

Future use of Certified Reference Materials in Europe

Final Report to the European Commission

A study aimed at assisting the European Commission in evaluating RTD needs and development strategies in the field of Competitive and Sustainable Growth, intended for use by the European Commission

Public version

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Preface

1 This report describes the study “Future use of Certified Reference Materials in Europe” which was carried out by PwC Consulting under contract No. G6MA-CT2000-02000, covering the period from 1 September 2000 to 30 April 2002. The contract was awarded following the call for tender with Official Journal Reference 2000/S 15-008075.

2 The study was commissioned by the Research Directorate General of the European Commission, Directorate C.II Competitive and Sustainable Growth II, Unit Measurement and Testing, Infrastructure. Scientific Officers in charge were Ms D. Bennink and Dr. E.A. Maier on behalf of head of unit Mr W. Raldow.

3 Managed by Dr. J.F. Modder and under the overall responsibility of Mr R.P.M. Overgoor, the PwC Consulting study team study consisted of (in alphabetical order):-

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4 The reported findings and opinions are those of PwC Consulting only; they are not necessarily endorsed by the European Commission.

5 PwC Consulting wishes to acknowledge the cooperation of the entire stakeholder community. Virtually without exception, requests for interviews were promptly granted. We are particularly grateful to the involved major producers of Certified Reference Materials, both the European and non-European ones, for the considerable amounts of time they set aside in support of this study. Furthermore, our gratitude extends to the attendees of the study’s workshop (Brussels, 5-6 February 2002): your presence really made a difference. Finally, we thank all stakeholders that completed and returned the study’s questionnaires.

Executive Summary

1 Prompted by the need for a strategy to identify key CRMs, in order to realise the full benefit of the CRM related policy of the European Commission at medium and long term, DG RTD commissioned the present study into “Future use of CRMs in Europe”. The study was carried out by PwC Consultants in the period of 1 September 2000 to 30 April 2002. The outcomes, conclusions and recommendations described in this report are those of PwC Consulting only; they are not necessarily endorsed by the European Commission.

2 Taken from the Terms of Reference the overall aim of the study was “to enable the European Commission to identify key CRMs for future research and production activities and fields for possible future collaboration”. In more detail, these objectives comprised:-

- (a) to identify the needs of the European end users of CRMs;
- (b) to assess the actual production schemes of the world-wide producers of (C)RMs;
- (c) based on the combined findings of (a) and (b):-
 - (i) to establish the key issues
 - (ii) to investigate the possibilities for future synergies among producers
 - (iii) to elaborate a dissemination strategy to potential users and policy makers.

3 Core element of the study was a comprehensive survey, by means of a questionnaire, of ideally all European CRM end-users as well as the worldwide (C)RM producers catering to the former. Where possible future new end-users, referred to as “potential end-users” were included as well. The questionnaires were complemented by a selected number of personal interviews, to allow for more in-depth investigation. Bearing the European Commission perspective in mind, issues and collaboration options were then derived from the results, validated and further elaborated in a workshop (Brussels, 5-6 February 2002) with representatives of all stakeholders, for subsequent dissemination to the stakeholder community.

Outcomes worldwide (C)RM producers

Producer questionnaires

4 Distribution of a paper version of the producer questionnaire to all parties in the COMAR database and publication of a web version, resulted in 25 responses admitted to analysis. Where possible and meaningful, results were analysed according to 3 identifiable producer types, i.e. large CRM producers (>10 CRMs), small CRM producers (≤10 CRMs) and pure RM producers. In general large CRM producers cover many sectors; small ones and RM producers tend to focus on a single sector, most often mentioned being Environment and Metals, respectively. Most large CRM producers and a small majority of the smaller ones are public research institutes, while a clear majority of the RM producers consists of private laboratories. In terms of CRM categories (based on COMAR and classifications employed by major producers), all are covered by current activities as well as future production schemes.

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Producer interviews

5 Interviews in person were conducted with 11 producers, including BAM (Germany), IRMM (part of the European Commission, located in Belgium) and LGC (UK) and the non-European ones NIST (USA), NMIJ (Japan) and NRC-CRM (China). In addition 3 experts on the same levels and ISO-REMCO, the most relevant standardisation body were included. EURACHEM was indirectly involved as several interviewees held board positions in this organisation.

6 Among the 6 aforementioned major producers, two different approaches to CRM development can be discerned, based on their philosophies towards characterisation and certification. On the one hand there exists an essentially centralist approach with tight control over the characterisation/certification by the certifying producer, involving predominantly proprietary laboratories, as most clearly demonstrated by NIST. On the other hand, there exists a more distributed approach, in which the producer only may have part of the final control over the actual certification, the characterisation executed by laboratories from many different organisations and not necessarily including the certifying producer itself, as seen with the EC. The other producers are in between the above extremes: BAM, LGC and NMIJ each appear to tend towards the centralist approach, whereas NRC-CRM's approach is very similar to that of the EC.

7 All of the interviewed CRM producers are in favour of actual co-ordination of development related activities, although the extent of the envisaged co-ordination appears to vary considerably. Joint CRM development being seen as incidental only, there appears to be full agreement that it is in everybody's interest to collaborate on supporting technology and method development.

Outcomes European CRM users

User questionnaires

8 Distribution of a paper version of the user questionnaire to all parties listed in the client databases of IRMM, LGC and Promochem and publication of a web version, resulted in 266 responses admitted to analysis. Where possible and meaningful, results were analysed according to either the sector of activity or the user type of which 3 are identified on basis of the number of CRMs used, i.e. large (>25 CRMs), medium (6-25) and small (≤ 5 CRMs) CRM users.

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9 Of the six main sectors that could be identified, users from the Food, Pharmaceutical and Metal sectors are accredited relatively more often than users from the other three sectors, i.e. Agriculture, Chemical and Environment. For Food and Environment, CRMs are more often used for method validation, while in the other sectors, CRMs are more often used for instrument calibration. For all sectors, the most prominent reason for using CRMs instead of RMs or control samples turns out prescription by internal quality system. The Pharmaceutical sector's CRM purchasing frequency is by far the highest with about 80% ordering at least once a month. In the other sectors, the purchasing frequency is markedly lower, with Agriculture ordering no more than once a year.

10 The bigger the user in terms number of CRMs used, the bigger the department and the more frequent CRMs are applied. In general, large CRM users have a better picture on the availability of CRMs and producers than medium and small users. Regarding knowledge and use of CRMs in their sector, large users are most positive on these issues, whereas medium and small CRM users perceive the knowledge and use of CRMs to be much less developed in their sectors. Large users interact relatively more often with CRM producers than medium and small users, especially on the issues of new CRM requests and measurement issues. Large CRM users are also more often involved in the feasibility phase and certification phase of the development process of new CRMs.

User interviews

11 Interviews in person were conducted with 13 users, only one having some experience in EU support programmes. Two distributors and an accreditation body were included as well. The interviews largely corroborate the questionnaire results. Most prominent finding in addition is that virtually all users seem to be confused by the terminology of the (C)RM field. No one appears to have a complete overview of the relevant offering and alternatives. Most readily acknowledge this aspect; some appear not even aware of their own lack of understanding.

Outcomes potential European CRM users

12 No clear indications were found that instrument / equipment manufactures or organisations fighting synthetic drugs qualify as potential CRM users, although both do have RM needs. The forensic laboratories, organised in ENFSI, appeared to focus very much on the Pharmacopoeia approach to solve their RM issues.

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Developing countries

13 Solidarity with developing countries is one of the objectives of the European RTD programmes. The position of third world exporters of agricultural produce to the EU was therefore investigated through a series of interviews with FAO representatives. Indeed many needs for RMs were established. In many cases a simple pure RM suffices, but CRMs are expected to be specifically appropriate for agricultural commodities with large trade volumes. In some cases, the exact needs of the developing countries may parallel those of the EU itself. However, in most cases the needs will be specific to the developing countries as analyte levels and urgency/impact may differ from those of the EU.

14 Furthermore, the interviews at FAO suggested that worlds of the Codex Alimentarius and of (C)RMs are very separate, while the issues appear highly comparable. FAO representatives expressed a need for intensification of the interactions.

Biotechnology

15 Biotechnology is the only area that consistently came up in the interviews with direct CRM stakeholders, whether in a producer or user context, as highly likely to generate entirely new metrological issues in the coming decade. In view of the encountered broad support for this opinion as well as the generally expected dynamics and high impact, the potential future of biotechnology was explored using scenario envisioning.

16 In an interactive on-line communication process, complemented by a parallel session during the CRM workshop, the biotechnology field was scoped and the most important drivers that would determine the situation in 2015 for Europe were selected by a panel of about 15 experts.

17 Four extreme scenarios were subsequently constructed in interviews and later validated by all experts, on basis of high and low combinations of the primary drivers:-

- (a) 'Rat Race', describing a situation where biotechnological products and processes are *not patentable* and industry faces *no restricting legal framework*.
- (b) 'Breeding Ground Europe', describing a situation where biotechnological products and processes are *completely patentable* and industry faces *no restricting legal framework*.
- (c) 'Critical Balance', describing a situation where biotechnological products and processes are *completely patentable* and industry faces an *extremely restricting legal framework*.
- (d) 'Exodus', describing a situation where biotechnological products and processes are *not patentable* and industry faces an *extremely restricting legal framework*.

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18 Finally, standardisation implications were identified. The average expected transition appears towards less restrictiveness by 2015. All sectors affected by biotechnology, i.e. healthcare, food, agriculture and environment, are expected to require standards, notably performance related. The applications and relative priorities appear very sensitive to the exact scenario balance realised in the actual 2015 situation. Only healthcare diagnostics emerges as a robust area of application.

Future CRM needs and offering

19 The key areas listed in the following table are proposed as being indicative for the need for future research and production:

Indicative Key (C)RM areas (in random order) per category, overall result	
Food and Agriculture	Meat Vegetable Matter Oils and Fats
Environment	Waters Sediment Soils
Biological and Clinical	Blood Serum and Plasma Water and Food Microbiology Pharmaceuticals GMO
Metals	Non-ferrous metals
Chemicals	Organic Gas (mixtures) Inorganic Gas (mixtures)
Pure Materials	Chromatographic Standards Elemental Analysis
Industrial Raw Materials and Products	Oils and Liquid Fuels
Material for Determination of Physical Properties	Optical Properties Mechanical Properties

20 The list is primarily derived from a ranking of the number of user organisations expressing a need on the area level in the survey. The apparent careful selection process and high consistency of the rankings per category among experienced and inexperienced (C)RM users, were interpreted as corroborating evidence. Due to the low number of producer respondents, the corresponding indications were less clear. However, in general these appeared in line with the user results. Only for the Biological and Clinical category, pharmaceuticals and GMO were added on basis of the producer results, as certain trends, in combination with the established future importance of biotechnology, suggested more significance.

Interactions in the (C)RM field as perceived by users and producers

21 In the study's workshop, interactive sessions were devoted to exploring the present and desirable interactions between the major stakeholder categories of CRM users and (C)RM producers as well as aspects that directly or indirectly affect these interactions. Communication emerges as the recurrent theme in all perspectives, including communication between users and/or producers and communication of users and producers together with the legislating parties. Furthermore, users, producers and legislators each "own" a proper aspect that indirectly, yet significantly influences communication, being metrological education, development collaboration and transport, respectively.

User perspective

22 In most sectors, users are not organised. Consequently, the communication of the users with the producers is insufficient as well, with the producer levels being perceived as not on a practical level. As a result, actual users in general do not have a good overview of which CRMs are available worldwide.

23 In general, the understanding by the average routine user of applied metrology principles is poor. Basic concepts and particularly aspects such as the definitions of RMs and CRMs, the differences between the two, and proper methods of (C)RM application are unclear or unknown to many users. This is principally attributed to an apparent theoretical focus of higher education and a lack of learning possibilities during the working life of a laboratory technician. Complicating factors are the confusing technical terminology and pure language problems.

Producer perspective

24 Producer-producer communication on the highest levels is quite good through platforms like EURACHEM and ISO-REMCO. On the lower levels, notably for smaller RM producers, there are however quality concerns as these tend to be less involved in such platforms.

25 Producers readily acknowledge that they do not fully understand the needs of the (potential) users, as there are no structured ways to reach these. All stress however, that interaction is actively sought. These activities cannot compensate for the absence of the proper communication fora, as is commonly deplored. Nevertheless, it is argued that there is considerably more understanding than actual follow-up suggests as budget restrictions or other priorities may limit the possibilities for consequent actions.

26 In principle, collaboration between producers is considered beneficial if alone for reasons of division of labour and sharing of costs. Regional collaboration is the obvious model to develop RMs with a predominantly regional application. In case of international trade related (C)RMs the need for worldwide collaboration appears obvious. However, RMs intended to satisfy needs with a direct relation to the functioning of the human body, in principle can be expected to have worldwide relevance as well. The same should hold for more and more RMs targeting industrial needs, as globalisation causes procedures and associated metrological problems to converge. The EU solution of networks of reference laboratories, with the one on food as working example, could be good models for improving worldwide collaboration and thus lowering of international trade barriers.

27 An issue to overcome is the fact that worldwide recognition starts with collaboration yet there is not much collaboration due to lack of worldwide recognition. Although RM needs with a direct relation to the human body may in principle be the same, the implementation in terms of analyte levels may differ. Convergence is expected, although opinions differ on the extent and time frames. Another issue which should be addressed when considering the scale of cooperation is minimisation of overhead.

Common perspective of Users and Producers towards the Legislators

28 (C)RM Users and Producers alike feel that the communication process with the legislating authorities needs to be improved significantly. Usually, only the prominent (C)RM producers maintain some relationship with legislating authorities that have a specific metrology development mission. Interaction with legislators that develop metrology dependent legislation is however very limited. To the (C)RM field, the resultant legislation appears to be largely an autonomous process. Thus, they are confronted with laws that from a metrological point of view may be to impractically, extremely costly or simply impossible to uphold.

29 A major issue in the realm of the legislators and directly affecting all stakeholders is the fact that transport of (C)RMs is cumbersome and slow as there is no specific customs code. Efforts to realise such a code are undertaken for quite some time now and are likely to succeed sooner or later. However, every day under the present regime causes new frictions and continues to limit the beneficial use of RMs to society as a whole.

Conclusions and Recommendations

Principal conclusions

30 What clearly emerged from the study is that many CRM issues in fact are part of much wider and deeper general metrology related issues. Dealing with the former in isolation does have a positive impact on society and has the advantage that, although still being a challenge, it is comparatively manageable. However, the full benefit to society will only be realised when the metrology related root causes could be tackled, which unfortunately has the disadvantage of being a far more daunting task. It is recommended that the EC continues the CRM focus, but increases the attention for general metrology. Both areas cannot be fully left to the market and should remain key interests at the EU level.

CRM related conclusions

31 The terminology of the (C)RM field is highly confusing. It is recommended that the major producers and/or their platforms reduce the ambiguity and the proliferation of acronyms.

32 The key (C)RM areas for future research and production, as identified previously, are likely good indicators, yet on the area level and per category only. Further prioritisation beforehand, to be included in RTD programmes, is not possible without a dialogue, nor very meaningful, as the priority of a specific (C)RM may not correspond to the average of the area it belongs to. Prioritisation afterward by improving the evaluation process appears a good alternative, as it is easier to implement and on the level of specific (C)RMs. It is recommended to the EC to increase the number of RTD initiatives by popularising the EoI mechanism among end users and, anonymously, to have the evaluation checked by a forum of experienced users.

33 The major CRM producers contacted in this study are in favour of co-ordination of CRM development activities. Regarding collaboration, there appears to be full agreement that it is in everybody's interest to join forces in research and development of supporting technology and methods. However, opinions differ regarding collaboration on actual CRM development. It is recommended to the producers to examine collaboration options on new CRM development more by focusing on the common rather than the differing aspects.

34 Enforcement of CRMs through regulation would be an obvious incentive. It is recommended to the EC and Producers to have explicit references to CRMs in accreditation schemes, relevant standards and test protocols, already at the national levels.

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35 Retrieval of the correct (C)RM and proper use is far from obvious to the average user. To improve the finding process, it is recommended to ISO-REMCO to implement a universal (C)RM portal. To improve to proper application, it is recommended to the CRM suppliers to include with every CRM a more detailed manual with examples of use, a reporting format of the results and a website address for further information as well as translations of all documentation.

36 It is recommended to the EC and Producers, to use crisis situations to promote CRMs to the users, thus increasing the visibility.

Metrology in the (C)RM context related conclusions

37 The average understanding of applied metrology principles among routine end users is low. This is generally attributed to the limited attention of higher education for the subject. At present additional training in the workplace is not used enough on a structural basis to counter the trend. It is recommended to EURACHEM and the EC to make sure that applied metrology principles are again included in the curriculum of all relevant studies. Furthermore it is recommended to develop more follow-up courses, largely based on practical examples, for periodical training of laboratory staff on metrology issues.

