

“Toxicological Data and Information Network – A European Challenge?”

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Results from the round table discussion

Participants of the round table

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Karin Feychting	Pharmacist in the poison centre in Stockholm. Working about product information being in contact with the industry. She has developed a new data base.
Frederike Wiebel	Biologist and toxicologist at the Henkel Company, Department of Toxicology with responsibility for the whole business unit detergents and cleaners.
Herbert Desel	Chemist and medical doctor working in the Göttingen Poison Centre. National co-ordinator of the TDI project.
Gerhard Heinemeyer	Clinical Pharmacologist, head of the sub-division Clinical Toxicology, Toxicovigilance in the BgVV.
Nick Edwards	Scientist in the London Poison Centre
Monique Mathieu	Doctor in pharmacy and head of the North of France Poison Centre in Lille. Member of the Intox programme of WHO/IPCS, member of the European Association of Poison Centres and Clinical Toxicologists. M.M. has also develop use of data collection in poison centre in the perspective of developing prevention for humans especially for risk assessment.
Bernd Glassl	German cosmetics toiletries perfume and detergents association, Frankfurt/M.
Alexander Campbell	Poisons Information specialist from the London poison centre and General Secretary of the European Association of Poison Centres and Clinical Toxicologists.
Wim Daeleman	Belgian Poison Centre (Brussels), responsible for the data management.

J. Tempowski

Now if you look at your programme, there is a list of six questions that this round table is going to discuss and debate. We are not going to look at these questions in the order they are written on this list. We are going to start by discussing the first question: what would be the benefits of international exchange of toxicology data in Europe and whether there are any disadvantages; then what data it would be useful to exchange; then what are the prerequisites for exchange of data; next how data can be exchanged; what mechanisms already exist, what has been tried in the past, and finally who are the key players.

So I have to go through all of these questions. I think that the idea is that the panel will discuss these issues but that if any of you in the audience wish to comments or to contribute your own experience, you are invited to do so

We will start with the first question „ What would be the benefits, what’s the purpose of data exchange“, why do you think it’s useful having an international exchange of toxicological data in Europe?

Would anybody like to volunteer?

F. Wiebel

Okay, I am thinking about cases we had to deal with and where we would have liked to have more data on health effects after misuse of products. The cases I am thinking about are very rare

poisonings and there is too little information to take from one country. For example cases of eye contact – eye contact is a very small portion of recorded cases - and so we are hoping that if we have access to exchange data it would be easier for us to see if there is a problem. It would be very nice if we could have all the information without having to contact to every single poison information centre.

M. Mathieu

I would like to comment on this. Yes, there are cases where poison centres would like to have access to product information from another country and we contact the poison centres. Our main problem is to install a collaboration between poison centres to act on a European level. In my experience, in computers there are tools that can facilitate things but do not create a collaboration by itself. It is a mean like a telephone, if you know someone has a telephone he can use it to call, if you don't want you don't use it. It's a tool so I think this was the discussion also in France to install a system that resolves every problem. Sometimes there are all work problems that we have to identify first to make collaboration that will avoid to be disappointed. So, to share the cases is a major problem we can share because it is a toxicovigilance system. We have to be cautious not to invent the tool before having the collaboration at the EU level.

G. Heinemeyer

As a member of the BgVV I can say that we are working at the interface between clinical toxicology and regulatory toxicology. So I would like to comment on that Monique has yesterday said about these two worlds of regulators and clinical toxicologists. And what I see from the regulatory aspect that for example in the existing chemicals regulation the requirements that are important for consumer products and substances in consumer products to be assessed are only poorly considered. This leads to risk assessment reports with much informations which are only very poorly valuable for poison centres. On the other hand, poison centres have data and, if their documentation is accurate, we get data on relevant substances for consumers. We noticed it yesterday. I would think that it is very important to adjust both. There may be two aspects, the first one is to prioritize which substances are important to assess and vice versa, if these substances that are important to poison centres will come to a regular assessment, the knowledge on these substances will also be enhanced. The regulators will have advantages / benefits and the poison centres will also have benefits. And this would be a very good task we can work on.

B. Glassl

What we should add is also is the interest of industry not having so many systems all over Europe and not to have to declare the same products twice or three or ten times for every European country, because mostly the formulations are the same and the names also. I think the concept of declaration of cosmetics can be a good example for developing a unique system, or for having a multinational system. It's the same information for every country.

H. Desel

I think we really have to differentiate the information about products and the information about cases. This is a little bit mixed. I think we have shown here and not only we but many other colleagues have shown that there is really some progress, some results in the way how product information is handled and how the change of the degree of product information can be ascertained. Everybody sitting here knows that exchange of case information is important, but only little technical work has been done as far as I see. I think a lot of questions have to be discussed before we talk about exchange of case information, what would you like to exchange, what would you document?. Is it necessary to have the symptoms, is it enough for you to have an example showing that there symptoms or that there are no symptoms. This is easier instead of having the degree or the type of the symptoms. I have the feeling that you should differentiate this in our further talk here before otherwise it is always mixed up.

