A·I·S·E

International Association for
Soaps, Detergents and Maintenance products

STAKEHOLDER WORKSHOP - PROCEEDINGS -

Classification and Labelling of mixtures under CLP for household detergents and cleaning products

Tuesday 1 September 2009, Brussels

INTRODUCTION

A.I.S.E. (the International Association for Soaps, Detergents and Maintenance Products), through its broad network across 42 countries, represents an industry sector delivering cleanliness and hygiene for millions of people. Household detergent and cleaning products are used every day by consumers in homes, schools and other private and public places across Europe. Consequently, product safety has always been a top priority for A.I.S.E. member companies.

Appropriate classification and labelling is key to driving safe use of household detergent and cleaning products. Industry aims to provide the correct classification reflecting the actual hazard of a mixture. Over-classification of a mixture may confuse consumers, "banalise" real hazardous products and thus, compromise consumer safety. In 2008, the new EU legislation on classification, labelling and packaging of substances and mixtures (CLP [1]) was adopted. The CLP regulation aligns existing EU legislation to the UN GHS. CLP clearly prioritizes classification and labelling based on data and evidence. Expert judgement, weight of evidence and bridging principles are key elements in the CLP scheme. CLP has also established the concept of classification networks which could be sector-specific[2].

A.I.S.E established, under the Dangerous Preparation Directive (DPD[3]), an approach by which the classification and labelling can be derived by comparing the mixture to be classified with reference formulations for which data are available. Experience gained so far with this approach indicate two areas that deserve specific attention, namely:

- the need for the approach to be robust and provide straightforward information and transparency, and
- the need to confirm which data can be used and are accepted for deriving the classification of a given mixture.

[1] CLP Regulation (EC) No 1272/2008
[2] ibid, Annex I, 1.1.0
[3] Dangerous Preparations Directive 1999/45/EC

OBJECTIVE OF THE WORKSHOP

The objective of A.I.S.E. is to develop a collective response to the new CLP challenges. This foresees the setting up of a robust, transparent and externally recognised system that assures appropriate and harmonised classification of household detergent and cleaning products across Europe. Through this workshop, A.I.S.E. invited stakeholders to a dialogue on possible ways for fulfilling the new CLP requirements, and shared with competent authorities initial ideas on the approach to weight of evidence and expert judgement with the view to achieving an appropriate classification. More specifically, the workshop aimed to illustrate the motivation of A.I.S.E companies for a data and evidence-based classification, and to share the status of in-vitro and other alternative test methods, as well as experiences with industry networks such as the A.I.S.E. approach and areas for its further improvement.

WHO ATTENDED ?

About 60 persons ranging from officials familiar with classification and labelling issues from national competent authorities (representing 15 EU countries), the European Commission and the European Chemicals Agency (ECHA) as well as industry representatives attended the workshop (see list of participants in Annex).

PROGRAMME

The format of the day was a series of presentations and two discussion sessions, and a summing up by the Moderator. This write up gives a summary of each of the presentations, the report back from the discussion sessions, and the summing up. The presentations have been circulated to the participants.

AGENDA OF THE WORKSHOP

PART 1	**Welcome and introduction to the day** **The Context :**	**Susannne Zaenker,** Director-General A.I.S.E. **Jim Bridges,** Moderator
	• Household detergents and cleaning products: Classification, labelling and safe use communication	**Sheila Kirkwood**, Mc Bride/A.I.S.E.
	• The CLP Regulation	**Uta Jensen-Korte,** European Commission, Brussels
	• Questions & Answers	**All**
PART 2	**The Process : Classification of Detergent and Cleaning Products and Industry Networks**	
	• Industry network in Germany : the Trustee Expert Model	**Christian Grugel,** Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz, Berlin
	• The needs of inspectorates and competent authorities	**Krista Bouma,** Voedsel en Waren Autoriteit Noord (VWA), Groningen
	• A.I.S.E. views on an industry network for Europe	**Sylvie Lemoine,** A.I.S.E.
	Questions & Answers	**All**
	Discussion I : **The Process - Industry Network - Needs and Expectations**	*In several breakout groups (summarised in PART 4)* Moderators : **Christine Drury, Véronique Scailteur, John Solbé, Thomas Petry**
PART 3	**Weight of Evidence and Data Requirements**	
	• A.I.S.E. concepts for Weight of Evidence and Expert Judgement - Examples	**Thomas Petry,** ToxMinds, Brussels
	• Experiences from Poison Control Centers	**Hugo Kupferschmidt,** Schweizerisches Toxikologisches Informationszentrum, Zürich
	• In-vitro test methods - Skin & Eye Effects	**Frank Henkler,** Bundesinstitut für Risikobewertung, Berlin
	• Questions & Answers	**All**
	Discussion II : **Examples - Read Across - Use of PCC and in-vitro data**	*In several breakout groups (summarised in PART 4)* Moderators : **Christine Drury, Véronique Scailteur, John Solbé, Thomas Petry**
PART 4	**Discussions & Conclusions**	**All**
	Debrief from Panel discussions	**Jim Bridges**
	Closing Remarks and next steps	
	End	

PROCEEDINGS

INTRODUCTIONS TO THE WORKSHOP

In her opening remarks Susanne Zaenker, Director-General of A.I.S.E. welcomed participants to a learning process among experts on the subject of classification and labelling of mixtures for households cleaning and detergent products. She encouraged an open dialogue between industry, authorities and academia on how best to achieve this.

