research for
man and environment

RIJKSINSTITUUT VOOR VOLKSGEZONDHEID EN MILIEU
NATIONAL INSTITUTE OF PUBLIC HEALTH AND THE ENVIRONMENT

RIVM report 679102 047

Uncertainty analysis of EUSES: interviews with representatives from Member States and industry

T. Jager

October 1998

This investigation has been performed by order and for the account of the Directorate-General for Environmental Protection, Directorate of Chemicals, Radiation and Safety of the Ministry of Housing, Spatial planning and the Environment, within the framework of project 679102 "Risk assessment methodology".

RIVM, P.O. Box 1, 3720 BA Bilthoven, telephone: 31 - 30 - 274 91 11; telefax: 31 - 30 - 274 29 71

Abstract

Ten representatives of the EU Member States and the chemical industry were interviewed to find out their views on applying uncertainty analysis to risk assessment of industrial chemicals. Although there was an interest expressed in this matter, uncertainty analysis was thought not to receive a high priority. This is mainly due to the concern that uncertainty analysis would lead to more work without necessarily providing more information. Several examples of probabilistic risk assessment would be useful if the way it affects decisions could be demonstrated. For uncertainty analysis to be accepted by all parties, it is important to keep it simple and transparent, and for the time being to restrict it to the exposure assessment.

Preface

I would like to thank all the participants for their willingness to participate in the interviews. The discussions we had were very helpful to narrow the gap between science and decision making. Transcripts of the interviews were send to the participants for comments but I have not received a reaction from three of them (Jose Tarazona, Steve Robertson and Anton Wilson). I therefore cannot guarantee that my transcript is an entirely error-free representation of our conversation.

Contents

Samenvatting

Tien afgevaardigden van de EU-Lidstaten en de chemische industrie zijn geïnterviewd betreffende onzekerheidsanalyse in de risicobeoordeling van industriële stoffen. De ondervraagden hadden uiteenlopende meningen over dit onderwerp maar een aantal algemene opmerkingen kunnen worden gemaakt. Er was over het algemeen een voorzichtige interesse in het quantificeren van onzekerheden, maar er was ook de zorg dat dit zal leiden tot meer werk zonder noodzakelijkerwijs meer informatie op te leveren voor de besluitvorming. Onzekerheidsanalyse lijkt geen hoge prioriteit te krijgen op de agenda van de lidstaten ook al ziet men het wel als een toekomstige ontwikkeling in de risicobeoordeling. De onzekerheid in de emissieschatting werd verschillende keren genoemd als een topprioriteit. Behalve een complete probabilistische risicobeoordeling kan onzekerheidsanalyse ook gebruikt worden om de betekenis van een deterministische risicoschatting te verduidelijken. Niet alleen de onzekerheid in de modelparameters, maar ook de invloed van natuurlijke variabiliteit moeten worden onderzocht. Het quantificeren van onzekerheden in de effectbeoordeling ligt gevoeliger dan in de blootstellingsschatting: de meeste ondervraagden voelen zich niet op hun gemak met een quantitatieve aanpak van de onzekerheid. Samengevat is er voldoende steun om het werk aan onzekerheidsanalyse voort te zetten. Een aantal voorbeelden van risicobeoordelingen waarbij een probabilistische risicomaat vergeleken wordt met de huidige TGD-aanpak kan verhelderend zijn. Wel moet er voor worden gezorgd dat dit op een simpele en transparante manier gebeurt en, vooralsnog, beperkt blijft tot de blootstellingsschatting. Het is vooral belangrijk om te laten zien hoe onzekerheidsanalyse de uiteindelijke beslissingen kan beïnvloeden.

Summary

Ten representatives of EU-Member States and chemical industry were interviewed regarding their views on uncertainty analysis in the risk assessment of industrial chemicals. The subjects had very diverging views on this matter but some general observations could be made. There was generally guarded interest in quantifying uncertainties but also concern that it would lead to more work and not necessarily give more information for decision-making. Uncertainty analysis does not seem to receive high priority on the agenda of the Member States although most people agree that it is a part of the future of risk assessment. The uncertainty in the release estimation was mentioned several times as a top-priority matter. Apart from a full-blown probabilistic risk assessment, uncertainty analysis can also be used to clarify the significance of a deterministic risk estimate. Not only the uncertainty in model parameters should be addressed but also the influence of natural variability. Quantifying uncertainties in the effects assessment is a more delicate matter than the exposure assessment: most interviewed do not feel comfortable with a quantitative calculation of uncertainty. Summarising, there is sufficient support to continue the work on uncertainty analysis. A few example risk assessments where a probabilistic risk measure is compared to the current TGD approach would be useful. Care must be taken to ensure that this is done in a simple and transparent way, and, for the time being, restricted to the exposure assessment. It is particularly important to demonstrate how uncertainty analysis will affect decision making.

1. Introduction

Risk assessment of new and existing chemicals in the EU is done according to a harmonised methodology (EC, 1996). The level of "risk" is characterised by means of deterministic quotient of exposure and effects (PEC/PNEC or Margin of Safety). As the data basis of these risk assessments is usually narrow, a considerable degree of uncertainty accompanies these calculations. From a scientific viewpoint, this uncertainty should be accounted for explicitly in the decision making. The advantages and disadvantages of probabilistic risk assessment in this legal framework have been extensively discussed (Jager & Slob, 1995; Jager, 1995; Jager *et al.*, 1997) but nevertheless, the people involved in risk assessment and risk management in the EU are hesitant to support these developments. For this reason, a series of interviews was conducted with ten representatives from several Member States and chemical industry to learn about their viewpoints on uncertainty analysis and probabilistic risk assessment. These interviews were especially important to investigate whether a probabilistic framework is feasible and what type of further studies are necessary in this respect.

The interviews were conducted on June 16-17, 1998 during the EU Technical Meeting on Existing Chemicals in Arona, Italy and focused on the following questions:

1. Do you feel comfortable with the current deterministic quotient approach? Is the degree of information sufficient to base confident decisions on? Is the approach (over-) conservative?
2. Do you think that quantitative insight in uncertainties can improve decision-making?
3. Uncertainty analysis allows to identify the main sources of uncertainty. Do you think this option is useful in refining a risk assessment?
4. Would it be a good idea to implement uncertainty analysis in an update of EUSES?
5. An uncertainty analysis for the exposure side is relatively straightforward. What can we do with the effects assessment? What type of RCR[1] suits the assessment best? Three options were presented (Jager *et al.*, 1997):
   a) leave it as it is; a fixed worst-case PNEC;
   b) make the assessment factors uncertain; instead of fixed factors one can use distributions based on historic data;
   c) try to estimate a dose-response curve for ecosystems and human populations in order to estimate a true "risk" level.
6. What kind of work must be done before you can support uncertainty analysis in the future? Example calculations for instance?

In the next chapter, the results from the interviews are summarised.

[1] RCR stands for Risk Characterisation Ratio. This term covers the deterministic risk quotients of the TGD and EUSES: PEC/PEC ratios for environmental endpoints and MOS for human health.

