3rd Annual Conference Preparing for REACH

28 – 30. March 2006, Renaissance Hotel, Brussels

Agrar informa

Dr. Uwe Lahl
Federal Ministry for the Environment, Natural Conservation and Nuclear Safety

"The German Position"

Ladies and Gentlemen,

My contribution to today's event is entitled "The German Position". It could also have been called "The Council Position". Germany has endorsed the political agreement in the Council. We find that our opinion is reflected sufficiently in this compromise. We are promoting the agreement so that it can swiftly find its way into the Official Journal.

I have chosen some components of this compromise to illustrate its structure and to present the position of the German government to you today.

I.

But let me briefly take a look back at how the political agreement in the Council came about. The second half of 2005 saw a lot of movement with regard to REACH:

We were lucky in the Council in that this decisive phase of the deliberations was overseen by a presidency which had made REACH a core subject and accompanied this dossier with an extremely committed and competent team. The British presidency used the results of previous presidencies as a basis and presented a diligently drafted compromise. Some amendments were adopted later to incorporate the opinion of the European Parliament, but this compromise pointed the way towards a political agreement in the Council.

After long and sometimes heated discussions, the European Parliament concluded its first reading of the REACH legislation at the same time as the Council reviewed the proposal of the British presidency. The Parliament worked out a compromise about the registration which found the support of the majority of MEPs and was in line with the basic ideas in the Council. The speakers of the Parliament and the Council thus

succeeded in finding convergence in their respective deliberations which now shows promise for a speedy completion of the process.

The compromise differs from the Commission's original draft in the following points:
- simplification of the registration process for small and medium-sized enterprises in particular,
- stronger role of the agency,
- improvement of the substitution incentive through the authorisation procedure.

From a German perspective, one important event cannot be left out of the presentation of events leading up to the compromise. Last year there were general elections and a change of government in Germany, right in the middle of the crucial phase in the REACH negotiations. We were grateful that the presidency and other delegations granted the new German government some additional time for consideration before the deliberations were concluded in the Council. Some issues which were particularly important to us and also contributed to a broader convergence with the European Parliament could be made part of the political agreement.

We find the agreement's strength lies especially in the balanced approach it takes to accommodating the interests of every stakeholder and in the fact that it offers a practicable solution for both enterprises and the authorities. The political agreement met with a broad and very positive response in Germany. In this evenly balanced version, REACH no longer constitutes such a controversial topic in our political debates. Business associations have also changed their strategies perceptibly and no longer oppose REACH but have instead entered into practical preparations. For many enterprises this was already the case at an earlier stage.

II.

Let me now take a closer look at some of the elements of the political agreement:

With regard to registration, the requirements for substances below 10 tonnes have been revised. In the revised version, only existing data must be submitted in the case of many of those substances. This revision became necessary as a result of the impact assessment, which showed that this volume was a decisive factor for competitiveness. The concerns of the small and medium-sized manufacturers and of the downstream users about the loss of substances for economic reasons all culminated in this tonnage range. The registration requirements have been modified to address these concerns. With regard to the environmental and health goals of REACH, and as an environmentalist myself, I cannot deny that this means a significant change for the worse, affecting half of all the substances covered by REACH. However, the German Environment Ministry was still able to endorse the modifications because a few years ago the chemicals industry in Germany already adopted a voluntary commitment a few years ago which requires enterprises to compile a minimum data set for all substances over 1 tonne per year. We can therefore assume – looking also at the findings in random sampling - that data is available to a significant extent and will then be submitted as existing data under

REACH. Incidentally, this voluntary commitment dates from the time when Germany's current Chancellor was Federal Environment Minister.

With respect to registration, I would like to emphasize that the solution found in the Council is almost identical in its core elements to the Nassauer/Sacconi compromise of the European Parliament. This is particularly true for the provisions for substances below 10 tonnes per year I described earlier. But it also applies to many other elements which share at least the same basic idea. Strengthening the exposure-related waivings is a case in point, as are the introduction of the "one substance-one registration" system including opt-out possibilities, the improvement of the GLP requirements and the introduction of exposure and application categories as an additional tool.