38 CRMs are necessary to ensure traceability at the highest levels. Complementing CRMs, non-certified RMs (also referred to as laboratory reference material or LRM) are more suited in the majority of cases where lower accuracy is acceptable in favour of short development time and lower pricing. Despite this greater need for RMs by the majority of the measurement and testing end users, there is no formal RM structure (development support programmes, trusted sources, etc.). It is recommended to the EC and Producers to establish a formal RM structure, organisationally comparable to the CRM structures in place. Preferably, this should not be a separate structure, but rather an extension of the present CRM structure to fully exploit the synergies between RMs and CRMs. Such an RM structure is expected to reinforce the position, and thus use, of CRMs, as the latter will then be part of an actual, comprehensive metrological framework.

39 The analytical metrology world is clearly very much segregated horizontally, as a comprehensive, structured way of interaction between the main stakeholders users and producers is virtually non-existent. This seems principally due to the limited degree of organisation of the users. It is recommended to the EC to establish permanent user-producer fora on the sector level as this is most logical to the users, who are the stakeholder to organise in the first place. These fora, where possible based on existing networks and preferably under moderation by independent experts, can be used to establish and, more importantly, to prioritise needs in a real dialogue, which is the only option to set meaningful overall priorities in areas with widely differing individual interests. The NIST conferences model seems a good way to organise the fora, using periodic gatherings in person when required, notably for the initiating phase including kick-off, but largely relying on on-line follow-up to minimise overhead.

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40 In addition, there appears to be a significant vertical segregation as well, at least between the “worlds” of (C)RM, of the Pharmacopoeia, of the Codex Alimentarius and perhaps also of the European forensic science laboratories. It is recommended to all high level stakeholders to establish or intensify relevant contacts on the policymaker’s and producer’s level to enhance integration and better exploit synergies.

41 Good laboratory practice should be more enforced. It is recommended to the EC and national governments to make accreditation mandatory in order to be allowed to operate an independent measurement and testing laboratory.

42 Hampering of shipping of reference materials causes significant impairment of practical quality control. It is recommended to the EC to speed up the process of creating one customs code for reference materials and, if possible, measurement equipment.

43 While metrology is essential to the upholding of many laws, the apparent ignoring of metrology specific issues in the legislative process, is highly demotivating to producers and users alike. Promotion of metrology would help to create a market pull for proper testing and facilitate justification of the costs associated with quality control thus contributing to an improvement of the overall quality level. Likewise, quality control should not so much be judged as such in absolute cost terms, but rather be related to the gains or overall losses when not applied. It is recommended to the EC to make sure that a measurement solution is available at the moment a directive is enforced. It is recommended to the Producers and EC to educate users that it is pointless to invest in equipment for quality control without being prepared to carry associated operational costs, which are small in comparison. It is recommended to the users and EC to educate the users clients that testing only makes sense with proper quality control.

Conclusions to the value of the study’s outcomes

44 Despite a somewhat disappointing overall response to the user questionnaire of about 3 % (taking overlaps in the distribution databases into account), it is felt that the outcomes of this study are at least on the sector level generally indicative for the needs users have and issues they face. Corroborating this assumption are the facts:

- (a) that most of the experienced users opinions, each deemed representative for many routine users, have been captured;
- (b) that the user interviews were well in line with the questionnaire results;
- (c) that the validation in the study’s workshop proceeded without major comments, and
- (d) that the outcomes correlate well with the user survey results and issues reported by a previous project focussing on the agro-food and environment sectors¹.

45 The producer results are felt to be quite accurate, as most of the relevant worldwide producers, in complemented by other stakeholders like experts and representatives of interest organisation at those levels, have been interviewed.

¹ Workshop on the use and prospects for reference materials for the quality control of agro-food & environmental analysis (SMT4-CT97-6522); Quevauviller Ph., Trends Anal. Chem. 18 (1999), 76.

Introduction

CRMs and the European Commission

1 In view of their importance to modern society, CRMs are among the first technology focus areas of the European Commission (EC). The EC's Bureau Communautaire de Référence (BCR), established already in 1973, started the strive to meet the need for European harmonisation of the measurements and tests carried out by metrology laboratories in the Member States by providing them with reference materials certified at the European level. Later on, BCR activities were taken over by the Research Directorate General (DG RTD).

2 R&D programmes for new CRMs are initiated at the level of DG RTD and its predecessors. The first programmes, aptly referred to as BCR1 and BCR2, existed independently. With the advent of the comprehensive Framework Programmes for Research and Technological Development (FP) in 1983, successive programmes were incorporated. Initially, incorporation of these programmes took place under the original name, leading to BCR3 and BCR4 in FP1 and FP2 respectively. Subsequently, these activities became part of more general metrology programmes, i.e. Measurement and Testing (M&T) in FP3, which was in turn expanded to Standards, Measurement and Testing (SMT) in FP4.

3 Up to FP4, the successive R&D programmes covered the full CRM development cycle including production and certification. In the current, nearly finished thematically oriented FP5, only the CRM feasibility study is supported under the "Growth" theme through a specific research objective of Generic Activity 2 "Measurements and Testing".

4 CRMs developed with support from European R&D programmes are referred to as BCR CRMs. With the over 400 BCR CRMs produced to date, the European Commission is the 2nd largest single CRM producer in the world.

5 The Institute of Reference Materials and Measurements (IRMM), located in Geel, Belgium and part of the Joint Research Centre (JRC) of the EC, has been and still is involved in many BCR CRM development projects. In addition, IRMM develops other CRMs, by analogy referred to as IRMM CRMs. Both BCR CRMs, since 1995 on an exclusive basis, and IRMM CRMs are stored and distributed by IRMM. Furthermore these CRMs are available from a limited number of distributors, specifically authorised by IRMM.

6 Prompted by the need for a strategy to identify key CRMs, in order to realise the full benefit of the CRM related policy of the European Commission at medium and long term, DG RTD commissioned the present study.

Objective and Scope of the Study

7 Taken form the Terms of Reference (TOR)² the overall aim of the study described in this report was “to enable the European Commission to identify key CRMs for future research and production activities and fields for possible future collaboration”.

8 In more detail, the objectives of this study comprised:-

- (a) to identify the needs of the European end users of CRMs;
- (b) to assess the actual production schemes of the world-wide producers of (C)RM;s
- (c) based on the combined findings of (a) and (b):-
 - (i) to establish the key issues
 - (ii) to investigate the possibilities for future synergies among producers
 - (iii) to elaborate a dissemination strategy to potential users and policy makers.

Overall Approach and Methodology of the Study

9 As prescribed by the TOR, core element of the study was to be a comprehensive survey, by means of a questionnaire, of ideally all European CRM end-users as well as the worldwide (C)RM producers catering to the former. Where possible future new end-users, referred to as “potential end-users” were to be included as well. The questionnaires were to be complemented by a selected number of personal interviews, to allow for more in-depth investigation. Bearing the European Commission perspective in mind, issues and collaboration options were then to be derived from the results for subsequent dissemination to the stakeholder community.

10 To implement the above, the study was divided in four phases, i.e.:-

- (a) Phase I: Inventory of CRM end-users (2 months).
- (b) Phase II: Investigation of future needs of CRM end-users and investigation of the strategies of (C)RM producers (first stage: 4 months).
- (c) Phase III: Investigation of future needs of CRM end-users and investigation of the strategies of (C)RM producers (second stage: 6 months).
- (d) Phase IV: Key issues, future collaborations, dissemination strategy (6 months).

² Annex A to this report

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11 Phase I focused on the development of a general classification system for the relevant, current CRM end-users and from their own perspective, in preparation of the to be elaborated questionnaire targeting them. Principal reason for this is the fact that most available information on users tends to be structured according to CRMs usage, i.e. representing the CRM producer's perspective. Due to time constraints, this part of the study was restricted to the client base of IRMM, access to which was kindly provided under a confidentiality agreement. For classification purposes only, this source is considered to provide sufficient representativeness of the users, particularly those relevant in the context of European programmes. A classification was thus derived from a desk study into the user organisation's activities as described on their web sites, for those clients with retrievable presence on the Internet (approximately 45%).

12 Also early in Phase I, the web site www.CertifiedReferenceMaterial.org was launched to market the study by providing an easy reference, to use as a tool to reach the stakeholder community where possible and, if deemed useful, to extend in time into a full communication platform.

13 Phases II and III focused on the generation of detailed views (in terms of general and CRM related activities, interests and future needs or strategies) on the European CRM end-user as well as the worldwide (C)RM producers catering to the former.

14 In Phase II, information was gathered with the main intention to allow the development of effective questionnaires. Therefore the most relevant European (C)RM producers in the study's context were visited for personal interviews. Likewise, a series of interviews was initiated with representative CRM end-users and other stakeholders, like distributors, standardisation bodies and experts. In addition to providing questionnaire content related information, the interviews and other research clearly made evident that the original strategy to rely solely on web based questionnaires, made available through the study's site, had to be adapted to ensure sufficient response. Thus, it was decided to retain the web-based concept, but shift the focus to traditional paper based questionnaires.

15 In Phase III, the actual questionnaires were finalised and distributed. Based on COMAR information, some 300 producer questionnaires were sent out. Using client information kindly provided by IRMM, LGC and Promochem under a confidentiality agreement, and/or through their kind help on the order of 10.000 user questionnaires were distributed to their European clients. About 500 potential user questionnaires were distributed directly by the European Commission or through their relations. Furthermore, hyperlinks to the web based versions of the questionnaires, were kindly put-up on the web sites of BAM, EURACHEM and Promochem. While continuing interview sessions with relevant European stakeholders, the major non-European CRM-producers were specific subjects in this phase and the three considered most relevant to the EC support scheme, i.e. NIST (US), NMIJ (Japan) and NRC-CRM (China) were visited for personal interviews.

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- 16 Phase IV focused on the wrapping up, comprising the following activities:-
- (a) analysis of the questionnaires;
 - (b) validation of the survey's principal findings;
 - (c) exploring possible scenario's for synergies in the (C)RM field, notably between producers;
 - (d) a biotechnology future exploration aiming to allow identification of emerging future CRM needs;
 - (e) and finally, integration and presentation of all outcomes.

17 Phase IV activities (b) and (c) were achieved by means of an intensive 2-day workshop in Brussels on 5-6 February 2002, in the presence of all major European CRM producers, a selection of end-users and a number of other stakeholders including CRM distributors, independent experts, and European Commission officials. Activity (d) was partly done at the same workshop and partly through a series of on-line consultation sessions, complemented by interviews in person³.

18 Other than that the activities of Phases II and III have been combined and that the actual end of Phase III and start of Phase IV were spread out over a longer period, there were no modifications relative to the TOR. Combination of Phases II and III was done to formally allow interaction with producers and users at the same time. Prolonging part of the activities of Phase III enabled a more thorough treatment of the current and potential end-users. All modifications have been made in joint agreement with the responsible European Commission representatives.

Reporting structure of the Study's Outcomes

19 Following this introduction, Chapter 1 will first provide two general frames of reference, developed by PwC Consulting to understand and present the outcomes in a more systematic way.

20 In Chapters 2 to 4 the results will be presented and discussed per key stakeholder category, i.e. worldwide (C)RM producers, current European users and potential "European" users, respectively.

³ Including these, overall 44 stakeholders have been interviewed. Full details of all interviewees are included in annex F to this report.

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21 Subsequently, in an integrated way, information will be presented intended to allow treatment of the two major cross cutting study objectives, being the identification of 1) key CRMs for future research and production activities, and 2) fields for possible future collaboration. Thus chapter 5 will compare the future CRM need and offering, whereas chapter 6 will discuss the possible or desirable interactions between the stakeholders and relevant issues exceeding the level of the stakeholder category.

22 Finally, in Chapter 7 overall conclusions and recommendations to the European Commission will be presented.

23 Several annexes with background and more detailed results complete the report.

1 Frames of reference

101 To facilitate a more systematic presentation and comparison of (relevant aspects of) the study's outcome, frames of reference for the organisation of the (C)RM field and the CRM development cycle were developed, which will be presented in the following sections.

Organisation of the (C)RM field

102 To understand the roles and relative positions of the stakeholders, the (C)RM field is defined in this report to have the following organisation.

103 Overall, four general categories of (C)RM stakeholders are identified, being:-

- (i) producers-users;
- (ii) mediators;
- (iii) communities;
- (iv) shapers.

104 General category (i) Producer-Users consists of the stakeholders that form the backbone of the (C)RM field:-

- (a) *Certifying producer*: Organisation controlling the development of CRMs from initiation to certification and authorised to issue certificates. Does not necessarily take care of (all the aspects of) the actual production itself. Usually all encompassing CRM focus, although not necessarily pursuing all sectors.
- (b) *Initiating Producer*: Organisation having significant control over the development of CRMs, also likely to initiate new CRM development. Usually, multi-sector or at least comprehensive single sector CRM focus. (Although not having entirely identical aims, a pure RM producer is very much like an Initiating Producer and is thus, for the purpose of this framework equated to one)
- (c) *Co-developer*: Organisation contributing to the development of CRMs, notably in the characterisation phase of the certification exercise. Usually, multi-sector or at least comprehensive single sector CRM focus.
- (d) *R&D User*: Organisation using a variety of ever changing CRMs in the development of new methods. Usually, multi-sector or at least comprehensive single sector CRM focus. ("Power user")
- (e) *QC User*: Organisation using a limited number of CRMs in periodical checks of the standard procedures, which in turn are applied for quality control purposes. Usually, CRM focus on single sub-sector(s). ("Routine user")

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- (f) *Potential User*: Organisation likely to benefit from using CRMs, but never having used any. The majority is assumed to have very limited understanding of the (C)RM concepts, if at all, because if they had, they would probably immediately have moved up to the ranks of the users, most likely to become QC users. Consequently, in general not very able to articulate metrological needs in CRM terms. (Interest organisations or experts, that represent groups of expected potential users, are usually better sources of information as their understanding of the metrological issues and consequent articulation in (C)RM terms is usually better developed)

105 Key feature of category (i) is the hierarchical organisation, with the Certifying Producer on top and the Potential User at the bottom of the chain, with each stakeholder from time to time adopting the roles of any of the “lesser order” stakeholders, obviously while retaining the original knowledge level. For example, the one Certifying Producer may act as Co-developer in a CRM development controlled by the other Certifying Producer. Likewise, even a Certifying Producer has QC user-like routine procedures, which have to be validated periodically. The “distances” between the various Producers-Users stakeholders are not necessarily equal. We feel that on average Certifying and Initiating Producers are actually quite close, whereas Initiating Producers and Co-developers appear wider apart. Co-developers hover around the border between producers and users, the experienced one having producer characteristics and the occasional Co-developer still being very much a user. R&D Users are very close to Co-developers, but the distance between R&D and QC Users is again felt to be quite substantial. From the definition Potential Users are only loosely connected to the backbone at considerable distance and are actually positioned on the very brink of the CRM field.

106 General category (ii) Mediators consists of the stakeholders that support category (i) stakeholders in one way or the other, comprising:-

- (a) *Expert*: Party possessing in-depth knowledge of certain aspects of CRM development or usage, usually micro enterprise.
- (b) *Distributor*: Organisation selling and distributing CRMs, developed by other organisations.

107 If there is a hierarchy in Category (ii), it exists only in the occasional case and will be quite loose. In general Experts are felt to be in the higher regions, depending on their background, in a level close to the Initiating Producer up to that of the Certifying Producer. Distributors are probably best situated on the same level as Co-developer: what the former lack in scientific understanding from day-to-day hands-on analysis, they make up with the breadth of their understanding of needs and application problems in general. Although Mediators not usually perform the actual roles of lower level Producer-Users, they usually have a fair understanding of the implications of that role as well as the corresponding metrological needs.

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108 General category (iii) Communities comprises only one type of stakeholder, being:-

- (a) *Interest Organisation*: Organisation covering the collective interest of certain players in the field. Usually, the influential players of the represented levels have leading roles through delegation of key personal to the Interest Organisation.

109 The level of the Interest Organisations may cover the entire range. Organisations with a metrology related focus are to be found in the upper regions, whereas organisations with a focus on a branch, having some metrology dependency, are likely to be on the levels of the QC user or the Potential User. Particularly in these levels, an Interest Organisation may be on a higher level than the one of the players its covers, as the former is more likely to employ relevant specialists, e.g. as a service offered to its members.