The Moderator for the day was Jim Bridges, Emeritus Professor of Toxicology at Surrey University, UK, and advisor to the EU on Emerging Risks and Risk Assessment Procedures. He introduced the day event as the start of a dialogue on appropriate classification for skin and eye effects. The processes would need to be transparent and scientifically rigorous, involve some form of partnership between industry and regulatory authorities, and maximise access to and transparency of data.

PART 1 CONTEXT SETTING

1.1 Classification, Labelling and Safe Use Communication

Setting the Scene, **Sheila Kirkwood** underlined that Industry's aim was to classify for effects on skin and eye to meet the legal requirements, and label so that consumers could also recognise the hazard correctly.

The label needs to make sense and fit with consumers' experience of the product.

Because household cleaning and detergent products are used everywhere and every-day, they are well understood. To achieve consumer respect for and use of the labelling it is therefore important to get it right.

The need for classification and labelling to be fit for purpose is well demonstrated by comparing a drain cleaner and a dishwash liquid. Under the CLP additivity method, both would be classified and labelled with the same corrosive pictogramme. In fact the drain cleaner is caustic and corrosive, and used with caution by consumers and stored with care. By contrast hand dish wash products have normally no or negligible effects in use when used direct on skin, and are used every day and often left by the sink. Across the wide range of products within and between categories there is an irritancy continuum (Fig 1) in which expert judgement and common sense have to play a part to achieve an approach that fits both purpose and user experience.

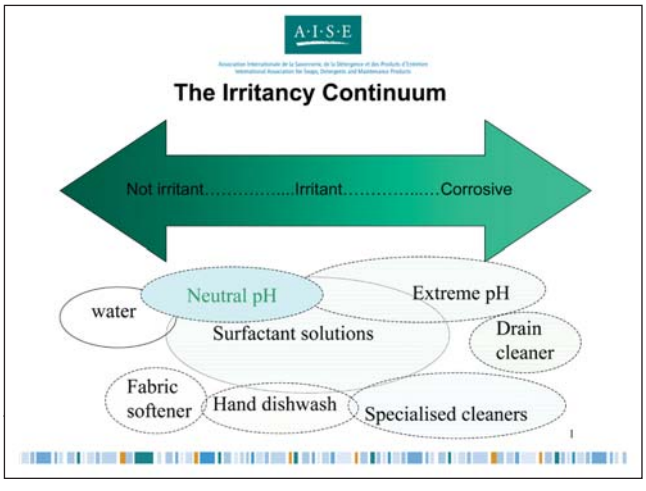


Fig1

of products all labelled as corrosive when experience and knowledge would differentiate them does not help consumers nor the objective of consumer protection.
There would be confusion and a risk of the warning symbols being devalued.
Poison centres have similar concern about lack of differentiation. Under CLP the more severe effects of drain cleaners and oven cleaners, would not be distinguished from other products having much less severe or negligible effects.
The current A.I.S.E. approach to classification under DPD is based on frame formulations and test data shared across the industry. The approach has been criticised not least because it applies LVET (Low Volume Eye Test) and HPT (Human Patch Test), neither of which are OECD approved tests. Under CLP there is more flexibility to use data and evidence. The industry sees this as a way to use existing data more fully, to add more data as appropriate methods become available, and as a way to share that data as envisaged under CLP.

As a start of the adaptations to CLP the database has been reviewed, and full details of the frame formulations made available in A.I.S.E. An expert has standardised and reclassified the data against CLP criteria, and suggested some key formulations for future in-vitro testing to help prepare benchmarks. Comments at this stage will help to achieve an approach that is sensible for the consumer, transparent for the regulator and manageable for the industry, especially an SME.

Question and Answer session following the presentation :

Asked about the link between the Objective of the workshop and CLP Guidance, Ms Kirkwood said the link is the clarification of guidance on the use of skin and eye data.

Questioned on the lack of epidemiological data, Ms Kirkwood said the Industry had, a very large amount of data from millions of uses over 50 years, and wanted to use it, although none of it was epidemiological as such.

Questioned on whether the industry was saying that CLP was not appropriate, she emphasised that it was only the additivity method, here specifically for skin and eye effects, that the industry thought was inappropriate, which is why they wanted to use the facility under CLP to use all available evidence to classify appropriately. Another participant suggested the industry had a problem if it wanted to treat household products and detergents differently from other chemicals. Ms Kirkwood replied that this was not the case.
The industry wanted to use the opportunities available in the CLP regulations.

1.2 The CLP regulation

Uta Jensen-Korte reminded everyone that this EU Regulation is based on GHS. CLP is therefore built on a global system.

Its essence is to achieve a common basis for classification and labelling to help safe handling across the world and within Europe. It will therefore also achieve further harmonisation of the internal market (this being a regulation under Article 95 of EU Treaty). There is therefore a duty to strive for a common understanding also, of how it should be applied.