Among the above, Germany considers waiving a particularly important element, i.e. that no tests need to be carried out if there is no relevant exposure. The Commission will provide further details for this relief in the registration requirements in line with the Council compromise. This will be useful and reasonable in view of reaching the protection objectives. A research project jointly supported by the German Environment Ministry and the Association of the German Chemical Industry which involved stakeholders from many fields demonstrated that this is possible. This research project was certainly instrumental in reaching a consensus concerning this issue.

Additionally, it was crucial for us that provisions on application and exposure categories be incorporated into the Council compromise. Our main interest was the facilitation of risk communication along the supply chain, which is a core element of REACH, to make sure that the users draw the correct conclusion on the basis of the substance information available. It is particularly important here that practical management by the stakeholders is ensured if we want the obligations and opportunities to be more than mere words on paper.

I would now like to turn to the authorisation procedure, an element of REACH which was thoroughly and heatedly discussed in the Council and Parliament. Both bodies have adopted decisions which, while they share the aim of going beyond the Commission’s draft and strengthening the role the authorisation procedure as a substitution incentive, they nevertheless differ considerably in the means of achieving this goal. This issue will continue to be important in the future process. If there is still a controversial topic with regard to REACH at European level, it is the question of how and in what cases REACH must ensure the substitution of hazardous substances.

The Council decided that as a matter of principle authorisation should be granted without any time limit. Authorisation should instead be reviewed periodically to see if the conditions for authorisation still exist. The intervals would be established on a case-by-case basis. Two aspects played a role in the Council’s decision with regard to substitution. On the one hand, every application for authorisation must include an analysis of possible alternatives and their technical and economic viability. Secondly, consideration of any authorisation would take into account the existence of

alternatives for the final approval. The latter, however, does not apply to substances with adequately controlled risks. In contrast to the original draft by the Commission, the Council's decision makes provisions for setting clear criteria.

The Parliament went much further in this respect. There are many details in which the two decisions differ, but the main difference is that the Parliament requires authorisation to be limited to five years. The existence of suitable alternatives should always provide grounds for denying authorisation.

In our opinion, the Council has found a much more realistic and practicable solution. An authorisation of only five years is disproportionately short with regard to the planning periods often required by industry, and raises doubts about the practicability of the whole authorisation scheme. Dealing with applications for the renewal of the authorisation would consume a large portion of the scarce resources of the agency despite the fact that most renewals would be approved anyway. The review envisaged by the Council compromise with intervals laid down case-by-case leads to regular review of the authorisation, at times also after five years. The review mechanism, however, offers the possibility to take the planning needs of the applicant into consideration as well as the effective use of the resources in the authorities for each individual case and situation.

These advantages also make the Council's decision a good solution in terms of substitution incentives. Incidentally may I point out here that an opinion about substitution incentives which only focuses on the question of whether, how often and to what legal extent the alternatives are examined by the authorities misses a fundamental point. If you look at the issue only from that angle, you overlook the fact that the actual incentive to find alternatives is generated through the authorisation procedure itself. Enterprises will think twice before applying for authorisation and may prefer using alternative substances and technologies. Any authorisation procedure requires a lot of effort and includes many uncertainties. And in addition to this, enterprises run the risk of negative publicity if the authorisation for a substance is either denied or subject to strict conditions. Alternatives which don't require any authorisation are easy to market, probably more so under REACH than ever before. Investments in this field can therefore be very attractive for the manufacturers. The fact that this goes hand in hand with abandoning particularly hazardous substances is, of course, to be welcomed from an environmental and health viewpoint. This effect, however, is inherent in the system as a whole and is not the result of masses of legally sound decisions by authorities to show that there is a suitable alternative for a particular type of application. I'm not at all sure, by the way, how often the authorities can even make such a decision with sufficient certainty.

