

#### **HEARING WITH REGARD TO THE RESTRUCTURING OF THE GERMAN ACCREDITATION SYSTEM**

On 29<sup>th</sup> April 2004 a hearing took place in the lecture hall of the Ministry of Economics and Labour (BMWA) with respect to the issue mentioned above – another step towards the legal regulation of the recognition and accreditation process in Germany. Representatives of nearly all accreditation bodies, from associations, industry and other interested parties were present – all in all approx. 150 persons.

MinDir Ulrich Becker, Mr and Deputy Assistant Under-Secretary Barz, Mr inaugurated the hearing. Although in times of deregulation, Mr Barz stated once again the reasons for a legal regulation of accreditation in Germany from the governmental point of view. Due to the variety of accreditation bodies in the mandatory and the voluntary area in general there is fragmentation of the accreditation landscape in Germany. In comparison to that, in most cases there is only one body to deal with the complex of accreditation and recognition abroad. Another fact mentioned is the problem of multiple accreditations and assessments as an additional cost factor for the economy. Furthermore, there are problems of acceptance of the German system in Europe as well as outside Europe causing disadvantages for the German export industry as the main part of the economic performance.

Mr Moritz from the BMWA once again explained the newest developments of the written statement of principles, which forms the precursor for the draft bill. The restructuring aims at an essentially better cooperation of all recognition and accreditation bodies to avoid multiple accreditations thus improving the services for the economy and the population in the long run. It goes without saying that there is a need for a uniform terminology. The competence and acceptance of the accreditation bodies is to be demonstrated based on equal requirements for the admission to be stated in the law. Moreover, the regulation aims at a load reduction as to administrative matters and at cost reductions for the economy.

The law is to include all bodies of the mandatory area, which carry out assessments of

competence of conformity assessment bodies (accreditation). The bodies in the voluntary area are allowed an adequate participation in the law. It is important to know that this law does not regulate the recognition procedure itself. The system is to be structured in sectors (technical areas). The requirement of the one-place-principle to have only one body for one sector was abandoned. In future, one competent authority (mandatory area) and one body close to the government loaned for the voluntary area are deemed to be the admission office. A steering committee with representatives of the federal government, the Lands, the accreditation bodies, industry, consumer organisations and other interested parties shall decide on the rules and the accreditation policy.

As the law pretends to be deregulatory, the comments of Prof. Dr. Bohne, Mr. were very interesting as regards to the topic “Debureaucratization by regulation – how things are?” In his statement he also referred to the relating problems of the federal government and the governments of the Lands with the planned draft bill to focus on it.

Hereafter, representatives of selected institutions had the possibility to present their point of view as to the planned bill formulating their expectations for the restructuring of the German accreditation system.

It was very good to hear that the Federal Agency of German Industry (BDI) after tenacious efforts was able to express a uniform and positive opinion with regard to the planned bill having thus achieved consent in its members’ associations. Ms Astrid Ingenhag presented this opinion as a résumé. Her motto was “Bill as far as necessary - auto regulation of the market as far as possible”. Correspondingly, the main requirements of the industry concentrate on minimizing the part of the legal regulations to have a bill with deregulatory character.

#### **TOPICS**

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The accreditation should in general be transferred to private bodies and the recognition should be reserved for as few public bodies as possible.

Furthermore, Ms Ingenhag required free competition for accreditation and certification. In addition, the system should be compatible in Europe and outside Europe. The mandatory and voluntary area have to be part of a common system subject to surveillance procedures. She also required a say of the industry for the setting of rules in both areas. There were requirements for the following:

- Bundesadler ("federal eagle" – national emblem) as unique symbol
- No limitations by the law for the technical fields of the accreditation bodies

Eng. Hans Meierhofer, also chair of the "Coordination Committee of the Mandatory Area" (KOGB), informed that from the point of view of the accreditation bodies in the mandatory area they supported the efforts of the BMWA to put the accreditation activities on a legal base setting up horizontal and sectoral rules for the conformity assessment thus avoiding a further fragmentation to the detriment of the economy. He fiercely rejected the abandonment of the principle up to now of the accreditation procedure "in one hand" envisaged in the written statement of principles in favour of a two-stage system (accreditation by private bodies as first stage and subsequent national recognition as second stage). In his opinion such a procedure is associated with the danger of higher costs, dwindling professional judgement of the authorities and therefore, decline of confidentiality by the costumers as well as apprehensions with respect to the protection of the environment and health, the public and technical security.