2. Interviews

Bob Diderich
INERIS, Departement Toxicologie - Ecotoxicologie
France

Do you feel comfortable with the current deterministic quotient approach?
So far yes. Not only considering the degree of information that you get from the quotient, but what I am most pleased about is that we are getting towards a very harmonised approach. We are all coming up with more or less the same values and we agree on the procedure which is a very important achievement. It provides sufficient information to base decisions on because we have been very flexible with the TGD. The TGD is sufficiently conservative, which is necessary in my opinion.

Do you think that quantitative insight in uncertainties can improve decision-making?
Not right now, especially for France as we do not have a long history of risk assessment. Taking decisions on risk assessments is pretty new and we are still struggling to convince everybody to go that way. Now we are coming to a point where we are trying to make decisions based on risk assessments, so for us it is way too early to question it again. For new chemicals, the same will tend to apply as we haven't taken many decisions yet. At least we have achieved risk reduction based on risk assessment. Risk management has been achieved by asking the notifier to withdraw their compound or to do another notification, and it has worked so far.

I think there are some people who will be more comfortable with a quantitative uncertainty analysis because it would allow us to convince people that we have looked at the uncertainty and variability and that there is a risk. But on the other hand, my feeling is that it would also give people fuel to say that, because the assessment is uncertain, we are not going to do anything.

Uncertainty analysis allows to identify the main sources of uncertainty. Do you think this option is useful?
Yes, but in the future. Right now, in 90% of the assessments, almost all of the uncertainty is in the release factors. So unless we know what the actual releases are, we can be pretty sure that that's where the uncertainty is. The PNEC is also uncertain but I'm not sure we care to know how big it is. I don't really worry about that because you can easily reduce the uncertainty in the PNEC by spending money on further tests.

Would it be a good idea to implement uncertainty analysis in an update of EUSES?
Before spending money on an update of EUSES I would spend some more money on release scenarios. I'm not opposed to uncertainty analysis, I have read most of the report and I basically agree but I am afraid that it will give fuel to industry to do nothing or to make discussions more difficult. We are not yet efficient in making risk reduction proposals and implementing them, so we would like to wait a couple of years before questioning the procedures for risk assessment. Uncertainty analysis would certainly slow down the process at this time as it will lead to more discussion and more reluctance to take actions.

What type of RCR suits the purpose of risk assessment best? What to do with the effects assessment?

The most useful feature of uncertainty analysis would be to see where most refinement is needed on the PEC side, although we usually know where it is. Given the kind of data we have in the effects assessment, I don't think you can do much more than we do now.

What kind of work would you like to see before you can support uncertainty analysis in the future?

Our main priority for further work right now is to characterise releases and to make scenarios for different uses and specific technologies. If we get the releases right, I would see the greatest benefit for uncertainty analysis in finding out on the PEC estimation where the largest uncertainties are. It would be useful to demonstrate uncertainty analysis in a risk assessment, but you already partially did that in the report. Only in a later step I would like to go to an integrated overall uncertainty analysis. You need to convince us risk assessors that uncertainty analysis is really going to help us in doing the risk assessments and making the decisions.

Bjorn Hansen
ECB, EC Joint Research Centre
Italy

Do you feel comfortable with the current deterministic quotient approach?
It is a useful decision-making mechanism but there are a lot of uncertainties which do not come to the surface. But it is convenient that you are making decisions because you bury the uncertainties in the MOS and in the assessment factors. In that way you are performing a kind of probabilistic risk assessment implicitly and you're trying to move somewhere to the top of the probability curve. The problem is that you have no idea where you are on the curve. In some cases you can base confident decisions on quotients, when you have a PEC/PNEC approach which is based on a very good database and a lot of monitoring data. That is what you want to regulate, the potential for problems. In other cases, when the uncertainty is too large, that is where you get into trouble because you use generic scenarios which are based on a precautionary policy. When you have a lack of information you still want to make decisions on whether risk reduction is needed. Clearly, there is a lot more uncertainty about it and therefore your confidence in those decisions is a lot less.

About the margin of safety approach, the way we are approaching it is fine. It is totally equivalent with the assessment factor approach, it just depends how you look at it. It is less explicit, but you can use assessment factors (like the Dutch approach) to interpret the margin of safety to get the transparency back in. The margin of safety approach allows people that don't like assessment factors to come up with their arguments. There is currently not enough consensus yet to go fully quantitative.

Do you think that quantitative insight in uncertainties can improve decision-making?
Yes it would, because the quantification of the uncertainties, at least as background information initially, would make the interpretation much easier for some people. The worry I have is that we finally have a system that is up-and-working now, and I don't want it disrupted. But the fact that you don't want a system disrupted should not prevent you from encouraging further developments.

Quantification of uncertainties and probabilistic risk assessment are the next step. If you look at the research recommendations coming out of SETAC, they all say that you need uncertainty analysis to indicate the reliability of your decisions. Potentially, it is a good thing to base decisions on a probabilistic risk assessment, but it depends on the practical application. The best way to decide whether this is a practical tool is to choose a number of assessments where you demonstrate it and supply it as background document. In the meeting the people presenting the risk assessment could make reference to this background if they feel they can use the results, in a very step-wise process. It could be that, by applying the current state-of-the-art in probabilistic risk assessment, you actually cannot make a decision because the variation is too big.

Uncertainty analysis allows to identify the main sources of uncertainty. Do you think this option is useful?
That kind of analysis can help you to refine the TGD a lot. It would be useful information to see which uncertainties influence the end results the most. In fact that is what we're trying to do implicitly already to assess which information would help us the most.

Would it be a good idea to implement uncertainty analysis in an update of EUSES?
To implement it in EUSES, you need all Member States to at least be comfortable with the idea. Using probabilistic risk assessment as background information would help people to feel comfortable with it, without it disrupting the current speed and mechanism that we have for decision-making.

What type of RCR suits the purpose of risk assessment best? What to do with the effects assessment?
The three options answer different questions, the best one to support risk assessment is the one where you fix the PNEC and where you have uncertainty in the exposure. It has to do with how you make decisions. When you get into the deal of probabilistic distribution of the PNEC, then you get into the discussion how much you want to protect which is very difficult. It is easier to accept that you have uncertainty in the PEC than to accept that you have uncertainty in the effects assessment. For the exposure assessment you have a reasonably clear conceptual model. Our PNEC approach now, although quite abstract, is one where you feel that you are sufficiently protective. You do not have enough information to do probabilistic effects assessment properly, but I can be convinced! It would be informative but it will probably take a long time to define all the distributions. Methodology development should never stop but it should proceed in small enough steps so that directions can be given.

What kind of work would you like to see before you can support uncertainty analysis in the future?
It is not something we will implement next year, but if you want to make risk assessment more realistic, that is definitely one of the roads to go down. You can use uncertainty analysis as background to say where the quotient is in the range of possibilities, not using it directly to base decisions on but as supportive evidence. If you look at the risk assessment regulations they clearly state that you have to take uncertainties into account, but there are no tools to do that at the moment. I think it is a useful tool in those cases where it supports decisions. If you have a decision based on no information, then probabilistic risk assessment is not going to help either but merely confuse things. It would be helpful when you can indicate at which percentile of the distribution your quotient lies to support decisions. If there are a lot of Member States who feel that they can use it, it can be incorporated more and more in risk assessments.