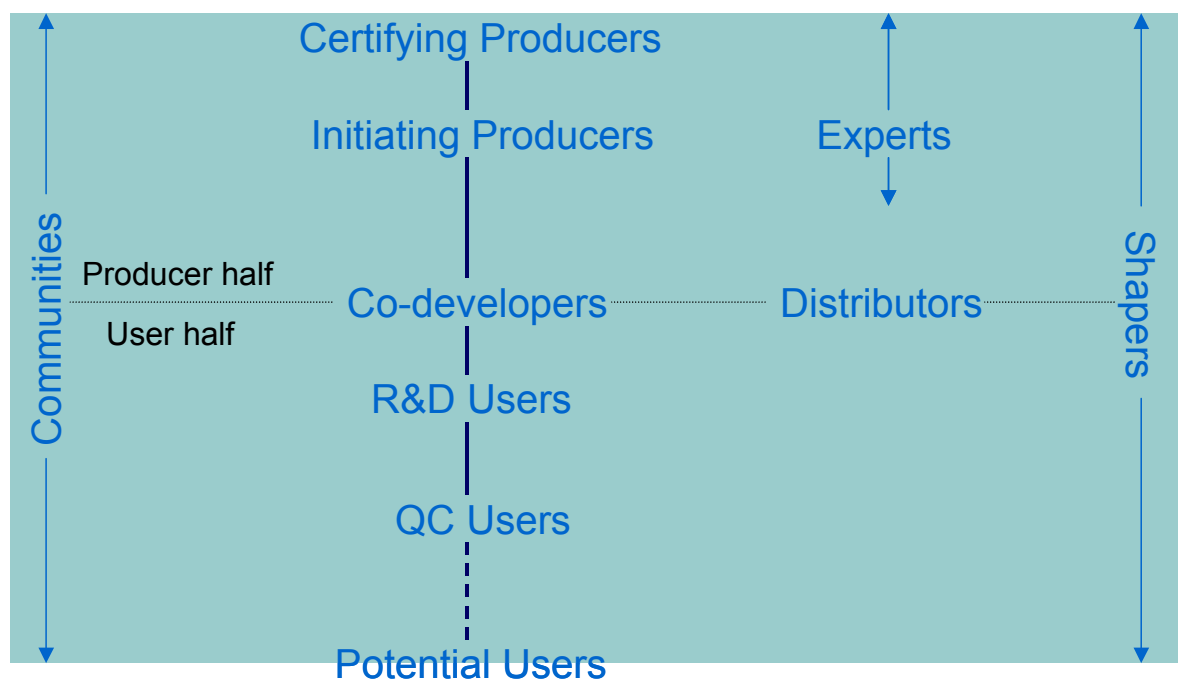
110 General category (iv) Shapers consists of stakeholders that essentially shape the (C)RM field and comprises two types of stakeholders, being:-

- (a) *Regulatory body*: Organisation developing and setting high level standard procedures or controlling their implementation.
- (b) *Legislative body*: Government organisation, issuing/implementing standards dependent legislation or issuing/implementing legislation in support of standards.

111 The level of the legislative body actually covers the entire range. Legislative bodies dealing with legislation in support of standards can be considered to be on the same level as Certifying Producers, while those dealing with standards dependent legislation are usually on the lower levels and may be as ignorant as the average Potential User. On the contrary, Regulatory bodies are by definition only to be found in the higher levels.

112 Figure 1-1 summarises the above description in a graphical representation of the (C)RM field.

Figure 1-1 Organisation of the (C)RM field



CRM development cycle

113 A variety of terms are in use for the different stages in realising a new CRM. To compare the activities of the producers, the full development cycle of a typical CRM, i.e. from 'scratch to batch', is defined in this report to consist of the following stages:-

- (a) preparation stage;
- (b) production stage;
- (c) characterisation stage;
- (d) certification stage.

114 The preparation stage covers all activities carried out to investigate if and how the candidate CRM can be produced and the required analytes can be determined. In case of BCR CRMs developed by the European Commission, this stage is referred to as feasibility study. In case of SRMs, i.e. CRMs developed by NIST, this stage is known as the development phase, comprising basic research and service development.

115 The production stage covers all activities to obtain sufficient quantities of the actual candidate CRM. Spiking, homogenisation and packaging into batches are considered part of this stage.

116 The characterisation stage covers all activities related to actual measurement and statistical treatment of the analyte values.

117 The certification stage covers all activities to certify the required analytes, including reconciliation of the analyte values obtained with different measurement techniques and drawing up of the actual certificate and certification report. Commonly, the characterisation and certification stages as defined here, are jointly referred to as the certification; production appears to be included occasionally as well.

118 Not all stages as defined here are necessarily consecutive. Particularly the characterisation and certification are prone to some interaction before the latter can be concluded.

2 Worldwide (C)RM producers

Specific data gathering approach

201 An inventory of the relevant views of the worldwide (C)RM producers was made by means of a questionnaire in the period of June to September of 2001. The questionnaire results were complemented by interviews, held from September 2000 to January 2002. The general outcomes of the questionnaires and interviews were subsequently validated in the study's CRM workshop on 5-6 February 2002.

Questionnaire results

Distribution and response

202 Overall, 302 copies of the producer questionnaire have been sent out by regular mail, based on the producer address data in the COMAR database. The number of returned questionnaires by mail was 17 (5,6%). It is noted that a substantial part of the producer questionnaires were sent to subdivisions of the same organisation or tightly related organisations. In addition, 16 producer questionnaires were returned because the address(-ee) was unknown. A thus corrected mail-out response would then approach 10%. The number of replies of the Internet based questionnaire was 12. After filtering out doubles and unfinished questionnaires, the total number of questionnaires admitted to the final analysis was 25.

Relevant cross sections for presentation of outcomes

203 The COMAR database aims to cover all RM producers worldwide, CRM as well as pure RM producers and with many RMs on offer or only a few. The producer type can be expected to have a significant influence on certain outcomes. Furthermore, the resulting differences have an obvious relevance to the objectives of the study. Therefore, correlation of the outcomes with the producer type was sought and indeed established.

204 The following presentation of the producer questionnaire outcomes will thus comprise these parts:-

- (a) Geographical distribution of the respondents.
- (b) Description of the statistically distinguishable types of producers and outcomes which clearly correlate with the producer type.
- (c) General outcomes, i.e. outcomes (i) for which correlation with the producer type does not provide meaningful information or (ii) for which such correlation was incomplete or deemed too weak.
- (d) Outcomes by CRM category related to the CRM production schemes and CRM needs.

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205 Aiming to provide an overview and to allow inter-comparison of the outcomes, this chapter summarises the highlights mostly in qualitative terms. The underlying data and graphical representations are included in annex D part 1, here referenced were appropriate as figure D1-x (bracketed).

Geographical distribution of the respondents

206 The questionnaires were received from a wide variety of (C)RM producers around the globe (Table D1-0). Including the interviewed producers, the geographical distribution of all involved producers essentially covers the majority of the (C)RM producing world, with notable exceptions of Australia and Brazil.

Outcomes by producer type

Distinguishable producer types

207 The producer types for which the best correlation with the responses was found, were “large” CRM producers, “small” CRM producers and pure RM producers, according to the definition in Table 2-1. A further distinction between RM producers could statistically not be justified.

Table 2-1: Definition of producer sub-populations and relative size (figure D1-8)		
Large CRM producers	Producing over 10 types of CRMs	37%
Small CRM producers	Producing 10 or less types of CRMs	25 %
RM producers	Producing RMs only	38 %

Producer resources and sales

208 Based on the size of the department, numbers on annual turnover related to CRM sales and the amount of CRM clients the organisation serves (figures D1-3 to D1-5), the distinction in larger and smaller CRM producers is principally made. Larger CRM producers have larger departments, higher turnover and serve a larger number of CRM clients than smaller CRM producers. RM producers on average seem to be in between large and small CRM producers in these terms.

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Type of organisation

209 Table 2-2 demonstrates that public research institutes dominate the CRM world, only a minority of the large producers being private laboratories. However, a clear majority of the RM producers consists of private laboratories. In all cases, the category “other” usually comprises some mix form between public and private.

	overall	Large CRM	Small CRM	RM prod
Public research institute	56 %	79 %	50 %	36 %
Private Laboratory	35 %	21 %	31 %	52 %
Other	9 %	0 %	19 %	12 %

Sector focus

210 The sector focus (figure D1-2) of the producers is very broad. The majority, including all large CRM producers, provided more than one sector as their sector focus. The Environment sector comprises the most CRM producers, particularly small CRM producers, followed by Metals and Chemicals. Five producers focus solely on the Metal sector (of which four are RM producers), three that indicated Environment as sole sector, and two that indicated Geosciences as their sole target sector.

Accreditation

211 Exactly half of all producers’ respondents are currently accredited, mainly based on ISO 17025 and ISO 9001. A higher percentage is working towards accreditation, again ISO 17025 mentioned most often where comments was provided. More specifically, (figure D1-6), large CRM producers are much more often accredited (just under 80%) than either small CRM producers (less than 20%) or RM producers (less than 40%).

General Outcomes

Internet use

212 Three-quarters of all respondents provided a company website, all but one of them provided an email address.

Views on the users

213 According to the responding producers, CRMs are sufficiently known, but not more than averagely used (figure D1-14 and D1-15). Interaction with users takes place most often on the subject of new CRM requests and to a somewhat lesser extent on measurement issues (figure D1-16). Least regular interaction takes place in the field of storage and training issues.

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214 The purpose for which the produced CRMs are used (figure D1-12) is mainly to validate a measurement method, followed by instrument calibration applications. Assignment of property values is least often mentioned.

215 In the opinion of the producers, the main reason for using CRMs (instead of RMs or samples) is prescription by the internal quality system (figure D1-13). Large CRM producers mention this reason least often, but indicate “explicit reference in national government directives” more often. Other potential reasons, such as “implicit requirements through accreditation schemes” or “required in proficiency testing” are mentioned fairly equal. The use of CRMs because of explicit CRM references in directives on international level is mentioned least often (figure D1-12).

Current CRM development aspects

216 According to the producers, the main drivers for developing new CRMs are upcoming or new (inter-)national government directives followed by new standardisation requirements (figure D1-17). Small CRM producers mention “scientific interest” relatively more often than large CRM producers or RM producers.

217 A majority of the producers involve other laboratories during the feasibility phase (figure D1-18); a higher percentage also involves laboratories from outside during the characterisation/certification phase of new CRMs (figure D1-20). The average amount of laboratories involved during both feasibility phase as well as characterisation/certification phase varies sharply, from 2 to as many as 100 external laboratories: trends could not be established. Almost all producers indicate to certify new CRMs according to ISO guidelines (figure D1-21).

218 Regarding “inter-producer” collaboration, most collaboration takes place in CRM development and distribution (figure D1-28). Differences here are relatively small, however.

Vision on CRM development aspects

219 According to the producers, the average acceptable maximum development period for a new CRM is 18 months (figure D1-23). This question also provided quite a scatter in answers, from 4 to 42 months, perhaps because this number is an average development period for all CRM types.

220 A majority of respondents are of the opinion that the certification procedure should ideally be performed on an international level (figure D1-24).

221 The opinions on the advantages of an international quality label for CRMs for the general recognition of measurements and confidence in measurement results is quite clear: a majority of the responding producers considers such a quality label to be advantageous to recognition (figure D1-30).

Outcomes by CRM category

Current CRM production schemes

222 Roughly 25% of the respondents produce up to ten different types of CRMs (figure D1-8). The only specific “smaller producer” sector (where, in a specific sector relatively more smaller producers are represented), is the Environmental sector (figure D1-2). The responses regarding the current production schemes of CRMs in given areas (table D1-11) show that Environmental, Metals, and Industrial Raw Materials are most often mentioned. Table 2-3 provides a detailed overview of the current production schemes.

Table 2-3: Number of respondents producing CRMs from a given area

# Food and Agriculture (Q1)	# Environment (Q2)	# Biological and Clinical (B)	# Metals (FN)
2 Meat 3 Fish 2 Vegetable matter 3 Cereals and crops 2 Fertilizers 2 Dairy products 2 Oils and fats 2 Alcoholic beverages 2 Other	4 Pesticides 5 Waters 2 Plants 6 Sediments 6 Soils 3 Sewage Sludges 3 Ashes and particulates 7 Other	0 Pharmaceuticals 1 Blood serum and plasma 1 Urine 0 Bone and tissue 1 Hair 1 Water and food microbiology 1 GMO 4 Other	6 Ferrous metals 7 Non-ferrous metals 1 Rare earths 2 Pure metals 2 Other
# Chemicals (IO)	# Pure materials	# Industrial raw materials and products (Y)	# Materials for determination of physical properties (P)
1 Organic gas (mixtures) 2 Inorganic gas (mixtures) 3 Oxides, salts 1 Paints and varnishes 0 Cosmetics and surfactants 2 Solvents 1 Other	5 Elemental analysis 2 Spectrometric solutions 2 Chromatographic standards 2 Stoichiometry 2 Organo-metallic compounds 3 Speciation 3 Isotopes 5 Other	1 Glass and ceramics 7 Ores 4 Minerals 2 Semiconductors 3 Refractories and carbides 3 Raw materials 1 Solid fuels 3 Oils and liquid fuels 0 Cement 2 Rocks 1 Polymers, organic fibres 3 Other	5 Thermal properties 4 Particle, film, surface prop. 3 Optical properties 1 Ion activity 1 Electrical properties 3 Viscosity 1 Polymeric properties 3 Mechanical properties 2 Other

CRM needs

223 The producers were asked which CRMs they regarded as relatively underrepresented in availability (table D1-25). In table 2-4 the results are presented by CRM area, the numbers indicating the frequency with which this area was ticked by the respondents.

Table 2-4: Number of producer respondents perceiving CRMs from a given area as being relatively underrepresented

<p># Food and Agriculture (Q1)</p> <p>2 Meat 1 Fish 2 Vegetable matter 2 Cereals and crops 1 Fertilizers 1 Dairy products 1 Oils and fats 2 Alcoholic beverages 2 Other</p>	<p># Environment (Q2)</p> <p>1 Pesticides 4 Waters 2 Plants 3 Sediments 3 Soils 4 Sewage Sludges 1 Ashes and particulates 1 Other</p>	<p># Biological and Clinical (B)</p> <p>4 Pharmaceuticals 3 Blood serum and plasma 2 Urine 1 Bone and tissue 0 Hair 4 Water and food microbiology 3 GMO 1 Other</p>	<p># Metals (FN)</p> <p>2 Ferrous metals 4 Non-ferrous metals 2 Rare earths 4 Pure metals 1 Other</p>
<p># Chemicals (IO)</p> <p>1 Organic gas (mixtures) 1 Inorganic gas (mixtures) 0 Oxides, salts 1 Paints and varnishes 1 Cosmetics and surfactants 1 Solvents 0 Other</p>	<p># Pure materials</p> <p>0 Elemental analysis 0 Spectrometric solutions 2 Chromatographic standards 0 Stoichiometry 2 Organo-metallic compounds 2 Speciation 1 Isotopes 2 Other</p>	<p># Industrial raw materials and products (Y)</p> <p>2 Glass and ceramics 2 Ores 1 Minerals 0 Semiconductors 4 Refractories and carbides 1 Raw materials 0 Solid fuels 1 Oils and liquid fuels 2 Cement 1 Rocks 1 Polymers, organic fibres 0 Other</p>	<p># Materials for determination of physical properties (P)</p> <p>3 Thermal properties 2 Particle, film, surface prop. 2 Optical properties 0 Ion activity 0 Electrical properties 1 Viscosity 0 Polymeric properties 2 Mechanical properties 2 Other</p>

224 For most areas, a correlation between categories of CRMs currently produced and CRM areas that are indicated as underrepresented does exist, with the marked exception of Biological and Clinical and to a certain extent Food and Agriculture (figures D1-25a to D1-25e). Thus, many producers restrict their opinions to the categories, they are currently active in.

Interview results

225 To obtain detailed information concerning the producers, 16 stakeholders in the higher levels were interviewed in person. The selection comprised 7 Certifying and 4 Initiating Producers. In addition 3 experts on the same levels and ISO-REMCO, the most relevant standardisation body were included. EURACHEM was indirectly involved as several interviewees held board positions in this organisation.

Specific results of the major Certifying Producers

226 In the context of this study, the three most relevant European CRM-producers other than DG RTD, i.e. in alphabetical order, BAM (Germany), IRMM (Belgium), and LGC (UK) have all been visited for personal interviews. Being an institute of the European Commission's Joint Research Centre, IRMM is clearly a key player in the study's context. BAM and LGC were specifically selected, as both are very influential producers as well as rather outspoken advocates of a common European metrological system.

227 In addition, three non-European CRM-producers were visited for personal interviews, being NIST (USA), NMIJ (Japan) and NRC-CRM (China). NIST was selected, as it is the biggest individual producer of CRMs in the world, apparently very dominant in worldwide metrological issues and, in view of the importance of transatlantic trade, a powerful counterpart of the European producers. Much along the same lines, NMIJ was selected as being the most relevant representative of the third economic bloc in the world. This choice was subsequently further corroborated, when it became clear that NMIJ had in fact recently been created to promote (C)RM sales to non-government bodies, which its predecessor institutes were not allowed to do. Finally NRC-CRM was selected, as there appeared not to be much insight into their methods of work and views, despite the fact that Chinese CRMs, referred to as GBW CRMs, are rather well known and appreciated in Europe as they are readily obtainable from European sources.