Explaining this further, Ms Jensen-Korte focussed on some of the provisions of the Regulation. Suppliers should self classify or respect the harmonised classifications in Annex VI, and ensure appropriate labelling before placing the product on the market.

This is similar to what has been in place for some 40 years in Europe. Ms Jensen-Korte noted that for the purpose of the CLP Regulation there is no obligation to test for health and environmental hazards.
Downstream users may use the classification of the supplier if they do not change the composition. There is more emphasis on cooperation than in the past.
The information duties under Self-Classification are to identify relevant information from as many sources as

possible, for example data generated by methods validated for the classification of transport of dangerous goods. Also to look at occupational data and accident databases. The duty is also to examine whether the data is adequate, reliable and scientifically valid.

With respect to testing, there is no obligation to test, except for physical-chemical properties. New information may be generated through testing, but look at all existing data first, and animal testing should only be used as a last resort. Human testing shall not be done for the purpose of classification but human data generated for other reasons may be used. The next step is to evaluate the information. There is more emphasis on Weight of evidence and expert judgement than under DPD. Weight of Evidence means all information, with human data normally having precedence, as set out in Annex I, and the guidance document just published from ECHA (August 2009). This also gives more information on how to apply the classification criteria for the various hazard classes.

There are specific provisions for mixtures: if data is available, use it. Special requirements apply for CMR, bioaccumulation and biodegradability: they shall be based on substance data. If no or inadequate data is available directly apply the bridging principle: use data on individual substances and similar tested mixtures.
This is a new aspect introduced by CLP. There are therefore different possibilities to apply. If none of these can be used, apply the calculation methods. Another new aspect is the setting of specific concentration limits (SCL's). Previously these were only possible by means of a comitology approach under the DSD. Under CLP, SCL's can be set by suppliers. Setting a higher SCL may be more difficult than setting a lower one as it will require conclusive scientific information. CLP includes guidance on setting SCL for skin and eye effects.

Ms Jensen-Korte talked very briefly about labelling noting the need for the product ID, hazard pictograms, signal words, hazard and precautionary statements, and the requirements on use of languages, noting requirements for updating labels, and the inclusion of some derogations.

Safety data sheets specified under Annex II of REACH are already in a format aligned with GHS, Ms Jensen-Korte advised that there is more revision work (Sept 2009) to adapt to UN GHS and CLP.

CLP legislation includes cooperation of suppliers. Suppliers in an industry sector may cooperate through the formation of a network or other means. This is highlighted as recital 24. This stakeholder workshop initiative is very much in-line with the CLP Regulation. The purpose of cooperation is to share experience, and where needed develop new experience.
The essential part is to fully document what is done and make it available to authorities on request. Equally important is the fact that each supplier remains fully responsible for the classification, labelling

and other requirements of CLP.
In conclusion CLP gives more emphasis to expert judgment and weight of evidence, especially on mixtures.
This provides more flexibility and introduces the new elements of the bridging principle and enabling suppliers to set SCL's.

PART 2 THE PROCESS – CLP AND INDUSTRY NETWORKS

2.1 Industry work in Germany: the Trustee Expert Model

Christian Grugel described the process that has operated successfully in Germany for 15 years, since 1994. It was developed to classify and label products that were irritant by calculation, but not irritant by experience. If they had been kept on the market with this calculation approach, consumers would have neither agreed with nor respected the labelling.

The challenge was to find a better alternative based on experimental data. Labelling must be real to people. The thought was to use a network, the central idea being to share experience and data, so that there could be joint use of experience and knowledge. This way comparative testing was available to all companies and no company had to rely only on its own data: this was much better for the quality of the classification: the big step being to move from only own data to all available data- most of it not published.

The way it works is that all documentation goes to a Trustee. The Trustee passes it to an expert. The expert considers the new formulation against a comparator formulation and provides the expert opinion to the Company via the Trustee. The expert does not know from whom the formulation came, nor does the company know who gave the opinion. Confidentiality is maintained. This is the Trustee Expert Model.

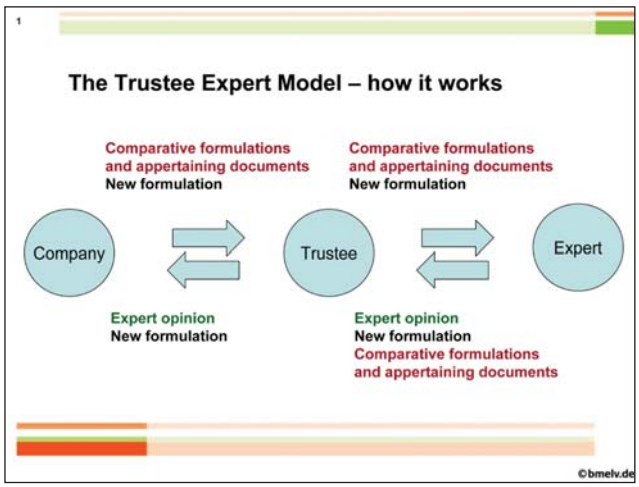


Fig 2

It has the industry association, IKW, as the Trustee, acting as a gateway between the companies and the experts. The experts making the comparisons have been academia from several universities.

