Implementation of the concept of Measurement Uncertainty in European Standards

Distribution of recommendations to CEN/BT according to priorities
(from the easiest actions to the more difficult and expensive ones and from the only CEN/BT decisions to co-partners or external decisions)

1. CEN/BT principles declarations

- Every new or revised European Standard including a measurement method or a test method providing quantitative results must address measurement uncertainty. A process for uncertainty evaluation or, if not possible, values of precision (i.e. repeatability and reproducibility) should normally be included (see paragraph 1.2 of the recommendations to CEN/BT : document CEN/BT/WG 122 N 26 E REV 4).

- Every measurement method or test method must be validated, possibly through interlaboratory comparisons. The values of precision of the method shall be obtained before the publication of the corresponding standard (see paragraphs 1.2 and 5.1).

- When standards include product specifications, in a transitional period, unless regulation or other standards requires, the results compared to specification limits should be interpreted without taking uncertainties into account, until the standards are revised (the product is accepted up to the limit and rejected beyond). These standards must be revised before 200X at the latest, in order to follow the CEN policy (see paragraph 3.3).

Comments : These three principle declarations could be expressed immediately by CEN/BT in terms of objectives (and not of means). These declarations could be introduced in CEN/BOSS.

2. Promotion of reference and sectorial documents

- To improve the status of reference documents, such as GUM and VIM, and transpose other documents such as ISO 3534, ISO 5725, ISO/TS 21748 (see paragraph 1.1).

Comments : The status of the reference documents could be quickly improved through the enquiry and formal vote (or UAP) process, which could also be used for the transposition of other documents.
CEN/BT could propose to launch the enquiries. Due to the lack of a general CEN/TC on metrology, CEN/BT or CEN/BT/WG 122 could follow these enquiries and deal with the result processing.

A CEN/BT declaration about the fact that these reference documents must be included in the normative reference chapter of each measurement method or test method standard would be also a means of promotion. This declaration could be expressed immediately by CEN/BT and introduced in CEN/BOSS.

- To support the establishment of sectorial documents dealing with uncertainty evaluation, consistent with reference documents (see paragraph 3.1). It is the best way for motivating CEN/TCs to adopt the reference documents (The members of sectors should decide which supporting documents are needed for their work).

Comments: That could also be done in CEN/BT declaration form.

### 3. Preparation and distribution of awareness documents

- **Communication with consumers, consumer associations and users of test results:** CEN should prepare and widely disseminate a short document written in simple words, including illustrative examples, which explains the concept of measurement uncertainty and its importance in ensuring the reliability of the results (see paragraph 2.1).

Comments: Relevant material already exists. The leaflet published by SP Swedish National Testing and Research Institute (see the enclosed document) could be taken up by CEN after authorization.

- **Communication with chairmen and convenors of CEN/TCs:** CEN should prepare and distribute to CEN/TCs a document about the basic principles of metrology in order to convince them of the need to address measurement uncertainty in all relevant standards. This document (citing reference documents) shall give practical advice on how to implement the concept of uncertainty in standards and what could be the contents of the paragraph dealing with uncertainty (see paragraphs 2.5 and 3.2).

Comments: CEN/BT/WG 122 could help CEN for the preparation of the document.

Possibly, a seminar or workshop should be organized by CEN to discuss the draft document, to allow sufficient debate with appropriate experts and to collate their comments and suggestions before its finalization.

- **Communication with industry, regulating bodies and European Notified Bodies:** CEN should prepare and widely disseminate a short (but more technical than the one for consumers) document to convince industry of the benefits of evaluating measurement uncertainty (see paragraph 2.3).

This document could also be addressed to the regulating bodies (which define specifications, tolerances and limit values) and the European Notified Bodies with adapted introductions.

Concerning the regulating bodies, it is essential that personnel are aware of the concept of uncertainty in order to be able to establish clear specifications and also to interpret properly the results from different laboratories (e.g. market surveillance actions or control actions) (see paragraphs 2.4 and 5.3).
As far as the Notified Bodies (designated by the competent authorities for CE certification activities) are concerned, it is important to carefully explain them the importance and the benefit of using uncertainty of measurement in the process of conformity assessment of products (see paragraphs 2.2 and 5.2).

Comments : CEN/BT WG 122 could help CEN for the preparation of the document for industry.

Concerning the regulating bodies, CEN could contact the leaders of the two European programs RegMet and MetroTrade.

- Communication with ISO TC 176 (quality) : CEN should have an action to the ISO/TC 176 (quality) in order to advocate an amendment of the ISO 9000 series with respect to uncertainty of measurement (see paragraph 2.1).

Comments : The work consists in the preparation of a letter to the ISO/TC 176 Chairman.

- Communication with editors of scientific journals : CEN should have an action (possibly through a document) to the editors of scientific journals in order to encourage them to adopt an appropriate editorial policy (see paragraph 2.1).

Comments : This work is not a priority at the moment.