Tessa Beulshausen
Umweltbundesamt (UBA)
Germany

Do you feel comfortable with the current deterministic quotient approach?
Yes I do, because if we determine a risk we usually have conclusion 1 first as the underlying data basis can be improved. In the refinement process we get a good idea when the point is reached where we do not have to draw this conclusion anymore and the data basis is well enough to have to go for risk reduction. The height of the quotient is not so important, it is important whether it is possible to improve the data set or not. For example, we do not need another test when the test result is not likely to lower the PEC/PNEC ratio below 1.

The current approach is not too conservative in general. We hope that we are protective and precautionary if we have little information. Our philosophy is that we do not have to prove that there is an adverse effect in the environment, but we identify a risk if industry cannot provide sufficient data for the conclusion that no adverse effects are expected. Regarding the effects assessment of the TGD, we do not agree that it is too conservative as you indicated in your report.

Do you think that quantitative insight in uncertainties can improve decision-making?
I'm afraid that it will not necessarily give more clarification for the risk reduction people or that it would help them in decision-making. Risk management is a matter of politics and a commercial question how expensive the measures will be. The most important thing is to identify from the whole life cycle of a substance the crucial step where we can apply few measures with large results, this is more important than the probability of a risk. The quotient is used to trigger some measure, but when you calculate the probability you have to make the decision how high the probability must be. You just postpone the decision that you have to make anyway. In the beginning you have very few data and you have a rough estimation but it is transparent that this conclusion is based on very few data. It is not science and is not a complete picture of the truth. When you use models, like in EUSES, it will become less transparent that it is a rough estimation, and you will loose even more transparency on the original data basis when you apply uncertainty analysis. It looks like very exact science but it is based on very rough assumptions. There may already be too much calculation in the TGD.

I think uncertainty analysis will not lead to better decision-making. It is another step that could postpone a decision. It takes us for example three years of work to finish a risk assessment for an existing substance and then it is called a "screening assessment". My fear is that a probabilistic risk assessment is even more time consuming and does not provide more information because the underlying data remain the same, we just have done more exercise with them.

Uncertainty analysis allows to identify the main sources of uncertainty. Do you think this option is useful?
It is normally quite obvious that the release estimation is the main source of uncertainty (in comparison with the physico-chemical data or ecotoxicological endpoints). Consequently, when we have a quotient larger than 1 because of unrealistic release estimation, we ask industry for measured effluent concentrations which are much less uncertain. But if the concern cannot be eliminated by data improvement (which is more likely when downstream users are concerned) we have to give it to the risk reduction people anyway. We do not need

an exact quantification of the main sources of uncertainty.

Would it be a good idea to implement uncertainty analysis in an update of EUSES?
EUSES already provides a lot of information and too many pages of report. Implementation of probabilistic risk assessment would only increase the amount of output. You cannot read through the EUSES results report and get a clear picture of the substance, even if an uncertainty analysis would be included. You need additional explanation about the underlying information and assumptions made as they are provided in the comprehensive Risk Assessment Report. So I think it is more important for the existing substances program to spend our limited resources to move forward. There are so many potentially dangerous substances with thousands of tons on the market, we have to do something. Everything that would hold us back even more should be avoided

What type of RCR suits the purpose of risk assessment best? What to do with the effects assessment?
If you would propose the alternative PNEC extrapolation for the effects assessment, I am convinced that Germany will oppose that because we do not think that the current approach is too conservative. The tested laboratory species are very different from the ecologically relevant species or the functioning of the entire system. We do not use the lowest NOEC per se, but we choose the most sensitive species out of the three species tested and not from the entire ecosystem. If only 95% of the species are protected this would not be acceptable if among the 5% lost are species that are judged valuable or esteemed either by public or by decision makers. The data basis is too poor to derive a kind of dose-response curve for ecosystems. We need to have long-term tests as long as we are not certain that we can extrapolate from short-term tests. I think it is better to use common sense than statistics here.

What kind of work would you like to see before you can support uncertainty analysis in the future?
I am not sure about that. Probabilistic risk assessment as background information will result in a higher work load for the future. At this moment there are already insufficient resources to do the few chemicals that we have to. We have to decrease the work and get results, and not be more comprehensive. What may be interesting is research on the effects side, to approach to a dose-response curve for ecosystems by comparing different substances with a good data basis to find out which conclusions can be drawn and which predictions can be made. On the exposure side, we need more reliable data for downstream uses which often occur. We need actual exposure data from industry more than we need uncertainty analysis.

Anton Wilson
Health & Safety Executive
United Kingdom

Do you feel comfortable with the current deterministic quotient approach?
I am comfortable with it as far as it goes but it would be helpful to know what the uncertainties are around the point that you are looking at. There is always a discomfort in risk assessment when the scientific process meets the legal one. The legal process means that you need a decision: can I release the chemical or not. Science is about uncertainties. I think we are grown-up enough to be able to say that there are uncertainties, but we are still asking you to do it. The second problem is about the interface between those with a scientific background, and those with no scientific background at all or a legal background. You will have problems explaining to someone without knowledge in modelling and uncertainty what the uncertainty means and what the difference is between right and wrong answers, good and bad answers, robust answers and fragile answers.

The current approach uses the information that you have got. Most of what our risk assessment is aimed at is reducing complex data down into a decision point, and it does that quite well. I am not sure that the information that you get is ideal for taking complex data and putting lots of uncertainties around it, because I don't know if we understand all the distributions well enough. The more factors we have in the risk assessment, the more complicated it becomes. I am not sure where we would like to go to increase our certainty. An example which caused me some concern is that there is a lot of pressure on us to reduce the numbers of animals that we are testing. However, when we reduce the number of animals, that will reduce the precision and increase the uncertainty.

There are some fundamental weaknesses in the margin of safety approach. You are looking at different organs and making judgments about the severity and the significance of different effects, which is very complicated. The amount of information that we gather does not allow to put distributions around the things you see. The margin of safety approach hopefully allows you to achieve comfortable space between the levels of exposure and where effects occur.

Do you think that quantitative insight in uncertainties can improve decision-making?
A lot of us are walking around with assumptions in their heads, that are about comfort zones, when we are comfortable between observed effects and exposure. It is surprising how little of that is explicitly stated. This is where uncertainty analysis could help to put on paper what you think the distribution is. The weakness in that is the assumption that you have learned something new just because we can describe it in a mathematical distribution. It may be that something quite wooly and uncertain is adequate for what we are trying to do. Potentially, where uncertainty analysis comes into its own is where you've got a very narrow margin and it becomes a hugely critical question.

It may not help decision-making, it may be postponing a decision by discussing which percentile to take. You have got to be absolutely sure what the distribution is and what the model is to make it a worthwhile investment. But maybe it is more of a gut problem, that biologists are not really into math.

Uncertainty analysis allows to identify the main sources of uncertainty. Do you think this option is useful?
The short answer is yes, you have to understand where your predictions are vulnerable.