Characteristics and working methods of the interviewed Certifying Producers

228 Table 2-5 provides an overview of the characteristics of the interviewed Certifying Producers.

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Table 2-5 Characteristics of the major relevant Certifying Producers (in alphabetical order)

	CRMs available (order of magnitude)	RMs available (order of magnitude)	Client base	CRM development drivers	Development aspects of proprietary developed CRMs
BAM	200	-	Industry and government (related) laboratories	Legislation and requests of official (industrial) committees.	Full development under control of BAM, often in co-operation with industrial associations Production: BAM always involved in homogeneity and stability tests but production can be done by others Characterisation / certification: 1) under full control of BAM 2) either by inter-laboratory comparison involving qualified industrial labs 3) or by BAM-internal certification study involving several labs/methods
European Commission: DG RTD & IRMM	450 (BCR + IRMM combined)	-	Industry and government (related) laboratories	Mainly legislation; Sometimes commerce	Preparation of BCR CRMs (aka feasibility): not necessarily IRMM involvement; Production: can be done by other parties; Characterisation / certification of BCR CRMs: 10-15 labs; DG RTD appointed certification committee includes IRMM; IRMM not necessarily involved in characterisation
LGC	120 proprietary developed; many more commercially distributed for variety of 3 rd parties	40 proprietary developed; many more commercially distributed for variety of 3 rd parties	Industry and government (related) laboratories	Mainly legislation; Sometimes commerce	Production: LGC always involved in homogeneity and stability tests but production can be done by others Characterisation / certification: LGC usually, but not always, involved
NIST	1300 SRMs	Couple, mostly (C)RMs distributed for 3 rd parties either as return favour or service to US clients	Mainly industry; Sometimes government (related) laboratories	Mainly legislation and standardisation; Sometimes commerce	Preparation (aka development phase, comprising basic research and service development): not necessarily NIST involvement; Production: can be done by other parties Characterisation / certification: 4) under full control of NIST 5) protocol and technical specification by NIST 6) data principally from NIST labs; occasionally external labs at complete discretion of NIST
NMIJ	160* (2010: 500)	?	Currently only government (related) laboratories; in future also some industry	Mainly legislation; Sometimes commerce	Full development controlled by NMIJ; Production: usually contracted out; Characterisation / certification: 10 labs avg., most NMIJ or AIST, yet often including external, labs as well
NRC-CRM	100 proprietary developed; 1000 distributed for Chinese 3 rd parties	200 proprietary developed; 800 distributed for Chinese 3 rd parties	Industry and government (related) laboratories	Mainly commerce; Sometimes legislation	Preparation: not necessarily NRC-CRM involvement; Production: can be done by other parties; Characterisation / certification: 8 labs avg. ; NRC-CRM chairs certification committee but not necessarily involved in characterisation

* Sales to non-government organisations not yet commenced at the time of the interview (September 2002).

Essentially two approaches to CRM development, i.e. centralist and distributed

229 When examining table 2-5, in general two different approaches to CRM development can be discerned. In all cases the preparation activities up to and including the actual production of the CRM to be, may be carried out by third parties, either on the latter's own initiative or through outsourcing the activities to them. The distinction is predominantly based on the philosophy towards characterisation and certification. On the one hand there exists an essentially centralist approach with tight control over the characterisation/certification by the certifying producer, involving predominantly proprietary laboratories, as most clearly demonstrated by NIST. On the other hand, there exists a more distributed approach, in which the producer only may have part of the final control over the actual certification, the characterisation executed by laboratories from many different organisations and not necessarily including the certifying producer itself, as seen with the EC. The other producers are in between the above extremes: BAM, LGC and NMIJ each appear to tend towards the centralist approach, whereas NRC-CRM's approach on the contrary can clearly be qualified as distributed with exertion of only slightly more control over the certification / characterisation than the EC.

CRM development approach of NRC-CRM strikingly similar to that of the EC

230 The differences in CRM development approach correlate quite well with the standardisation history of the territory covered. In the USA, UK, Germany and Japan, standardisation was essentially from the beginning taken care of at the national level, making tight control over the development a more or less intrinsic feature.

231 In China, the regions have always been highly autonomous on the operational levels. Due to the size of the country, this model was already used under the old empires to administer the country and basically has not undergone significant changes up to today. As a result, a number of capable (C)RM producers had evolved more or less independently, at the time that standardisation again became a topic at the state level in the early 1980s. Reasoning that the standardisation gap with the industrialised countries could be closed the quickest with many different producers, only the final control over (C)RM development and production was centralised by the creation of NRC-CRM.

232 Due to its origins in the nation states, the EU also comprises many independent laboratories, well capable of producing CRMs. Although the historic time scales of China and Europe differ considerably, they have produced a comparable situation as regards the environment for, and consequently the approach to, CRM development.

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As a rule no extensive insight in the CRM pipeline given

233 Focus areas for CRM development programmes appear rather well known in most cases and tend to converge for the different producers. In contrast, in general, definition of the CRM development pipeline is restricted to the very near future only. This seems primarily attributable to the fact that the development drivers tend to originate outside the control sphere of the NMIs / IMIs, causing consequent CRM development to be essentially reactive in nature.

234 Currently, NMIJ is the exception to this rule by working according to a published detailed list⁴ of CRMs, which ought to be available by 2010.

Collaboration common desire: technology / methods rather than CRM development

235 All of the interviewed CRM producers are in favour of actual co-ordination of development related activities, although the extent of the envisaged co-ordination appears to vary considerably.

236 While there clearly is a willingness to collaborate, all producers stress that the CRM needs and development drivers in most cases are specific to each producer / territory, as a result of which actual joint CRM development on a world-wide scale is expected to be at best incidental. Particularly in those case were CRMs are relevant to international trade, the IVD situation being a prime current example, joint development is seen to be well feasible and even desirable. However, CRMs required as a result of legislation are expected to have considerably less common relevance.

237 While actual joint CRM development clearly has significant constraints, there appears to be full agreement that it is in everybody's interest to collaborate on supporting technology and method development.

Miscellaneous results at the general Producer level (not necessarily common to all)

238 As regards quality control, many users appear well prepared to make considerable investments in equipment, yet are reluctant to bear the relatively small increase in operational costs associated with regular calibration and validation of the employed procedures. Users should thus be made aware that this economisation is counterproductive as the latter are essential complements to make the initial investment pay off.

239 Many laws, of which the upholding is very metrology dependent, seem to be developed without any consideration for the associated metrological issues. At the very least, funds should be made available in the implementation phase to develop the necessary measurement toolkit.

⁴ Currently, the list is only available in Japanese, but an English version should be available soon.

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240 Only a comparably limited number of measurements require the traceability that CRMs bring. Instead many more can do with a lower guaranteed metrology level, but depend more on rapid availability of the reference materials, especially in crisis situations. Non-certified RMs (by some advocated to be better referred to as laboratory reference materials or LRMs) fill this gap, development times can be rather short and, partly as a result of the latter, prices will be significantly lower. Yet, there are no formal structures for RMs in place, causing a limited offering and of inconsistent quality as not all commercial producers adequately follow the ISO guides.

241 It should be born in mind that there are substantial differences in the metrology cultures of Northern and Southern Europe. Northern countries have a long tradition emphasising the position of quality control, causing a strive for the highest possible levels. In Southern countries quality consciousness is a more recent development with many still in the process of catching up.

Workshop results

242 During the study's workshop, the general results of the producer questionnaire and interviews were validated essentially without opposition. Only the separate treatment of the smaller and bigger producers was recommended (*implemented in this report*).

3 Current European CRM users

Specific data gathering approach

301 An inventory of the relevant views of the current European CRM users was made by means of a questionnaire in the second semester of 2001. The questionnaire results were complemented by interviews, held during the whole of 2001. The general outcomes of the questionnaires and interviews were subsequently validated in the study's CRM workshop on 5-6 February 2002.

Questionnaire results

Distribution and response

302 In a first wave about 2200 questionnaires were distributed to clients of IRMM and/or LGC. By September 2001, a total number of 159 mail-out questionnaires were returned, making the percentage of returned questionnaires for this subpopulation close to 7,5%. In a subsequent wave about 8000 questionnaires were distributed to clients of Promochem. At the closure date (when no more returned questionnaires were admitted) of 15 January 2002, the total returned mail-out questionnaires was 241. The total number of completed Internet questionnaires was 33. After removing obvious doubles and unfinished questionnaires, and four questionnaires from outside Europe (Canada and Thailand), the total amount of users questionnaires admitted to analysis was 266.

Relevant cross sections for presentation of outcomes

303 The replies to the in-depth questions of the questionnaire are very much sector as well as CRM user type (in terms of CRM usage) specific. Hence answers will be much more meaningful when cross-sections of the answers by different sector and CRM user type are made.

304 The following presentation of the user questionnaire outcomes will thus comprise these parts:-

- (a) Geographical distribution of the respondents.
- (b) Outcomes by sector.
- (c) Outcomes by CRM user type.
- (d) General outcomes for which correlation with the sector or CRM user type (i) does not provide meaningful information or (ii) for which such correlation was incomplete or deemed too weak.
- (e) Outcomes by CRM category related to the CRM use and CRM needs.

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305 Aiming to provide an overview and to allow inter-comparison of the outcomes, this chapter summarises the highlights mostly in qualitative terms. The underlying data and graphical representations are included in annex D part 2, here referenced were appropriate as figure D2-x (bracketed).

Geographical distribution of the respondents

306 Germany and UK/Ireland tend to relatively over-represented in the responses (figure D2-0). This might be attributable to the fact that a considerable part of the LGC and Promochem client address database consist of respectively Anglo-Saxon and German clients. It could also be a reflection of the relative popularity of (C)RM usage in Northern EU countries, in combination with the size of the territory in number of user terms. Since this survey cannot be a completely representative reflection of equal parts of the European CRM population (since the size and distribution of this population are unknown in the first place), its aim never intended to be that but rather more to be indicative on trends and issues by size and sector, this aspect should not be seen as a disqualifier.

Outcomes by sector

Distinguishable sectors

307 The sector focus of users varies strongly. While a majority of respondents (176, or 66%) denote a single sector as their main focus, 2, 3 or 4 sectors are marked by others. The Environmental and Food sectors are mentioned most often as being part of the user's sector focus (figure D2-2).

308 To ensure surveyability of the results only the six largest sectors (based on overall user response) of the 16 defined in the questionnaire, are included in this analysis by sector. These six main sectors comprise: Environment, Food, Agriculture, Chemical, Metal and Pharmaceutical. To be able to make valid cross sections by sector it was necessary to filter out those respondents that indicated more than one target sector. The remaining population after filtering was 137, distributed according to table 3-1.

Environment	42	Agriculture	11	Metal	17
Food	35	Chemical	19	Pharmaceutical	13

User impression of sector structure

309 The perception of the sector structure by the respondents from each sector is summarised in Table 3-2 (figure D2-3). It should be noted that these figures are indicative only because overall only 48 responses to this question were received.

Table 3-2: Averaged perceived sector structure (%)						
	Food	Agriculture	Chemical	Pharmaceutical	Environment	Metal
Large Institutes	13	48	4	29	32	14
Smaller Institutes	27	20	8	0	23	7
Large Companies	32	15	46	41	14	49
Smaller Companies	27	18	42	30	30	23

Accreditation

310 Overall, a small majority of respondents (53%) is accredited (figure D2-6a). 47% is working towards (additional) accreditation (figure D2-7a). These are not simply the complementing non-accredited laboratories, as also accredited laboratories are still seeking accreditation in other fields. Users in the Food, Pharmaceutical and Metal sectors are accredited relatively more often than those in the other three sectors.

CRM use

311 Pharmaceutical, Metals and Environment are the top three sectors in terms of numbers of different CRMs used. Relatively few different CRM types are used in Food, Agriculture and Chemical sectors (figure D2-9a).

312 For Food and Environment, CRMs are more often used for method validation, while for the other sectors, CRMs are more often used for instrument calibration (figure D2-12a). On average, CRMs are used in 85% of the cases for quantitative purposes, like determination of amounts of analyte content (figure D2-13).

313 The most prominent reasons for using CRMs instead of RMs or control samples (figure D2-14a) are explicit CRM reference in standardisation/normalisation requirements in the Agriculture and Chemical sectors, while these are underrepresented in the Environmental and Food sectors. Prescription by internal quality system is the most important factor for all sectors. International and national government directives play a relative larger role in the Pharmaceutical sector. Prescription by instrument manufacturer does not play a significant role according to users from all sectors.

314 The Pharmaceutical sector's CRM purchasing frequency is by far the highest with about 80% ordering at least once a month. In the other sectors, the purchasing frequency is markedly lower, with Agriculture ordering no more than once a year (figure D2-16a).

315 The main source of information in all sectors is the CRM supplier (figure D2-17a), the Internet being the second most consulted source, except for the Metal and Chemical sectors, which indicate Workshops and conferences and Journals/scientific publications and, respectively, as the second most often used source of information on new CRMs.

CRM development and communication

316 On average, the price of CRMs is found to be high, but it is recognised that this high price is unavoidable for a CRM. Only in Agriculture a majority of respondents is of the opinion that prices are unreasonably high. In the Pharmaceutical sector almost half of the respondents share this opinion (figure D2-22a). Also in the Agriculture sector, and to a certain extent in the Food sector, the perception of availability, familiarity and use of CRMs is less than the average of other sectors (figures D2-19a, -20a, -21a, respectively).

317 The Environment, Pharmaceutical and Metal sectors interact most frequently with CRM producers on new CRM issues. The Pharmaceutical sector interacts most frequently with CRM producers on new CRM requests and measurement issues. The Food, Agricultural and Chemical sectors interact relatively seldom on new CRM requests (figures D2-23a1 to -23a4).

318 Three main drivers for developing new CRMs were identified, i.e. new or upcoming national or international government directives, new or upcoming standardisation requirements, and scientific interest. Scientific interest proved the least powerful driver of the three. In the Pharmaceutical sector the main driver is new international government directives, while this is a much less powerful driver for the Metal sector. For the Environmental, Food, Agriculture and Chemical sectors, new standardisation requirements are considered to be roughly equal in importance compared to new or upcoming national or international government directives (figures D2-31a1 to -31a3).

Outcomes by CRM user type

Distinguishable CRM user types

319 To be able make cross sections by CRM user type, a clustering of responses was made based on the number of CRMs used. These clusters were defined on a more or less balanced distribution (figure D2-9) of at least three groups of users in each cluster.

320 The three clusters of table 3-3 were found to correlate best with the frequency of CRM use in that respect that those users that use a relatively large amount of CRMs also use CRMs more frequently (figure D2-11b). The CRM user type therefore distinguish those users that use fewer CRMs relatively fewer times each year, those that use more CRMs relatively more times each year, and a CRM user type in between.

Table 3-3: Definition and distribution of CRM user types		
Large CRM users	Over 25 CRM types	15%
Medium CRM users	6-25 CRM types	33%
Small CRM users	1-5 CRM types	52%

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Resources

321 On average, CRM users that use more CRMs have larger departments (figure D2-4b). Department accreditation does not show strong size related differences, on average the percentage of accredited laboratories is roughly the same (figure D2-6b, -7b).

CRM use

322 The purpose of the CRMs is only marginally more for method validation and assignment of property values for large CRM users than for small and medium CRM users (figure D2-12b). For all CRM user types, the main reason for using CRMs instead of RMs is prescription by the internal quality system. Accreditation is the next important reason for small and medium CRM users, whereas prescription by instrument manufacturers and references in international government directives are more prominent for large CRM users (figure D2-14b). Large CRM users tend to buy CRMs on a more frequent basis than medium and small CRM users (figure D2-16b). There is only limited size related correlation on sources used for information on new CRMs: the supplier is by far the most important source for all user types, followed by the Internet; journals and workshops / conferences gain importance with the user size, but the differences are marginal (figure D2-17b).

CRM development and communication

323 In general, large CRM users have a better picture on the availability of CRMs and producers than medium and small users (figure D2-19b). A large majority of the users are of the opinion that CRMs have high prices, the fraction believing these to be unreasonably being about 20 % in all three users categories (figure D2-22b). Regarding knowledge and use of CRMs in their sector, large users are most positive on these issues, whereas medium and small CRM users perceive the knowledge and use of CRMs to be much less developed in their sectors (figures D2-20b and -21b, respectively).

324 On the issue of user's interaction with CRM producers on new CRM requests, measurement issues, homogeneity and sampling issues, and storage and training issues (figures D2-38 to D2-42, results show that large users interact relatively more often with CRM producers than medium and small users, especially on the issues of new CRM requests and measurement issues (figures D2-23b1 to -23b4). Large CRM users are also more often involved in the feasibility phase and certification phase of the development process of new CRMs (figures D2-24 and -25, respectively).

325 The price the CRM user is prepared to pay for a new CRM ranges from below EUR 10 to over EUR 1000. The price depends very much on what type of CRM the user is requiring. The average price a user is prepared to pay for a new CRM is EUR 235, however, with a broad range and less than 50% of the respondents provided an answer. The more frequent CRM users using more types of CRMs are prepared to pay more for a new CRM (figure D2-28).

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326 The drivers for developing new CRMs (new standardisation requirements, new (inter)national government directives, scientific interest) have also been analysed by CRM usage profile (figure D2-31b1 to –31b3). The same as for the analysis by sector, scientific interest is seen as the least powerful driver of the three. No clear CRM user type correlation can be found for any of the three drivers.