4. Training and support

4.1 Training for chairmen, secretaries and persons in charge of the development of measurement standards - Establishment of a CEN uncertainty advisers group (see paragraphs 3.1, 4.1 and 4.2)

Comments : CEN shall encourage the national representatives of European associations such as EUROLAB, EURACHEM, EUROMET and NORDEST, to help for training the persons in charge of developing measurement standards, when the country deals with the chairmanship and secretariat of a CEN/TC. If necessary, the national representative may be used as consultant. In this case a CEN uncertainty advisers group is not necessary.

4.2 Transverse CEN body on metrology and testing

It is proposed that CEN examines the possible need for a transverse BT/TF or CEN/TC on metrology and testing. The objective of this group is to provide European interface with ISO on uncertainty issues (see paragraph 4.3).

Comments : CEN could launch a vote about the creation of such a structure.

5. COOPERATION WITH THE EUROPEAN ORGANIZATIONS (see chapter 5)

Comments : As a general rule, CEN should associate the European Commission and the different European organizations for a good cooperation and coordination for this matter. If necessary a seminar or workshop should be organized by CEN.

5.1 Support for interlaboratory comparisons (method validation)
It is essential to define a proper policy at European level (CEN/EEC) of interlaboratory comparisons and to obtain financial support from the Commission, in order to systematically organise interlaboratory comparisons for the validation of the measurement or test methods (see paragraph 5.1).

Comments: CEN should contact EPTIS secretariat in order to organize cooperation and help for interlaboratory comparisons, and associate the European Commission to the discussions.
Important information to our customers concerning the quality of measurements

1. Do you use results of chemical analyses as a basis for your decisions and judgements?

Those of us working in accredited laboratories or dealing with issues concerning the quality of measurements, would like to inform you about some important changes concerning the way the results of measurements are presented. These changes make it easier for you as an end-user to make correct decisions.

2. Nobody is perfect!

Results of analyses cannot be perfect! We hope this does not come as a big surprise to you. We use the term measurement uncertainty to describe this lack of perfection.

3. The analytical process

In each step of the analytical work, from sampling to the final measurement, deviations from the true value occur and measurement conditions vary. We take measures and perform controls regularly to assure that these deviations and variations together are small enough to make sure the end result fulfils your requirements. When we don’t have full information about all of the steps, e.g. when sampling and initial sample preparation are performed by you as a customer, you can assist us by providing detailed information about how that work was performed. Our experts are ready to advise on all matters regarding sampling. Please contact the laboratory beforehand.

4. Results should be fit-for-the-purpose

The accuracy of the results must of course not be too low nor too high since this would increase the costs. It should be fit for the intended purpose. If you are unsure on what level of accuracy you need, do not hesitate to contact the laboratory.
5. Uncertainty and limiting values

Many analyses are made to assure that limiting values are not exceeded. Without information about the measurement uncertainty it may appear to be very easy to make decisions, but these decisions may be incorrect, with, e.g., economical consequences when rejecting instead of accepting a product, causal consequences when returning a verdict of guilty instead of not guilty, or medical consequences when carrying out an unnecessary treatment. There are numerous examples!

A result with and without measurement uncertainty

With a realistic measurement uncertainty the information included in the result becomes much more useful.

6. It will be easier to compare results

Most laboratories have until now chosen not to state measurement uncertainty in the test report. Instead, such information has only been given when the customer has asked for it.

In the future, information about the measurement uncertainty will appear more frequently in the test report. It is also possible that you will bump into new and unfamiliar quality terms. This is due to the fact that there are new international guides and standards describing a common and partly new terminology. One of the objectives is to make it easier for you as a customer to compare test results.

7. What could it look like?

When reporting the test result we will give the normal information about what we have measured. When the results are followed by uncertainty statements, they are presented as intervals within which the true values are expected to lie with a certain level of confidence (usually 95%). In the example below the lead content is 1.65 ± 0.15 mmol kg⁻¹, that is between 1.50 and 1.80. The measurement uncertainty is also often reported relatively, in %.

| Total lead content (Pb) | 1.65 mmol kg⁻¹ |
| Measurement uncertainty | 0.15 mmol kg⁻¹ (9.1%) |

The stated uncertainty is an expanded measurement uncertainty (U). It was obtained by multiplying the combined-standard uncertainty u with a coverage factor k equal to 2. This corresponds approximately to a 95% confidence interval.

8. All's well that ends well...

The requirements for a consistent way of reporting test results are increasing. Therefore, those of us involved in measurements are eager to assure ourselves that we understand your needs. You will notice this in your contacts with us before, during and after the test assignment. We hope that you will be satisfied with the final result.

"Based on SP INFO 2000:23, developed by SP and Förenningen Ackrediterade Laboratorier (Fal.), in collaboration with the National Food Administration, SWEDAC, the Swedish Environmental Protection Agency and the Swedish Water and Wastewater Association (VAV)."