Would it be a good idea to implement uncertainty analysis in an update of EUSES?
Yes I think so, have a go and see what happens. It does appear to me that uncertainty analysis in risk assessment is so clear cut and dry that we exactly know the direction where we're going, so just try it. Don't get discouraged too quickly! It might make decisions more difficult but I am not afraid that industry would use it to delay measures, I would be more worried that it works the other way around. It will take some time before it will be routine, it may be a good idea to run it in parallel to decide if it's worthwhile. Try to go over one or two substances that have been agreed and see what comes out. It will take more time and discussion, so to keep the assessments rolling, you'll need to keep uncertainty analysis on the side for awhile.

What type of RCR suits the purpose of risk assessment best? What to do with the effects assessment?
I think it would take years to work out dose-response relationships for humans, we can really only do it for two substances. For other substances there is just not enough information. If the data do not support a sophisticated analysis, then there is not a lot of point in doing it. It would be fun to do it, but whether it leads to an improved quality of decision is another question. If you have human data, it is usually of obscure exposure situations. In animal data you have different organs, different animal species, different strains, different dosing regimes, different effects, etc. it would be extremely difficult to combine that mathematically. It would be helpful if you could put confidence intervals around the margin of safety to give more robustness to the decision. For instance based on the steepness of the dose-response relationship in the experimental animals.

It is always the argument that there is a lot of sophistication but not a lot of added value. If you can't get the degree of precision that is needed then what is it adding that you couldn't have said verbally. People can be comfortable with that without needing any mathematical assumptions. But I think there's a value in just trying it, and looking at different approaches.

What kind of work would you like to see before you can support uncertainty analysis in the future?
Find a substance with a lot of data, and look at the distributions. See which distributions are appropriate. There are chemicals with a good set of data for a really good statistical analysis. With two or three of these we can have some clues on how to proceed. It would be helpful to have good data to see if the distributions are consistent. You can only learn it by doing it.

Tom Feijtel
NV Procter & Gamble ETC
Belgium

Do you feel comfortable with the current deterministic quotient approach?
In our opinion, the deterministic point value is totally misleading in the sense that it is a multiplication of a number of worst cases assumptions which are continuing to the 99.99th percentile. In absence of knowledge this is fine for a first screening phase, but when you go to a more refined risk assessment uncertainty analysis is a necessary next step. As a screening tool you want to be conservative but people must accept higher tier information. This higher tier information should be used to make a distribution, but it seems that people feel uncomfortable stepping away from default values because they are so used to these values.

The question is, is this risk assessment at all relevant, does it reflect the concentration that one would monitor in the environment. If this approach works to select the bad chemicals, we should not call it "risk assessment" but perhaps call it "priority setting and risk management" and then you don't need EUSES. Then you can ignore to a large extent actual environmental concentrations but you can do it on the basis of tonnage and fictive environment, and focus on the dirty dozen.

Do you think that quantitative insight in uncertainties can improve decision-making?
I am convinced that uncertainty analysis will improve decision-making but before getting there, one needs to get everybody on board in terms of what it means. You have to be transparent in the underlying assumptions to get people used to looking at distributions instead of single numbers. I would do it graphically because you can get much more information from a graph. Internally, for all our risk assessments, we are doing uncertainty analysis standard but we know that the person who is doing it is an expert. You almost need a kind of manual on what are the type of variables you can assign a distribution to and how to do it.

it is important to know up front what your protection goals are and start to make a difference between environmental variability and actual uncertainty. One has to capture this information in frequency distributions, and then decide what you want to protect. You need to be transparent, so if we talk about protection levels we must know which percentile is relevant. What would be extremely interesting is to start collecting the information on environmental variability and start engaging in stakeholder discussions to decide which type of environment we want to protect. I am not afraid for endless discussion, it is not because you have a graph on risk probability that it will go on forever. You need to have a discussion beforehand on a number of generic examples, on what it means and how we are making decisions on this type of information.

The mathematical approach and the data that you need and a distribution of the input parameters needs to be agreed upon and transparently captured among the Member States. That is the very first step. Part of that is the discussion on percentiles and confidence levels; we must engage in a debate on what we're trying to protect. ECETOC is also looking at this in a more dedicated way by examining some of the distributions and trying to develop routines for uncertainty analysis. We think that we need to capture environmental variability so we have developed GREATER, with a Monte Carlo engine, as a higher-level tool. What is lacking though, is the distribution of other input parameters like vapour pressure and *Kow*.

Uncertainty analysis allows to identify the main sources of uncertainty. Do you think this option is useful?
Yes absolutely, as a kind of sensitivity analysis. It allows risk assessors to tell industry that a chronic NOEC is not going to solve your problem that, for instance, you need a BCF test or refine your releases. That is also how the tool is going to be used more and more in industry: where do you get the biggest "bang for the buck." It may also help to diminish the number of animal tests or to justify them in a specific case.

Would it be a good idea to implement uncertainty analysis in an update of EUSES?
We would like it and I think it is technically possible, for sensitivity analysis and decisions for next steps it is very interesting. Our problem with EUSES is that the boxes are so fixed. We like to have more information in the boxes, for instance on variability which also reflects Member States' worries about how representative the standard environment is. Environmental variability and uncertainty must both be included in the exposure distribution

What type of RCR suits the purpose of risk assessment best? What to do with the effects assessment?
I would directly integrate uncertainties in exposure and effects in a probability curve, like the calculation and visualisation of the uncertainty in the "fraction unprotected." I am in favour of statistical methods for effects and exposure assessment in a risk characterisation because you make better use of the available data.

What kind of work would you like to see before you can support uncertainty analysis in the future?
Before you develop a methodology all the way through you can start on the end results for a number of chemicals which were discussed at a previous meeting and explain in a very condensed way what it means, and see how it compares to the classical approach. Then discuss it at a Technical Meeting, preferably with environment and human health combined. The underlying assumptions need to be clear but it is good to enter discussion this way. For a start, you could ignore environmental variability and look only at uncertainty in input parameters.

ECETOC is willing to participate in work on uncertainty analysis and in work on parameter distributions (for example release estimates). My idea is to have an ECETOC task force on uncertainty analysis or sensitivity analysis with experts from different Member States. We have to pool what is happening in terms of thinking about uncertainty and engage in some type of task force or "concerted action program" to share ideas and methodologies. We as industry think this is the future and we will continue with it anyhow, internally. On the long-term this will have to be adopted in risk assessment.

Jose Tarazona
Lab. for Ecotoxicology, Conservation CIT-INIA
Spain

Do you feel comfortable with the current deterministic quotient approach?
If you look for worst case, yes you can use the deterministic approach. You at least can be more or less sure that the chemical is acceptable if there is no risk. It can be improved, obviously, but it is not so bad. I don't know if it's too conservative, we have not been able to find data were the PNEC is not conservative enough. This degree of conservatism is necessary to get it accepted from a regulatory point of view.

In the current approach, you ignore the uncertainty. But I think we must first try to solve the uncertainty in concepts, for example how to extrapolate from single species and laboratory data to ecosystems; what is the real meaning of the PNEC and then we can try to reduce the uncertainty in the data. If we start by looking at the uncertainty in the data, we are not covering the real uncertainties in the process. So we get a system that is more complex, it is difficult to be transparent with probabilistic risk assessment. If you put a lot of effort into one type of uncertainty which is not relevant, you feel that you are more certain which is in fact not true.