He generally is afraid of eroding accreditations of the bodies in the mandatory area. The assessment of competence is to be seen in connection with the subsequent conformity assessment – therefore, there must not be any separation. In his opinion there are more problems in connection with additional costs for the scheduled licence fees, which serve to cover the system financially. Furthermore Mr. Meierhofer doubted the independence of the accreditation bodies in the voluntary area mostly brought into being by associations. Last but not least he raised the requirement that the Office of the Steering Committee should be settled in the mandatory area finally fearing that the federal system of the Federal Republic of Germany will pose immense problems to such a planned regularization.

The author of this article as speaker of the accreditation bodies in the voluntary area (NGB) also welcomed the planned legal regulation. At the beginning of his statement, in a humorous but decisive manner, he rejected the remarks of his previous speaker regarding the lack of independence of the accreditation bodies represented by him. Ms Ingenhag had already mentioned a better part of the arguments in favour of a legal regulation. There is

a particular request to subject the accreditation bodies of the mandatory area and the voluntary area to the law initiating a joint exchange of experience also for the reason that the assessors in part work for both areas. In addition, double accreditations have to be avoided; the service accreditation has to be offered in the mandatory and voluntary area more favourably. Efforts have to be made that the original idea of a deregulatory law is to be taken into account. In particular, both areas united in a law make a commitment in order to use all possible synergy effects and to cooperate. That way, a two-stage system could be adopted as already applied in nearly all-European countries. Private accreditation bodies would perform the accreditation as competence assessment whereas administrative matters such as notifications and approvals continue to fall into the responsibilities of governmental accreditation bodies.

Both systems have to be able to use the national emblem, the Bundesadler as before. Both systems, in defined intervals, should be subjected to surveillance by a neutral body against the same requirements.

The next speaker was Mr. Tilmann Burgraef from the Association of Independent Testing Laboratories (VUP). He also stated that his association would welcome a regulation by law mentioning that in the voluntary area the accreditation against DIN EN ISO/IEC 17025 is the indisputable and accepted standard. To his regret, this system at first had been unsuccessful and later very slowly in reaching the desired acceptance of the governmental bodies in the mandatory areas. In the mandatory area, the testing laboratories have to confront with a variety of governmental bodies. The federalism leads to the fact that the competence is often to be proved several times towards the federal states.

He also declared that the work in the voluntary area was to be improved and that in his opinion several problems were to be criticised.

Subsequently, Dr. Kreinberg, Mr., from the company TÜV-Product Service, gave a few drastic examples on the burden for the economy due to multiple accreditations and assessments. That way different bodies require as far as 10 recognitions for the complex of chain saws. In this respect it was not astonishing that he pronounced himself in favour of a regulation by law having high hopes that by this means the system could essentially be simplified.

Ms. Gehrke, Manager of the Association of Material Testing Institutions in Germany representing exclusively "Third Party Testing Centres", on behalf of the Associations' members also pronounced herself in favour of a regulation by law offering aid and comfort to the Ministry for such a plan.

## REPORT ON THE FINANCIAL YEAR 2003

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She pointed out that the DAR had done valuable work but had finally been abortive, as it had not had any juridical possibilities to discipline its members as the whole system had been established on a basis of a gentlemen agreement. In case of a regulation by law, necessary steps should be taken. She presumed another difficulty in fixing the details so that the mandatory and the voluntary area could identify with them.

Also the statements of the Association of German Engineers and EUROLAB Deutschland welcomed a regulation by law. The latter referred to its extensive written comment. All subsequent statements of associations, other stakeholders and accreditation bodies referred to the same direction. Giving further comments here, would be taking things too far.

At the end of the hearing, Min.Dir. Becker, Mr. resumed the most important results:

- The main objective of the regulation by law continues to be the abolition of the separation between the mandatory and voluntary area.
- The integration of the voluntary area is done on a voluntary basis.
- All accreditation bodies in future are subject to the same requirements.
- For the same circumstances, in future there are to be the same accreditation rules.
- Appropriate international standards as well as legal liabilities are to be the yardstick for this purpose.
- The principle of mutual recognition at both the national and international level is to be implemented.
- The bill shall also be path breaking for future European regulation of accreditation, possibly by means of a horizontal European Directive.
- Particular importance is to be dedicated to the cooperation of the German economy in organizing the system.

Scheduled steps towards the accreditation law:

- In the coming days, on the basis of the written statement of principles and the results of the hearing, a draft bill is to be prepared.
- The active advisers are deemed to continue working on the project.
- An intensive dialogue is to be carried with the departments of the federal states and their admission offices.
- The prerequisites in terms of organization and others have to be established as soon as possible.
- The bill is still to be adopted in this legislation period.