Over the 15 years of operation on detergents and hand dish wash products creating 580 expert opinions, 75% have been for

small companies, and only 25% for big companies. Of the 18 opinions on cleaning products since March 2004, 50% are for small companies. In addition to generating better classification, the trustee expert model saves resources and new testing by using all available data in the network. Safety precautions applied are only those where experience and labelling are consistent. Consumers therefore trust safety precautions.

An interesting consequence of the system is that when a company received an opinion that a product would need to be labelled as a hazard, they were more likely to change its formulation to reduce the hazard, than to place it on the market. Thus, the system has stimulated the competition for less hazardous products.

Question and Answer Session following the Presentation :

Asked about the Experts, Mr. Grugel suggested there were various options for recruiting experts. In this model it was academia, it could also include experts from industry. The key requirement is to ensure a high quality of experts. Asked if there was ever 'congestion' with there being few experts, Mr Grugel replied that this was not a problem; all information being available to all experts helped ensure an efficient process.

Questionned on the role for authorities in the German model, Mr Grugel said that it was useful to be involved as a stakeholder and to be aware of the process, but he noted that it was very important that Authorities play no part in how the product is classified and labelled. They should remain impartial.

Participants suggested there could be a role for consumer representatives, and noted that imports of products which were classified and labelled differently would give rise to problems.

It was also suggested that the large amount of data available at Poison centres be included in the evidence base. Many exposures recorded at Poison centres concern situations of accidental or intentional abuse. They, therefore, provide 'stress tests', for example if the formulation is not harmful when misused. It was also noted that appropriate classification and labelling is important to poison centres because over or under classification can lead to over or under treatment

2.2 Needs of Inspectorates and Competent Authorities

Krista Bouma explained the organisation and operation of the Food and Consumer Product Safety Authority (VWA) in the Netherlands, from her perspective as a public health officer in the Groningen Laboratory. The VWA was formed in 2002 from the merger of two inspectorates under the Ministry of Health. It has 5 regional offices and three main tasks: supervision, risk assessment and risk communication. Household Chemicals are a small part of a broad agenda including animal safety, alcohol & tobacco, food safety to product and equipment safety. Each region has a specialised team of product safety inspectors, supported by laboratories with broad expertise in chemical & microbiological analysis.

The focus of enforcement work is always on consumer protection. Enforcement of chemical substances and preparations involves checking the product file and Material Safety Data Sheets, checking the labelling, simple checks such as pH and flash point, and checking compliance with the legislation, including the general product safety directive. All companies must have a register of complaints and what action was taken. Market surveillance of products involves sampling in retail stores and analysis in the VWA laboratory.
For example, checks can be made for allergenic fragrances in detergents, and for preservatives in liquid detergents.
VWA observes that more consumers have sensitising reactions, so Annex 17 of REACH and sensitising substances classified R43 are important.

On labelling, what is wanted is realistic classification and labelling: classification based on the actual situation and labelled accordingly. The legal system sets the basis for the approach: expert judgment combined with common sense gives the right application of the law. An example is VWA attitude to the Alkali/acid reserve method for pH-extreme formulations. Although this method is not approved as sufficient in legislation, VWA's experience is that is works well in practice and it is supported and published scientifically.

VWA uses it because it prevents over classification, and therefore avoids the corrosive symbol being devalued. Similarly the system of reference formulations based on LVET and HPT is not in line with legislation as these are not OECD approved tests, but they are the best available and they provide an acceptable approach. If consumer complaints were to arise, VWA would no longer accept it.
VWA cooperates with the industry association, NVZ, based on a shared interest in compliance, realistic labelling and consumer protection. VWA also works closely with the other Inspectorates:

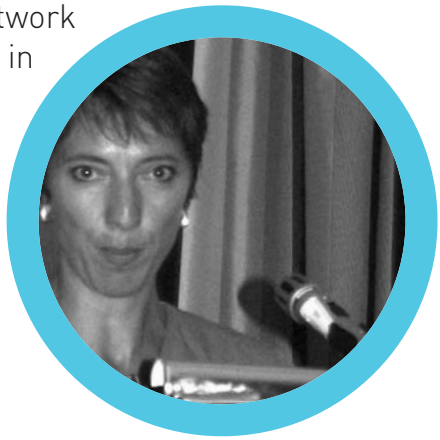
VROM for industrial products and raw materials, and the Labour Inspectorate concerned with occupational safety.
All Inspectorates are involved in the enforcement of the REACH legislation. Alignment on methods and how to do an inspection is not always easy. Under GHS-CLP there are even more Ministries involved – 5 in total. Training to help achieve a common approach is underway: VWA is leading on a common approach to sanctions.

Enforcement under GLS-CLP is from the starting point of consumer protection, which means realistic classification and labelling: no under or over classification.
It is fortunate that CLP leaves room for expert judgment. Common sense should be added to that.