Do you think that quantitative insight in uncertainties can improve decision-making?
If it were possible to calculate the real uncertainty, then the answers is yes, but it is too early to do that. I would support a probabilistic approach but it is a second step. I am not really afraid for endless discussion, the problem is how you present the uncertainty. It would be very useful to see the entire distribution instead of a single number. It is a good thing to use all information that you have got. By using the probabilistic approach we can probably reduce the uncertainty in a significant way. Apart from the variability in the data I would also like to see the uncertainties in the concepts addressed, although it would be a problem to make that quantitative.

I prefer the probabilistic approach for the effects assessment. When you have a lot of data you accept that 5 percent of the species are not protected, in the same way it should not be problem for a regulator to use a percentile from a probability distribution for risk. But you should not say that by protecting 95 percent of species that you protect the ecosystem, because then a regulator would want to know whether this five percent includes endangered species. For exposure assessment, you should use probabilistic approach in a different way then you proposed: for the scenario, not really for the uncertainty in the data. Even when you have quantified the effect of the uncertainty in the data on the single number, you would still not know how relevant the specific scenario is. A clear example is the dilution where we assume a dilution factor of 10. It would be nice to have a probability distribution of the dilution in different rivers or for different European conditions and then to use this probabilistic approach in relation to where the industries are located.

Uncertainty analysis allows to identify the main sources of uncertainty. Do you think this option is useful?
This only works for data uncertainty, not for the conceptual uncertainty in the assessment which is the most important factor.

Would it be a good idea to implement uncertainty analysis in an update of EUSES?
I think it is useful if we are able to quantify the real uncertainty. I am not sure that by including a probabilistic distribution on the data that you can use that to reduce uncertainties. For implementation in EUSES, we need to have sufficient information, you cannot use data from other chemicals to make distributions. I can only accept a probabilistic approach when you have the real data for the specific chemical that you're looking at. You must ask industry for the data that you need, otherwise they'll have to accept conclusion 3, to reduce risks. When you have more data you can reduce uncertainty and feel more confident about a decision. Furthermore you should first use the deterministic approach and use probabilistic risk assessment only when the quotient is larger than 1.

What type of RCR suits the purpose of risk assessment best? What to do with the effects assessment?
If you have sufficient data, I would support the approach for the potentially affected fraction. But you should not extrapolate from acute to chronic because you're also introducing uncertainty as you don't know the mechanism of uptake and toxic action. I can accept a probabilistic approach when it is based on real data for that chemical, not when it's extrapolated from other chemicals or from acute data. You need at least eight chronic data for each taxonomic group, you must not assume that they have the same toxic mechanism. You need data to reduce uncertainty. If you have clear differences between taxonomic groups you can extract information from the data by expert judgement, not by using some kind of model. If you do not have the data, you have to use the deterministic approach.

What kind of work would you like to see before you can support uncertainty analysis in the future?
I would try to compare approaches. I am not sure for exposure assessment, but for the effects, you can compare statistical approaches and predicted risks with field data and mesocosm data. Performing a probabilistic risk assessment for an existing chemical would be useful if you have sufficient information, if you need to extrapolate a lot to create data that you do not have, then not.

Ivar Lundbergh
National Chemicals Inspectorate (KEMI)
Sweden

Do you feel comfortable with the current deterministic quotient approach?
Comfortable enough to still use it, but in a lot of cases we should have a better basis. For example regarding site-specific information from industry, very often what is presented in the report are point estimates. Maybe that should be more averages or 90 percentiles of releases over the year. So you get a feel for what you're exchanging your defaults scenario with. In many cases it is just one figure without deviation or ranges. It works the way it is now but it is up to the rapporteur first to judge whether the obtained data are acceptable. Our view is that we should get better data more often from industry when we are exchanging defaults to site-specific information.

To us, it would not make sense to use uncertainty analysis on defaults scenarios because the variability will be enormous. The present default settings more or less compare to the Dutch situation whereas the situation in northern Sweden or southern Spain is very different.

It might be too conservative in some cases when you're sometimes adding realistic worst-case assumptions together. On the other hand, we don't have all the exposure information that is really available. We have not been aware of all use patterns that can create risk. So generally, I don't feel that we are over-conservative.

Do you think that quantitative insight in uncertainties can improve decision-making?
I don't think that is a question you can answer with yes or no but I think it is useful to describe your uncertainties. Among the colleagues I have discussed this with, we all have a sympathy or interest in probabilistic risk assessment. As scientists we are interested in probabilistic risk assessment, but as a civil servant in the program, it is not the right time or the right medicine to incorporate it. I am afraid that it would take too much time to collect all the information and it would take time to get used to in the beginning. Maybe you could introduce some of these techniques in a smaller part of the risk assessment.

We are already basing decisions on very uncertain results, if you would have a description of that uncertainty that would be possible to use in decision-making. Generally speaking, it is desirable to have that. But then you end up with the question, what is the minimum requirement to really say that you have a probability distribution. For the present work in the technical meetings, I think the time pressure is such important part of it that introducing more data requirements and uncertainty analysis would not be the right approach at the moment.

Specifically for site-specific assessments, we should be able to get better variability in the data so you can compare your PNEC with some kind of variation in time and space. It would be interesting to work with alternative scenarios and we are trying to make a more realistic Nordic scenario to see what comes out. Maybe we could also do that for other European regions. Then again, what happens in most of our reports is that we start out with a PEC using default scenarios and we introduce more site-specific information as we go along. The first default scenario more or less provokes the companies to submit specific information.

Uncertainty analysis allows to identify the main sources of uncertainty. Do you think this option is useful?
It might be useful. Primarily, if we wanted to change the risk assessments and the way they are done, I would like to include more uncertainty description in a narrative, qualitative way. It would be useful if you could use sensitivity analysis and define crucial points. I think we could certainly include more description on where we are confident that we have fairly good database and where we are less confident, where we find the larger uncertainties. That can be in a more qualitative way, to make more clear that it is not just a point estimate, both for the risk assessors as for the risk reduction people taking over afterwards.

Would it be a good idea to implement uncertainty analysis in an update of EUSES?
I don't know enough about uncertainty analysis and about the details and the practicality to have an idea what should be implemented in EUSES. We would like to have a more qualitative description in the risk assessment report. We have not discussed an implementation in a more quantitative way in EUSES and I think it is not the primary interest at the moment.

What type of RCR suits the purpose of risk assessment best? What to do with the effects assessment?
Ideally, the probability distribution of effects, but as we interpret it, that is the HC5 method. We have been discussing it and we're not using it in our agency, the main point for that being that four data points are necessary and we seldom have four points. I don't feel very comfortable with extrapolating acute data to chronic data with uncertainty, this is too much statistics. I am careful about introducing those statistical methods and really believing in them. A problem with probabilistic methods is that you might give an impression of a higher precision then you really have. Now it is more transparent how crude the current method is. When you start introducing statistical methods and start to talk about getting nearer to the truth, sometimes you create more faith in these figures than I would like to give. The most pragmatic or workable option, at least at this moment, would be to fix the PNEC and to vary the exposure.