All participants agreed on finalizing the project with success and as early as possible.

Univ. Prof. Dr.-Ing. habil. Kurt Zielger  
Speaker of the accreditation bodies in the voluntary areas (NGB)

On the Shareholders' Meeting of DAP on 23<sup>rd</sup> April, the annual report 2003 already scrutinized could be presented and explained by the DAP's Managing Director. Thanks to the intensive work of our approx. 250 assessors and technical experts, the staff of the DAP Office, and especially thanks to the confidence shown by our costumers, the sales revenue could increase by another 20 % as compared to the previous year. With a total of 4.3 Mill. Euro this sales revenue is the biggest since the foundation of the German Accreditation System for Testing. This success is to be attributed to the number of initial accreditations or applications for reaccreditation and to the conversion of accreditations from the DIN EN 45001 standard to the DIN EN ISO/IEC 17025. At the same time, the stock of orders as compared to the previous year could essentially be diminished.

The accreditations of testing laboratories, inspection and certification bodies mainly contributed to the result mentioned before. Interlaboratory comparisons, training of assessors, special trainings and information meetings were also a factor in the increase of sales. 96 initial accreditations and 153 reaccreditations were granted. 412 assessments for surveillance (including extensions) were carried out. Only 29 assessments for surveillance had to be transferred to the year 2004 (in the meantime finished).

In the financial year, five interlaboratory comparisons with 164 German and 117 foreign participants were carried out with our partners The Federal Institute of Material Research and Testing (BAM) and the Institute for Proficiency Testing (IfEP) at the College of Higher Education in Gelsenkirchen. The assessor trainings organized by the DAP Office were well attended by 456 participants in total. In addition, eight information meetings and activities for the exchange of experience referring to the standard DIN EN ISO/IEC 17025, to the Drinking Water Ordinance and to medical laboratories with 278 participants were organized. For 80 persons, four special trainings were organized in Iran.

The staff expenditure of the DAP Office had to be increased as compared to the year before. In the accreditation department, two new places of employment were established to manage the increased volume of work at the required level. That way, as compared to before, approx. 2/3 of accreditations could be managed by the Lead Assessors of the DAP Office, 1/3 was assigned to the external Lead Assessors.

The increase in the sales was accompanied with a lean management of the accreditation process initiated in 2002 and consequently continued in 2003 with in part considerable price cuts: for instance since autumn 2002 already the fees for the application of the first reaccreditation have been reduced

by 25 % and for the second reaccreditation for our long-time costumers by 50 %. Furthermore, the fees for small testing laboratories with less than 5 employees have been reduced by as far as 20 %. Last but not least, the whole costs for the accreditation and reaccreditation have been reduced by 5 % since 1<sup>st</sup> October 2003. This cost reduction has also been born by our assessors – I would like to than them once again. As a matter of fact, in this connection we now will be implementing them the promised reduction of costs as referred to the hours of work.

Two of these organizational measures have been described in this booklet: the preparation of the certificate annex by the help of the Perinorm at the DAP Office as well as the introduction of the new accreditation reports for Lead Assessors and assessors during the on-site assessment and the following documentation. Naturally, there shall not be any drop in quality of the assessment and accreditation. The aim is to reduce the bureaucratic expenditure in order to save time and costs.

Dr.-Ing. Klaus Berner  
Managing Director of DAP

### **INCREASED EFFICIENCY IN PREPARING CERTIFICATES**

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Preparing the accreditation certificate, especially the annex to the certificate, there is a cooperation of the Lead Assessor, the technical assessors and the DAP Office. For all persons involved the preparation of the annex to the certificate is time-consuming. To minimize the costs and to make the preparation of the certificate more efficient, in future the database of the Beuth Edition (Perinorm) is deemed to be directly involved.

The annex to the certificate handed over at the end of an accreditation process contains the test methods for which the DAP confirms the competence to our costumers being therefore the integral part of the accreditation. The DAP is aware of this central position of the annex to the certificate making efforts to express the individuality of our costumers by listing the test methods as precise as possible integrating the peculiarities specific to the laboratories.

The standard DIN EN ISO/IEC 17025 forming the basis of the accreditation of testing laboratories basically says in chapter 5.4.2 that the laboratory shall ensure it uses the latest valid edition of standard.

To comply with this requirement and in general to prepare the certificates more efficiently, in future the database of the Beuth Edition (Perinorm) is deemed to be directly involved as central source of information.