On the A.I.S.E. approach, it could be good, but it will be essential that all companies participate, and for it to include products being imported. It needs to be transparent and for there to be a good network between industry and authorities.

2.3 A.I.S.E. views on an Industry network for Europe

Sylvie Lemoine set out the concept of a network as it might look in practice. She emphasised that this was 'brainstorming' approach, for discussion, inspired by the Trustee Expert Model in Germany, but in the knowledge that it would need to be different for Europe.



A.I.S.E. considers that applying 'weight of evidence' using expert judgement to the data available on A.I.S.E. products is the lead option today to maximise the use of existing information and derive appropriate classification of mixtures for the industry under CLP. In essence the approach is needed because the additivity method does not give the appropriate answer with regard to skin and eye classification and ultimately for consumer protection in the detergent products sector, even though it may work well for other sectors. However expert judgement involves some subjectivity whereas companies and authorities need predictability. The system needs to address to be transparent on this be transparent.
Under the CLP legislation there is an option to set up a data and expertise sharing network, with all documentation being available to authorities. Companies remain responsible for their classification.

What follows is a draft proposal of how such requirements could be met (Figs 3 & 4). It would be structured around two main pillars: an expert steering group to organise the work and an expert pool to make the actual classification recommendations based on expert judgement. Links to authorities would have to be further determined: it could be as stakeholders only, as advisers or something else.
Authorities would not want to be seen as endorsing the judgements, but it will be relevant to know whether the process is in line

with authorities' expectations. It may also be that the approach could be relevant to other sectors. The process would start with the data available now in the industry.

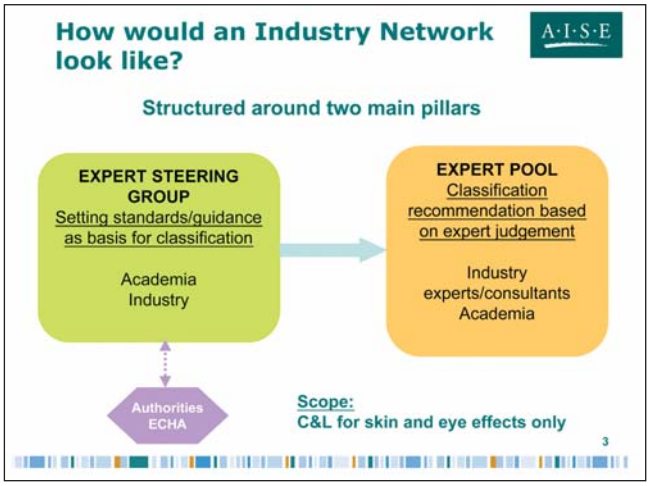


Fig 3

The classification and labelling process will need tools, such as IT tools, rules and continuous improvement processes to ensure it operates in a harmonised and transparent way. Some feedback on the draft concept from authorities and other stakeholders is a necessary first stage before embarking on detailed development of the tools for the network.

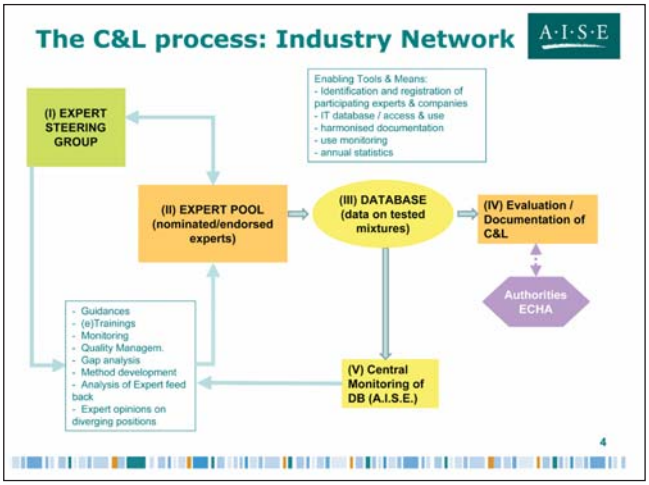


Fig 3

The role of the Expert Steering Group would be to develop CLP Guidance for the sector, to look at gaps in information and test methods, to engage in training and quality management, to select and endorse experts, and provide mediation. Its composition would be academia and industry and perhaps also regulators. An important aspect is that the activities of the expert group, as one element of collaboration under the CLP legislation, would be fully transparent.

The Expert Pool would be the focus of the documentation: using the wide range of information in the database to generate decisions, and providing feedback to the Expert Steering Group. Some form of benchmarking among experts is likely to be necessary, for example by the means of ring tests. The system would be open to all companies, and the Expert pool would consist of academia and industry experts.

The IT database would contain summaries of existing test data in mixtures.
There would be a 'matchfinder' to identify the closest formulation in the database, from which to apply the bridging principle. The reference formulations would be, as a start, the 186 on which the industry has data today, including in-vivo tests, but would further evolve over time.

The evaluation and documentation will need a consistent approach in using the database and harmonised documentation. There are many aspects of the system
to be resolved, including access rights, cost sharing, and administration arrangements; also how best to disclose data to competent authorities when there is an inspection.
Experts would use a standard recording sheet for classification outcomes, which would then be the property of the company. This is a learning-by-doing process.
Views in the discussion session will help the refinement of the concept. This needs to be a system that is European, works for all Member States, and all Companies, and achieves the expected level of transparency.