J. Tempowski

Thank you very much, I think we will be going on to talk about what types of data will be exchanged. Dr. Feychting, please?

K. Feychting

I just want to remind you of the importance that we evaluate the information that we put into the system that we will share, especially the cases. I mean we have these meetings with the EAPCCT where we exchange experiences about cases. We discuss them and we know the cases have passed

the scientific board where they have been evaluated. We know they are “good” cases and I think this is very important. I mean if we take the example we heard with the supercleaner (washing-up liquid) I don't think it is very useful for poison centres in Europe to get information about all these harmless cases. It's just cases that are not harmless and of course, cases with new substances, or new kinds of substances in products, as e.g. the one we heard about yesterday, the nailpolish remover with gamma-butyrolactone. In these cases it's very important to be able to exchange information.

J. Tempowski

So, if we're looking at the question of what's the purpose of it all and why we are pursuing this, we are talking about the benefits on the industry side. Less effort, I suppose, is involved in getting the information that can be useful for determining the safety of products. From the perspective of poison centres I think we focus perhaps more on the product data side and simplifying access to product data.

Are there comments on that?

F. Wiebel

It's not only less work that we would like to have, but it would be very much appreciated if the categories would be the same, the general data collection: what is actually documented, how deep into the case is something documented, or how is other data - for example from medical doctors - how is this incorporated into the system. Things like that would be very helpful, I think, also because the quality of the data that is collected would be much better. Apart from the greater number of cases that would be the major advantage - the connected systems would have the same standard.

G. Heinemeyer

Just to add a little bit. I think it is not only important to differentiate what Dr. Desel said but also to differentiate the information that is put into a system of poison centres. This means product information, case information, and substance information. The other question is what's getting out of this system. First of all we need proper information to have a good quality of advice, to have a good quality of documentation, which should be enhanced by an implementation of standards, as we have learned yesterday and today. I think we should talk about these standards for documentation. In the next step then, if the documentation is OK, we can talk about evaluations, but without a good documentation there will never be a good evaluation of the poison centre information at all. That's the crucial point.

J. Tempowski

This is very important. I see that we have a request from the audience.

L. Onyon

It is to remind and it goes long in the way of quality documentation. I thought the very interesting comments made by our german colleagues that learning from experience about the cases that didn't require intervention and so sharing these cases as well, they don't need any hospitalization and stay at home because everybody wins.

J. Tempowski

That's a very important point, thanks. It's very interesting because these are positive results. So, who is doing this for industry? Who is doing this for poison centres? We were told yesterday about the benefits to regulatory agencies of having access to human case data. Is there anybody else who we would direct this activity towards, who could benefit from this proposal to have an electronic data exchange in Europe. The consumer, I suppose, who at the end of the day we seek to serve.

Audience: Funding authorities

J. Tempowski

Funding authorities – there are obvious the benefits in meeting the needs of funding authorities.

What about disadvantages? Presumably there are some problems that I'm sure that people think of . Are there disadvantages with sharing data – perhaps we should differentiate between sharing product data and sharing case data? Is there anybody to make a comment about what the problems or disadvantages might be in having a centralized collection of product data? Alex.

A. Campbell

With reference to case - data I think there may be medico-legal problems or difficulties that may arise with regard to exchange of confidential patient information across Europe. Such considerations may bring their own logistic or bureaucratic problems that will need to be overcome. Similar confidentiality issues may arise with product data as well.

K. Feychting

I would just remind you of the language problem. It's obvious we have a language problem if we're going to share data. I mean we all read and understand and write in English, but for me when I'm talking to a physician I want to do this in Swedish and I want to read in Swedish when I'm discussing a case with a physician. The language problem is of great importance I think.

N. Edwards

I think the problems we have is going to be that although there may be a good will in poison centres and industry to collect European data, especially product data, the problem is that there is a mismatch between the desire to do it and the legislative framework in which it is done. The legislative framework is such that the directives that come from the EU and then national authorities impose their own local law and there is often a different interpretation, sometimes a widely different interpretation of the European directive -. Although it may be desirable to deposit the information in one place. The practicalities are unreal and I don't see that this could happen. I think the idea that each country has a central contact point obviously makes a lot of sense. The idea that we have a single European monolithic data base seems very impractical. Access to all the people to data is different. Portals are possibly a way forward but if we are going down the road of proposing a single point of deposit for European product data then the thing would be dead in the water. I think case data is a different matter and I agree with Alex that there is a big issue about confidentiality and how you transfer data between each other. I think European poison centres have more chance of agreeing some standards that allow the collation and collection of case data than we have of a single European product data base.

J. Tempowski

And of course we should also remember that we're not talking about countries in the European Union but that we're talking about whole of Europe. So there are countries that have quite different legislation, perhaps there may be no legislation.

Are there any comments from the panel?

H. Desel

I think we have shown that it is not really necessary to have such a European monolithic data base for all because maybe not all data are important for every poison centre everywhere. If we come on the way to have some kind of format where the data may be exchanged so everybody as in our system I showed you yesterday even every poison centre has its own data base in the TDI system. It should have or may have the same data but the technique is also to have different data or only parts of the data for example. If we have an easy way to exchange these everybody does not need to have everything and we do not have to have one data base at a centralized position. This would be a disadvantage of such a centralized system, where will you build it up, how would you keep it and so on. I think, the technique is so up to date that this is not really necessary anymore.

