many an SDS must be available in more than 25 different languages: this calls for standardisation. It must be possible to translate the SDS 'at the push of a button'. The German industry has taken the initiative to expand the catalogue of risk phrases such the extended safety data sheet can answer to the REACH requirements and can still be automatically translated into all the EU languages. The project has already advanced to a stage that very soon drafts for all the standard 'Risk Management Measures' will be put to the end-user industries.

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