With regard to authorisation too, therefore, from the German perspective it would be desirable for the Council's compromise to prevail in the second reading.

III.

These thoughts on authorisation lead me to make some remarks on the environmental assessment of the Council's compromise. The aspects I have shown so far and the positive elements of the political agreement I have pointed out looked at how REACH can be made practicable for the enterprises concerned. But what does the situation look like from the perspective of environmental protection, consumer protection and health and safety at the workplace?

If you look at the compromise as a whole and from a certain distance, I think you can say one thing for sure: after many years of preparation significant progress has been reached for environmental protection, consumer protection and health and safety at the workplace to an extent that many people would no longer have expected. Apart from the setback for substances below ten tonnes per year which I commented on earlier, the core principles of REACH have remained untouched.

The provisions of the original draft regulation by the Commission concerning regular tests for long-term risks in the case of substances of higher volumes – for example testing them for their CMR properties – have been adopted without major changes. This can be called the heart of REACH.

Despite all tendencies to the contrary in the deliberations, the shift of responsibility to the enterprises for identifying risks and handling chemicals safely remains intact. The authorities will have free resources to carry out systematic and scientifically sound reviews to determine the need for state action in the field of priority substances. The tools for doing so have been improved greatly in comparison to the legislation in force. The procedure to ban substances or restrict their use has been simplified. The authorisation procedure will be introduced in an improved form compared to the Commission's draft. I have already explained the differences between the solutions offered by the Council and the Parliament in this respect.

Further improvements for environmental protection and consumer protection which the Council has made to the Commission's draft concern the registration of substances which are deliberated released from products. These are generally products destined for the private end-user. Basically, the registration has to follow the same principles that apply to the substance itself.

The Council also succeeded in anchoring the idea of quality assurance for the submitted data in the political agreement, at least on a voluntary basis. This has always been an important item for the German government as the added benefit of REACH depends heavily on the quality of the information gained.

Furthermore, the assessment provisions, in particular the requirements for evaluating the test proposals, have been made more practicable. It is now possible, without much red tape, to ask for completion in the case of incomplete test proposals without having to use the complex compliance check procedure.

Another point of importance for Germany is the consistent avoidance of duplicated animal testing by the provisions requiring joint submission of data and mandatory sharing of data. We have long had good experience with comparable regulations in Germany and are pleased that this model has been adopted by REACH.

From the perspective of environmental protection and health care, it is certainly beneficial that the agency is required to publish information, even though this was adapted at the end of the Council deliberations to accommodate the need to protect trade and business secrets.

For me all this means that, if the Council's compromise is adopted in its current version, REACH is an undeniable success also in terms of environmental issues. It is the nature of a compromise that nobody gets everything they wanted. The council compromise however is attractive in that the British presidency managed to unite at least the most fundamental requests of all parties involved.

IV.

Ladies and gentlemen, I have presented some aspects of the political agreement on REACH to you today. I pointed out those aspects which are important for the manufacturers and those which are of importance for the protection of the environment and the consumers. Those of you who experienced the negotiations in the Council know that the political agreement is a complete package which would not be improved by unravelling it. We are therefore decidedly against that and will strongly support the Finnish presidency in its effort to reach a swift decision together with the Parliament in terms of an "adoption in second reading" on the basis of the Council's proposal.

The die is cast for REACH. Now the time has come for the industry concerned as well as for the authorities to prepare for the practical implementation in the future. For us, this means, for instance, the first phase of adjusting our national chemical legislation and making the authorities fit for their future tasks. We need to set up help desks to assist smaller and medium-sized enterprises in understanding and implementing the new requirements. We need to give qualified input for developing the various guidance documents on REACH and contribute to setting up a European Chemical Agency capable of fulfilling its functions.

We have set the agenda. I support this agenda together with my colleagues from the other Member States. I hope that we will all succeed in putting this agenda into practice as soon as possible for the benefit of the industry, the environment and the consumers.