PART 3 WEIGHT OF EVIDENCE AND DATA REQUIREMENTS

3.1 A.I.S.E. Concepts for Weight of Evidence & Expert Judgement-Examples.

Thomas Petry's presentation showed how Weight of Evidence and Expert Judgment might be applied in practice for detergents and cleaning products.
If existing physico-chemical, human and in-vitro or in-vivo test data together with other information meets CLP criteria, then it will be possible to classify accordingly.

If it is not possible to apply the CLP criteria to the data directly – for example if some data conflicts, then look at data on similar tested mixtures and ingredients.
If the comparator products are similar in their chemical and toxicological profiles, use them as reference mixtures and apply the Bridging Principle, taking note of the boundaries defined in the legislation.
If the reference itself or the data for the reference are not suitable as judged by experts then generate new data or classify by other methods, such as specific concentration limits, or calculation.

Expert judgment will give correct weights to the information available. For eye irritation hazard for detergent products data will include in-vitro, animal data and human experience, including occupational and poison centre information. For skin irritation hazard, human clinical data will also be relevant. Data will be GLP or equivalent quality. If data sets conflict, then classify according to the more severe result.

➔ The first example is for a Liquid Detergent:

The data shown listed the pH, the ingredients classes, the name of the ingredients, the CLP skin and eye classification (i.e.: Category 1 or 2.), the % in the new product formulation and the % in the reference formulation. Available information is listed – i.e. test studies: eg. LVET and HPT Bridging conditions are largely but

not exactly met, therefore weight of evidence and expert judgment is applied by comparing the level of the different classes of ingredients between the reference and new formulations. The level of classified ingredients is lower in the new product, and the higher level of soap (unclassified) in the new formulation is not assessed to modify the irritation potential. LVET and HPT data do not indicate classification. Market surveillance and poison control data do not indicate any market issues. Evaluation result: not to classify for skin or eye irritancy.

➔ The second example is for a Dishwashing liquid:

Formulation and test data are listed in the same ways as for the liquid detergent. There are two reference formulations, but neither meets the bridging conditions exactly, so apply weight of evidence and expert judgment. Levels of classified ingredients are lower in the new formulation. LVET data on both reference formulations indicate category 2 classification under CLP. The new product tested in-vitro, indicates a mild irritant. Market and Poison Centre data do not show any market problems. The result is to classify Category 2 eye irritant and not to classify for skin irritancy.

3.2. Experiences from Poison Control Centres

Hugo Kuperschmidt introduced the topic of Poison centre information on household cleaning products by data showing very similar population-adjusted numbers of enquiries and clinical outcomes in the US and in Switzerland. This indicates that data available is quite robust.

There are 80 poison centres in 33 countries in Europe and networks in France, UK, Scandinavia and Germany- Austria-Switzerland. Poison centres give expert advice, generally to doctors or vets, in toxic emergencies. There is standard reporting on 6 key questions: patient identification; toxic agent identification; route and time of exposure; dose; and what happened since.

Poison centres maintain two data sets: case data and toxic agent data. For cases, caller data, patient data, toxic agent, route and circumstances of exposure, description of the incident, advice given and prognosis are recorded in a standardised way. There are steps for the confirmation of clinical data, agent involved and exposure. Data is then translated into a uniform language, and a standardised assessment of severity and causality is made. However standardisation is not fully harmonised between poison centres

Product identification is crucial but often difficult to perform. For poison centres to be able to give correct advice, the description of the incident and the agent/product involved must be matched with the product data (formulation and hazard characterisation) provided by the manufacturer.

Product characterisation is best done with a product ID, as product names may be misleading; detailed product composition provided to poison centres needs to be dated. Product information should also carry the date of release as products used may be of a previous composition.

Human data is much discussed. In comparison with animal experimental data, human data are much more heterogeneous, (age distribution, pre-existing morbidity, diet and other environmental factors; circumstances of exposure). Often there is exposure to multiple agents, and the dose is often unknown. Despite the heterogeneous nature of human data, its big advantage is that it is human, and the number of cases is high. Poison centres contribute to case studies spontaneously reported, and to toxico-vigilance which is also relevant data. Limitations of poison control data arise from the absence of direct access to the patients, and the spontaneous reporting character of the system which leads to an under reporting in some cases and the fact that the focus is on acute rather than chronic exposure.

Another limitation for a European approach is the lack of harmonisation in the categorisation of agents and symptoms.

One recent example of a multicentre study by poison centres is the MAGAM study ('Multinationale retrospective Analyse von Daten der Giftinformationzentren zur Frage korrosiver Augenläsionen durch feste Maschinengeschirrspülmittel und anderer Wasch-, Pflege- und Reinigungsmittel'). It is a retrospective analysis using data from 9 poison centres in Germany, Austria and Switzerland on 162 cases of eye exposure to automatic dish wash products in a database of almost 2 million records for all products. An important finding on the issue of product identification is that the product was identified in only 25% of cases at the time of the call. A further 50% were identified retrospectively, but in 25% the product identity remained unclear (approximate numbers).