What kind of work would you like to see before you can support uncertainty analysis in the future?
Personally I need much more information and hands-on experience on what it really means. Your report will help, it can start the process of thinking about uncertainties. Another option to reach more people may be to arrange seminars, trying to propagate the ideas. People working with these risk assessments could be made more aware of the EPA risk assessments guidance and their new documents dealing with description and reduction of uncertainty. It is generally good for our risk assessments to have this as a background. If you would like to introduce uncertainty analysis in EUSES, I think you need to create much more know-how about what happens in these boxes to get people to be interested, and accepting such developments. An example of a probabilistic risk assessment for an existing substance would help to get a good idea, I would read it and I think it would make an impact, but I'm not sure in which direction!

Henrik Tyle
Danish Environmental Protection Agency
Denmark

Do you feel comfortable with the current deterministic quotient approach?
No I do not feel comfortable with the current approach. It is too much driven by a quantitative PEC/PNEC assessment. In that respect your ideas about uncertainty analysis are very interesting because we need a more qualitative kind of influence on how we assess chemicals. That will of course create management problems because the agreement will be more ad-hoc, but it will also be more scientific. I do not think it is feasible to change the decision framework but I would like to to use the TGD in a flexible way. We should use certain elements of what you are addressing in the report, but also other kinds of analysis which could throw light on the uncertainties in what we are doing.

Do you think that quantitative insight in uncertainties can improve decision-making?
I liked the report, it was clear, and also the way you go through the different parameters distributions and also to try to tell where we do not know how the distributions are but for convenience we just do it a certain way. We don't know really much about various distributions of parameters, for some we do for others we don't. The section on dose-effect curves was not comprehensively enough explained, it is too short and you refer to Dutch monographs. Therefore the examples were also not entirely clear.

Uncertainty analysis allows to identify the main sources of uncertainty. Do you think this option is useful?
I think this is one of the main advantages of uncertainty analysis, which parameters are most important and crucial for a decision. I think that is the biggest advantage that you can use it as a guidance on where to look closer and where it doesn't matter. I would also like to have this information on the effects side, but I don't think we can get it from uncertainty analysis. It is much more simple. The food chains that we look at are not very representative, for example bioaccumulation in mussels may be quite important. The scenario setting may often be more important than parameter distributions, which kind of creatures do we think are representative. The TGD is not really flexible in this. In the exposure assessment I think that the scenario setting is more important than the parameter uncertainty. I would like to see alternative scenarios because nature is different in different parts of Europe. But still, uncertainty analysis can be used regardless of whether scenario settings are important because for each scenario you can make a kind of uncertainty analysis. How uncertainty about fate related properties influences the outcome is important and should be worked upon as well as on improvement of the release factors.

Would it be a good idea to implement uncertainty analysis in an update of EUSES?
People will hesitate but if you can show on a screen how certain parameters influence the PEC distribution and how this will make an impact on your decisions then it could have some impact on what we are doing. But you have to be able to do it in a very easy way to facilitate interpretation and to get more feeling for the system. EUSES is not very user-friendly, what I'm dreaming of is a system where you could change the value of parameter and immediately see the effect on the final results so that you get to know your system. Then people would learn how to play around with it. It must be a graphic interface, it could be fun really!

What type of RCR suits the purpose of risk assessment best? What to do with the effects assessment?

I think if we're going to perform uncertainty analysis it has to be the simplest one, where you fixed the PNEC, and not the potentially affected fraction of species. I don't think that our level of knowledge is sufficient to do this distribution of the PNEC, apart maybe from a few examples where we have a huge amount of data. In ecotoxicology we do not address the mode of toxic action like we do in toxicology. It is often claimed that ecotoxicology is too little eco, but is also too little tox! The relevance of the toxic effect is not really discussed. With a fixed PNEC it is more clear that we admit that it is a guess.

You may protect five percent of the species but what if all the primary producers are in the lower end of the distribution? It is those simple basic arguments again. It is disturbing that the shape of this curve will change radically if you have a strange data point. It uses all the available information but what if the basic data are already a bit of a guess, the data are biased and may not be relevant or representative. It is almost impossible to prove that this distribution does not fit. Because of these arguments, I proposed to keep the statistical method as additional information in the TGD, as supportive evidence. There should always be room for interpretation, it could influence the choice for an assessment factor.

For narcotic chemicals, if they are only having this mode of toxic action, it is acceptable to extrapolate from acute to chronic and even to ecosystem effects. But for chemicals with a specific mode of action, I think we should really use more qualitative assessments. That is why the Nordic viewpoint is that accumulation and biodegradation and the intrinsic fate related properties should also influence the choice for further testing and the assessment factors. We want to be more certain for chemicals which cannot be removed, which will be distributed and build up in the environment. This is something which may be more important to discuss then uncertainty analysis.

The Dutch proposal for human assessment factors is a sign that more transparency is needed in the human effects assessment. The margin of safety is usually referred to by those who don't want to explain why a certain margin is sufficient or not. To me it is just a matter of taste where you use assessment factors or margins of safety. But also here our database and what we are doing is so crude that it would be overkill to use distributions.

What kind of work would you like to see before you can support uncertainty analysis in the future?

The best way would be to include it in the assessments while we are going along with the normal way of doing things. We do that for instance for a "borderline ready" chemical, put it in EUSES as ready biodegradable and, after that, put it in as inherent, and see what happens. You could see that as a kind of simple uncertainty analysis.

Steve Robertson
Chemical Assessment Unit, The Environment Agency
United Kingdom

Do you feel comfortable with the current deterministic quotient approach?
No I do not feel comfortable, because most people regard the PEC/PNEC as a description of the level of risk, and I don't think that is correct. A higher ratio does not necessarily describe higher risk, you have to understand the uncertainties in the PEC/PNEC ratio. This does not hamper the decision whether there is a risk, but in terms of your degree of precision. For example, I hate the A and B tables. Not because they don't serve their purpose, but as a description of reality they fail because they are in themselves not a valid basis for risk assessment. They are not an attempt to show the uncertainties. Rather, it provides a potential release, which is sufficiently worst-case to persuade industry to give me the specific information they are reluctant to give. That is where I would specifically talk about uncertainties. I have to use the tables that will give me a snapshot of where I will have to do more, but for me the uncertainty there is so high that I would not be prepared to take a risk management decision based on those data. This is a kind of qualitative uncertainty analysis. It would be great if it were possible to that attach uncertainties to the release estimates, and I would guess that RIVM would be able to do that. That is also a problem, that RIVM is the only one who can do that, there has to be something more to base your distributions on.

Do you think that quantitative insight in uncertainties can improve decision-making?
Yes, the more certain you are about your risk calculation the more confident you feel about the decisions to take. It may lead to more discussion but in the end of the day, it could make the acceptance of a decision lighter. You could always draw up rules to say that you should not take decisions on risk management when the certainty is too low. Uncertainty analysis would be useful for me to show that the result of a generic assessment is quite uncertain and could be anywhere within a large range. It helps to put a degree of confidence to the results because a single value is just not credible.

Uncertainty analysis allows to identify the main sources of uncertainty. Do you think this option is useful?
Uncertainty analysis allows you to explain to somebody else why you have insufficient information for a proper risk assessment, that you have to get those bands narrower. That gives an impression of how wide or narrow your range is and what you can do to make them narrower. It would be very useful to know what parameters contribute most to the variance in the end results.