General outcomes

Internet use

327 228 respondents (86%) included an e-mail address in their response, while 99 respondents (37%) provided a company website address. 12% of the returned questionnaires were completed on the Internet.

Type of organisation

328 The majority of responding organisations are industry laboratories (30%), i.e. a laboratory directly associated with a product manufacturer (including R&D). Public research institutes (27%) and private laboratories (17%) are also mentioned often (figure D2-1).

View on the suppliers

329 The degree of satisfaction of the user with the additional support from the supplier has been analysed aggregated over all respondents, since cross sections by sector and by size do not provide any significant new insights in the results, most likely since many suppliers sell CRMs in a variety of sectors, to all sorts of users. On average, the user is contented with the additional support from the supplier, in terms of expertise, customer feedback facilities, accompanying information and support on storage and stability control of CRMs (figure D2-18).

Vision on CRM development aspects

330 The average maximum acceptable development time is 12 months. Due to the relatively low number of respondents to this question, no breakdown of this question did provide meaningful additional insights.

331 A clear majority of the users agrees that an international quality label is beneficial for the recognition of measurements and confidence in measurement results (figure D2-30).

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Outcomes by CRM category

Current CRM use

332 Correlating with the number of respondents by sector, CRMs from the Food and Agriculture and Environmental categories are mentioned most often (figure D2-10). Table 3-4 (table D2-10) provides a more detailed description of the areas from which CRM are currently used.

Table 3-4: Number of respondents using CRMs from a given area

# Food and Agriculture (Q1)	# Environment (Q2)	# Biological and Clinical (B)	# Metals (FN)
43 Meat 39 Fish 39 Vegetable matter 46 Cereals and crops 13 Fertilizers 36 Dairy products 50 Oils and fats 14 Alcoholic beverages 15 Other	61 Pesticides 77 Waters 37 Plants 74 Sediments 77 Soils 47 Sewage Sludges 37 Ashes and particulates 21 Other	19 Pharmaceuticals 43 Blood serum and plasma 32 Urine 6 Bone and tissue 13 Hair 21 Water and food microbiology 11 GMO 3 Other	34 Ferrous metals 42 Non-ferrous metals 13 Rare earths 31 Pure metals 7 Other
# Chemicals (IO)	# Pure materials	# Industrial raw materials and products (Y)	# Materials for determination of physical properties (P)
18 Organic gas (mixtures) 14 Inorganic gas (mixtures) 20 Oxides, salts 11 Paints and varnishes 7 Cosmetics and surfactants 20 Solvents 12 Other	38 Elemental analysis 44 Spectrometric solutions 53 Chromatographic standards 4 Stoichiometry 13 Organo-metallic compounds 9 Speciation 19 Isotopes 1 Other	15 Glass and ceramics 15 Ores 14 Minerals 3 Semiconductors 5 Refractories and carbides 13 Raw materials 8 Solid fuels 29 Oils and liquid fuels 13 Cement 16 Rocks 6 Polymers, organic fibres 0 Other	10 Thermal properties 5 Particle, film, surface prop. 9 Optical properties 6 Ion activity 6 Electrical properties 24 Viscosity 3 Polymeric properties 13 Mechanical properties 9 Other

CRM needs

333 By analogy with the producer questionnaire, a correlation between CRMs currently used and required new CRMs can be established (figure D2-26b). Table 3-5 (table D2-26a) provides a more detailed overview of the areas where CRMs are perceived as relatively underrepresented.

Table 3-5: Number of user respondents perceiving CRMs from a given area as being relatively underrepresented

<p># Food and Agriculture (Q1)</p> <p>21 Meat 15 Fish 24 Vegetable matter 20 Cereals and crops 11 Fertilizers 20 Dairy products 29 Oils and fats 13 Alcoholic beverages 17 Other</p>	<p># Environment (Q2)</p> <p>26 Pesticides 40 Waters 17 Plants 29 Sediments 35 Soils 14 Sewage Sludges 9 Ashes and particulates 18 Other</p>	<p># Biological and Clinical (B)</p> <p>9 Pharmaceuticals 25 Blood serum and plasma 12 Urine 3 Bone and tissue 4 Hair 14 Water and food microbiology 8 GMO 2 Other</p>	<p># Metals (FN)</p> <p>7 Ferrous metals 20 Non-ferrous metals 5 Rare earths 7 Pure metals 5 Other</p>
<p># Chemicals (IO)</p> <p>10 Organic gas (mixtures) 6 Inorganic gas (mixtures) 3 Oxides, salts 5 Paints and varnishes 4 Cosmetics and surfactants 6 Solvents 9 Other</p>	<p># Pure materials</p> <p>11 Elemental analysis 9 Spectrometric solutions 27 Chromatographic standards 3 Stoichiometry 3 Organo-metallic compounds 8 Speciation 6 Isotopes 1 Other</p>	<p># Industrial raw materials and products (Y)</p> <p>9 Glass and ceramics 6 Ores 5 Minerals 3 Semiconductors 5 Refractories and carbides 8 Raw materials 5 Solid fuels 12 Oils and liquid fuels 4 Cement 4 Rocks 8 Polymers, organic fibres 3 Other</p>	<p># Materials for determination of physical properties (P)</p> <p>2 Thermal properties 2 Particle, film, surface prop. 4 Optical properties 0 Ion activity 1 Electrical properties 3 Viscosity 2 Polymeric properties 5 Mechanical properties 2 Other</p>

Interview results

334 To obtain detailed information concerning the current user, 16 stakeholders up to the level of co-developer were interviewed in person. The selection consisted of 7 QC-users and 5 R&D users, with private, non-profit and government backgrounds, from Belgium, France, Germany, Greece, Italy, The Netherlands, Sweden and United Kingdom, essentially covering all sectors. In addition a Co-developer, 2 Distributors and an Accreditation body were included.

335 In general, the interview results corroborate the outcomes of the user questionnaires. Furthermore, as more angles could be investigated than in a simple questionnaire, additional relevant aspects were encountered. Highlights of the latter will be reported in the following paragraphs.

Miscellaneous results at the general user level (not necessarily common to all)

336 The distinction between “Quality Control” and “R&D” users, as put forward in chapter 1, is quite pronounced. In terms of CRM needs, QC users tend to be rather introspective and preoccupied with the shorter term. In many cases, the use of a CRM follows from the selection of specific measurement and testing equipment and either recommendation or actual prescription of the CRM by the equipment’s manufacturer. On the contrary, R&D users have a broader view on CRM issues as they often develop test procedures for others to implement. Selection of a particular CRM is usually the result of a more extensive process, scanning and testing many options, with a principally leading role for the R&D user itself. Yet, despite these differences, the general findings for QC and R&D users are comparable although the extent may vary with the specific knowledge level on CRMs.

337 Essentially all users highly appreciate having CRMs in the first place and consider support for their development on an EU level perfectly logical but also a necessity as the directives, which in most cases form the basis for application of the CRMs, are issued at that level. That being said, particularly the more experienced users stress that non-certified RMs have many uses as well, while not getting a proportional share of the support on the EU level.

338 Virtually all users seem to be confused by the terminology of the (C)RM field. No one appears to have a complete overview of the relevant offering and alternatives. Most readily acknowledge this aspect; some appear not even aware of their own lack of understanding. Furthermore, the subtleties of the European support efforts for CRM development are ill understood; as a rule, all is equated to BCR, originating from Brussels.

339 Confusion in the metrological domain is not restricted to (C)RM related issues. Particularly physical measurements oriented users complain about a variety of partly overlapping, yet not fully compatible, standards in Europe e.g. in the area of colour measurement.

340 Particularly in the chemicals sector, CRMs seem to be used to produce secondary RMs for cost reasons.

341 Users from Southern EU countries, regardless of their metrological knowledge, suggest a preoccupation of the CRM producers with Northern issues. Consequently purely “southern” needs are thought to be not well taken care of by European support programmes.

342 As regards accreditation, most users have mixed feelings. Although it helps to improve overall quality, it is still no guarantee. Therefore the generally accepted view seems to be that while being a prerequisite for commercial service provision, the costs of getting and maintaining accreditation do not outweigh the benefits in case of internal clients only.

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343 Overall web-literacy appears very low amongst the users. Many users indicate not to use the Internet at all when searching for new CRMs and one QC user did not even have web access in the first place, as a consequence of the official organisational policy. Even more experienced users may use the web for on-line catalogue checking only. In general, paper based information seems clearly preferred, some even relying on outdated catalogues only.

344 All users express a clear need for some way of structured interaction with CRM producers and similar specialists to obtain more information, guidance etc. Furthermore most users are strongly in favour of a European quality label for CRMs for additional confidence in the quality and clarity; some even hope for lower prices as a result of such a label. A minority of users argue that a label is only a label and that there other aspects more important than that, but none opposes the idea.

Workshop results

345 During the study's workshop, the general results of the questionnaire and interviews were validated. Most notable comments that were made in addition were:-

- (a) It would be helpful if the required CRMs would be described in as much detail as possible (*implemented in this report as far as possible*).
- (b) The textile sector was not separately identified, while this was expected by some to comprise many users of (C)RMs (*additional analysis of the data failed to reveal specific evidence to that effect*).

4 Potential European CRM users

Specific data gathering approach

401 By analogy with the approaches for the producers and users, a specific questionnaire for the potential CRM users was developed and distributed to people with a general interest in metrology during the last quarter of 2001.

402 Independent from the outcome of the questionnaires, in the course of the study four areas were identified where new categories of CRM users could likely be found or develop in the coming decades, i.e.:-

- (a) Instrument / equipment manufacturers.
- (b) The fight against synthetic drugs.
- (c) Developing countries with agricultural exports to the EU.
- (d) Biotechnology.

403 These four areas were investigated in the period from the last quarter of 2001 to the first quarter of 2002. For areas (a) to (c), the principle sources of information were interviews with (deemed) relevant experts and stakeholder organisations; for area (d) a future exploration was considered most appropriate. In view of the consequent differences in the data gathering approaches for the areas, details will be included in the respective descriptions of the results.

Questionnaire results

Distribution and response

404 400 copies of the potential user questionnaire have been distributed to the participants of the “10e Congrès International de Metrologie”. Another estimated 100 copies have been sent out through M&T. 11 copies have been returned, and 5 web based questionnaires were completed, totalling 16, or 3,2%.

Outcomes

405 The output from the potential user questionnaire was very diverse with a relatively small population, and in many cases appeared to include in fact actual CRM users. It was considered therefore not possible to derive any valid or meaningful statements on the current issues and needs of the potential CRM user. For this reason no statistical analysis was carried out.

Results for investigated areas

Instrument / Equipment manufacturers

406 Already at the beginning of the study, instrument and equipment manufacturers were proposed by the European Commission officials as candidate potential users. However, despite considerable effort, there were no individual potential users identified, that could be interviewed to yield meaningful results in the context of this study. Subsequently approached interest organisations were neither very open, nor provided meaningful information.

407 Interviewed (C)RM producers and Experts on that level, acknowledged the general RM needs of the instrument / equipment manufacturing branch. However, in general a widespread and justifiable need for CRMs was doubted because of expected rapid changes and small volumes.

Synthetic Drugs

408 Synthetic drugs are a topic rapidly gaining momentum, with potentially relevant consequences for parties involved in fighting these, as possible potential CRM users. Thus, the associated metrology issues were investigated in interviews with the supervisory co-ordinator of the “Phare Synthetic Drugs Project” and the chairman of the European Network of Forensic Sciences Institutes (ENFSI).

409 Drugs in general are a challenging subject. CRMs however, do not seem widely applied in this area. The general approach is largely pharmacopoeia based and pure materials appear the principal reference substances in use, with purity, availability and price as the most important issues. In addition, security and transport are problematic topics, as can be expected for narcotics related substances.

410 However, an even bigger concern of ENFSI are the relatively large discrepancies in measurement values between the member laboratories as repeatedly demonstrated ring tests. This is thought to be only partly attributable to improper reference materials or different methods; rather, a lack of understanding of applied metrology by the laboratory staff, is expected to be a major reason.

411 The metrology issues of synthetic drugs appear largely the same as for other drugs. No justified associated specific need for certain types of CRMs could be established.

Developing Countries

412 Solidarity with developing countries is one of the objectives of the European RTD programmes. From this viewpoint, the European Commission officials suggested third world exporting countries of agricultural produce to be likely candidate potential CRM users. It is envisaged that without adequate quality control, the latter will a hard time meeting ever more stringent EU-trade regulations, with detrimental effect on their exporting position.

413 Collaborations of the UN organisations WHO and FAO, particularly the Joint Expert Committee on Food Additives (JECFA), were expected to be the appropriate circles to interview, possessing the required overview. A preparatory interview with an expert previously involved in JECFA, referred specifically to the FAO side as having the better understanding of metrological issues. Therefore, FAO representatives involved in JECFA the Codex Alimentarius Committee (CAC) that it supports as well as the related Joint Meeting on Pesticide Residues (JMPR) have been interviewed.

Relevant background information of JECFA, CAC and JMPR

414 The Joint FAO/WHO Food Standards Programme issues the Codex Alimentarius, whose food standards are accepted as such by over 150 countries⁵. Between 1993 and 1995 all Codex Alimentarius standards were introduced in European regulations. The CAC, maintaining the Codex, is principally composed of food analysts; neither metrology/traceability experts nor representatives of ISO-REMCO are involved. The approach to standardisations is very similar to the pharmacopoeia one.

415 JECFA supports the CAC in relation to residues of veterinary drugs and contaminants like heavy metals or toxins. This is achieved via two publications issued by JECFA, i.e. the “Compendium of Food Additive Specifications” and its periodical addenda, describing the information on additives in a way very similar to pharmaceutical SRSSs, and the “Guide to JECFA Specifications” describing the analytical procedures. To date about 1400 additives have been evaluated, resulting in about 1000 specifications. JECFA compiles the specifications as a result of published calls for data, which invite to submit data on the compound of interest.

416 In addition to JECFA, the CAC is supported by individual consultations on e.g. BSE, feeding stuffs, GMO and microbes. In parallel to JECFA/CAC, JMPR takes care of pesticides, however more from a plant focus.

417 JECFA, CAC and JMPR cannot independently decide on what substances or topics to cover. These originate all from specific requests of FAO or WHO members.

⁵ Most notable exception being the USA

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Needs of FAO

418 JECFA feels it is too dependent on private companies for the Compendium data including the listed RMs, particularly as regards veterinary drugs residues. Involving more neutral bodies would be preferred for a practically worldwide standard. In addition, companies may follow their own policy in providing the RM, e.g. restricting supply to clients only.

419 With developing countries actually starting to process agricultural products, JECFA is more and more approached with questions in relation to the Compendium's RMs. However, due to lack of funding and suitable back-office, JECFA cannot distribute these RMs. Therefore, JECFA would be interested in exploring co-operation options with other parties which could perhaps lead to a distribution system.

420 (C)RM and traceability related issues in general are felt to be of relevance to the Codex Alimentarius but are not recently discussed by the CAC and cannot be addressed without a formal request of a FAO/WHO member state. While officially having an observer role only, the EC is treated as a member. The EC can therefore prompt the CAC to take action, DG SANCO being the appropriate party in this respect.

Needs of developing countries

421 In developing countries, import/export related laboratories of government bodies and larger industries, like beer breweries, are the principal CRM users. Even there, the general understanding of quality control principles is limited, let alone in smaller laboratories. Although the knowledge level varies by country, overall Asia seems to do somewhat better than Latin America, with central Africa considerably lagging behind. General training (e.g. seminars) in CRM use and related issues as quality control and testing. In addition to insufficient knowledge, constraints for application of RMs are:-

- (a) Price.
- (b) Impairing of shipping due to customs regulations.
- (c) Differences in tolerable levels and type of contaminants with respect to Europe.

422 The level of the required RM per food additive strongly varies. In many cases a simple pure RM suffices, CRMs being expected to be more appropriate for agricultural commodities with large trade volumes. Vegetable products (most relevant analytes being microtoxins, pesticides and, where appropriate GMO) like rice, coffee, wheat, barley, peanuts, oils seeds like soya are thus current and near future products of interest. In addition nuts, in all varieties, are gaining in importance, with a likely future candidates being organic foods, e.g. herb extracts. Prime animal products (most relevant analytes being microbes, pesticides and hormones) include meat, fish, eggs and powdered milk.

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423 In some cases, the exact needs of the developing countries may parallel those of the EU itself. However, in most cases the needs will be specific to the developing countries as analyte levels and urgency/impact may differ from those of the EU. An example of the latter category are RMs for pure pesticides as many pesticides sold to developing countries appear to be substandard, with the by-products being even more toxic.

424 In addition to provision of the appropriate (C)RMs, extensive and widespread training on the principles of measurement, testing and proper RM use is a prerequisite to achieve better product quality in developing countries and thus improve their competitive position and exporting capabilities to industrialised countries.

Biotechnology

425 Biotechnology is the only area that consistently came up in the interviews with direct CRM stakeholders, whether in a producer or user context, as highly likely to generate entirely new metrological issues in the coming decade. In view of the encountered broad support for this opinion as well as the generally expected dynamics and high impact, it was decided to launch a more extensive study to map the potential future of biotechnology.