In conclusion: poison centres need valid and accurate data on product identification and formulation for medical purposes as well as for toxicological vigilance. Poison centres have large databases on acute toxic exposures. However there is insufficient harmonisation among poison centres or between poison centres and authorities and industry. A common effort to provide product data to poison centres on a European basis would reduce the administrative burden on manufacturers and facilitate poison centre information internationally.

3.3. In-vitro test methods - Skin & Eye effects

Frank Henkler gave a summary of recent developments in the area of alternative methods from the perspective of the German Federal Institute for Risk Assessment (BfR), which is a scientific advisory body to the Federal Ministry of Food, Agriculture and Consumer Protection and ZEBET, the Centre for Alternative methods to Animal Experiments in Germany. The validation of alternative methods is mostly done using a prospective approach: Following test development and a pre-validation phase, a more detailed analysis of the reproducibility, applicability and relevance of the test method is performed in ring trials and the results, if appropriate, evaluated by the Scientific Advisory Committee (ESAC) of the European Centre of Alternative Methods (ECVAM).

Most recently, in-vitro tests methods to predict skin irritancy, based on already validated and accepted protocols for skin corrosion, have been developed. It took over ten years, but in 2008, ECVAM recommended three human skin models (EpiSkin, EpiDerm and SkinEthic) as stand alone test methods for the prediction of the skin irritancy potential of chemicals. These methods have not been validated for mixtures. Notably, when compared with historical erythema score data from Draize skin tests (from the ECETOC database), these in-vitro test systems achieved a much better prediction of irritant versus non-irritant properties, in particular because fewer substances score in the cut-off range of 50% cell viability.

In addition, the data from various validation studies were re-analyzed to fit the GHS-classification system, resulting in improved predictability. ESAC and the OECD expert group have now concluded that these tests are suitable for GHS classification.

For eye irritation testing, the EU has recognised four in-vitro methods to predict severe eye irritation (R41). OECD Test Guidelines for the BCOP and ICE tests are consolidated and have passed the OECD council and, thus, received worldwide regulatory acceptance whereas IRE and HET-CAM need further analysis. All four tests have previously been endorsed by the EU as sufficient for the classification and labelling of severe eye irritants (R41). Work is also underway to develop a strategic test regime to test the range of irritancy from negative to irritant to corrosive on skin and eye. In this respect, the Silicon Microphysiometer seems currently the most promising approach for the development of a stand alone method to predict eye irritancy.

ESAC has also agreed on recommendations for the LVET (Low Volume Eye Test). This will be published at the end of September 2009. No further tests, or

development of new in-vivo tests should be done, but existing data from LVET tests on household detergents and cleaning products, and their main ingredients, may be used for classification and labelling purposes. Furthermore, existing LVET data of the A.I.S.E. use domain could be used as supplementary reference data in the context of future validation studies.

PART 4 DISCUSSIONS AND CONCLUSIONS

For the Discussion sessions the workshop separated into four groups. All addressed both topics and there was a balance of Industry, Member States' authorities and European regulators in each group. The summary here reflects the range of views and issues raised on each topic across the four groups.

4.1. DISCUSSION 1 : The Process - Industry Network- Needs and Expectations.

The first Discussion focussed on the issue of networks and how the collaboration described in the CLP legislation could work in practice in the detergents and household products sector, reflecting on the experience of the Trustee Model in Germany, the practical needs of surveillance and enforcement by authorities illustrated by the Netherlands, and the ideas for a system put forward by A.I.S.E.
Although there was general understanding and acceptance of the A.I.S.E. ideas, there were concerns among some participants that the A.I.S.E. suggested model may not be necessary. If it was to go ahead there would need to be full agreement on the objectives: a high level of consumer safety and a level playing field for all companies in the industry including importers.
Most thought it would be a step forward. There was concern among a few participants that A.I.S.E. might want products not to be classified. But there was widespread acknowledgement that over and under classification are not good for public health, and that it was important to get classification right.

The basic elements were generally agreed: the need for appropriate classification; that new approaches needed to be used because calculation does not always mirror reality, and that the supplier is always responsible and liable. Indeed all responsibilities in the process need to be very clear: the experts for their opinions; the company for its classifications; the authorities for examination and enforcement.
Some thought there could be an advisory role for authorities especially in the design of the system and its rules, but there was unanimous agreement that authorities should not be involved in the classification decisions in any way.

Concerning the process for the network and guidance, it should have a simple structure, be workable, sector specific, and available to all companies particularly SME's. Consistency and quality would depend on there being a well organised process. Data and opinions need to be available to all experts. To be transparent,

authorities will need good documentation that is both consistent and readily available when it is requested. This should be as an easily understood and harmonised dossier; authorities have to look after many different sectors. Making frame formulations available will not be sufficient. To meet member states requirements, ask them!
The designers of the system should remember that the ultimate customers for the dossiers that record the expert's decision and reasoning are authorities.