Would it be a good idea to implement uncertainty analysis in an update of EUSES?
The more you try to go into complicated scenarios the more complicated it gets. But even simple processes are not something you can do by hand. It always depends on how you visualise it, if it is transparent. But the answer to your question is, can you do it any other way? There are two long-term ways forward for EUSES: one is implementation of emission scenario documents, other is the issue of uncertainty.

What type of RCR suits the purpose of risk assessment best? What to do with the effects assessment?

I can accept the logic of the statistical approach, that you can make a distribution of sensitivities when you have enough data points. It is just that is difficult to use because I think you need at least five data points. Furthermore you may run into trouble when you say that five percent of species is expendable. There could be valuable species in that five percent. Nevertheless, we look at the spread in the toxicity data implicitly, you would feel more confident when the NOECs are close together. For the aquatic I can certainly accept some concept of uncertainty in the effects assessment but I think you can more easily put uncertainty factors on your PEC only. For biological systems that is more difficult to accept. I'm not sure enough is known about biological variation to be able to do that.

It states in the guidance documents that the assessment factors are indicative values, it is a precautionary approach, but it does leave a bad feel. We do not know what the quantitative uncertainties are so as a qualitative approach we set the assessment factors. I think, you do not know enough about the possible errors in effects assessment to really perform quantitative uncertainty analysis. For the PEC side, it is clear because you have model calculations. I cannot see how you can give me the uncertainty in the assessment factors when you have no model. For the aquatic environment it may be possible because we have a lot of knowledge there, it would be possible to address uncertainty quantitatively there when you have sufficient information.

What kind of work would you like to see before you can support uncertainty analysis in the future?

That is a tricky question. I know what would convince me: that is to see it happen. Give me something that I can actually use. What you're looking for is some confirmation that you can do it and people will accept it. Before you can do it you'll have to convince the Dutch government that they will find it useful. All I can say is I would find it useful, particularly in the area of risk management to be able to tell our risk management people that my calculation of risk has got this level of confidence. I think that is extremely important. But you'll have extreme opinions, someone like myself who is receptive to uncertainty analysis and you'll have people that are sceptical, who take a precautionary approach and don't care about uncertainty because they take the extreme anyway. In the UK we tend to be pragmatic, we tend to try to balance the pros and cons, and uncertainty can help in the process. Provide me with some examples, a demonstration on some existing chemicals would be useful, and see what the implications are. Then you are in a position to make a judgement. I believe you will find the UK receptive to that.

Jack de Bruijn
Centre for Substances and Risk Assessment, RIVM
The Netherlands

Do you feel comfortable with the current deterministic quotient approach?
Yes but I am very well aware that it can be improved, I could feel more comfortable. I am comfortable because in most decisions, one has looked at the main sources of uncertainty, not very quantitative but in a qualitative way. For most of the crucial points, additional information is usually available. Even though default values and scenarios are used, it is extensively discussed before any decisions are taken so I believe that our risk estimates are in the right of order of magnitude. Decisions are based on the total package of information; a decision on marketing or risk reduction will seldom be based on base set data alone.

Several parts of the methodology can be quite conservative. For example, emission estimation is hampered by the fact that we have so many substances and so many types of use and different industrial processes that we try to capture in 15 categories. So within a category you can have a very large degree of variation. Also the fact that we use more or less the same estimates for high production volume chemicals as for low production volume chemicals is a source of conservatism. This is where a lot of criticism comes from.

Do you think that quantitative insight in uncertainties can improve decision-making?
It would help on a number of points, it would help making further decisions, to ask for specific information. Now we do that based on intuition or expert judgement, but it would be a good thing if you could make that more quantitative and transparent. Another point which I think is very important is that when you have a ratio smaller than one, you can visualise that you can still have considerable probability that it is higher than one in reality, and of course also the other way around.

I am not afraid that would complicate the discussions and the decision-making, it just take some getting used to. You need insight in the meaning of these uncertainties, try to make clear what the advantages and disadvantages are. Especially policy makers need help in understanding and dealing with uncertainties. After a couple of years, I think most people see the gain of it. From the scientific world, I know that uncertainty analysis is stimulated and the advantages are displayed. I can agree with that, but it is for science to clarify it and to show what is to be gained. You will often find that science is ahead of policy. People need an instrument to play with and to feel comfortable with uncertainty analysis.

Uncertainty analysis allows to identify the main sources of uncertainty. Do you think this option is useful?
Yes, I think it will be useful. It is something we already do but in a more qualitative way. A quantitative approach could give interesting information.

Would it be a good idea to implement uncertainty analysis in an update of EUSES?
Not in the sense that anyone can do everything that he wants, but it may be possible to implement something to provide insight in the uncertainties. In the default setting, I would not allow people to change distributions etc. You should not confront people at that stage with a choice for the shape of the distribution.

What type of RCR suits the purpose of risk assessment best? What to do with the effects assessment?

Although the concept is interesting, I still have doubts about the dose-effects approach. It suggests that we know more about the ecosystem than we actually do. Making a dose-response relationship is just a simple calculation but to suggest that this is what is actually going to occur in the system, that is the crucial step for me. I know we more or less do the same with the current approach as we try to cover several uncertainties in an assessment factor. We are not sure, we are extrapolating, we know that we on some points are conservative but we don't make hard statements. A dose-response approach makes too much statements.

I think the uncertainty in the PEC is most important. I can imagine looking at uncertainty in acute to chronic ratios but I would try to make a distinction between chemical classes. I think you cannot throw all chemicals together, you'll always get some results but it will only give you a false uncertainty. I think then you would focus on a wrong part of the assessment. More is to be gained by looking more in depth into mode of action and try to extrapolate on that basis.

What kind of work would you like to see before you can support uncertainty analysis in the future?

You have to do it by using examples, they could be hypothetical. You especially need to show what it means in terms of decision-making: would you make a different decision when you look at uncertainties? That would provide insight for policy makers and may lead to acceptation. I don't think that the Technical Meeting is the right group for this discussion. When you do it, you have to do it the framework of an update of the Technical Guidance Documents. It would be good to have something available at that time. Then you will have a group of people who can specifically tackle this subject, and they will probably have time for it at that moment. I think that most people are prepared to think about it when they can see the added value.