J. Tempowski

Thank you very much. I think that the model of the TDI is very interesting, could be very well explored elsewhere and we have a comment from the audience?

M. Lulei

Yes, my name is Michael Lulei, I am from the German chemical industry association and I would like to support Mr. Edwards. I think the third step made may be the creation of a central entity in Europe but the first step should be the harmonization of all exchange systems, not only the exchange systems between the poison centres within Germany or Europe but also harmonized system to fill in the data. So and I would like to know what are the plans in the future in Germany and in Europe to harmonize the systems that industry enterprises can fill in the data in a harmonized way.

G. Heinemeyer

First of all, at one of the last meeting in Lille we had the discussion on product circulation between European centres. We agreed that total product information must not be exchanged to each centre, but it is very important to circulate information where the source is, where centres can get it from. Every centre should give a list of products they are aware on. If there is a case which is very seldom than the centres having the data can be contacted.

To answer Mr. Lulei it is very important to have standard formats and the preparation of software is a most proper way is a most proper way of standardisation and harmonization. To mention the INTOX project, which is now used in around 70 or 80 countries around the world, the most important effect INTOX had was that this programme harmonized the documentation in clinical toxicology. And this is independent on the responsible agency which. To mention the german situation for the chemicals the BgVV and the successor, the BfR¹ will be responsible for this and what we hope is that EMIL can be taken over to the other products that are distributed in our country, to paints, to lacquers, to adhesives and pesticides. To the biocides it is already possible. I think this programme is powerful enough to solve these questions – we already have the harmonization in our country if everybody use this system.

J. Tempowski

Thank you very much. Gerhard has mentioned INTOX and Lesleye has also mentioned the INTOX system which uses harmonized terminology and controlled vocabulary for documenting cases and also for creating product data bases. The terminology is defined and the definitions are agreed by an international working group and will hopefully have international applicability. The work that has gone into the INTOX terminology has informed the development of systems in other countries as well.

To go back to benefits - we talked about the benefits to industry and to poison centres. Putting on a WHO hat for the moment, there is also a benefit in terms of estimating global burden of disease through collection of harmonized case data and in terms of getting a more accurate assessment of the impact of the exposures to chemicals on human health. In many countries, this statistical information about exposures to chemicals is not very good and as a consequence I think the problems of poisoning and exposures to chemicals are underestimated: the extent of the problem is not fully realized in every country and so issues of poisoning tend to be low on the list of priorities in a country when it is deciding how to spend its health budget, because these things are uncounted therefore it seems there are no problems.

Is there anybody else to make any comments on this issue on benefits and problems; the problem of confidentiality is quite a significant one I think when it comes to case data. Different rules apply in different countries about what information is possible to transmit about our patients. We have European legislation concerning the European privacy laws which is quite strict and can present some problems with scientific research.

M. Mathieu

I see also, another advantage is to make the product formulations and the substances more comprehensive for clinical toxicology call use, because sometimes and as it was said yesterday, you can find 15 components that sometimes a chemist cannot understand what it is. So it will have an impact on harmonization, on the language how we use the terms. If we want to use cases and to relate a case to a substance than we have to know about the substance.

J. Tempowski

In my experience you may eventually identify a chemical but still may not know how toxic it is – this happens many times when looking at formulations. That brings us round to Lesley's point yesterday that regulators are investigating chemicals and trying to make toxicity assessments but they're focusing on the things that are't in products. We want to know about these mysterious ingredients in products. We may have the case data here that can contribute to toxicity assessments.

L. Onyon

The issue of confidentiality of product composition is central to the issue of being able to connect cases of poisoning with chemical products with the risk assessment reports that are made by national

¹ BfR: „Bundesinstitut für Risikobewertung“ [Federal Institute for Risk-Assessment], the institute which is founded as a successor of the BgVV.

and international agencies. Problems with knowing what chemicals are in the products is made even more difficult when you consider the numbers of products on the market. I am interested in learning a bit more about the concept of frame formulations and wondering in what situations these have been used. They seem to have worked in situations where the type of formulation is changing rapidly and is very commercially sensitive, such as cosmetics. Do you think they might provide a useful interchange mechanism between the poisons centres needs for simple readily accessible information and the risk assessors need to know what chemicals might be in which products and the detailed composition? From a regulatory perspective, frame formulations might also provide a way of controlling the amount of hazardous ingredients in different product types.

N. Edwards

Yes, the frame formulations for cosmetics started in 83 in the UK with the British trade association of cosmetics, toiletry and perfumery and became after many discussions to be the COLIPA frames. At the same time as discussions we're having with CTPA we had the same discussions with SDIA (the soap and detergents industry association). In the 80s frame for household cleaning products were produced and we started the discussion the manufacturers of disinfectants and other hygienic products. Those discussions fell because of the 88 European directive. We felt that because of the dangerous European preparations directive there would be no need for these other discussions to continue. Although it hasn't turned out to be useful from our (Poisons Centre) point of view. The other thing is that frame formulations take away the apparent desire, which was expressed yesterday, to link individual ingredients to adverse health effects.