426 In view of the fact that developments in biotechnology seem to have only just begun and the widely expected tremendous development potential in the coming decade, simple extrapolation of the current metrological needs, is likely to leave many emerging sub-areas untreated. Therefore, it was deemed relevant to have a different approach in which first the potential future of biotechnology in general by 2015 was explored, bearing the European perspective in mind. If and where possible this general future description was to be refined at a latter stage from a metrological point of view, with the aim to allow experts to predict related RM needs in general.

427 Rather than arriving at a single description of the future of biotechnology, with likely limited probability of capturing the real situation, the possible extremes were investigated by employing the "Scenario Envisioning" methodology. Scenario envisioning relies on involvement of external experts from all angles (technical, social/ethical, economical/business and political), both generalists and niche specialists, to refine and develop the relevant aspects in a dialogue.

428 In an interactive on-line communication process, complemented by a parallel session during the CRM workshop of 5-6 February 2002, the biotechnology field was scoped and the most important drivers that would determine the situation in 2015 for Europe were selected by a panel of about 15 experts. Quite convincingly, the following drivers emerged from the process:-

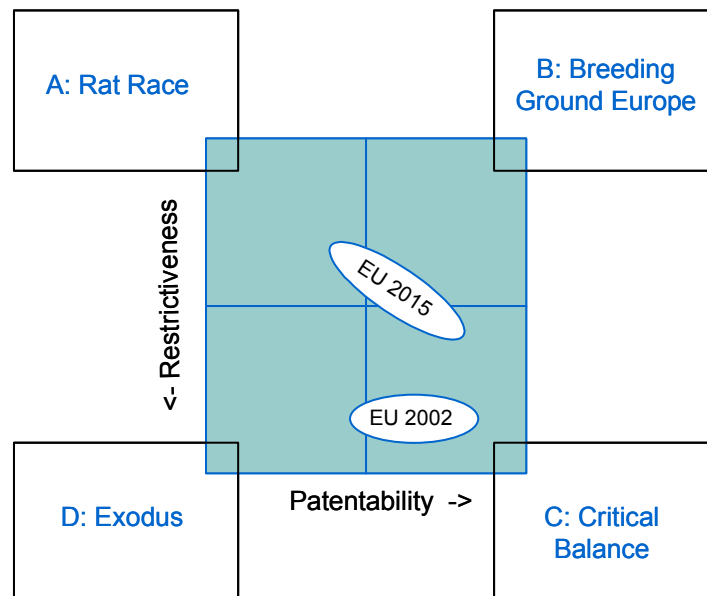
- (a) The extent to which biotechnological products and processes are patentable, ranging from not patentable to completely patentable.

- (b) The restricting effect of the regulatory and legal framework (a combination of the strictness and the ambiguousness of the regulatory and legal framework on development and application areas of biotechnology), ranging from not restricting to extremely restricting.

429 Four extreme scenarios were created by combining high and low situations of the aforementioned primary drivers, to serve as starting points for the scenarios. The latter were subsequently actually constructed in four personal interviews with biotechnology experts, each having a specific background (politics, business, society, science), yet capable of providing an overview. After validation of the results by all experts thus far involved, this process afforded the following four scenarios⁶:-

- (a) 'Rat Race', describing a situation where biotechnological products and processes are *not patentable* and industry faces *no restricting legal framework*.
- (b) 'Breeding Ground Europe', describing a situation where biotechnological products and processes are *completely patentable* and industry faces *no restricting legal framework*.
- (c) 'Critical Balance', describing a situation where biotechnological products and processes are *completely patentable* and industry faces an *extremely restricting legal framework*.
- (d) 'Exodus', describing a situation where biotechnological products and processes are *not patentable* and industry faces an *extremely restricting legal framework*.

Figure 4-1 Biotechnology scenarios and perception of actual 2002 and 2015 situations



⁶ Full descriptions of the scenario's are included as annex G

430 In general there was wide agreement on the validity of the descriptions of the extreme scenarios among the experts. However, concerning the relative positions of the current situation and expected situation in 2015 for Europe, opinions differed. Acknowledging that only a few experts provided their expectations on this topic, all placed the current situation in the lower quadrants, with scenario C being dominant. While one expert considered horizontal transition towards scenario A more likely for particular areas by 2015, most placed the expected future situation in or towards the upper quadrants. Although the horizontal component of the transition in the latter case still varied, i.e. increased and reduced patentability both being held possible, a clear majority thus expects less restrictive regulation by 2015.

431 A selected number of experts provided input for the subsequent translation of the extreme scenarios into standardisation related issues. Table 4-1 summarises the overall results.

Table 4-1: Standardisation aspects of the extreme biotechnology scenarios					
	Standardisation need	RM range	Sector	RM purpose	RM development lead party
A: Rat Race	virtually absent	-	-	-	-
B: Breeding ground Europe	high	wide	Healthcare Food Agriculture Environment	Mainly performance standards; some composition standards	Principally industry
C: Critical Balance	high	wide	Healthcare Food Agriculture Environment	Mainly performance standards; some composition standards	Principally government
D: Exodus	low	very limited	Healthcare Food Agriculture Environment?	Essentially only composition standards	Essentially only government

432 Combining the expert input concerning standardisation issues (table 4-1) and the average expected transition upwards in the right quadrants by 2015 (cf. figure 4-1), boiling down to an increasing influence of the B scenario, the contribution of the industry in the provision of RMs should thus increase. All sectors affected by biotechnology are expected to require standards, notably performance related. The applications and relative priorities appear very sensitive to the exact scenario balance realised in the actual 2015 situation. Only healthcare diagnostics emerges in this case as a robust area of application, i.e. important regardless of the actual scenario balance.

5 Future CRM needs and offering

User derived data

501 On basis of a survey, valid comparisons of the expressed CRM needs are only possible at the category and area levels. The variety in the information and details provided about individual CRM types (by necessity an open question in a general survey) simply precludes a meaningful comparison at that level. The latter has also been encountered in a previous survey based attempt⁷.

502 Furthermore, given the generally encountered notion (cf. Chapters 3 and 6) that the understanding of RM terminology by the average user is not necessarily fully developed, a mix up of CRM and RM issues is not unlikely for many user respondents. Therefore, despite specifically requesting CRM related areas of current use and future needs, it is assumed that the questionnaire responses are better understood to apply to both CRMs and pure RMs, taken together as (C)RMs. It should be noted however, that the latter is not a major reduction of the CRM specific value as in the majority of cases it can be expected that areas with a high need for CRMs have a high need for pure RMs and *vice versa*.

503 The criteria employed by the respondents in the present survey to select a (C)RM area as relatively underrepresented are unknown. Nevertheless, on a questionnaire-by-questionnaire basis, the choices appear quite selective and suggest a careful consideration process. Although there is a marked correlation between the (C)RM areas of current use and perceived underrepresentation / future need, most respondents ticked other areas in the same categories, some even in others, as well. The fact that the overall rankings by category in tables 3-4 and 3-5 (Chapter 3) are very similar, is largely attributable to an aggregation effect.

504 Given the number of 266 respondents, in our opinion therefore the number of organisations expressing a need on the area level, as reported in table 3-5, can be interpreted as indicative of the future priorities. However, it is unlikely that the respondents' distribution over the categories is indeed representative for the user population as a whole. Neither can it be expected that the selection criteria are mutually scaled among categories, while the issues can be very different. Therefore, the indications are assumed to be restricted to each individual category. Table 5-1 reports the thus obtained ranking from reworking table 3-5.

⁷ Workshop on the use and prospects for reference materials for the quality control of agro-food & environmental analysis (SMT4-CT97-6522); Quevauviller Ph., Trends Anal. Chem. 18 (1999), 76.

Table 5-1: Ranking of (C)RM areas according to all users (266 respondents)

# Food and Agriculture (Q1)	# Environment (Q2)	# Biological and Clinical (B)	# Metals (FN)
1 Oils and fats 2 Vegetable matter 3 Meat 4 Cereals and crops 4 Dairy products 5 Fish 6 Alcoholic beverages 7 Fertilizers	1 Waters 2 Soils 3 Sediments 4 Pesticides 5 Plants 6 Sewage Sludges 7 Ashes and particulates	1 Blood serum and plasma 2 Water and food microbiology 3 Urine 4 Pharmaceuticals 5 GMO 6 Hair 7 Bone and tissue	1 Non-ferrous metals 2 Ferrous metals 2 Pure metals 3 Rare earths
# Chemicals (IO)	# Pure materials	# Industrial raw materials and products (Y)	# Materials for determination of physical properties (P)
1 Organic gas (mixtures) 2 Inorganic gas (mixtures) 2 Solvents 3 Paints and varnishes 4 Cosmetics and surfactants 5 Oxides, salts	1 Chromatographic standards 2 Elemental analysis 3 Spectrometric solutions 4 Speciation 5 Isotopes 6 Stoichiometry 6 Organo-metallic compounds	1 Oils and liquid fuels 2 Glass and ceramics 3 Raw materials 4 Ores 5 Minerals 5 Refractories and carbides 5 Solid fuels 6 Cement 6 Rocks 7 Semiconductors 8 Polymers, organic fibres	1 Mechanical properties 2 Optical properties 3 Viscosity 4 Thermal properties 4 Particle, film, surface prop. 4 Polymeric properties 5 Electrical properties 6 Ion activity

505 A feeling for the dependability of the herewith-obtained overall ranking by category can be obtained by analysing the outcomes for different subpopulations. In this particular case, it seems most relevant to compare the outcomes for users which are likely to have an above average understanding of (C)RM issues with those of the others, then comprising an increased majority of less experienced users.

506 Two groups of experienced (C)RM users can be distinguished in the present survey, which both deserve independent investigation as they are largely, but not completely, complementary. These groups are:-

- (a) Users that have been involved in feasibility studies or certification exercises, by definition (cf. Chapter 1) consisting of Initiating Producers or Co-developers, therefore in principle all known to the EC (35 respondents).
- (b) The large CRM users of table 3-3, i.e. those using over 25 different CRMs, comprising some of the above, but in majority consisting of R&D users which are not yet known to the EC (66 respondents).

507 Tables 5-2 and 5-3 report the rankings of the users that are involved in certification or feasibility of new CRMs and those that are not, respectively (tables D2-26b, -26c).

508 Tables 5-4 and 5-5 report the rankings of the users that use over 25 CRMs and those that use under 25 CRMs, respectively (tables D2-26d, -26e).

Table 5-2: Ranking of (C)RM areas according to organizations *involved in feasibility or certification of new CRMs* (35 respondents)

# Food and Agriculture (Q1)	# Environment (Q2)	# Biological and Clinical (B)	# Metals (FN)
1 Vegetable matter 1 Cereals and crops 2 Oils and fats 3 Meat 3 Dairy products 4 Fish 4 Alcoholic beverages 5 Fertilizers	1 Soils 2 Sediments 3 Waters 4 Pesticides 5 Plants 5 Sewage Sludges 6 Ashes and particulates	1 Blood serum and plasma 2 Water and food microbiology 3 Urine 4 Hair 4 GMO 5 Pharmaceuticals 5 Bone and tissue	1 Non-ferrous metals 2 Ferrous metals 2 Pure metals 3 Rare earths
# Chemicals (IO)	# Pure materials	# Industrial raw materials and products (Y)	# Materials for determination of physical properties (P)
1 Organic gas (mixtures) 2 Inorganic gas (mixtures) 2 Oxides, salts 2 Paints and varnishes 2 Cosmetics and surfactants 2 Solvents	1 Chromatographic standards 2 Elemental analysis 3 Isotopes 3 Speciation 3 Spectrometric solutions 4 Stoichiometry 4 Organo-metallic compounds	1 Oils and liquid fuels 2 Glass and ceramics 3 Polymers, organic fibres 4 Raw materials 5 Ores 5 Minerals 5 Semiconductors 5 Refractories and carbides 5 Rocks 6 Solid fuels 6 Cement	1 Optical properties 1 Mechanical properties 2 Polymeric properties 3 Thermal properties 3 Particle, film, surface prop. 3 Electrical properties 3 Viscosity 4 Ion activity

Table 5-3: Ranking of (C)RM areas according to organizations *not involved in feasibility or certification of new CRMs* (231 respondents)

# Food and Agriculture (Q1)	# Environment (Q2)	# Biological and Clinical (B)	# Metals (FN)
1 Oils and fats 2 Meat 2 Vegetable matter 3 Dairy products 4 Fish 4 Cereals and crops 6 Alcoholic beverages 7 Fertilizers	1 Waters 2 Soils 3 Pesticides 3 Sediments 4 Plants 5 Sewage Sludges 5 Ashes and particulates	1 Blood serum and plasma 2 Water and food microbiology 3 Pharmaceuticals 3 Urine 4 GMO 5 Bone and tissue 5 Hair	1 Non-ferrous metals 2 Ferrous metals 2 Pure metals 3 Rare earths
# Chemicals (IO)	# Pure materials	# Industrial raw materials and products (Y)	# Materials for determination of physical properties (P)
1 Organic gas (mixtures) 2 Inorganic gas (mixtures) 2 Solvents 3 Paints and varnishes 3 Cosmetics and surfactants 4 Oxides, salts	1 Chromatographic standards 2 Elemental analysis 3 Spectrometric solutions 3 Speciation 3 Isotopes 4 Stoichiometry 4 Organo-metallic compounds	1 Oils and liquid fuels 2 Glass and ceramics 3 Polymers, organic fibres 4 Raw materials 5 Ores 5 Minerals 5 Semiconductors 5 Refractories and carbides 5 Rocks 6 Solid fuels 6 Cement	1 Optical properties 1 Mechanical properties 2 Polymeric properties 3 Thermal properties 3 Particle, film, surface prop. 3 Electrical properties 3 Viscosity 4 Ion activity

Table 5-4: Ranking of (C)RM areas according to organisations using *over 25* types of CRMs (66 respondents)

# Food and Agriculture (Q1)	# Environment (Q2)	# Biological and Clinical (B)	# Metals (FN)
1 Cereals and crops 1 Oils and fats 2 Meat 3 Vegetable matter 3 Fertilizers 3 Dairy products 3 Alcoholic beverages 4 Fish	1 Soils 2 Pesticides 3 Waters 3 Plants 3 Sediments 4 Sewage Sludges 4 Ashes and particulates	1 Pharmaceuticals 2 Blood serum and plasma 2 Urine 2 Hair 3 Bone and tissue 3 Water and food microbiology 3 GMO	1 Non-ferrous metals 2 Pure metals 3 Ferrous metals 3 Rare earths
# Chemicals (IO)	# Pure materials	# Industrial raw materials and products (Y)	# Materials for determination of physical properties (P)
1 Cosmetics and surfactants 2 Organic gas (mixtures) 2 Inorganic gas (mixtures) 2 Oxides, salts 2 Paints and varnishes 2 Solvents	1 Chromatographic standards 2 Organo-metallic compounds 3 Elemental analysis 3 Isotopes 4 Spectrometric solutions 4 Stoichiometry 4 Speciation	1 Raw materials 1 Polymers, organic fibres 2 Oils and liquid fuels 3 Glass and ceramics 3 Refractories and carbides 4 Ores 4 Minerals 4 Semiconductors 4 Solid fuels 4 Cement 4 Rocks	1 Optical properties 1 Viscosity 2 Thermal properties 2 Particle, film, surface prop. 2 Ion activity 2 Electrical properties 2 Polymeric properties 2 Mechanical properties

Table 5-5: Ranking of (C)RM areas according to according to organisations using *25 or less* CRM types (200 respondents)

# Food and Agriculture (Q1)	# Environment (Q2)	# Biological and Clinical (B)	# Metals (FN)
1 Oils and fats 2 Vegetable matter 3 Meat 3 Dairy products 4 Fish 4 Cereals and crops 5 Alcoholic beverages 6 Fertilizers	1 Waters 2 Soils 3 Sediments 4 Pesticides 5 Plants 6 Sewage Sludges 7 Ashes and particulates	1 Blood serum and plasma 2 Water and food microbiology 3 Urine 4 GMO 5 Pharmaceuticals 6 Bone and tissue 6 Hair	1 Non-ferrous metals 2 Ferrous metals 3 Pure metals 4 Rare earths
# Chemicals (IO)	# Pure materials	# Industrial raw materials and products (Y)	# Materials for determination of physical properties (P)
1 Organic gas (mixtures) 2 Inorganic gas (mixtures) 2 Solvents 3 Paints and varnishes 4 Oxides, salts 4 Cosmetics and surfactants	1 Chromatographic standards 2 Elemental analysis 3 Spectrometric solutions 4 Speciation 5 Isotopes 6 Stoichiometry 7 Organo-metallic compounds	1 Oils and liquid fuels 2 Glass and ceramics 2 Polymers, organic fibres 3 Ores 4 Minerals 4 Solid fuels 5 Refractories and carbides 5 Raw materials 5 Cement 5 Rocks 6 Semiconductors	1 Polymeric properties 1 Mechanical properties 2 Optical properties 3 Thermal properties 3 Particle, film, surface prop. 3 Viscosity 4 Electrical properties 5 Ion activity

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509 From tables 5-2 and 5-4 it is obvious the categories Chemicals and Materials for Determination of Physical Properties, have that little experienced user input that a comparison with their counterpart categories from tables 5-3 and 5-5 cannot be justified. However, when comparing the other categories of tables 5-2, 5-3 and tables 5-4, 5-5, respectively it is striking to note the similarity of the top ranked (C)RM areas. Although, the individual positions within the rankings may differ, the same 2 to 3 areas (depending somewhat on the number of areas and the frequency of indication) essentially reoccur in all categories. Moreover, these rankings have excellent correspondence to those in the user gross list in table 5-1.