Even though not all test methods to be accredited are by far covered in the Perinorm, approx. 70 % of them is involved. The integration of sophisticated computer application thus will result in a simplified handling and increase in quality of the annexes to the certificate.

In future, always if there is the necessity to revise an annex to the certificate during an initial accreditation, a reaccreditation or extension of the accreditation, a draft of the annex to the certificate updated with the Perinorm is scheduled to be available to all parties all through the on-site assessment.

Of course the laboratories as before are in charge of informing the DAP for which test methods they would like to be accredited. As a means of support, in near future sector-specific sample certificates to be updated in regular intervals will be made available on DAP's website.

The presentation of the individual standard test method on the certificate will change in so far as the exact title of the standard concerned in the Perinorm will be listed on the annex to the certificate even if it may contain redundant information in part. Deviations specific to the laboratories or restrictions of standardized test methods will be listed as before on the annex to the certificate.

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### **INTRODUCING NEW REPORT FORMS FOR THE ACCREDITATION**

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In the course of minimizing administrative work steps for the Lead Assessors and Technical assessors with regard to the quality documents the documentation of the assessment on-site has been revised at the DAP Office. This change especially refers to the handling and layout for the following DAP forms: checklist, necessary / submitted documents and records on-site, sheets of objective evidence on-site and assessment report against DIN EN ISO/IEC 17025 : 2000 of the Lead Assessors and technical assessors. In future, the laboratories will completely fill in the detailed checklists before the assessment of the laboratories; the same will apply to the device-specific part of the sheets of objective evidence. There will not be any changes concerning the handling of plan of assessment on-site and the non-conformity report.

As before, the DAP report is oriented on the structure of the associated reference standard and continues to be valid for all phases of accreditation. With regard to the requirements for the management and the technical requirements, now specific reports of six pages instead of 12 are to be worked

out. An evaluation system with regard to the individual bullets of the standard has been adopted. A résumé is deemed to describe the significant realities in detail specific to the laboratory.

In a phase of three months from May 2004 on before approval, the new pro forma documents will be tested by the Lead Assessors of the DAP Office and by selected external assessors. Analogously, the report preparation for inspection and certification bodies will be adopted to the new proforma documents.

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### **INTERNATIONAL INTERLABORATORY COMPARISON EA-9 TO ANALYSE PAH IN SOIL**

In 2003, under the charge of the DAP and in cooperation with the Federal Institute of Material Research and Testing (BAM) and the Institute for Proficiency Testing (IfEP), the first international interlaboratory comparison was organized as EA interlaboratory comparison for environmental chemical products in soil. Polycyclic aromatic hydrocarbons (16 EPA PAHs) should be determined in a natural contaminated soil as single substance and a sum.

The BAM made available the samples of the interlaboratory comparison. They contained the 16 EPA PAHs in concentrations of 0.3 – 23 mg/kg or as a sum approx. 136 mg/kg. The BAM with an anterior interlaboratory comparison determined the reference values for the concentrations of the singular PAHs and the criteria for the dispersion. The set points for the dispersion were determined individually for each parameter and were between 10 % (sum of 16 EPA PAHs) and 25 % for the first four extractable substances.

In June last year the samples were sent to 31 laboratories in 11 European countries. Only one of the 31 laboratories was not accredited for the test method. The five German participants had exclusively been nominated by the DAP.

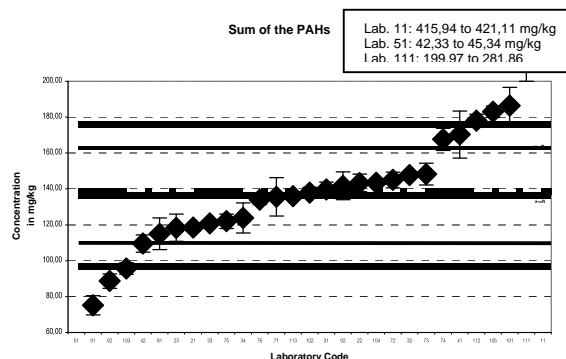
Table 1: Number of nomination per country

Country	NAB	Nominations
Poland	PCA	1
Belgium	BELTEST	3
Sweden	SWEDAC	5
United Kingdom	UKAS	2
Bulgaria	BAS	1
France	COFRAC	2
Denmark	DANAK	5
Norway	NA	1
Finland	FINAS	2
Germany	DAP	5
Austria	BMWA	3

The laboratories could choose their test method for the analysis. HPLC and GC were used. The test method mostly used was GC-MS applied by 18 from 31 laboratories. In the case of liquid chromatography, the fluorescence detection was mostly used.