For practical reasons in poison centres discussion about frame formulations are very useful, but if you go back from individual cases to individual constituents than the frames are a danger.

G. Heinemeyer

This leads me to the discussion about what frames mean and what are the considerations for frames. I think, the cosmetic frame formulations are an example for an extreme frame giving only very general information. Generally, frames helps industry to keep confidentiality, and this means that the formulation details are not totally known. On the other extreme of the frame concept there would be a frame containing for instance individual names of the substances as ingredients, but the amounts of the substances are only given very generally. The level of a frame should depend on the category of products. Because cosmetics are belonging to a category that is rather untoxic, the frame is very unspecific. Some ingredients that are of toxic relevance have to be given quantitatively. If we change the category to more toxic relevant ones, the substances should be given more precisely. For example, this is valid to pesticides, having highly toxic ingredients. The poison centre needs the exact name, and for household products, they are probably in between. So we need the terms of the ingredients, but we don't need the percentage, depending on the category.

B. Glassl

It's not only the confidentiality, which is important but it is also important that the system is practicable. If you have to precise too much, in case of changes of the percentage of an ingredient, you have to resend a notification and this will charge many persons in the companies and also in the poison centres. So I think only to send the information which has to be in the poison centres in the case of an accident. The frame formulation has to be sent without making shure what kind of anionic surfactant is present in the product, because there is no toxicological relevance.

J. Tempowski

Is there anybody with a different view?

P. Jacobsen

I just have a comment on the efforts to link a specific product to a specific case. I think it is very costly to collect information on all products that the population might be exposed to and then through case statistics find out who get diseased from poisonings with specific kinds of products. In concept, it is the same as in the case control or in the cohort study in epidemiology: If we want to collect information on a huge population where the event is very rare we would never choose to make a cohort study. We would make a case control study because this would be more cost efficient. That means that Poison Centres should collect information on case-by-case basis if we want to make toxicovigilance in order to identify dangerous products. We should never make a construction that maps exposure of the whole population and to all products. There is no reason to make such data collection. There is sparse

evidence. We have heard of three different events where new products came up with unexpected toxic effects: That was γ -butyrolactone, lamp oil and one more. That's too rare to justify a large scale surveillance. Instead we should focus at identification and evaluation of only the unusual cases. ...

N. Edwards

I agree. What I was saying was that appeared to be a goal. I don't think that should be the goal. I think for the majority of the cases the data we have are adequate. A frame would give a better, an easier access. But it wouldn't give you, if the goal is to do this, a direct link between cases and particular compounds; a frame tends to act against you.

M. Mathieu

I would like to raise the problem that we have to ask a good question for what special purpose but not only for what purpose in general we need data. Why do we need a full formulation? It can be for some advice in the poison centre, it can be for research, for evaluation and for risk assessment. I don't know. Very important is that many things are possible, but it is also a question of mean, of budget. We can not do everything, so as Matthias Brockstedt said this morning we have to find the adequate measure for the adequate problem. But its also the same for databases. For what purpose we need what. For example in the case of an accident in most of all cases the frame formulation is sufficient to give adequate advice by a poison centre, but for identification of problems, exposures, exposures on long term, exposures on multiple and small amounts, you need the formulation. Then you can find that there are exposures in ten years by small amounts, there are some ingredients in cosmetics, in cleaning products, in walls in what's ever, sometimes you have chronic pathology that you don't understand. In such cases we need to look at this and if we really want to do risk assessment we need that for regulatory purposes. My comment was just we have to categorize and to give priority to what we want.

J. Tempowski

Is there another question about poisons centres' effort and what are the objectives of poison centres, what can a poison centre achieve? How good are poison centres at picking up the effects of low level exposures? If anybody wants to comment on that?

L. Onyon

We are doing the retrospective feasibility study I talked about yesterday to illustrate some of the strengths and weaknesses of poison centre information in identifying cases that are of interest to risk assessors. No amount of retrospective study will tell you everything and we hope to undertake a prospective study that will further test the system out. In a perspective study it will be possible to identify in advance the products which contain the chemical substances of interest or to otherwise identify in advance the cases of interest. These could then be "flagged" so if a poison centre receives a relevant call then information can be collected. From the results of the retrospective and prospective studies we would get a better understanding of the type of questions poison centres should be able to help with. Parallel work must be carried out with risk assessors to find out from them what information they need in order to make risk assessments stronger - more scientifically and evidenced based. As has been touched upon by others there are a lot of costs to involve a poison centres in risk assessment work and lot of ways that you can set things up to answer different questions.

J. Tempowski.

The second question is what data could be exchanged: cases, products, substances, possibly other data? I think it was thought that case data is useful for certain purposes and product data is useful as well. Can I take it that you are agreed that we think it's useful to exchange that data? What about other kinds of data, for instance what about substance information? We talked about that different organisations that write monographs on substances which they generally keeps themselves, is there any scope of sharing that sort of data? The INTOX databank has poisons information monographs available, internationally. Does anybody think that there is value on sharing information on substances? Is there information to share?