3. Conclusions

The interviews conducted shed more light on the viewpoints and needs of the risk assessors applying the TGD and EUSES. Interviews like this are a convenient way to ensure that the scientific developments meet the needs of the decision makers. Several general conclusions could be drawn from all these interviews:

- Implicitly, uncertainties are taken into account. Most risk assessors seem to have a pretty good feel when the point is reached where they can take a confident decision.
- Currently, uncertainty analysis is not seen as a high-priority issue. A more accurate release estimation is currently the top-priority as this is the stage where the largest uncertainties are expected.
- It may not be necessary to base decisions on probability distributions but the distribution can be used to indicate the significance of the deterministic quotient. This may be a more feasible first step than a full-blown probabilistic risk assessment.
- The main perceived disadvantages of uncertainty analysis are the time consumption and the fact that it suggests a higher degree of accuracy than you actually have: you still have the same data basis but the probability distributions suggest a considerable degree of scientific knowledge about the behaviour of the chemical.
- Parameter distributions must be accurately quantified. There seems to be little confidence in "expert-derived" or "not-unreasonable" parameter distributions.
- Not only the uncertainty in input parameters, but also natural variability must be addressed. This has so far not been adequately covered in this series of reports.
- Quantifying the uncertainties in the effects assessment has little support because the data basis and degree of knowledge are perceived as insufficient. The best way to refine the effects assessment in the future is to look at the mechanisms of toxic action.
- The chemical industry seems particularly interested in quantifying uncertainties to make risk assessment" more realistic".
- Despite their concerns, most representatives see uncertainty analysis as an interesting future development. Some example risk assessments would be useful, especially when it can be demonstrated how it will affect decision making.

Summarising, there seems to be a guarded interest in uncertainty analysis among most of the people interviewed although it does not receive high priority at this moment. There seems to be a gap between the scientist and the risk managers. In the scientific community, uncertainty analysis is broadly accepted as a necessity when presenting model results. The risk manager, however, has to deal with the legal aspects and a decision must be reached within a certain time frame. A series of probability distributions, although very scientific, does not seem to be an obvious help in this process. The best way to proceed with the work on uncertainty analysis is to try to bring together these two fields: it must be demonstrated how risk management can benefit from the extra work needed in performing and understanding probabilities. A few probabilistic risk assessments can be performed as example and the results can be compared to the current TGD approach. At this moment, it is important to keep an uncertainty analysis simple and transparent and to restrict it to the exposure assessment. Furthermore, some work is required to study how variability can be taken into account.

References

EC (1996). Technical Guidance Documents in support of Directive 93/67/EEC on risk assessment of new notified substances and Regulation (EC) No. 1488/94 on risk assessment of existing substances (Parts I, II, III and IV). EC Catalogue Numbers CR-48-96-001, 002, 003, 004-EN-C. Office for Official Publications of the European Community, 2 Rue Mercier, L-2965 Luxembourg.

Jager, D.T. (1995). Uncertainty Analysis of the Uniform System for the Evaluation of Substances (USES): Example Calculations. Bilthoven, National Institute of Public Health and the Environment (RIVM). Report no. 679102 032 .

Jager, D.T. and W. Slob (1995). Uncertainty Analysis of the Uniform System for the Evaluation of Substances (USES). Bilthoven, National Institute of Public Health and the Environment (RIVM). Report no. 679102 027.

Jager, T., M. Rikken and P. Van der Poel (1997). Uncertainty analysis of EUSES: Improving risk management by probabilistic risk assessment. Bilthoven, National Institute of Public Health and the Environment (RIVM). Report no. 679102 039.

Appendix 1 Mailing list

1 Directoraat-Generaal Milieubeheer, Directeur Stoffen, Veiligheid en Straling, t.a.v. dr. C. Plug
2 Directoraat-Generaal Milieubeheer, Directeur Drinkwater, Water en Landbouw, t.a.v. dr. J. Al
3 Plv. Directeur-Generaal Milieubeheer
4 Drs. M.A. van der Gaag, DGM/SVS, SG UBS
5 Drs. A.W. van der Wielen, DGM/SVS, SG UBS
6 - 15 EU-OECD Commissies d.t.v. Prof. Dr.C.J.van Leeuwen
16 - 35 OECD-RAAB d.t.v. Prof. Dr.C.J.van Leeuwen
36 Drs. F. Baerselman, LNV, SG UBS, SG Bestrijdingsmiddelenbeleid
37 Prof.dr. J.S.M. Boleij, CTB, SG UBS
38 Ing. R. Faassen, RIZA, SG UBS
39 Dr. M. Lans, CTB
40 H. Roelfzema, VWS/IGZ, SG UBS
41 Ir. D.J. Bakker, TNO
42 Dr. S. Trapp (Univ. Osnabrück, Germany)
43 Dr. S. Schwartz (Univ. Osnabrück, Germany)
44 Dr. B. Hansen (JRC/ECB, Italy)
45 Dr. T. Beulshausen (UBA, Germany)
46 Dr. ir. T.C.J. Feijtel (Procter & Gamble, ECETOC, Belgie)
47 Dr. I. Lundbergh (KEMI, Sweden)
48 Dr. S.M. Robertson (the Environment Agency, UK)
49 Dr. H Tyle (National EPA, Denmark)
50 Dr. J.V. Tarazona (CIT-INIA, Spain)
51 Dr. R. Diderich (INERIS, France)
52 Dr. A.J. Wilson (HSE, UK)
53 Dr. M.A.J. Huijbregts (Universiteit van Amsterdam, The Netherlands)
54 Dr. D. Pennington (EPA, Cincinnati, USA)
55 Drs. A. Ragas (Katholieke Universiteit Nijmegen, The Netherlands)
56 Prof. Dr. J. Koeman (LUW, Wageningen)
57 Dr. F.M. Carpanini (ECETOC, Brussels, Belgium)
58 Dr. J. Everts (LOCUSTOX, Senegal)
59 Depot van Nederlandse publikaties en Nederlandse bibliografie
60 Directie RIVM
61 Sectordirecteur Stoffen en Risico's dr. G. de Mik, SG UBS
62 Sectordirecteur Milieuonderzoek
63 Sectordirecteur Volksgezondheidsonderzoek
64 Hoofd Laboratorium voor Bodem- en Grondwateronderzoek
65 Hoofd Laboratorium voor Blootstellingsonderzoek
66 Hoofd Centrum voor Stoffen en Risicobeoordeling
67 Hoofd Laboratorium voor Afvalstoffen en Emissies
68 Hoofd Laboratorium voor Ecotoxicologie
69 Hoofd Laboratorium voor Effectenonderzoek
70 Hoofd Laboratorium voor Luchtonderzoek

71 Hoofd Laboratorium voor Water- en Drinkwateronderzoek
72 Hoofd Afdeling Voorlichting en Public Relations
73 - 81 Projectleider UBS, RIVM-Taakgroep UBS, d.t.v. drs.T.G.Vermeire
82 - 95 Beoordelingsgroepen H en H/M d.t.v. Drs.A.G.A.C. Knaap
96 - 101 Beoordelingsgroep M d.t.v. Ir.J.B.H.J. Linders
102 - 104 Centrum voor Stoffen en Risicobeoordeling
105 - 107 Laboratorium voor Ecotoxicologie
108 Dr. J.H.M. de Bruijn, CSR
109 Ir. M. Hof, CSR, SG UBS
110 Prof.dr. C.J. van Leeuwen, CSR, SG UBS
111 Ir. A. van der Linden, LBG
112 Ing. J.A. Montfoort, LAE
113 Dr.ir. F.A. Swartjes, LBG
114 Dr. M.P. van Veen, LBO
115 Dr. H. Loonen, ECO
116 Dr. D. Van de Meent, ECO
117 Auteur
118 SBD/Voorlichting & Public Relations
119 Bureau Rapportenregistratie
120 Bibliotheek RIVM
121 - 141 Bureau Rapportenbeheer
142 - 150 Reserve-exemplaren