The consensus value of the laboratories for the concentrations of the individual PAHs from the interlaboratory comparison astonishingly coincides with the reference values proposed by the BAM. As an example graph 1 illustrates the sum of the PAHs with an exception of acenaphthylene, which is very close to the detection limit required by the interlaboratory comparison (0.3 mg/kg). Here the consensus value is twofold higher. The recommendation therefore was not to involve this parameter for the evaluation of the laboratories.

Graph 1: Representation of results of the sum of the PAHs



Also the estimated measurement uncertainty and the applied test method were asked about. Five of 31 laboratories indicated to have estimated the deviation according to the GUM. The majority of the laboratories (18) estimated the deviation obtained as from in-house quality assurance such as control charts. Only on third of the laboratories stated the extended uncertainty. According to the various methods used to estimate the measurement uncertainty, there were larger dispersions as in the case of other interlaboratory comparisons with values between 1,5 % and 125 %. Most of the laboratories estimated their measurement uncertainty with 15 % - 30 %. Due to the larger dispersions, an evaluation of the laboratories with an integration of the measurement uncertainty was not done.

Within Europe, the use of PAHs to determine environmental contaminations is differently handled; in part only 6 PAHs are used for the evaluation or only benzo[a]pyrene together with the sum of the PAHs. Due to this circumstance, there was no uniform evaluation criteria – the accreditation bodies have to determine their own criteria based on the national realities.

Presuming that passing an interlaboratory comparison, at least 80 % of all parameters have to be

between  $\pm 3$  z-score, seven laboratories would not have passed the interlaboratory comparison which is within the bounds of what is usually found in complying with the tasks of an interlaboratory comparison.

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## **INFORMATION MEETING AND EXCHANGE OF EXPERIENCE IN MATERIAL TESTING**

For the first time on 21<sup>st</sup> April 2004, the sector committee material testing initiated and together with the DAP organized an information meeting with accredited bodies and stakeholders in the area of material testing. This meeting aimed at imparting up-to-date information to the accredited bodies on the activity of DAP and recommendations related to practice for the sector-specific implementation of selected technical requirements of the DIN EN ISO/IEC 17025.

Introductorily Dr. Berner, Mr. (DAP Managing Director) and Dr. Höhne, Mr. (DAP) informed the 67 participants on the DAP results of the accreditation and training activities in Germany and abroad in the last financial year. In detail, there was given an overview of the positive process of the week-long evaluation by an international evaluator team in February 2004 which recommended that DAP remained signatory to the MLA for Testing and Certification (Products) and became a signatory to the MLA for Inspection Bodies. The attention of the participants was called to the information of the BMWA's efforts to transfer the split German accreditation system in an efficient and uniform at international level recognized system (see article on the hearing at BMWA).

Mr. Triebel (chair of the sector committee material testing SK-MP from the Sachsen-Anhalt Department of Material Testing LMPA) introduced the technical topics analyzing the stated non-conformities of the assessors during the assessments on-site. Besides some weak points in fulfilling the quality requirements, a concentration in determining the measurement uncertainties, the validation of test methods, the metrological traceability of the measurement and testing technology and in reporting the results in accordance with the standard was apparent in the technical area.

That is why Dr. Frenz, Mr. (IfEP) in the following contribution to the discussion explained all steps to determine measurement uncertainties. Based on various examples he made the difference clear between the measurement uncertainty and the uncertainty of results, which in part is not considered in practice. Additionally, Mr. Triebel presented a work instruction as an example on how to determine measurement uncertainties. In the following, Dr. Frenz emphasized the topic of proficiency testing explaining its aims. He explained how to proceed in determining the assigned value, the assigned standard deviation of the proficiency test and how to calculate and evaluate the laboratory's performance. In detail, Dr. Frenz presented the results of the proficiency tests in the last year giving a foresight to the scheduled proficiency tests in 2004. In the following Dr. Lehmann, Mr. (DAP) considered the proficiency tests to be a means to evaluate the technical competence of the testing laboratories. In this connection, he informed about the different types of proficiency tests explaining the evaluation of the results of the proficiency tests by DAP. Finally, the EPTIS database, an information system of providers of interlaboratory comparisons was presented.

In all contributions to the discussions, the participants were given examples related to practice and pragmatic ways of implementing the requirements of the standard, which essentially contributed, to the successful course of the information meeting.

The discussion stimulated by the participants show that there is a need for discussion especially with regard to the implementation of the technical requirements. Another information meeting in an adequate interval was considered to be very helpful by all participants.

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