P. Jacobsen

I think this is a pretty good idea, and it's cost effective. However its outside the scope of what we're discussing here. We don't need the discussion.

J. Tempowski

Is there any other information to be exchanged

G. Heinemeyer

Concerning case data I think data exchange is partly done by preparing annual reports. Everybody has access to annual reports, these are the most important statistical data poison centres create.

J. Tempowski

What about the European Union harmonized annual report? Everybody, all poison centres in the European Union once sent their data to an agency in Brussels, which then published them as a single European Report. So the European Union imposed a standard on the kind of information that should be provided by poison centres. It's true every poison centre produces an annual report but they produce different kinds of reports. And they produce reports that are not necessarily comparable. So there is a need of comparability of data from different centres.

G. Heinemeyer

That's the question of the standards.

J. Tempowski

OK

A. Stürer.

Stürer from the poison control centre Mainz. I have a question and would come back to substances. Do we have in Europe one list of substances in the different languages? If not why don't we prepare this list and publish it in the internet? This would be a big impact for all the poison centres and for industry. To have one big list of substances in the different languages, like the INCI-list² prepared by COLIPA³ for cosmetics?.

U. Haas

Ulrich Haas from Henkel, Germany. In the new EU chemicals policy there will be a list of all chemical substances on the market produced. This list will come in 12 to 20 different European languages.

Audience: when?

It's dependent on the workload of the European Commission. There are several plans on the way calling for 2006 up to 2010 or more.

G. Heinemeyer

We shouldn't forget that we already have an international language for substance identifications. That is the chemical abstracts registration (CAS) number. If this is documented correctly you can find any substance, with some exceptions but most of them you can. This is the international system for identification of course.

U. Haas

The CAS system contains not only substances but products and mixtures as well. It's not a good system to identify substances only.

G. Heinemeyer

That's not an argument against CAS

J. Tempowski

Okay we want to proceed to question three, what are the prerequisites for data exchange on cases or products, perhaps not substances. Gerhard has already mentioned several times the issue of standardisation of data. Does anybody have anything to say about standardisation? Case data? Does

² INCI: International Nomenclature for Cosmetic Ingredients

³ COLIPA: **C**omitee de **L**iaison des **A**ssociations **E**uropeennes de **I**ndustrie de la **P**arfumerie des **P**roduits **C**osmetique et de **T**oilette

standardization already exist in Europe, do you know? We know that in Germany, there is national standardization.

G. Heinemeyer

I think, we had lots of discussions about this point. We didn't had a final agreement, there are already a very few items to be discussed concerning formats of cases. Probably the situation in Europe is very similar, everybody knows what a case means and how to describe a case properly, but there are format differences. The discussion about standards should therefore include this, and this discussion should be made first of independently on data structures. The second step should then consider how the structures can adjusted into data bases and, vice versa how the structures can be adjusted to the data formats.

J. Tempowski

What's the obstacle of having standardized formats of data?

G. Heinemeyer

If we talk about the exchange of information we have to harmonize it. This means standard formats. A good method to harmonize is to circulate a computer programme. That's what happen with INTOX.

M. Mathieu

I don't agree with you, it's not only the computer, it's the definition of the format of the data. If you know the special definition than its okay, what ever the computer you use, and you can exchange and you can transfer from one database to another. We transfer data from other systems into our data base, the first question is how are the terms and the definitions. In the INTOX programme we had lots of discussions and we had agreed at an international group to main definitions. It's a start and you can try to use it that to make the definitions more accurate and better. The problem is that in each centre we want to invent new definitions.

G. Heinemeyer

Just not to misunderstand me, I totally agree with you. The computer helps us, he convinces us to make definitions. Before the computer area we had very different definitions for the same thing, but in the computer we are convinced to harmonize them. The computer is not the objective of the work but the instrument we work with.

J. Tempowski

There are two aspects on the formats, deciding what data elements to collect, which information I'm going to collect, or are all poisons centres are going to collect the same information, or at least the same minimum data set? And then the other question is, do we mean the same thing when we say an "accidental exposure" for instance or "occupational exposure" - that's a definition issue.

P. Jacobsen

I'm a little confused when you talk about exchanging information on cases. Is it information on individual cases?, then you don't need to harmonize. If you want to exchange knowledge about the first case poisoned by gamma butyrolactone in a nail polish remover then you just inform everybody that nail polish remover might contain something that make small children unconscious. But if the need to harmonize is for statistical purposes than harmonization should aim at registration of the same variables with the same meanings: i.e. same age levels, and the same hierarchy for product types and so on....

J. Tempowski

Well, I think we're talking about the possibility of pooling the data of several centres to meet the need of Dr. Wiebel, for instance. She has got the products and she is interested to know what the effects of eye exposure are. And there are five cases in Germany, two cases in the UK and five cases in France, and ten cases in Poland. How can we pool these data and then analyse them, and derive something useful from this?