510 In view of the established correlations between the rankings of relevant subpopulations and their counterparts, as well as with the gross list, it seems that the indications per category are actually quite good. The consistency of the similarities between those categories for which a comparison seems justified, suggests that the indications of the categories Chemicals and Materials for Determination of Physical Properties may be taken directly from the user gross list.

511 Based on the above described results, and taking into account the number of areas per category, it is tentatively proposed that the areas listed in table 5-6 indicate the key areas of (C)RMs for future research and production, based on the user input.

Table 5-6: Indicative Key (C)RM areas (in random order) per category, based on user input	
Food and Agriculture	Meat Vegetable Matter Oils and Fats
Environment	Waters Sediment Soils
Biological and Clinical	Blood Serum and Plasma Water and Food Microbiology
Metals	Non-ferrous metals
Chemicals	Organic Gas (mixtures) Inorganic Gas (mixtures)
Pure Materials	Chromatographic Standards Elemental Analysis
Industrial Raw Materials and Products	Oils and Liquid Fuels
Material for Determination of Physical Properties	Optical Properties Mechanical Properties

Producer derived data

512 The ranking of the needed (C)RMs according to the producers can be interpreted from table 2-4 (Chapter 2). Due to the low number of respondents, the ranking is not too dependable. Particularly the categories Food and Agriculture, Chemicals, and Pure Materials have such low frequencies that a ranking by category is essentially meaningless. There are quite good overlaps of the producer rankings in the categories Environment, Biological and Clinical, and Metals with the proposed indicative key (C)RM subcategories (table 5-6), which may be interpreted as corroboration of the latter.

513 In general and taking into account the low number of producer respondents, it is unclear how to interpret the differences that still exist in the categories with substantial overlaps and also in the other categories. However, with reference to the results of the biotechnology future exploration (cf. Chapter 4), it is felt that for Biological and Clinical, the differences can be explained by the on average better feeling of producers for emerging trends. Thus, it is proposed that pharmaceuticals and GMO should be seen as key (C)RM areas as well. The significant lack of correlation for the latter areas between current production (cf. Chapter 2, virtually absent in table 2-3) and relative underrepresentation / future need (top ranking in table 2-4) is taken as further corroboration.

514 For a number of reasons a gap analysis between the indicative key (C)RM areas, proposed on basis of the user data, and the future production schemes of the producers proves unfortunately virtually impossible on basis of a general questionnaire based survey. Indeed all areas are in principle already covered by the current production activities of the producers (cf. table 2-3). However what really counts is a comparison at the individual (C)RM level of the needed (C)RM with the pipeline of the producers. As in general only limited insight is given in the latter, a gap analysis is difficult. Furthermore, even when production of an individual needed (C)RM is actually planned, there is no firm guarantee that the need will be solved as the budget may still be insecure; this may particularly apply to long term plannings.

Overall key (C)RM areas

515 As the criteria employed by users and producers are not likely to be mutually scaled, especially if the assumed higher sensitivity to emerging trends of the latter is correct, their rankings in the category Biological and Clinical are hard to prioritise. Although the number of key areas in that category will then be relatively high, it is nevertheless felt most appropriate to include the contribution from both stakeholder categories as such.

516 Table 5-7 thus lists the overall key (C)RM areas as extracted from the survey data.

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Table 5-7: Indicative Key (C)RM areas (in random order) per category, overall result	
Food and Agriculture	Meat Vegetable Matter Oils and Fats
Environment	Waters Sediment Soils
Biological and Clinical	Blood Serum and Plasma Water and Food Microbiology Pharmaceuticals GMO
Metals	Non-ferrous metals
Chemicals	Organic Gas (mixtures) Inorganic Gas (mixtures)
Pure Materials	Chromatographic Standards Elemental Analysis
Industrial Raw Materials and Products	Oils and Liquid Fuels
Material for Determination of Physical Properties	Optical Properties Mechanical Properties

6 Interactions in the (C)RM field as perceived by users and producers

Specific data gathering approach

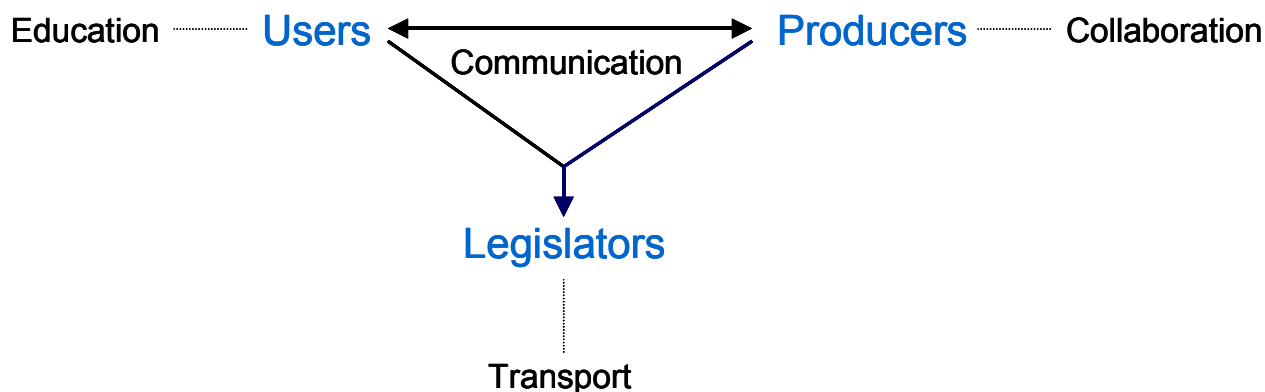
601 In the study's CRM workshop on 5-6 February 2002, four interactive sessions were devoted to exploring the present and desirable interactions between the major stakeholder categories of CRM users and (C)RM producers as well as aspects that directly or indirectly affect these interactions. The first two parallel sessions each examined the subject from the perspective of a single stakeholder category, i.e. either that of the users or that of the producers. The principal issues that were identified in this process, were further elaborated in two subsequent parallel sessions, both taking either view angle into account.

General outcomes

602 The results of the individual sessions⁸ and follow-up discussions will be treated here in an integrated way, also taking into account as well results from interviews and desk study if appropriate. Consecutively, the perspectives of the user, the producer and the common perspective, will be presented.

603 Communication emerges as the recurrent theme in all perspectives, including inter stakeholder communication, i.e. user-user and producer-producer, communication between users and producers and communication of users and producers together with the legislating parties. Furthermore, users, producers and legislators each "own" a proper aspect that indirectly, yet significantly influences communication, being metrological education, development collaboration and transport, respectively. Figure 6-1 graphically combines the interaction (related) issues, to be discussed in detail in the following sections.

Figure 6-1 Schematised interaction related issues in the (C)RM field



⁸ Reports of the individual sessions that were drafted and discussed in the workshop are included as annex I

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User perspective

Communication according to the user

User-User communication is virtually non-existent

604 There is wide agreement that CRM users are poorly organised. Organisations like EURACHEM are perceived as too high level, particularly for QC users, to fulfil this function. Moreover, in view of the wide variety of specific needs and issues between sectors, communication should better be arranged at the sector level in the first place. The present situation is that users in general cannot prioritise their sectors CRM needs.

User-Producer communication leaves much to be desired

605 Largely due to the absence of an organised communication between users, the communication of the users with the producers is insufficient as well. There are not enough good meeting opportunities to interact, like workshops, and those meetings that are organised are felt to be at too high a level.

606 From individual interactions with the producers, the general perception among the users is that producers have a limited understanding of the actual user needs and do not seem interested in providing customer support. Specific points of criticism, include:-

- (a) decisions on which CRM to develop appear to have been taken without proper market research or involvement of users at all;
- (b) user requests do not seem to be taken along;
- (c) “after sales customer care” is uncommon;
- (d) training and manuals for new CRMs for the users are seldom at the level of the user’s requirements.

607 As a result, actual users do not know where to look for the right information, let alone potential users. Users in general do not have a good overview of which CRMs are available worldwide. A universal (C)RM portal is seriously missed.

Education of QC user laboratory staff

Expertise in applied metrology leaves much to be desired

608 In general, the understanding of applied metrology principles is poor in the QC user laboratories. Basic concepts and particularly aspects such as the definitions of RMs and CRMs and the differences between the two, are unclear or unknown to many users. Also proper methods of handling and using CRMs cannot be considered common knowledge among laboratory personnel.

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Shortcomings of the formal schooling are not compensated on the job

609 The fact that higher education appears to focus on theory rather than application of analytical chemistry is seen as a prime reason for the lack of understanding. Concepts like GLP are not taught with sufficient strength.

610 This situation is not remedied during the working life due to the cost competitive nature of the quality control test market. Laboratory clients are generally not aware of metrological quality issues, let alone the existence and purpose of CRMs. As a rule, clients wish a test to be as cheap as possible and to produce a report that is fit for their (e.g. legal) requirements. They do not care much about how the test is done by the laboratories, as long as the requirements are met. Quality not being the prime issue, the resultant cost drive does not encourage laboratories to invest in follow-up training and education beyond the bare minimum.

611 Two additional factors complicate matters further, i.e.:-

- (a) The technical language used in documentation such as books, manuals, CRM catalogues and certificates is not commonly interpreted the same by all parties involved: different terminologies can have the same meaning, while in other cases one terminology can have different meanings depending on the context.
- (b) On a more basic level, the working language of the international scientific community, English, is not understood to the same extent by all users in Europe. While this may not be the case for the higher-level decision-makers and laboratory management, this is often the case for the people who carry out the tests. Certificates, manuals etc. only distributed in the English language are a known cause of problems to non-native English speaking staff of laboratories.

Producer perspective

Communication according to the producer

Producer-Producer communication on the higher levels is quite good

612 The major CRM producers find adequately functioning communication fora in EURACHEM for general metrology issues and ISO-REMCO for RM specific issues. However, pure RM producers and particularly the smaller ones, are not necessarily represented in these organisations, causing comparable concerns regarding their metrological quality as with QC users.

613 Although there is worldwide agreement with regards to the quality of (C)RM production, as laid down in ISO guide 34, application of the guide by producers unfortunately still varies. Mutual recognition is the way to overcome the latter, at least between the major producers. Mutual recognition can in principle best be negotiated through ISO-REMCO, although not all countries are represented yet. All desired on the one hand, full representation in ISO-REMCO is likely to cause more bureaucracy and slow decisions down on the other hand, notably as a result of expected raising of non-scientific trade issues. IUPAC is suggested as a possible alternative organisation for mutual recognition negotiations, although it is very much science orientated.

Producer-User communication should be improved, but is not as bad as it appears

614 Producers readily acknowledge that they do not fully understand the needs of the end users, and in particular those of the potential ones, as there are no structured ways to reach these. All stress however, that interaction is actively sought e.g. through exhibitions, by cooperation with distributors, etc. Surveys are also employed, albeit with mixed results: a recently carried out comprehensive survey in Japan is thought to give a good indication of the needs, but other surveys are known to produce disperse results and forecasts that did not match subsequent demand. These activities thus cannot compensate for the absence of the proper communication fora, as is commonly deplored. Nevertheless, it is argued that there is considerably more understanding than actual follow-up suggests as budget restrictions or other priorities may limit the possibilities for consequent actions.

615 (C)RM producers admit that not everything possible is done to support end users. Yet also in this case, it is argued that there are still some helpful initiatives. Notably, the COMAR database, despite its access restrictions, is seen as a good but undervalued source of information. In addition, significant efforts are invested in the proprietary web sites.

Collaboration between (C)RM producers

Inter-producer collaboration makes sense in many cases

616 In principle, collaboration between producers is considered beneficial if alone for reasons of division of labour and sharing of costs. The sometimes-contradictory views on the desirable scale of such a collaboration can essentially be reconciled along the lines of a “fit for purpose” strategy regarding regional versus worldwide collaboration scales.

617 A major issue which should be addressed when considering cooperation is overhead. The associated bureaucracy of any collaboration, let alone worldwide ones, is bound to cause additional costs, direct related to invested effort as well as indirect related to travel and subsistence, and inflexibility, e.g. by increasing the response time to crisis situations. Furthermore, it is argued that there must remain a healthy balance between cooperation and competition to drive creativity.

Regional collaboration suited for limited scale usage

618 Regional collaboration is the obvious model to develop RMs with a predominantly regional application. This category comprises RMs intended to satisfy specific local legislation or industry/trade needs, like in the latter case certain alloys or glasses. Avoiding unnecessary increases of the development overhead costs and short response times were cited as the main drivers to restrict the collaboration scale.

Worldwide collaboration suitable for general human need related (C)RMs

619 In case of international trade related (C)RMs the need for worldwide collaboration appears obvious. However, RMs intended to satisfy needs with a direct relation to the functioning of the human body, notably in the clinical, environmental and food sectors, in principle can be expected to have worldwide relevance as well. The same should hold for more and more RMs targeting industrial needs, as globalisation causes procedures and associated metrological problems to converge.

620 Main reasons cited to corroborate the added value that worldwide collaboration of (C)RM producers could bring in cases as described in the previous paragraph, include:-

- (a) Support of worldwide recognition, which is a cornerstone in achieving universal traceability in practice, in addition to Mutual Recognition Arrangement of the Meter convention⁹.
- (b) Sharing of responsibilities between producers.
- (c) Most efficient way to approach extremely challenging (C)RM areas, e.g. microbial or natural physical state RMs.

621 An issue to overcome is the fact that worldwide recognition starts with collaboration yet not much collaboration due to lack of worldwide recognition. Although RM needs with a direct relation to the human body may in principle be the same, the implementation in terms of analyte levels may differ. While acknowledging this point, it is argued that a converging trend in levels is visible. For pure calibrants convergence is expected to be relatively easy; in the case of matrix CRMs the situation is considerably more difficult but even here, optimists expect convergence in time.

EU wide collaboration is a practical in between scale

622 EU wide collaboration already brings a lot of additional overhead with restricted recognition, although valuable in itself, in return. Yet, this scale is seen as having its own merits because certain solutions might be replicable to a worldwide scale. For example, the EU solution of networks of reference laboratories, with the one on food as working example, could be good models for improving worldwide collaboration and thus lowering of international trade barriers.

⁹ Although good from a traceability perspective, it should be remembered that mutual recognition is likely to cause job loss in smaller QC laboratories.

Common perspective of users and producers towards legislators

Communication

User/Producer communication with legislators is far from optimal

623 (C)RM Users and Producers alike feel that the communication process with the legislating authorities needs to be improved significantly. Two types of legislating authorities need to be distinguished in this context, i.e.:-

- (a) Those that have a technology related mission with explicit support of development or implementation of metrology, notably DG Research on the EU level.
- (b) Those that have a more general mission to which metrology is only a means, usually in an implicit way with consequent low visibility, in the implementation/upholding stage. Example legislators on the EU level include DGs Environment, Health and Consumer Protection, Trade to name a few.

624 Usually, particularly the more prominent (C)RM producers maintain some relationship with the former type of legislating authorities. However, coordination of the producer efforts tends to be limited. A major issue is the fact that pure end users, who should be the beneficiaries of the developed technology, are essentially not involved at all, despite efforts of the legislators to reach the user. In this situation, legislators understandably tend to be overly hesitant to follow prioritisation directions from the producers. Being the direct beneficiaries of the available funds, without clear underpinning by the users, producers can thus only exert limited influence on the legislators. Joint action of users and producers towards this type of legislators is therefore in everybody's interest as users are more likely to be able to solve their metrological problem, producers are more likely to develop what is really needed and thus legislators are more likely to support solving a genuine societal issue.

625 Interaction with the latter type of legislators is usually very limited or non-existent. To the (C)RM field, the resultant legislation appears to be largely an autonomous process. Thus, they are confronted with laws that from a metrological point of view may be to impractically, extremely costly or simply impossible to uphold. Furthermore, as a rule development funds are not foreseen in the legislative process. It is obvious that both users and producers have a lot to gain by joint action towards such legislating authorities.

Transport of (C)RMs

626 A major issue in the realm of the legislators and directly affecting all stakeholders is the fact that (C)RMs do not yet have a general-purpose customs code. Instead they are treated according to their specific composition, causing all kinds of associated problems. The most notorious example is that of an RM for shellfish toxin, intended to protect human health by allowing proper identification of contaminated shellfish batches, which qualifies as a weapon with associated import and export restrictions. Polluted soil RMs, qualifying as hazardous wastes, suffer from similar problems. But also food RMs may have transport restrictions, e.g. as a result of trade conflict driven bans.