The expertise used must be valid, and not involve authorities, and the output must be independent, not biased, following the model of a scientific committee, even though real independence would not be possible. Authorities may want to be able to talk directly to the expert, as expert to expert, in special cases if there is a point of clarification or challenge in the dossier.

Self regulation and quality assurance of the experts is essential for the credibility and competence of the system. Training and exchange between experts as well as updating of information will be key aspects of maintaining quality. The transparency needs to include the criteria for expert selection, i.e. the science that will underpin the system, and quality assessments of the output. The Expert pool should consist of a small group of recognised experts across Europe. It would be relevant to include poison control centre expertise.

4.2. DISCUSSION 2 : Examples - Read-Across – Use of PCC and in-vitro data

The discussion focussed on applying the rules of the new regulation. Guidance had been issued recently by ECHA. This discussion therefore concerned more specific guidance for the sector. The sector would use the bridging principle and apply expert judgement, and had a large amount of information. The examples shown earlier (see above 3.1) and the application of bridging by 'reading across' were therefore highly relevant for the sector, as was the use of additional information from poison control centres and the issues arising from the type of test data and the availability of alternative methods.

There was agreement that the pooling and organisation of existing information would be very important. This should be done with a pool of Experts, so recruiting and training would be an early priority.
The work should include developing some general principles and guidance, and defining and agreeing what is similar by comparing new formulations to existing formulations. There was general agreement on the issues related to dealing with heterogeneous data sets and, as in the previous discussion, there was a common view that efforts should be taken to avoid under and over classification.

The transparency of the information as illustrated in the presented case studies was viewed as an important step forward allowing the regulatory community to reproduce the steps involved in weight of evidence evaluation, and to independently assess the quality and validity of the underlying information.

It would also be necessary to consider what other evidence should be obtained. For example the development and validation of in-vitro test methods for mixtures is needed to support weight of evidence evaluations, because read-across may be difficult for mixtures without this. This is particularly important if weight of evidence evaluations are based on non-validated methods such as the LVET and HPT, and non-consideration of this data would lead to over classification.

A key concern identified by the regulatory community is the eligibility of basing a weight of evidence evaluation on methods not validated by an internationally recognized validation authority. While the scientific validity of such assessment was not put in question, concern was raised about potential vulnerabilities in case of legal challenges. The use of validated methodologies is generally regarded as 'legal insurance', also because of lack of expertise that may reside within inspectorates to fully reproduce the weight of evidence evaluations.

The CLP legislation specifies the identification of all other information, and there was agreement that a large amount of different information is available: poison control data on extreme exposures – (there was a view this should be harmonised nationally due to language rather than at European level); complaints registers (the EU Commission has a study on harmonisation of complaints); 'carelines' and occupational data. Although all of this information is collected for other purposes, it would be morally and ethically wrong not to use it for classification, if the data is of sufficient quality.

There was a view that in applying weight of evidence and expert judgement we should not 'reinvent the wheel': existing approaches and use of guidelines for transport should be examined and modified as appropriate for the sector. It was noted that ECHA is planning to review consistency of approach across member states, so it would be sensible to wait a couple of years for this.

The weight of evidence approach and bridging mean that wider information such as that from poison centres can be very relevant, but it must be carefully assessed against CLP criteria. There is likely to be a mosaic of data, each element of which should be considered independently against CLP criteria. To apply bridging, both pillars need to be understood: reference formulations need to have a robust data set. The facility in the legislation to set specific concentration levels (SLC), may become important, if suppliers of ingredients increasingly have the data to do this and this substance data is available before more robust data can be available on mixtures.

4.3. In Conclusion

In his summing up, Jim Bridges drew some conclusions from the workshop and suggested some next steps. He defined the key issue as the common purpose of CLP. This is to provide consumers, workers and others with accurate, trusted, readily usable information relating to the skin and eye effects of household detergents and cleaning products. The task is how to start achieving this. The process needs to be transparent and available and trusted by the key stakeholders.

Key components of the process would be : access to and effective utilisation of all relevant data for skin and eye effects, and a method of data analysis and interpretation that can be demonstrated as best scientific practice, and a utilisation of the data to provide the most appropriate labelling and safety data sheets. All this needs a robust and sustainable framework.

There are many matters to be resolved: access to the data sources; handling of confidential data (how can the industry be transparent if the authorities can't see the data?); weighting of different types and quality of data consistently and transparently ; developing best practice in data extrapolation and bridging; ensuring labelling and safety data sheets meet users requirements.

On the framework for the process and challenges, factors to consider were how to be effective in achieving the common purpose; how to be transparent to stakeholders and, therefore, trusted and harmonised. At the core of the framework being proposed there would be some form of expert groups to develop the guidelines for data gathering and carring out assessments. What are the criteria for membership of these groups, how do we to achieve high and consistent standards, and how should link they to other stakeholders ?

For the next steps, Jim Bridges said that information from the workshop would be put on the website, including a report of the meeting. All participants were invited to share their further thoughts on how to meet the common purpose, and A.I.S.E. would do more work on the proposal in the light of comments in this workshop, and circulate the outcome. All were thanked for their contributions to the workshop.

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