M. Lulei

Yes, I got the impression from our society everything is standardized up to now. We have the german institute for standardization and we have the European CEN and the ISO and I'm impressed that the

data exchange between poison centres as I learned is not standardized in a way within Germany and within Europe that we can make useful solutions for that and we can get useful results out of that and I wonder if this wouldn't be an initiative of the BgVV to take standardize all this in Europe and within Germany.

J. Tempowski

Thanks to BgVV for volunteering to take on that task!

G. Heinemeyer

Yes, this is the work we are dealing since the last ten years after introducing chemical legislation in our country. This brings us back to the question of Dr. Wiebel to look for the incidences of poisonings. If you have only a national level, or probably a poison centre level, then you need years to get certainty of what happens and if you extend it to the other countries and to as much co-operation as possible, then the incidences will be observed in a shorter time. This is the most important reason for exchanging case data to decrease the time for getting certain incidences. The question which has to be combined with this is, which data are needed. Of course, we don't need to exchange all the information we have, but only a very small set of data.

F. Wiebel

I think we all agree it would be very nice to have a standardised system, but maybe we could start with a description of the situation: what is collected where. Industry is usually not interested in showing that there is a problem but in showing that there is not a problem. We need to know what has been collected. If we say, okay, we haven't had severe cases of irritation in a certain country, but this country doesn't actually record irritation cases, then this was not a valid assumption. So, maybe as a start, we can try to collect and compare what the poison centres are actually documenting at the moment, to see where we are and to see the differences between the centres. Because it would take very long to actually standardise the whole system but it might be useful to see which information can we actually use now.

H. Desel

We already mentioned the effort of the European annual reports of all the things I think that you make use of. It started just before the time I started to deal with clinical toxicology. To my experience or what I can see what the main disadvantage was they couldn't use any categories for products that are somehow comparable, and this is the reason why we have included the categories into our project. If you don't have categories you can only count for the total numbers to tell how many calls for pharmaceuticals or so you had. This would never help you. You need some categories on some kind of cosmetics or so, you can get reliable numbers on this. Without any categories you would hard manage that, and if you have a system you have to categorise any case, any call you have. This is a lot of work and I'm not sure whether all centres are able to do it.

F. Wiebel

That's exactly why I suggested to make a description of the situation as it is now. Maybe every country has a different categorisation, so if we know that a certain category does not exist in a certain country then we don't have to look for it in that country.

H. Desel:

So look at the annual reports

N. Edwards

I would ask; what we felt we would know that the Americans don't know; because the situation is that every year in US TESS is. We recently used it for some work for the European Union on the safety of packaging of medicine and poisoning in childhood. Although this data is US and not Europe, it exists. If we are talking about standardization and, we were thinking about using INTOX or writing it afresh, then shouldn't we look what TESS is doing?

M. Mathieu

There is a need of harmonization of product classification of use between manufacturers and poison centres because we don't use the same definitions and that is to reinforce, not only between poison centres but also between all users of the data. I had the experience in household products when we

asked the manufacturers for that kind of subgroup and we were very surprised to find things that were classified differently. And we have to understand what is behind the classification. For manufacturers, the purpose is for the market, and we made the classification for another purpose, so there is a need also to harmonize the definition, to speak the same language between all users of classification.

G. Heinemeyer

I would propose that the following message should be brought to the governing board of the EAPCCT that EAPCCT should install a working group, an official working group that have the task to work out standards for data exchange for products, cases, and substances, and these standards should be published officially in Clinical Toxicology. Then we will have a basis for further discussions. There has a very practical work to be done, and I see the EAPCCT as the only actor in this field, WHO has already done work but the practical thing is that the European centres, agencies and also industry must have help in this field.

L. Onyon

As I said yesterday, as a follow-up and using the information collected in the small feasibility study, the WHO is currently undertaking some work to look at the compatibility of the existing formats used by the poison centres that were involved in the study. . This would begin to identify the scope of any international compatibility project and also see if INTOX already has the capability to combine data from different countries. The feasibility study involved seven countries, not only from Europe but also from outside Europe including Japan, Uruguay and Australia. . In starting this work it has to be remembered that INTOX was developed at a stage when poisons centres largely used paper formats for recording their case data. It benefited enormously from being developed internationally, in particular it benefited from building upon the wide consensus among poisons centres about what was best practice case reporting. When INTOX was developed the concepts and practice of electronic data interchange was not as well developed as we see now. In developed countries a number of different computerised recording systems have been established and the WHO wants to make sure that whatever system is used that global data collection is possible. I very much support the comments by Dr. Wiebel. I think we shouldn't set up goals so high as to need standardisation in order to collect a global picture of poisoning but we want compatible systems... Just on this point of view and again to pick up the discussion about unusual cases Developing countries have their own problems in their own geographical cultural conditions. The products they are using are the products still largely imported from European manufacturers and the responsibility of the manufacturers of course is export behind the European boundaries. Exchange of product information is therefore vital from the point of view of not exporting hazards to developing countries without the information necessary to manage those hazards. It is obviously also of interest to European companies that emerging issues with European products in developing countries is monitored.