627 In the best case, these transportation problems give rise to cumbersome administrative procedures, causing cost penalties to the user in the form of increased shipment costs and delayed reception. In the worst case, stability sensitive (C)RMs may become completely unusable if the storage conditions are not properly met while being held up.

628 Efforts to realise a specific RM customs code are undertaken for quite some time now and are likely to succeed sooner or later. However, every day under the present regime causes new frictions and continues to limit the beneficial use of RMs to society as a whole.

7 Conclusions and Recommendations

Principal Conclusions

Many CRM related issues are part of more general metrology issues

701 The terms of reference of the present study enforced a clear CRM focus. A separate section will therefore be dedicated to conclusions and recommendations relating fully or largely to CRMs, with the envisaged principal action owner(s) between brackets.

702 However, what clearly emerged from the study is that many CRM issues in fact are part of much wider and deeper general metrology related issues. Dealing with the former in isolation does have a positive impact on society and has the advantage that, although still being a challenge, it is comparatively manageable. However, the full benefit to society will only realised when the metrology related root causes could be tackled, which unfortunately has the disadvantage of being a far more daunting task. In any case, a separate section will also be dedicated to more general metrology related conclusions and recommendations.

703 Recommendations:-

- (a) Continue focus on CRMs as the direct benefit to society is tangible and sufficiently substantial. (Action: European Commission)
- (b) Focus in future also on general metrology issues as the lasting benefit for society is expected to be higher and, indirectly, it will still contribute to solving or reducing CRM specific problems. (Action: European Commission)

Facilitation of proper metrology cannot be fully left to the market

704 Application of proper metrology has a tremendous impact on society as a whole, in terms of saved direct costs (justified pricing of goods) as well as indirect costs through enhanced quality of life (dependable food, reliable healthcare, protection of the environment). In general, commercial interests drive the market to furnish measurement standards of its own accord in support of the former category. However, as regards the latter category, on the individual level, the associated costs of quality control are perceived high, whereas the direct benefits are less obvious and the penalty for not being accurate seems low in comparison, particularly in the short term. Therefore, affirmative action by governments is required as standards in support of this category are less likely to be developed otherwise.

705 Recommendation:-

- (a) Support for the metrology infrastructure and promotion of proper metrology should continue to remain key interests at the EU level. (Action: European Commission)

CRM related conclusions

Terminology is confusing

706 Different terminology is used for essentially identical concepts, e.g. CRM and SRM. Likewise other terminology may have multiple meanings. The most notable example of the latter category is probably RM, referring to either general or non-certified reference materials, respectively depending on the context.

707 Recommendation:-

- (a) Reduce the ambiguity of the terminology and the proliferation of acronyms as they tend to (further) confuse the end-users. (Action: Certifying Producers, EURACHEM, ISO-REMCO etc.)

Indications for key (C)RM areas for future research and production seem quite strong

708 An analysis of the (C)RM needs on the area level as expressed in the user survey, shows consistency among the different subpopulations in the top ranking types by category. Moreover, there is also considerable overlap with the top ranked (C)RM areas originating from the producer survey. It is thus felt that the areas, as listed in table 7-1, are indicative for the overall true (C)RM needs for future research and production.

Table 7-1: Indicative Key (C)RM areas (in random order) per category, overall result	
Food and Agriculture	Meat Vegetable Matter Oils and Fats
Environment	Waters Sediment Soils
Biological and Clinical	Blood Serum and Plasma Water and Food Microbiology Pharmaceuticals GMO
Metals	Non-ferrous metals
Chemicals	Organic Gas (mixtures) Inorganic Gas (mixtures)
Pure Materials	Chromatographic Standards Elemental Analysis
Industrial Raw Materials and Products	Oils and Liquid Fuels
Material for Determination of Physical Properties	Optical Properties Mechanical Properties

709 When generalised, the more specific (C)RM needs relating to potential users in developing countries and the biotechnology area, as originating from our research, are essentially also included in the areas listed in table 7-1.

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710 Further prioritisation between the areas per category, let alone between the categories, is not possible based on data collected through a general questionnaire, as prescribed for the present study. Due to the size of the field, in terms of categories covered and the wide variety in associated issues, an overall well balanced decision between costs and benefits is extremely challenging. Hardly any individual or single organisation possesses a complete, detailed overview of all economical and political implications. A questionnaire inherently does not permit a dialogue, required in such conditions to harmonise and scale the individual opinions and criteria, thus preventing an overall prioritisation.

711 As a gap analysis between (C)RM needs and production, much for the same reasoning as in the previous paragraph, did not reveal meaningful information, it is not possible to recommend more specific CRM priorities for the EC RTD programme on basis of this study beyond what is summarised in table 7-1.

712 Prioritisation beforehand thus remaining a formidable challenge, the next best thing, i.e. prioritisation afterward by improving the evaluation process appears easier to implement. Furthermore, the latter is likely more accurate and reliable as it will be on the level of the specific CRM. Ways to improve the evaluation process include increasing the number of CRM development initiatives and consultation of the field in the evaluation process.

713 Recommendations:-

- (a) Popularise the currently little known Expression of Interest (EoI) mechanism among the end users. What might help is publication of rejected EoI for the information of other producers, so that users have a better chance that their need may be taken up. (Action: European Commission)
- (b) Check the decision of the evaluators in an experienced user forum, consisting of organisations active in feasibility or certification and R&D-users from the applicable sectors, by means of a simple electronic procedure (probably better email than web based). These parties appear well capable of representing the user in general (cf. Chapter 5), while assumed to be able to take more balanced decisions on basis of their wider experience. In case evaluators and forum largely reach the same conclusions, the support by the field for the outcome will be increased. If there are major differences between the evaluators and the forum, the bias of the evaluators could be re-examined. (Action: European Commission)

Future collaboration between producers could go well beyond supporting technology only

714 The major CRM producers contacted in this study are in favour of co-ordination of CRM development activities. Regarding collaboration, there appears to be full agreement that it is in everybody's interest to join forces in research and development of supporting technology (e.g. natural physical state preparation, delicate sample transfer techniques) and methods (e.g. sampling). However, opinions differ regarding collaboration on actual CRM development.

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715 On the one hand, the majority of the producers stress that the CRM needs and development drivers in most cases are specific to each producer / territory, as a result of which actual joint CRM development on a world-wide scale will at best be incidental. Essentially only in cases where CRMs are relevant to international trade joint development is seen to be well feasible and even desirable. However, CRMs required as a result of legislation are expected to have considerably less common relevance.

716 On the other hand, notably experts on the producer level backed by the occasional producer, argue that there is ever more commonality in CRM drivers. Globalisation causes procedures and associated metrological problems to converge, which should produce similar needs for industrial CRMs. Likewise, CRMs intended to satisfy needs with a direct relation to the functioning of the human body, notably in the clinical, environmental and food sectors, in principle should have worldwide relevance. Although the implementation in terms of analyte levels may still differ, even in this respect convergence is to be expected in time.

717 Recommendation:-

- (a) Examine collaboration options on new CRM development by looking into the common aspects first. (Action: producers)

CRM use should be enforced through regulation

718 Explicit prescription of CRM use in metrology dependent legislation, would be a major stimulus, but is likely to be counterproductive to quality control as it slows down introduction of improved measurement and testing procedures. Only somewhat less compelling, but significantly less suffering from the time constraints of the legislative process, the level of the regulation would be the more appropriate one.

719 Recommendations:-

- (a) Incorporate explicit references to CRMs in accreditation schemes, relevant standards and test protocols, already at the national levels. (Action: European Commission, Producers)

Facilitation of the processes to find and properly use CRMs is required

720 For the average user, it is hard to get a good overview of the available CRMs and to select the most appropriate one. In addition, once retrieved, proper usage is far from obvious.

721 Recommendations:-

- (a) Implement an independent universal (C)RM portal, incorporating some selection aid. (Action: ISO-REMCO)
- (b) In addition to a certificate and basic instructions, include with every CRM a more detailed manual with examples of use, a reporting format of the results and a website address for further information as well as translations of all documentation. (Action: Producers, Distributors)

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Promotion of CRMs will improve their visibility

722 The benefits that CRMs can bring are relatively unknown to the average QC user. The perception of being expensive does not prompt the user to improve the understanding of CRMs either. Promotional activities can contribute to a more positive opinion on CRMs with consequent wider application.

723 Recommendations:-

- (a) Use crises (e.g. BSE, dioxin in poultry etc.) to pass the CRM message. (Action: European Commission, Producers)

Metrology in the (C)RM context related conclusions

Understanding of applied metrology principles among QC users needs to be improved

724 The limited understanding of the basic principles of analytical quality control by the laboratory staff of the average QC user organisation, is generally attributed to the fact that at present higher education devotes insufficient attention to applied metrology. Additional training in the workplace appears the most practical and direct solution for the short term. For a long-term solution, higher education should be persuaded to adapt the curricula. Whatever the approach, taking the not necessary well developed language skills among the (prospective) laboratory staff into account, the training should predominantly be in the national language to be most effective.

725 Recommendations:-

- (a) Teaching of applied metrology principles should be included in the curriculum of all relevant studies. UNESCO has been mentioned as a possible mediator between the metrology world and the institutes of higher education. (Action: EURACHEM, European Commission)
- (b) Follow-up courses, largely based on practical examples, should be given periodically to keep laboratory staff updated on metrology issues. On-line methods should definitely be looked into for this purpose.

More support for lower level reference materials required to get a real metrology system

726 CRMs represent the metrological top and have their own purpose and value in ensuring traceability. Yet, most measurement problems do not require a reference material of the highest metrological level, being stable for prolonged periods of time like CRMs. Speedy availability, i.e. short development time, often is a necessity, particularly in crises situations. Even if the development of CRMs could be significantly shortened, they would be overqualified and therefore too costly for these measurements; furthermore CRM development budgets and capacity simply restrict meeting all these needs.

727 Non-certified RMs (also referred to as laboratory reference material or LRM) are the better solution in these cases. Despite this greater need for RMs by the majority of the measurement and testing end users, there is no formal RM structure (development support programmes, trusted sources, etc.). There are only some small scale, by definition restricted, initiatives to that effect, but most of the development attention goes to CRMs.

728 Recommendation:-

- (a) A formal RM structure, complementing and organisationally comparable to the CRM structures in place should be established. Preferably, this should not be a separate structure, but rather an extension of the present CRM structure to fully exploit the synergies between RMs and CRMs. For example, materials developed in the first stages of a full CRM development could be made available on a structural basis as RMs. If well organised, such an RM structure could in turn reinforce the position, and thus use, of CRMs, as the latter will then be part of an actual, comprehensive metrological framework. (Action: European Commission, Producers)

Integration of metrology worlds will greatly improve the general quality control level

729 The analytical metrology world is clearly very much segregated horizontally, as a comprehensive, structured way of interaction between the main stakeholders users and producers is virtually non-existent. This seems principally due to the limited degree of organisation of the users; in general the producers have relatively good contacts. Although probably being partly inherent, the imbalance between user need and producer offering is thus considerably bigger than it could and should be, having a negative impact on quality control.

730 In addition, there appears to be a significant vertical segregation as well, at least between the “worlds” of (C)RM, of the Pharmacopoeia, of the Codex Alimentarius and perhaps also of the European forensic science laboratories (the latter two essentially following a pharmacopoeia-like model). While the general issues of these “worlds”, and consequently the potential solutions, seem highly comparable, they operate largely independently, developing their own approaches and methodologies. It goes without saying that the virtually non-exploitation of the synergies also has a negative impact on quality control.

731 In general, the stakeholders in the analytical metrology world exhibit a strong tendency to focus on what differentiates them rather than on what they have in common. There is clear potential to reduce the cost or improve the output relating to quality control by enhanced co-ordination.

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732 Recommendations:-

- (a) To counter the horizontal segregation, permanent user-producer fora need to be established on the sector level as this is most logical to the users, who are the stakeholder to organise in the first place. These fora, where possible based on existing networks and preferably under moderation by independent experts, can be used to establish and, more importantly, to prioritise needs in a real dialogue, which is the only option to set meaningful overall priorities in areas with widely differing individual interests. Surveys should be employed with great care for general inventories or targeted audiences only: the wider the field, the more generic the questions and the more general the conclusions. The NIST conferences model seems a good way to organise the fora, using periodic gatherings in person when required, notably for the initiating phase including kick-off, but largely relying on on-line follow-up to minimise overhead. (Action: European Commission)
- (b) To counter the vertical segregation, contacts on the policymaker's and producer's level should be established or intensified. (Action: European Commission, Producers, Codex Alimentarius Committee, EURACHEM, ISO-REMCO, etc.)
- (c) Measurement traceability should be introduced as a topic for discussion in the Codex Alimentarius Committee. (Action: European Commission / DG SANCO)

Good laboratory practice should be enforced

733 Legislation in general on laboratory practices is not sufficiently well developed in many countries. With reference to CRMs, while it is undesirable to include specific metrology procedures in legislation, explicit referencing of relevant regulations would be a major incentive. The obvious candidate in this context is accreditation as it is known to improve the average quality level, while acknowledging however that accreditation is not guaranteed to be a watertight system, nor solve all problems.

734 Recommendations:-

- (a) Accreditation should be made mandatory in order to be allowed to operate an independent measurement and testing laboratory. (Action: European Commission, National Governments)

Facilitation of the shipping of metrology related goods will be a major incentive

735 Practical metrology relies heavily on the exchange of goods (samples, references, equipment), national but ever more international, between laboratories, clients and suppliers. Administrative burden and delays of shipping in general already cause money losses, reducing the profitability of the cost competitive measurement and testing market with all kinds of adverse consequences. Moreover, stability sensitive materials can become completely worthless if not measured in time or (particularly relevant to RMs) stored at inappropriate conditions for too long times.

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736 Recommendation:-

- (a) Reduce international shipping problems, by creating one customs code for reference materials and, if possible, measurement equipment. (Action: European Commission)

Promotion of metrology will improve the acceptability of associated costs

737 While metrology is essential to the upholding of many laws, the apparent ignoring of metrology specific issues in the legislative process, is highly demotivating to producers and users alike. Acknowledgment of the status of metrology would help to create a market pull for proper testing and facilitate justification of the costs associated with quality control thus contributing to an improvement of the overall quality level. Likewise, quality control should not so much be judged as such in absolute cost terms, but rather be related to the gains or overall losses when not applied.

738 Recommendations:-

- (a) Have some measurement solution (method, references etc.) available at the moment a directive is enforced. This at least implies adequate dialogue of the legislators with the producers and developers. It could also include specific earmarking of funds. (Action: European Commission)
- (b) Users should be made aware that indeed quality control has its price (cost estimated at 5% of the turnover) but that this money is well spent. They should understand that the potential accuracy of the equipment can only be achieved by proper procedures, including reference materials. Although the costs of reference materials may seem high as such, they are usually only a fraction of the investment in the equipment. (Action: Producers, European Commission)
- (c) The clients of the users, and perhaps the general public even more, should equally be made aware that quality control does not come free but that this money is well spent. They should understand that the returned values essentially have no meaning without proper control, making it pointless to have a test done in the first place. (Action: Users, European Commission)

Conclusions to the value of the study's outcomes

739 Despite a not overly high overall response to the user questionnaire of about 3% (taking overlaps in the distribution databases into account), it is felt that the outcomes of this study are at least on the sector level generally indicative for the needs users have and issues they face.

740 First, the response after distribution to IRMM and LGC customers only, amounted to 7.5 % and comprised the lion's share of the experienced users (i.e. initiating producers and co-developers, in their user roles, as well as R&D-users). Our interviews showed these experienced users to have a quite good overview of related QC-users needs. Thus most of the opinions and views, the majority originating from users not formerly known to the European Commission, are believed to be captured anyway.

741 Second, all user interviews, although acknowledged to be held with a mere fraction of the potential total, corroborated the general questionnaire results.

742 Third, the user results that were presented during the workshop of 5-6 February 2002, were validated without major comments by an audience essentially comprising all stakeholders.

743 Fourth, in general the outcomes correlate well with the user survey results and issues reported by a previous project¹⁰, obtained on basis of a different methodology to identify the users.

744 The producer results are felt to be quite accurate, as most of the relevant worldwide Certifying Producers have been interviewed in person, complemented by interviews with some European Initiating Producers, as well as a number of Experts and representatives of Interest Organisation at those levels.

¹⁰ Workshop on the use and prospects for reference materials for the quality control of agro-food & environmental analysis (SMT4-CT97-6522); Quevauviller Ph., Trends Anal. Chem. 18 (1999), 76.

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A Terms of Reference

PWC CONSULTING

B Questionnaire Design

PWC CONSULTING

C Questionnaire Processing and Interpretation

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D Questionnaire Results in Detail

E Biotechnology in 2015: descriptions of extreme scenarios

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F Attendees of the CRM Workshop dd. 5-6 February 2002

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G Reports of the CRM Workshop's parallel sessions