H. Desel

We have heard a lot of presentations about product information. My feeling is that we are really a few more steps forward in product information. We have already definitions. I'm not familiar with all that case documentation and standardizations here, and I would like to discuss this product section a little bit more for the time left.

J. Tempowski

OK, is there anybody who wants to start that off, the issue of product data?

H. Desel

We have seen there are some technical developments in Europe, we have learned here by some presentations, some of them being realized, for instance the Italy-system, and from our system, but if we look behind, information that could be exchanged is not totally identical, although there is a great overlap. To a high degree the information is similar, and we have also learned that different authorities in Germany have different needs, but what I see from the technical view, all these needs can be combined. So what we have presented from the TDI-project is on one hand an exchange format. This exchange format is properly described and allows to transfer data on products in a secure way that can be readily imported by the importers of the computer systems. On the other hand we have shown that we have a protocol, describing how we do this procedure; what is important? Important is either the identification of the sender, we have to be really shure that we know who is sending the message. And I think, having a format that is well displaying the data without doubts, this is a need that has to be

exchanged together with the information in any case. If the information is only slightly different to another one, it should be able to identify that, which is made by the protocol including all that information. We have shown this in the TDI project, that we have already done this on a national level as Dr. Glassl has pointed out, and industry has to send the data to one of the two authorities or to a poison centre. We don't take the same data set, but different ones with respect to the legislation or the agreed standards. We have managed to have at least one programme for data input, and the data come out and they can be used for the different purposes. Our feeling is that this is an example, a perspective for other branches of industry and even for a European level of exchange.

J. Tempowski

There is a European format for product information. The EAPCCT, SDIA AISE format, which is focused on consumer products. We have also heard that there is a Nordic cooperative products data base.

G. Heinemeyer

Yes, what I like to say is to combine what Dr. Desel has said and what I have mentioned earlier. I think this TDI exchange format named Rosetta is not an official European format. It is accepted for German poison centres and for German industry. But before going to Europe, we must have an official approval by a competent institution or association. For me this is the EAPCCT. So, what we have to do is to bring all the formats which have been worked out on national bases, the German, Italian, Nordic and others to a group of the EAPCCT which can evaluate these formats and then would publish a common official approved format. I'm sure, this format would be very close to the existing ones. If we agree that a European exchange is needed we have to do this formal process. Nobody can say "my format is the right one".

J. Tempowski

Again this issue - the format is the combination of the elements of information that are included in the record and the definitions and those elements are. And the product categorization is something that comes up in different systems and has to be standardized as well.

B. Glassl

Which period of time would you expect for this harmonization.

A. Campbell

It's hard to say, because a working group actually has to be set up, with the approval and agreement of the EAPCCT board. If the consensus from this meeting is that this is appropriate, I will take this request to the next board meeting in October.

The work of the EAPCCT working groups is largely conducted via electronic communication, and it obviously may take some time for the standards to be agreed and approved. I agree that there should be participation from regulators in this working group as well.

J. Tempowski

There are some international standards? aren't there, is there a standard for MSDS and the Intox product format, is this alright, Lesley?

L. Onyon

There are some existing international standards for product data I thought.

M. Lulei

I like to mention my last question and missed the answer, why is this not taken up by a European standardisation institute CEN? Would this be a solution

N. Edwards

There are two things I think that happen at these level. First of all, CEN produce standards in response to legislative pressure. However, the standard for MSDS's is not helpful for poison centres but because there is a law it is difficult to ask for more as there is no law to back it up, no European law anyway, so we can send it and the manufacturer could ask, why do you want to do so?

Secondly the European association household products committee is used to talk about the cosmetic frames with COLIPA and the AISE to set up the original soap and detergent industries standard

format. These committees existed at a time when the association - it seems to me - had a different view about its role, and in the last few years the EAPCCT seems to have lost its nerve, in terms of its relationship with industry. At one time the European association could act with industry because they are acting *for* poison centres. It seems to me that now the European association doesn't think that at all and they have given away its voice. It's a shame and I agree with Gerhard that we should give it to the EAPCCT and the European association should drive it forward. If it doesn't drive it forward I don't know who will. Even if we do, without Governmental approval industry could rightly say 'where is the law, we have the MSDS law and I need to fill up these formats but nowhere does it say I have to fill up the AISE form'.

B. Glassl

To my opinion there is no need to have law for product information. So we strongly support the voluntary basis.

H. Desel

I like to make a technical remark, what we are going to realize. As an example for European harmonization just to take this form which was on a paper, we took it and transferred it to a form that can be read by computers. And another technical remark I will make here is that we have a new kind of general usable format, mentioned by Dr. Stamm, named XML This is a kind of format which allows to exchange structured information between totally different systems. The advantage of this XML format is that the sender who produces the data in this format can check whether his data are conform with this standard, which is agreed on from different sites. So if the sender decides "I want to send my data" by e.g. a data acquisition programme like EMIL or others or he decide "I have a big database where my products are in" he can export his data and use the XML data format. He can check whether the data are formally correct before sending. This is a very big advantage. From the experience we have made in the TDI project, when we started and tried to communicate with the EMIL software on one hand and the TDI software on the other hand we learned when we tried to accept the different files we had to tell the sender what's wrong which took many cycles of communications. The XML allows the sender to check his data for himself. He will send then a correct and structured information. This is what we mean, just transfer this on an agreed standard format for these detergents on a computer form which is compatible with XML format and this may be a basis for exchange. This would work in any country. This could be made easily within a few months.

J. Tempowski

Do you have an idea to what extent the TDI format matches the Italian format or that of the Nordic system?

H. Desel

At the first view I expect a great agreement between the formats. What I see is that the difference is not in format but in the protocol. As I pointed out we spent a lot of time to make an identification of the sender. This is not the central point in the Italian system. The protocol refers to another level than the format.

P.E. Anderson

I'm from the Norwegian product register :In Norway we have legislation and we have a database in the internet. It will be called the product information bank. It will contain XML files direct from Norwegian producers for all kind of products, for which they had made MSDS, and the MSDS will be possibly send by an XML file directly to this bank. This is a pilot project starting within a few months.

L. Onyon

I'm really impressed to the TDI exchange format and things we are talking about in the last five to ten minutes are very sensible in terms of how to move forward and possibly to the EAPCCT. I'm impressed of the German initiative because it reminds me to another impressive German initiative which took place approximately twelve years ago and this is the IUCLID database which is of course the heart of the European Chemicals Regulation and housed at the Joint Research Centre based at ISPRA.. I wonder you have included in your plans any cooperative activity with the people in ISPRA in terms of linking product data with the IUCLID substance data base because that would seem to make sense. The system there is a well established substance data base which is recognized worldwide and includes product, substance and toxicity data collected electronically from the

European chemical industry. The European chemical industry did much development work for this system and it is now accepted among all countries of the OECD. Have you had discussions with the people at IUCLID, perhaps working together, extending the TDI principle and exchanging your information with the IUCLID substance data base?

H. Desel

Short answer is: No. Of course we have talked about substance identification during the process of developing software exchange formats. Finally we could not agree on a closed list or system that are sufficient enough to all the needs we will see. So what we decided to start first of all with EMIL with selected kind of products of the kind of industry we heard about. We will see how many substances will be included and then decide how the list will be enlarged. May be this is an important task to do and also the BgVV as Dr. Heinemeyer said has mentioned another list which is carefully checked up and a lot of work is also integrated there and after some time we will look at the different lists and if we have a European view then this approach may be very important. Please remind also the language problems.

J. Tempowski

Does anybody else have any to say about IUCLID and if we're talking about manufacturers wanting to give product data only to a single place, to a single organisation, might they prefer to give it to IUCLID for instance rather than to poison centres or other national bodies?

We will almost going too close I think. It's a good idea to say that we generally agree to exchange product data; that we agree that we need some standardization of formats, that some significant work is also to be done in some countries, to make it possible to built up a framework. The European Association of Poison Centres should be asked to play some sort of co-ordinating role. There should also be input also from industry and perhaps we should also be looking at IUCLID as well and contribution of the Joint Research Centre.

Do you agree with that, very brief summation?

We haven't said we want to set up a mega European products data base, what we have said we can agree on formats of sharing the information internationally so each country can take it's own responsibility upon it's data, is that fair to include it into the conclusion.

H. Desel

May I add a remark, please. I try to emphasize again, the one discussion is on the format, and the other discussion is, on a higher level, on the protocol, how it works.

J. Tempowski

Okay so as far as the formats go some work is to be done and more on case records is required. As far as protocols go, the same, but presumably the first step is to have a working group to look at formats and protocols.

We also had a question about what mechanisms already exist, and I think that this has already been discussed over the last day, yesterday and this morning. Whether any lessons could be learned from what's been done in the past - if anybody wants immediately to say what not to do...? There is no time to go to into the sad history of ENS.

L. Onyon

Will there be a preparation of a report of this meeting?

J. Tempowski

This is a very good point and there will be a report.

G. Heinemeyer

The most important thing now is how to proceed with the problem, and the idea I have is whether it would be useful to have a discussion forum in the internet for getting ideas, to discuss the ideas and to forward them. There should also be another meeting in the next one or two years, and this meeting should be organised on behalf of the EAPCCT; of course, this is the organisation of poison centres and clinical toxicologists and I know that there are also toxicologists from the industry as members. The cosmetic frame formulations initiative is a good example for co-operation of industry and EAPCCT. Why shouldn't this be expanded to other industrial associations? I think this a very normal

way and it is the only working one. There is one alternative, that is that industry could say, we do only provide the information in a special format, then the poison centres are convinced to accept them or not. So we have to bring the opinions together.

To add some technical remarks: We will have all the presentation of the workshop, and I like to ask all presenters, who didn't had a powerpoint presentation to send me copies of the overheads, and if you have them in electronic form, please send to me electronically, you see, this is a very modern kind of communication. We had recorded the round table discussion, and we will give it back originally as far as possible. We will send the discussion remarks to every speaker, who can then correct. So we will have a proper report.